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LE PROTOCOLE DE NAGOYA SUR L'ACCÈS AUX RESSOURCES GÉNÉTIQUES ET LE PARTAGE JUSTE ET ÉQUITABLE DES AVANTAGES DÉCOULANT DE LEUR UTILISATION – INTÉGRATION EN DROIT NATIONAL EN PARTICULIER AU VIETNAM

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THE NAGOYA PROTOCOL ON ACCESS TO GENETIC RESOURCES AND THE FAIR AND EQUITABLE SHARING OF BENEFITS ARISING FROM THEIR UTILIZATION – INTEGRATION INTO NATIONAL LAWS, IN PARTICULAR IN VIETNAM

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If a little prince said to us: “draw me a picture of biodiversity”, we naturally would draw examples of rich biodiversity. Then, the little prince said “draw me this biodiversity being shared between poor people”, we would draw a picture of these people improving their livelihoods through the fair and equitable benefit-sharing of biological resources, allowing them to continue living in harmony with nature, and to support and protect such rich biodiversity.[1] These pictures show the true meaning of the saying “La biodiversité: “c’est une assurance-vie”.[2]

[1] This thought came when I was reading « *Si le petit prince nous disait aujourd’hui: “dessine –moi un paysage!”, out naturellement on dessinerait un paysage rural avec des arbres, une rivière, des fleurs, des oiseaux et des animaux, bref on traduirait visuellement la biodiversité. On ne dessinerait sûrement pas une étendue de mais ou de soja OGM ou une forêt de conifères. Si plus savant le petit prince disait: “dessine-moi la biodiversité!” on dissinerait de même un paysage riche de sa diversité. Le paysage est bien la restitution visuelle de la biodiversité, sa concrétisation pour l’homme. Il est un livre ouvert sur le passé et le présent de la biodiversité.*” By M.Prieur, *Paysage et biodiversité*, Revue Juridique de l’Environnement, Biodiversité et évolution du droit de la protection de la nature : réflexion prospective, numéro spécial, 2008, p.185

[2] Le sénateur Jean-François Le Grand, président du groupe sur la biodiversité au Grenelle de l’environnement, cited by M.Prieur, *Paysage et biodiversité*, Revue Juridique de l’Environnement, Biodiversité et évolution du droit de la protection de la nature : réflexion prospective, numéro spécial, 2008, p.185

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[3] Par Paulo Affonso LEME MACHADO, Professeur à l'Université méthodiste de Piracicaba, Brésil, à PRIEUR.M, *Pour un droit commune de l'environnement*, Dalloz, 2007, p.241

SUMMARY OF CONTENTS

SOMMAIRE DE MATIERE

LIST OF ABBREVIATIONS

CBD	United Nation Convention on Biological Diversity
CITES	Convention on International Trade in Endangered Species of Wild Fauna and Flora
COP	Conference of the Parties
COM	French overseas collectivities
COP/MOP	Conference of the Parties serving as the meeting of the Parties
EIA	Environmental impact assessment
EU	European Union
EC	European Commission
FAO	Food and Agriculture Organisation of the United Nation
GR	Genetic resources
GATT	General Agreement on Tariffs and Trade
ICJ	International Court of Justice
MAT	Mutually agreed terms
MEA	Multilateral environmental agreements
MEDDTL	Ministry of Ecology, Sustainable Development, Transport and Housing of the Republic of France
MARD	Ministry of Agriculture and Rural Development of Vietnam
MONRE	Ministry of Natural Resources and Environment of Vietnam
MOST	Ministry of Science and Technology of Vietnam
Nagoya Protocol	Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity
NGO	Non-government organization
PIC	Prior informed consent
PPC	Provincial People's Committees
PTOM	Pays et territoires d'outre-mer (Overseas countries and territories)
R&D	Research and development
SMTA	Standard Material Transfer Agreement
TAAF	French Southern and Antarctic Lands
TK	Traditional knowledge associated with genetic resources
TRIPS	WTO Agreement on Trade-Related Aspects of Intellectual Property Rights
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization
UNESCO	United Nations Educational, Scientific and Cultural Organization
UNCLOS	United Nations Convention on the Law of the Sea
UPOV	The International Union for the Protection of New Varieties of Plants
$	United States Dollars

GENERAL INTRODUCTION

Contrary to traditional views of 'absolute protection' of biodiversity, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization (Protocol) provides for privatization, commercialization and marketization of biodiversity to maximize benefit arising out from bioprospecting and its utilization. In economic and market respects, the core issues covered in the Protocol: contract/agreement – mutually agreed term (MAT), parties of contract – sellers and buyers or providers and users and objects of the contract – genetic resources (GR) and their utilization, and/or traditional knowledge associated with genetic resources (TK). However, there are broader issues beyond economics and markets, the Nagoya Protocol addresses: moral responsibilities of GR users; rights of local and indigenous people and communities, justice and equity and sustainable development including principles of intergenerational and intra-generational equity.

In analyzing the Protocol, GR – which have been linked 'green gold'[4]- are not only seen as resources for development, but also for promoting conservation of nature and environmental protection. This regulation of GR could be characterized as "Selling nature to save it"[5] and reflects global policies, even though the approach has been criticized in practice[6,7].

Therefore, the Nagoya Protocol attempts to balance between rights and responsibilities, between provider and users and other stakeholders, between developed and developing countries, between economic interests and morality. Each component of the access and benefit-sharing regime under the Protocol elaborates different rights and responsibilities to parties and relevant stakeholders. Each stakeholder has different interests and positions of influence and power to control the process of setting up and operationalizing the international access and benefit-sharing regime. Thus, the attempt to balance rights and responsibilities may meet many difficulties in implementation as stakeholders are more likely 'to sell nature' for maximum interest but less willing to sacrifice their interest 'to save nature'. There are also many challenges in the substance and procedure of legal obligations for compliance under the Protocol, as implementation struggles to realize the idea of "Selling nature to save it".

However, it appears that there is now no better alternative than to take the approach of the Protocol that "acknowledges the potential role of access and benefit-sharing to contribute to the conservation and sustainable use of biological diversity, poverty

[4] http://www.apec.org.au/docs/CuritibaReport3_21_06[2].pdf, http://archive.unu.edu/update/issue37_7.htm
[5] MC AFEE.K, *Selling Nature to Save It? Biodiversity and the Rise of Green Developmentalism, Environment and Planning D: Society and Space* April, 1999
[6] CASTREE.N, *Bioprospecting: from theory to practice (and back again)*, Blackwell Publishing Ltd, © Royal Geographical Society (with The Institute of British Geographers) 2003, p11
[7] PRATHAPAN.K.D, PRIYADARSANAN.D.R, *Biological Diversity: A common heritage,* Economic & Political Weekly, April 2, 2011 Vol XLV No 14, p 17

eradication and environmental sustainability and thereby contributing to achieving the Millennium Development Goals"[8]. Accordingly, 'selling nature' to have "fair and equitable sharing of the benefits arising from the utilization of genetic resources" for "contributing to the conservation of biological diversity and the sustainable use of its components" or 'saving nature' – is the objective of the Nagoya Protocol to implement objectives of the Convention on Biodiversity (CBD). All countries' members are required to pursue the objectives of the CBD. However, each country follows its own goal of development and has different economic, social and cultural context and ethos. Thus, considering the problems and challenges of the Protocol, many countries are still questioning whether to ratify or accede to it.

In the interaction between international law and national law, the process of international law becoming part of national law is crucial. Despite the question of whether to accede the Protocol and the period of time it takes for the Protocol to obtain its fiftieth instrument of ratification or accession to come into force, research of the integration of the Nagoya Protocol into national law is important in terms of both process and implementing the legal provisions of the Protocol into practice.

The Nagoya Protocol

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (the Protocol) was adopted in October 2010 by the 10th Conference of the Parties (COP 10) of the Convention on Biological Diversity (CBD). The Protocol was opened for signature from 2 February 2011 to 1 February 2012. No reservations may be made to the Protocol. It requires the deposit of the fiftieth instrument of ratification, acceptance, approval or accession by States or regional economic integration organizations that are Parties to the CBD to enter into force .[9]

The Nagoya Protocol is a landmark for the international governance of biodiversity and a milestone in the development of the international regime governing biodiversity. The Protocol reaffirms the fair and equitable sharing of benefits as one of the highest priorities for biodiversity conservation and sustainable use. The Nagoya Protocol has created a set of rules to facilitate, promote and ensure its effective implementation.

The Protocol is expected to provide greater legal certainty and transparency for both providers and users of GR, creating a framework that promotes the use of GR and associated traditional knowledge (TK) while strengthening the opportunities for fair and equitable sharing of benefits from their use. This approach aims to create new incentives to

[8] Preamble of the Nagoya Protocol

[9] Article 33.1 of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity. *Opened for signature 2 February 2011*. Available online: http://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf Accessed 17 December 2011.

conserve biodiversity, sustainably use its components, and further enhance the contribution of biodiversity to sustainable development and human well-being.

For the first time, the Protocol establishes a basis for the legally-binding implementation of access to GR and benefit-sharing. The Protocol's main contributions to the development of international law and policy on access to GR and benefit-sharing include the articulation of the objectives, definitions, scope and relationship with other international instruments, principles, basic requirements of fair and equitable benefit-sharing, access to GR and any associated TK, compliance mechanisms, the basis for a global multilateral benefit-sharing mechanism, an access and benefit-sharing Clearing-House, and measures to provide for raising awareness, building capacity, and transferring technology.

However, the Protocol has been criticized as "imperfect" and "incomplete," because of ambiguities, gaps and generalities. For example, the temporal scope of the Protocol is not clear, there is no requirement for disclosure in patent applications and measures to support compliance are not clear. Therefore, the Protocol also is only a starting point, and the remains dependend upon the domestic implementation to address these gaps and weaknesses.

The Convention on Biological Diversity

The CBD opened for signature at the Earth Summit in Rio de Janeiro in 1992, and entered into force in 1993. This is an international treaty for the conservation and sustainable use of biodiversity, with 193 Parties[10]. The CBD has near universal participation among countries committed to preserving life on Earth.

The CBD is the first global treaty to address comprehensively all aspects of biological diversity - genetic resources, species and ecosystems. It is also novel in approach. It moves away from a view of biodiversity as a 'global commons' towards a more dignified view of nature as of 'common concern' to human kind. This was an important evolution and perhaps even a revolution. In essence, even if we consider biodiversity as a resource for our exploitation, we should value it for what is and ensure that future generation can also appreciate it.

Therefore, "one of the main features of the CBD is that it combines the aim of conserving biological diversity with economic objectives"[11]. Accordingly, the two first objectives of the CBD are for better conservation and for sustainable development, and the third objective of CBD is for the equitable sharing of the benefits arising from the utilization of GR. The significance of the third objective of the CBD is the need to

[10] www.cbd.int, last accessed 17 December 2011

[11] KLEMM.S.B, MARTINEZ.S, *Access and benefit-sharing good practice for academic research on genetic resources*, Swiss Academy of Sciences, 2006, p.11

guarantee access to GR by the developed countries and permit the developing countries to control access and receive benefits. The third objective is also to help the developing countries to reoccupy their economic share of wealth. The underlying assumption of this approach is that there can not be effective conservation without financial and economic benefits to underpin conservation efforts.[12]

However, "the CBD is a framework agreement". Firstly, it leaves it up to individual Parties to determine how most of its provisions are to be implemented. Its provisions are mostly expressed as overall goals and policies, rather than as hard and precise obligations. Secondly, its emphasis is placed on the possibility for the Conference of the Parties (COP) to further negotiate annexes and protocols.[13] It was in the COP framework of the CBD that the elaboration and negotiation of the Nagoya Protocol and the Cartagena Protocol on Biosafety were drafted and agreed to.

As the CBD is only a framework agreement, there are many gaps under this type of international treaty. There are for example challenges to achieve the implementation of its third objective to guarantee access to GR by developed countries and permit the developing countries to control access and receive benefit. These challenges include: the definion of intellectual property right; GR and what constitutes of 'utilization of GR' to determine scope of regulation, and indirect practical impacts of enforcement and implementation. The CBD framework also does not adequately address the lack of predictability or timing of a decision on access of provider countries and there is a lack of supporting legislation in user countries for an intellectual property right regime to disclose the origin of the GR used in the invention. The Bonn Guidelines, which was adopted by the CBD COP 6 in 2002, also can not resolve the gaps and lacks.

The CBD also has the technical obstacles in the relationship between its scope of application and other relevant international agreements[14]. Although, the initial approach for elaboration of the CBD was comprehensive to regulate biodiversity as a whole, the access to GR and fair, equitable benefit-sharing has been dealt with using a sectoral approach. International Treaty on Plant Genetic Resources for Food and Agriculture under the Food and Agriculture Organization (FAO) (hereafter called as FAO's treaty) shares similar objectives as the CBD as they relate to GR. The FAO's treaty seeks to implement these objectives in another manner. Therefore, the provision of the CBD on access to GR and benefit-sharing, concerns GR for non-food and non-agriculture uses that are fore mainly chemical and pharmaceutical purposes.[15]

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[12] JEFFERY. I. M, QC, FIRESTONE. J, BUBNA. L. K, *Biodiversity Conservation, Law + Livelihoods, Bridging the North – South Divide*, Cambridge University Press, 2008, p.15

[13] GLOWKA.L, BURHENNE-GUILMIN.F, Synge.H, *A guide to the Convention on Biological diversity*, IUCN, Environmental Policy and Law Paper No.30, 1994

[14] AUBERTIN.C, PINTON.F, BOISVERT.V, *Le marché de la biodiversité*, IRD, Édition 2007, p.15

[15] JEFFERY. I. M, QC, FIRESTONE. J, BUBNA. L. K, *Supra*, p.36

Regarding substantive rules of certification disclosure of origin of material in patent application and including derivatives, the CBD left question to decide which forum is best placed to take action. The World Intellectual Property Organization (WIPO) now has a mandate to work on intellectual property right related issues, but in fact there is slow progress with many complex obstacles such as technical problems for granting patents for inventions using GR and TK and disclosure of the origin of GR; different points of view and conflict interest.[16]

As a Protocol to the CBD, the scope of regulation in the Nagoya Protocol is also consistent with the CBD. Article 3 of the Protocol confirms that the Protocol shall apply to GR within the scope of Article 15 of the CBD and to the benefits arising from the utilization of such resources and also apply to the TK within the scope of the CBD and to the benefits arising from the utilization of such knowledge. In the relation to the others international agreements and instruments, the provisions of the Protocol shall not affect the rights and obligations of any Party deriving from any existing international agreement. "Where a specialised international access and benefit-sharing instrument applies that is consistent with, and does not run counter to the objectives of the Convention and this Protocol (like the FAO's treaty), the Protocol does not apply for the Party or Parties to the specialised instrument in respect of the specific GR covered by and for the purpose of the specialised instrument"[17]. These are factors are the focus of study of this thesis. This thesis will not make a deep analysis to the GR or access to GR and benefit-sharing under the scope of regulation of FAO's treaty or the intellectual property right aspects of on access to GR and benefit-sharing are under negotiation of WIPO.

Definition of genetic resources

GR are the centre of the access and benefit-sharing process that is the subject of regulation under the Nagoya Protocol. First, the definition of GR is significant to determine the scope of regulation and application.

However, there are already various definitions of GR at international level and national level[18]. The CBD defined that "GR" as "genetic material of actual or potential value". The definition of GR under the CBD is a key official definition that is understood and applied most broadly at present. Here, "genetic material" means any material of plant, animal, microbial or other origin containing functional units of heredity[19]. Therefore, the definition of GR is developed by basis on definition of 'genetic material' and 'functional units of heredity'.

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[16] See more http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_20/wipo_grtkf_ic_20_5.pdf
[17] Article 4.4, the Nagoya Protocol
[18] UNEP/CBD/WG-ABS/9/INF/1, *The concept of Genetic resources in the CBD and how it relates to a functional international regime on ABS*, FNI, Oslo, Norway 2010, p.6
[19] Article 2, the CBD

The definition of 'genetic material' is clarified by Article 2 of the CBD, which refers to any biological origin 'of plant, animal, microbial or other origin containing functional units of heredity', but, those genetic materials only become GR if they have actual or potential value. This expression therefore recognizes and differentiates between GR and biological resources based on the realization of 'value' of genetic materials. "Biological resources" includes GR, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity[20]. GR are thus a subset within the wider classification of biological resources or biological resources could contain a GR[21].

In relation to the definition of 'value', ordinary understanding of the term is not restricted solely to economic value. Value is commonly understood as being 'social, economic, cultural and spiritual in nature.'[22] "In consequence, any type of value might be relevant when one is to determine whether something is to be regarded as 'GR' or not. This leaves to term 'value' without limiting effects on the scope of the definition." [23]

The definition uses both 'actual' and 'potential' to define the value aspects of 'GR'. This could be read as a reference to the both state-of-the-art technology and likely future technologies: the actual value would then concern the value of genetic material in combination with the techniques known and developed as at the time of access; whereas potential value could then be understood as the possible new techniques in the future which may realize the potential value of the functional units of heredity. "Actual value might be more or less evident or clear. Also, actual value is not static as the material might have one value in some types of uses and a different value in other kinds of uses." [24]

"The reference to 'potential' value is broader and adds a dynamic aspect to the definition of 'GR' in several ways. The value of the material at access timepoint is potential in the sense that one cannot know the specific value before it has been realised. Also the value might prove to be for something else than originally thought. Thus, also where there are no evident current values, the genetic material could qualify as being GR. The use of the term 'potential value' captures future ways of realising the value of the functional units of heredity. Potential value entails also a reference to knowledge and technological developments, as the material will probably be recognised as having new values as knowledge and technology change."[25]

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[20] *Ibid*
[21] UNEP/CBD/WG-ABS/7/2, *Report of the meeting of the group of Legal and technical experts on Concepts, terms, Working Definitions and sectoral approaches*, seventh Meeting of the Ad Hoc Open Ended Working Group on Access and Benefit-Sharing (WG ABS 7), 2008, Annex, p. 6
[22] UNEP/CBD/WG-ABS/8/INF/3,*The Role of Commons/Open Source Licenses in the International Regime on Access to Genetic Resources and Benefit Sharing*, by Paul Oldham, July, 2009, p. 28.
[23] UNEP/CBD/WG-ABS/9/INF/1, *Supra*, p.9
[24] UNEP/CBD/WG-ABS/9/INF/1, *Ibid*
[25] UNEP/CBD/WG-ABS/9/INF/1, *Ibid*

The genetic material is being used today in genomics, proteomics, bioinformatics, and synthetic biology. In addition, with the new development knowledge of GR, "it is a fairly straightforward matter to read and copy long sequences of DNA (deoxyribonucleic acid) or to exchange nucleotides in naturally occurring genetic material. This indicates that the interpretation of the definition of 'GR' and their uses need to be dynamic as regards new technologies, in order to meet the overall objectives of the benefitsharing objective and obligation in the CBD".[26]

'Functional units of heredity' are not defined in the wording of the CBD. "'Functional unit' is a broad concept". This broadness could be capured in the words 'working or operating', where the emphasis is any way of having a function or operation. "'Functional' includes a dynamic element as the state of knowledge and technology necessarily develops through history". Thus, there is also a dynamic element is included in the definition of 'functional units of heredity.[27] Following A Guide to the CBD by the IUCN in 1994, 'Functional units of heredity' was defined to "include all genetic elements containing DNA and, in some cases, RNA (ribonucleic acid), for example, seeds, cuttings, sperm or individual organisms". The definition also includes "DNA extracted from a plant, animal or microbe such as a chromosome, a gene, a bacterial plasmid or any part of these".[28]

As outlined above, genetic materials can only become GR if they have actual or potential value or 'GR' are a subset of 'genetic material'. The distinction between the two terms on the basis of whether or not the material is 'of actual or potential value' seems to signify that genetic material only becomes a GR when a use can be ascribed to it or is likely to be ascribed. But, of course, it can be argued that virtually all genetic material is potentially valuable at least until proven otherwise. Therefore, whether such a narrow view is justified might be questioned.[29]

The importance of genetic resources

GR have significant potential benefits through access or making use of them. "They provide a crucial source of information to better understand the natural world and can be used to develop a wide range of products and services for human benefit. This includes products such as medicines and cosmetics, as well as agricultural and environmental practices and techniques."[30],[31] The Nagoya Protocol also recognizes the importance of GR

[26] *Ibid*, p.17
[27] *Ibid*, p. 8
[28] GLOWKA.L, BURHENNE-GUILMIN.F, Synge.H, *Supra*, p.23
[29] *Ibid*, p.22
[30] CBD, introduction of ABS, available at http://www.cbd.int/abs/information-kit-en/ last accessed March 1, 2012
[31] STOIANOFF. P. N, *Accessing biological resources, complying with the Convention on Biological Diversity*, International Environmental Law and Policy Series, Kluwer Law International, 2004, p.7- p.16

to food security, public health, biodiversity conservation, and the mitigation and adaptation to climate change[32].

In general, GR have ecological, scientific, social, educational, cultural, aesthetic, e and intrinsic values that are shared by the world at large. A wide range of sectors undertakes research and develops commercial products from GR. The sectors include "the pharmaceutical, biotechnology, seed, crop protection, horticulture, cosmetic and personal care, fragrance and flavor, botanicals, and food and beverage industries"[33]. GR have "economic value in making agricultural or pharmaceutical product, which need to be shared by the global community but could instead accrue to those that own or control a given resource"[34]. (See more in Annex 3 of the thesis)

However, considering scope of regulation of the CBD, the FAO's treaty and the Article 4.4 of Nagoya Protocol,[35] this section concentrates to introduce the importance of GR in these aspects of non-food and non-agriculture.

"Biodiversity is no longer seen only as raw material for the satisfaction of basic human needs, but also as value resources for the highly sophisticated development of pharmaceuticals for the cure of human illnesses. The medical qualities of plants and animals are found in their GR".[36] Access to GR by western company is not something new, even before the development of biotechnology, foreign industries had access to GR through access to plant and animals, but without the sophisticated technology. Nowadays, the development of biotechnology allows for the creation and modification of products or processes derived from GR.

Over the past decades, "the rapid development of modern biotechnology has enabled us to use GR in ways that have not only fundamentally altered our understanding of the living world, but has also led to the development of new products and practices that contribute to human well-being, ranging from vital medicines to methods that improve the security of our food supplies. It has also improved conservation methods that help safeguard global biodiversity. GR can be put to commercial or non-commercial use". "In commercial use, companies can use GR to develop specialty enzymes, enhanced genes, or small molecules. These can be used in crop protection, drug development, the production of specialized chemicals, or in industrial processing. It is also possible to insert genes into crops to obtain desirable traits that can enhance their productivity or resilience to disease." [37] "Enzymes have been used for more than 60 years by textile, detergent, food, feed and

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[32] Preamble of the Nagoya Protocol
[33] LAIRD. S, WYNBERG. R, *Access and benefit-sharing in practice: trends in partnership Across sectors*, Technical Report No 38, CBD and UNEP, p. 9
[34] STOIANOFF. P. N, *Supra*, p. xiii
[35] See more note 12, page 9 of this thesis
[36] STOIANOFF. P. N, *Supra*, p. xiii
[37] CBD, ABS introduction, theme: use of genetic resources, p 2, available at http://www.cbd.int/abs/information-kit-en/ last accessed March 1, 2012

other industries to make high-quality products and to make production processes more cost-effective and efficient, and therefore more environmentally sound by minimizing the use of water, raw materials and energy". "Enzymes are proteins found in every living organism and are the 'tools of nature', cutting and pasting products and speeding up vital biological processes in cells. Those used in the industrial biotechnology industry are usually found in microorganisms, in particular bacteria and fungi. The importance of microorganisms to both pharmaceutical and biotechnology research and development (R&D) programs cannot be underestimated".[38]

In non-commercial use, "GR can be used to increase knowledge or understanding of the natural world, with activities ranging from taxonomic research to ecosystem analysis." Acadamic and public research institutions usually conduct this work. "The distinctions between commercial and non-commercial use, and the actors involved, are not always clear cut. Companies can cooperate with public entities on commercial research, and sometimes research with no commercial intentions leads to a discovery that has commercial applications."[39]

In other words, scientific and commercial interests in GR are interrelated. "Scientific research and development has many aspects ranging from basic research without any clear applied objective, through to strategic basic research to applied research where clear goals are in mind. Interaction with industry is possible at various points along this research continuum and a major aim for industry is to develop a product process or services form the research and development. The scientific interest in biodiversity is very broad. At global level where one of the aims is to try understanding the evolution of organism and their interaction together with gaining further knowledge of climate and climate variations, at the regional level there is also interest in ecological aspect, as well as ethnobotany and medicinal plants and the use of such plants by regional communities." There is interest in the science community with respect to ecology, ethnobotany and medical plants and finally at the molecular level. "The molecular level encompasses the chemistry of natural products, the search for-new-drug-lead- compounds, the search- for-new-biological and pharmacological tools, the chemical basis of ecology and molecular events effecting evolution of organisms." Other examples include "the chemical basis of biological interactions, the development of new pharmaceuticals and the use of natural product extracts and pure compounds in pharmaceutical application. Further research is being pursued on the biosynthesis of natural products and the enzymes involved, at tissue culture production of metabolites via bacterial fermentation technology. There is thus a

[38] LAIRD. S, WYNBERG. R, *Supra,* p.14
[39] *Ibid*

great need to maintain bacterial diversity and an understanding of molecular biology in relation to the definition of GR.[40]

There is a need to take a closer look at the commercial use of GR in accompany with biotechnology industries, which include a wide range of activities such as pharmaceutical, industrial, and agricultural technology. "It is estimated that 40% world trade comes from biological products and processes that the world market for biological resources has reached over US$ 900 billions in recent years".[41] For the pharmaceutical industry, "chemical compounds or substances produced by living organisms found in nature continue to play an important role in the discovery of leads for the development of drugs and contribute significantly to the bottom line of large pharmaceutical companies". In the industrial biotechnology, "enzymes are used by textile, detergent, food, feed and other industries to improve the efficiency and quality of their products and production processes. Industrial biotechnology companies are particularly interested in GR found in areas with high species diversity, as well as in extreme or unique environments, like salt lakes, deserts, caves, and hydrothermal vents". In the agricultural biotechnology, "seed, crop protection and plant biotechnology industries rely heavily on GR. Resources with traits that improve performance and farming efficiency for major crops are a key focus area for large seed companies. There is considerable growth in the value of the market for plant biotechnology-based products". [42]

The importance of the non-commercial use GR is expressed by various activities. Taxonomy is the science of describing and naming species, of which GR is a key source of information. "Taxonomic research provides crucial information for effective environmental conservation". For conservation, "GR are the building blocks of life on earth. By developing our understanding of them, and conserving them, we can improve conservation of threatened species, and the communities who depend on them".[43] GR also are important for culture because "GR diversity, cultural diversity is interdependent, especially among indigenous peoples. Natural and cultural resources have spiritual values and are fundamental to indigenous peoples'cultural, spiritual, economic and political survival as distinct people. Their ethno-pharmacological knowledge also can aid in pharmaceutical research and development".[44]

Many pharmaceutical companies and ethnomedicinal scientists are studying GR in search of their medicinal qualities. The driver of this search is the economic potential of pharmaceutical products able to be developed from these sources. Some experts have

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[40] STOIANOFF. P. N, *Supra*, p. 9
[41] FRANCESCO.F, SCOVAZZI.T, *Biotechnology and International law*, Studies in international law, Hart Publishing, 2006, p. 405
[42] CBD, *introduction of ABS, theme: use of genetic resources*, p. 2, available at ***http://www.cbd.int/abs/information-kit-en/*** last accessed March 1, 2012
[43] *Ibid*
[44] STOIANOFF. P. N, *Supra*, p. 193

estimated that "medicinal plants located in developing countries contribute approximately $30 billions per year to the pharmaceutical industry of developed countries. Other has estimated global retail sales of the related pharmaceutical products are worth some $80 - 90 million".[45] As Laird and Wynberg note, "natural development of drugs, contribute significantly to the bottom lines of large pharmaceutical companies: between January 1981 and June 2006, for example, 47 % (per cent) of cancer drugs and 34 % of all small molecule new chemical entities for the treatment of all disease categories were either natural products or directly derived therefrom. Research into specific natural products is usually directed by existing knowledge, often directly from indigenous or local communities, but now in many cases as transferred through the 'public domain'".[46]

The development of new pharmaceuticals is one of the key objectives of GR exploitation. There are many previous examples of success in this area. "Many natural products or plant derived compounds are used currently as pharmaceuticals. Plants, in particular, are an indispensable source of pharmaceuticals",[47] "40% of the US prescription drugs and 63% of all anti-cancer drugs are based on natural product. Furthermore, plant derived pharmaceutical salves were in excess of $70 billion worldwide in 1996. 80% of the world's population used botanical medicines as first line of treatment. The current successes with the natural product pharmaceuticals provide a driving force to identify new bioactive natural products with pharmaceutical potential. The compound *Mevacor* has annual sales of $700 million, *Vinblastine* and *vincristine* have annual sales of $180 million, and taxol which has annual sales of $500 million it is derived from the *Pacific yew* tree is highly effective in treatments of breast and ovarian cancer."[48]

An approach of new pharmaceuticals is the ethnobotanicals which are being developed from plant sources, involving the study of medicinal plants. This uses traditional knowledge which built up over centuries from generation to generation of indigenous communities for enthnobotanical filtering of the plants. "There have been many compounds developed as results of the study of medicinal plants and one recent success has been of the isolation of the anti-malarial compound artermisinin and its derivatives from the Chinese medicinal plant *qingho*. If plants alone are considered, it is estimated that there is approximately 250,000 species of higher plants but only a small percentage of these have been tested for useful bioactivity."[49]

Therefore, the importance of GR in pharmaceuticals is not separated from the importance of the TK. "In the context of access and benefit-sharing, TK refers to the

[45] *Ibid* , p. 224 – 225
[46] LAIRD. S, WYNBERG. R, *Supra,*
[47] CORREA.M.C, *Protection and promotion of traditional medicine implication for public health in developing countries*, University of Buenos Aires, August, 2002, p.8
[48] STOIANOFF.P.N, *Supra,* p.12
[49] STOIANOFF.P.N, *Ibid*

knowledge, innovations and practices of indigenous and local communities related to GR. This TK is developed through the experiences of communities over centuries, adapted to local needs, cultures and environments and passed down from generation to generation." The TK "is a vital source of information for identifying uses of GR that humanity as a whole can benefit from. This knowledge is particularly valuable for bioprospectors, or users of GR, who use it to guide them to plants, animals and microbes that are already known to have useful properties. Without this knowledge many species currently used in research and commercialized products may never have been identified."[50]

TK permits to become familiar with certain techniques for the conservation of biological diversity. This offers us indication of what could be a use of an eventual industrial or commercial application of medicinal plants and edible plant. From that, it shows significant economic value. It is estimated that the annual value in the global market of products derived from genetic and biological resources between $500 - 800 trillions per year. On conservative estimates, only 10% of this amount is derived from resources derived from TK, i.e an approximate value of $50 trillion annually. Anothers example of the economic value of TK is in the demand for "herbal medicines", which has grown dramatically in recent years. The world market for such medicines has reached, according to one estimate, $60 billion, with annual growth rates of between 5% - 15%.[51]

Our current understanding of GR owes a great deal to the TK of indigenous and local communities. It is essential that the value of TK is understood and valued appropriately by users, and that the rights of indigenous and local communities are considered during negotiations over access and use of GR.

Therefore, the Nagoya Protocol also recognizes: "the interrelationship between GR and TK, their inseparable nature for indigenous and local communities, the importance of TK for the conservation of biological diversity and the sustainable use of its components, and for the sustainable livelihoods of these communities".[52] It also recognizes "the unique circumstances where TK is held in countries, which may be oral, documented or in other forms, reflecting a rich cultural heritage relevant for conservation and sustainable use of biological diversity".[53] However, like the CBD, the Nagoya Protocol does not provide any definition of TK and indigenous and local communities or reference to other sources of international law on these issues.

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[50] CBD, *introduction of ABS, theme: traditional knowledge*, p.2, available at http://www.cbd.int/abs/information-kit-en/ last accessed March 1, 2012.
See more TEIXEIRA-MAZAUDOUX.A.C, *Protection de saviors traditionnels associes aux ressources genetiques : Cardre juridique international*, Université de Limoges, 2007, p.7 – p.20

[51] CORREA.M.C, *Supra*, p. 8
[52] Preamble of the Nagoya Protocol
[53] *Ibid*

Definitions of access to genetic resources and benefit-sharing

Access to GR and benefit-sharing refers to the way in which GR may be accessed, and how the benefits that result from their use are shared between the people or countries using the resources (users) and the people or countries that provide them (providers).[54] However, in the scope of CBD, access and benefit-sharing is strictly international in nature, "only applies where the country provides the genetic resource is different from the country with jurisdiction over the user and/or his activities utilizing the genetic resources".[55]

"Access and Benefit-sharing" is, by definition, "the fusion of two concepts which are politically and (to a very limited extent) legally or contractually linked. In general, 'access' is perceived to be primarily the responsibility of the source country, source community or individual, while 'benefit-sharing' is founded on the user (private company or entity) to be made legally effective by the country with jurisdiction over that user"[56].

Article 15 of the CBD provides a global set of principles for access to GR as well as the fair and equitable distribution of the benefits that result from their use. These principles, then, were enshrined in the Nagoya protocol. In general, access to GR and benefit-sharing is based on prior informed consent (PIC) being granted by a provider to a user and negotiations between both parties to develop mutually agreed terms (MAT) to ensure the fair and equitable sharing of GR and associated benefits.

Under the international environmental law, PIC is a one of the common forms of informed consents[57]. MAT is negotiated between a user (who seeks to GR access, is an individual or a company or an institution) and an actual provider (who may be an entity, a local community or an authority. MAT is made under type of a contract or a permit in case the actual provider is the authority.

An underlying assumption in Article 15 of the CBD and the Nagoya Protocol for PIC and MAT is the application of the principle of national sovereignty. Here there is a need to balance the benefit arising out from utilization of GR between the users of GR (which mostly are the developed countries) and the providers of GR (mostly are the

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[54] CBD, introduction of ABS, p. 3, available at http://www.cbd.int/abs/information-kit-en/ last accessed March 1, 2012

[55] TVEDT. M. W, YOUNG. T, "*Beyond Access: Exploring Implementation of the Fair and Equitable Sharing Commitment in the CBD*", IUCN Environmental Policy and Law Paper No. 67/2, 2007, p.6, noted that "This is unlike the implementation of the other two primary objectives, both of which focus primarily on the Contracting Parties' domestic activities. Nothing in Article 15 imposes any responsibilities, or even recommends any governmental action, relating to domestic use of the country's own genetic resources. While it is unlikely that the ABS system can function if domestic uses are entirely exempt, the choice of whether or how to regulate them is the country's sovereign choice"

[56] TVEDT. M. W, YOUNG. T, *Beyond Access: Exploring Implementation of the Fair and Equitable Sharing Commitment in the CBD*, IUCN Environmental Policy and Law Paper No. 67/2, 2007, p.2

[57] For example, the Basel Convention on the control of transboundary movements of hazardous wastes and their disposal, 1989, Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade 1998.

developing countries with rich biodiversity). Accordingly, the provider countries should facilitate for access to GR, and *vice versa*, the users should work to realize benefit-sharing.

The access and benefit-sharing system may apply "to research carried out for either purely scientific or commercial ends, for which organisms or parts thereof (the "GR") and/or related TK are obtained ("accessed") from a country that is party to the CBD and – in case of TK – it is the indigenous and local communities".[58]

Elements of access to GR and benefit-sharing process

As outlined above, access to GR and benefit-sharing is actually a process of negotiation to reach the agreement on access, utilization and sharing of benefit arising from the accessed GR. The process is based on the balance between main elements including 'access' and 'benefit-sharing', and two main subjects, including 'provider' and 'user'. To keep the balance, the necessary element is 'compliance' that is required of both "provider' and 'user' during their 'access' or 'benefit-sharing'. The element of 'access' is based on the principle of PIC and MAT, and the element of 'benefit-sharing' must be in accordance with MAT. The 'compliance' ensures PIC and MAT are both implemented.

However, the term "access" has not yet been officially defined. Thus, its meaning depends on its interpretation by the providing countries and their practices. Therefore, the term 'access' may involve various activities, for example: entering a location where GR are found; simple surveying activities; the acquisition of GR or their study/examination for scientific and/or commercial purposes.

Article 5 of the CBD defines the main requirements of access to GR and benefit-sharing to be the PIC of the provider countries and the MAT between the parties. The conditions of the access to GR and benefit-sharing are outlined under Article 15.4 and 15.7 respectively of the CBD. Here, PIC is permission given by the competent national authority of a provider country to a user prior to accessing GR in line with an appropriate national legal and institutional framework. MAT is an agreement reached between the providers of GR and users on the conditions of access and use of the GR, and the benefits to be shared between both parties.

National law will regulate providers of GR because the States have sovereign rights over natural resources under their jurisdiction. They are obligated to put in place conditions that facilitate access to these resources for environmentally sound uses. Providers agree terms, which include PIC and MAT, for granting access and sharing benefits equitably. The concept of 'provider' relates to the issue of ownership of GR that also depends on the national law. In some countries, GR may belong to the State in accordance with the Constitution which provides indirectly or directly to the legal status of GR; for example in

[58] KLEMM.S.B, MARTINEZ.S, *Supra*, p.15

the Philippine[59], and Vietnam[60], while, in the others countries like the Australia, the State governments and individuals own the GR found on their respective lands in accordance to common law principles[61].

Users of GR are a diverse group, including "botanical gardens, industry researchers such as pharmaceutical, agriculture and cosmetic industries, collectors and research institutes with different purposes from basic research to development of new products".[62] The users are responsible to share the benefit arising from the GR of the providers.

Other stakeholders in the access and benefit-sharing process, there are also National Focal Points and Competent National Authorities. The National Focal Points are responsible to provide information and to facilitate access, as users need a clear and transparent process that details who to contact and what the requirements and processes are in provider countries in order to gain access. Competent National Authorities are bodies established by governments and are responsible for granting access to users of their GR, and representing providers on a local or national level. National implementation measures establish how Competent National Authorities work in a given country.[63]

The requirements for PIC are legal certainty, clarity and transparency of access and benefit-sharing in domestic legislation. Other regulatory requirements that include fair and non-arbitrary rules and procedures; a clear and transparent written decision by a Competent National Authority and in a cost-effective manner and within a reasonable period of time.[64]

The key content of PIC is the right to GR access should be obtained with prior consents of the GR provider, unless otherwise determined by the provider. The provider and person who seeks the access should negotiate to reach agreement of the access and sharing benefit based on PIC. Therefore, the GR provider has a right to receive the necessary information relating to access, such as who the uses of the GR, objective of utilization, risks and potentialities derived from this access and utilization. Based on this information, the provider will make decision to allow access or not, the level of access and how to share benefit, plan of sharing benefit, types and rate of sharing benefits. The access to GR is only recognized based on conditions which are agreed by the parties. This principle is to be implemented at all related levels, especially in the local community which the GR. To implement this principle, and in accordance with the Nagoya protocol, it requires to define which agency will be responsible to receive prior inform to access and

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59 UNEP/CBD/WG-ABS/5/5, *Report on the Legal status of genetic resources in national law, including property law, where applicable, in a selection of countries*, fifth Meeting of the Ad Hoc Open Ended Working Group on Access and Benefit-Sharing (WG ABS 5), 2007, p. 17, "the EO 247 recognizes the clear framework for property rights to biological resources put forward in the Philippine constitution: the Philippine State owns all forests, wildlife, flora and fauna, and other natural resources (Section 2, Article XII)".

60 Article 17.2 of the Constitution 1992 of the Socialist Republic of Vietnam

61 UNEP/CBD/WG-ABS/5/5, *Supra*, p. 9

62 CBD, Introduction of ABS, *Ibid*, Theme: access and benefit-sharing, p. 4,

63 See more Article 13 of the Nagoya Protocol

64 Clause 2, Article 6, the Nagoya Protocol

bioprospect GR and granting permit to access GR. In addition, there are the others conditions of the access such as methods, means, objectives, plans of the access, time, subjects, ensurance of biosafety and protection of ecological environment.

The requirements for MAT are: clear rules and procedures for MAT shall be set out in writing, with a dispute settlement clause; terms on benefit-sharing, including in relation to intellectual property rights; terms on subsequent third-party use, if any; and terms on changes of intent, where applicable.[65]

Benefits arising from the utilization of GR as well as subsequent applications and commercialization shall be shared in a fair and equitable way with the provider of such resources and may include monetary and non-monetary benefits. The Nagoya Protocol suggests but does not limit application of a list of kind of monetary and non-monetary benefits in its Annex[66].

The fair and equitable sharing of benefits under MAT between parties include research results, and interest obtained from GR used for commercial purposes or other purposes. This may apply to the benefits acquired from biological technique or technology basing on GR and TK. Mostly, the requirements of benefit-sharing are descried by agreement of GR access like a conditions for access to GR.

The 'compliance' includes compliance with legal obligations of national legislation and procedures and mechanism on compliance with the Protocol. The measures to suppport compliance through monitoring of GR utilization under the Nagoya Protocol are to design checkpoints and an 'internationally recognized certificate of compliance'. A permit or its equivalent issued at the time of access of a permit or its equivalent as evidence of the decision to grant PIC and of the establishment of MAT, which us made available to the Access and Benefit-sharing Clearing-House, shall constitute an internationally recognized certificate of compliance.[67]

However, elements of access and benefit-sharing regulated by the Nagoya Protocol contains by itself many problems that affect to the process of its integration into national legislation, because of the general nature of provisions on obligations of user countries, lack of detailed provisions for measures to support compliance, as well as enforcement at national level. These problems will be analyzed by the Title 2, Part 1 of this thesis.

The importance of the access and benefit-sharing

The Nagoya Protocol acknowledges the potential role of access and benefit-sharing to contribute to the conservation and sustainable use of biological diversity, poverty eradication and environmental sustainability. In this way the Protocol can contribute to the

[65] Point f, Clause 2, Article 6, the Nagoya Protocol
[66] Clause 1, 3, Article 5, the Nagoya Protocol
[67] Clause 2,3, 4 Article 14, the Nagoya Protocol

achievement of the Millennium Development Goals, as well as, the linkage between access to GR and the fair and equitable sharing of benefits arising from the utilization of such resources[68].

In theory, access to GR can lead to benefits for both users and providers. Access and benefit-sharing ensures that the way in which GR are accessed and used maximizes the benefits for users, providers, and the ecology and communities where they are found.

Users seek GR to deliver a range of benefits; from basic scientific research, such as taxonomy, to developing commercial products which contribute to human well being, such as pharmaceuticals. Providers of GR grant access to these resources in return for a fair share of the benefits that result from their use. In cases where research and development leads to a commercialized product, monetary benefits such as royalties, milestone payments or licensing fees must be shared with the provider.

Providers of GR are persons who are entitled to provide access to GR and share the benefits resulting from their use in accordance with national law. The benefit-sharing provisions of the CBD and the Nagoya Protocol are designed to ensure that the physical access to GR is facilitated and that the benefits obtained from their use are shared equitably with the providers. In some cases this also includes valuable TK that comes from indigenous and local communities. "Providers can also benefit from technology transfer or the enhancement of research skills. Ideally, these benefits will also be used to improve conservation and the sustainable use of biological diversity. For developing countries, granting access to GR in exchange for a share of monetary and non-monetary benefits could contribute significantly to poverty alleviation and sustainable development."[69]

It is vital that both users and providers understand and respect institutional frameworks such as those outlined by the CBD and the Nagoya Protocol. These help governments to establish their own national frameworks which ensure that access and benefit-sharing happens in a fair and equitable way

Access to GR depends on using the TK of indigenous and local communities, "the access and benefit-sharing rules recognize the value of this knowledge by requiring users to obtain permission to use it, and to share any benefits that result from its use with the communities who own it."[70] However, these benefits can only be realized remains an unfulfilled idea. It has not been fulfilled in practice because of too many conflicts of interest between stakeholders, unbalanced power relationships of parties and many other difficulties in its realization.

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[68] Preamble of the Nagoya Protocol

[69] CBD, Introduction of ABS, *Ibid*, Theme: access and benefit-sharing, p.10

[70] CBD, ABS, theme: access and benefit-sharing, p.2, downloaded from *http://www.cbd.int/abs/information-kit-en/powerpoint.shtml* , accessed 6 March , 2012

The Nagoya Protocol is different from the UN Framework Convention on Climate Change as there was not a number of conditions for countries from the Global South (referred as developing countries) and countries from the Global North (referred as developed countries). The Convention divides countries into three main groups to differing commitments: the industrialized countries, countries with economies in transition and developing countries[71]. This difference is explained by the nature of approach and view between two treaties. As explained above, the Nagoya Protocol does not pose absolutely direct responsibilities of GR conservation for the countries, but through privatization, commercialization and marketization of biodiversity to maximize benefit arising out from bioprospecting, and then to use these benefits for biodiversity conservation. Thus, in respect of contract law, there are factors of free will and voluntary consent to enter into contract of access to genetic resources and benefit-sharing. In respect of GR utilization and development of science and technology, one country may be both provider and user of GR, or one country from the Global South also may be user country or one country from the Global North also may be provider country, or *vice versa*. Therefore, the Nagoya Protocol does not impose certain conditions on countries from South or countries from North like the Convention on Climate Change. The number of ratifications of the Convention on Climate Change therefore also is different between the Global North and the South. There are only 42 countries in Annex I, that are industrialized countries and countries with economies in transition from the Global North[72]. There are 153 members countries of the Convention which are from the South.[73]Amongst the 92 signatures of the Nagoya Protocol, 31 signatures are from the Global North.[74] This figure seems to show the fact that countries from the South which sign to the Protocol are less than the ratification to the Convention.

The problems of integration of the Nagoya Protocol into national laws

"Law in general is a multi-faceted and complex phenomenon and this holds true for international law also".[75] As being one of new international treaties, the Nagoya Protocol has these chacteristics: there is a complex relationship with other treaties and the rest of public international law.

Generally, the integration of international law into national law is the process in which international agreements become part of or are applicable to the national law of a

[71] Annex I Parties include the industrialized countries that were members of the Organisation for Economic Co-operation and Development in 1992, plus countries with economies in transition, including the Russian Federation, the Baltic States, and several Central and Eastern European States. Annex II Parties consist of the Organisation for Economic Co-operation and Development members of Annex I, but not the economies in transition Parties, Non-Annex I Parties are mostly developing countries. See more http://unfccc.int/parties_and_observers/items/2704.php
[72] http://unfccc.int/parties_and_observers/parties/annex_i/items/2774.php, last accessed 9 July 2012
[73] http://unfccc.int/parties_and_observers/parties/non_annex_i/items/2833.php last accessed 9 July 2012
[74] http://www.cbd.int/abs/nagoya-protocol/signatories/ last accessed 9 July 2012
[75] G.J.H.VAN HOOF. *Rethinking the sources of International law*, Kluwer, 1983, p.20

sovereign state. A country integrates a treaty in the national legal system by passing domestic legislation that gives effect to the treaty.

The process by which an international treaty becomes part of the national law can be called 'incorporation', 'adoption', 'transformation', or 'reception'. Because there is "a general duty for states to bring domestic law into conformity with obligations under international law, but international law leaves the method of achieving this result to the domestic jurisdiction of states. They are free to decide how best to translate their international obligations into internal law and to determine which legal status these have domestically. On this issue, in practice there is a lack of uniformity in the different national legal systems".[76] However, following Triepel, it can not be said that an integration of the international law by the national law, when the received law ("droit à recevoir") is really the international law. There never has the integration of the international law if the content of the national law is not responded exactly to the content of the regulation of the international law. It is impossible to know exactly the true 'acceptation' or 'incorporation' of the international law norms into the national law. [77]

Each process by which international treaty becomes part of the national law can be characterized either as: monist or dualist. "It is often said that the doctrines of incorporation and transformation correspond with 'monism' and 'dualism' respectively"[78]. Following doctrine of incorporation, «le droit international public fait automatiquement partie du droit interne », following doctrine of transformation, «le droit international public n'est incorporé au droit public interne qu'à la suit d'une loi ou d'une décision de justice »[79] Incorporation in the civil law is the union of one domain to another[80]. « Incorporation dans une vue dualiste des relations entre le droit international et le droit interne, se dit du mécanisme de réception du premier dans le second »[81].

According to monist system, international law and domestic law are parts of the same legal order and international law is automatically incorporated into national law. Conversely, under a dualist system, international law and national law are two separate systems of law operating in its own area of competence. The rules of international law can operate in a national law only if they are deliberately transformed into it.[82]

It is difficult for this thesis to choose the terminology or concept which is neutral and can express the process of which international treaties become part of the national

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[76] MALANCZUK. P, *Modern introduction to international law,* Routledge, New York, 1997, p.64
[77] TRIEPEL. Henrich, *Droit international et droit interne*, Éditions Panthéon Assas, 2010, p.167
[78] HAMID.A.G, SEIN.K.M, *Judicial application of international law in Malaysia: an analysis*, presented at the Second Asian Law Institute Conference, Faculty of Law, Chulalongkorn University,Thailand, May, 2005 http://www.malaysianbar.org.my/international_law/judicial_application_of_international_law_in_malaysia_an_analysis.html#1
[79] Dictionaire de l'anglais jurisdique, Business management series 2004,
[80] Black law dictionary, 6th Edition, West publishing, 1990, p. 766
[81] UNIVERSITÉ FRANCOPHONES, Dictionnaire de droit international public, Bruylant Bruxelles, 2001, p.368
[82] HAMID.A.G, SEIN.K.M, *Supra,* note 66

law of a sovereign state. Considering debate over "monism" and "dualism" as theoretical models for construing relationships between international law and national law, the term "integration" seems to be a neutral term for the both doctrine and both system of law in literature[83].

However, some scholars considered that "the entire monist-dualist debate is unreal and artificial, because it assumes something that has to exist for there to be any controversy at all - and which in fact does not exist - namely a common field in which the two legal orders under discussion both simultaneously have their spheres of activity. It is more useful to leave this dogmatic dispute aside here and to turn to the general attitude of international law to municipal law"[84]. Therefore, the thesis will not enhance the debates of doctrines relating to process of integration, but it analyzes limitation of existence of the two doctrines as problems for integration of international law into national law. In addition, this thesis considers the other characteristics of international law that may cause problems to the process of integration of the Nagoya protocol into national law, such as weakness of international law in enforcement in comparison with national law, "lack of central institutions, is heavily dependent on national legal systems", "the legislature, more recently, upon the topic of sanctions and compliance without recognizing the historical, structural and functional differences between legal systems within states".[85] The analysis of problems of international law in the particular case of the Nagoya protocol and other the intrinsic problems of the Nagoya protocol itself that will be discussed before attempting to find solutions to address these problems and contribute to find better ways of integration of the Nagoya protocol into national law.

In summary, corresponding with the process by which the Nagoya Protocol becomes part of or becomes acceptable into the national law, the thesis will outline studies and analysis of problems of the Nagoya Protocol itself in Part 1 and problems of integration in Part 2. The Nagoya protocol in the international context will therefore be analyzed in Title 1 of Part 1 which includes analysis of the relationship with the other relevant international treaties. All the content and intrinsic problems of the Nagoya Protocol in both legal, technical and scientific aspects, will be covered by Title 2 of Part 1. Part 2 of the thesis will clarify all related legal problems of process of integration into

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83 The term "application" also is a popular and neutral use in public international law, such as COMBACAU.J, SUR.S *Droit international public*, 5e Edition, Monthrestien E.JA, Paris, 2001; DAILLIER.P, PELLET.A, *Droit international public*, 7e Edition, NGUYEN Quoc Dinh, LGDT, 2002; DUPUY, P. M., *Droit international public*, 9e édition, Dalloz Sirey, Paris, 2008, DUPUY.P.M, KERBRAT.Y, Droit international Public, 10 e Edition, Dalloz; BEURIER.J-P, *Droit International de L'environnement*, 4e edition, Alexandre Kiss, Editions A. Pedone, Paris, 2010. But this term is very broad and general. It covers all process of integration, translation, compliance and implementation of international treaty or customary law in national jurisdiction. Therefore, it may be not appropriate with the actual context of the Nagoya Protocol, which still does not come into force or may be unpredictable for when it will come into force. It needs deposit of the fiftieth instrument of ratification, acceptance, approval or accession by States or regional economic integration organizations that are Parties to the CBD (Article 33.1)

84 MALANCZUK. P**,** *Supra*, p. 63

85 MALANCZUK. P, *Ibid*, p.4 – p. 63

national law and discuss this with reference to case studies of some typical national legal systems on access and benefit-sharing. Title 1 of the Part 2 includes analysis of legal points of views of integration, the problems of non-self executive treaties, the principles, methods and ways that can be applied to the integration of the Nagoya Protocol into national law. Title 2 of Part 2 analyzes the case studies of Brazil, South Africa, France and particularity of Vietnam's legislation.

In four countries of case studies, Brazil, South Africa, France signed the Nagoya Protocol, but Vietnam did not sign the Protocol.

The methodologies for the thesis are dialectical and historical materialism. This is common methodologies for all sciences, and will be applied during the whole research of thesis to ensure principles of objectiveness, comprehensiveness and concrete historicity. The specific methods of doing research of thesis are analysis, synthesis, statistics, survey, comparison and assessment.

Because the Nagoya protocol is a newly adopted treaty, law on access to GR and benefit-sharing is anew law's area. However, there are shared experiences of its implementation in others countries. This thesis will therefore use comparative law as one method of study. This method also will be used to find the unity and diversity of development of access and benefit-sharing international law and national legislation. The comparative law approach also allows us to clarify the contradictions, conflicts of different national legislation on access and benefit-sharing. The thesis clarifies the rules of development, operation, features of social structures, specific economic context of countries, reasons and deep root of problems that are considered for the best assessment and provides recommendations on how to improve international law and national legislation. The basic comparative law tools that will be applied to this research include: comparison of time, space, internal and external factors. The level of comparison is from legal norms with consideration of legal institutions and legal systems, implicitly social factors, sources factors, principles, social bases.

The thesis will contribute to a comprehensive, authentic analysis and assessment of the Nagoya Protocol and international access and benefit-sharing mechanism, arguments and discussions of methodology, approach and provide recommendations for improving its integration into national law.

PART 1 – THE NAGOYA PROTOCOL AND RELEVANT LEGAL ISSUES

Despite the efforts of people around the world and calls for protection from the international community in recent decades, the biodiversity of the planet continues to worsen. A large number of international agreements have been signed with the aim to improve the protection of biodiversity and there are different approaches and methods for

elaboration of these agreements. Under the CBD, the Nagoya Protocol is based on a common approach of conservation and sustainable use, with a central objective being Access to Genetic Resources and the Fair and Equitable Benefits Sharing arising out of their utilization.

This treaty has had one of the longest and most tense negotiations, but the Protocol has proved that it is necessary, and it has played a role in biodiversity conservation and sustainable use by being cited by many research papers and projects before and after being approved. Notwithstanding criticism or commendation, the Protocol has been recognized as part of the international regime: "the international regime is constituted of the CBD, the Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of the Benefits Arising from their Utilization, as well as complementary instruments, including the FAO's treaty, the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of Their Utilization".[86]

This first Part of the thesis analyzes the Nagoya Protocol in the process of the development of access and benefit sharing in the international regime. It will be focused on the interrelation between the Protocol and other relevant treaties on access to GR and benefit sharing or related issues. The international political, and socio-economic effects of the Protocol also will be considered. This Part also takes a deep analysis and commentary to each emerging issue of the Protocol following each component of access and benefit sharing. This analysis will be considered with the question of the integration of the Protocol into national law for effective implementation.

Accordingly, this Part consists of two titles: Title 1 – The Nagoya Protocol – process of development of international regime on access to genetic resources and benefit sharing, and Title 2 – Substance's development of the Nagoya Protocol.

[86] UNEP/CBD/COP/10/L.43/Rev.1, *Advanced unedited text reflecting the decision as adopted on the basis of document*, 2 November 2010, COP 10, CBD

TITLE 1 – THE NAGOYA PROTOCOL - PROCESS OF DEVELOPMENT OF INTERNATIONAL REGIME ON ACCESS TO GENETIC RESOURCES AND BENEFIT-SHARING

It has been nearly forty years since the first session of the UNEP marked the starting point of international reflection on the necessity of biodiversity conservation in 1973. Forty years of development of international biodiversity governance is a small amount of time in the history of natural evolution, but it seems to be a very long amount of time in the process of finding a common goal among the international community in the conservation of nature, degradation and loss of biodiversity. Being one integral part of international biodiversity governance, the international regime on access to genetic resources and benefit sharing has also undergone a long process of establishment and development.

Under this title, a picture of the development of the international regime on access to GR and benefit sharing will be clarified. This picture covers the practical needs of the treaty and why it the formation of an international treaty regulating access to GR and benefit sharing was required. It also undertakes an analysis of the relevant international treaties in relation to the Nagoya protocol.

It is very important to understand the background of an international treaty, including the history of its development in order to find answers or explanations for its problems or shortcomings. This will be analyzed in the next Title of the first part of the thesis. It is also necessary to have a comprehensive view of a treaty in the international legal system and to understand its interrelation with other relevant treaties. No international treaty can exist as a separate entity. However, the interrelation may also facilitate or hinder the integration of the international treaty into national laws.

Therefore, this Title 1 of Part 1 includes: Chapter 1 - Legal and practice needs of access to genetic resources and benefit sharing and Chapter 2 - Access to genetic resources and benefit sharing under related treaties.

CHAPTER 1 – Legal and practice needs of access to genetic resources and benefit-sharing

Section 1 - Necessities of an international regime on access to genetic resources and benefit-sharing

The necessity of an access and benefit-sharing international regime is generally originated from: I – the fact of degradation and loss of biodiversity in general and GR in particular, and awareness of responsibilities to natural conservation in term of international justice or deal with global concerns for sustainable development; II - Requirements of the relevant treaties like the CBD, FAO's treaty and Bonn Guidelines to constitute an international regime on access to GR and benefit-sharing.

§ I - The fact of biodiversity degradation, loss and awareness of responsibilities to national conservation for sustainable development

On the contrary of the role and importance of the GRs and growth of sectors utilizing GRs, there is a significant reduction in the rate of biodiversity, it is concluded that "unprecendented additional efforts would be needed to achieve, by 2010"[87]. And in the view of sustainable development, « La diminution de la biodiversité se traduit par une diminution de la variabilité génétique susceptible de réduire les possibilité developmment de nouveaux médicaments dans l'avenir ».[88]

A – Utilization's growth and resources' degradation

1) Some facts and figures justification

In industry trends, in 2006, "the global market for pharmaceuticals grew 7% to $643 billion (up from $601 billion in 2005 and $559 billion in 2004). About 50% of this growth was in the US market, although the relative contribution to future growth continues to move away from the US and the five major European markets, with low-income countrie's contribution increasing".[89] The biotechnology industry spans a wide range of activities. It includes pharmaceutical, cosmetic, horticulture, agricultural and industrial process biotechnology. "The industry as a whole grew more than 14% during 2006, with revenues of public companies greater than $70 billion. Biotechnology is one of the most research-intensive industries in the world, and in 2006, research and development (R&D) investment grew by 33% over 2005. There is an increasing dominance of modern biotechnology, or genetic engineering; and the rate at which commercial varieties can be commercialized… Ornamental horticulture is growing both in size and worth. The world import trade value in horticulture (live trees, plants, bulbs, roots, cut flowers and foliage) in

[87] JEFFERY. I. M, QC, FIRESTONE. J, BUBNA. L. K, *Supra,* p.26
[88] BONNIEUX. F, DESAIGUES. B, *Économie et politiques de l'environnement*, Dalloz, 1998, p.6
[89] LAIRD. S, WYNBERG. R, *Supra,* p.12

2006 was US$ 1 4.386 million, up from the 2005 figure of $12.245 million… The global market in botanicals (herbal dietary supplements) is comprised of a few different components: in 2005, a $3–4 billion market in raw/crude plant material; extracts derived from this material worth roughly $4–5 billion; and a market of $21 billion for botanicals and functional foods. The global herbal personal care and cosmetic sector in 2005 was roughly $12 billion. Total sales of herbs/botanicals in the US in 2006 were $4.6 billion; sports and nutrition products were $2.4 billion; and natural personal care and household products was $7.5 billion. The US market value for "healthy foods", which comprise functional foods, natural and organic foods and "lesser evil" foods, totaled $120 billion out of $566 billion (21.2%) in 2006 and grew 7.4%." [90] "During this same period the global sales value of functional foods…"better for you" applications, was $31.4 billion, representing 5.3% of the $590 - billion food industry… 56% of functional food sales were in functional beverages, an industry that has seen continued growth and is believed to be more exploratory and innovative than food. Along with this trend is increasing interest in new products from biodiversity by some of the largest beverage companies in the world, including drinks incorporating the African *baobab* and *marula* trees, amongst many other species." [91]

However, the GR extinction and degradation, which is due to various reasons, still existing without effective sollution of prevention. "17,291 species out of the 47,677 assessed species are threatened with extinction. The results reveal 21 % of all known mammals, 30 % of all known amphibians, 12 % of all known birds, and 28 % of reptiles, 37 % of freshwater fishes, 70 % of plants, 35 % of invertebrates assessed so far are under threat. Of the world's 5,490 mammals, 79 are Extinct or Extinct in the Wild, with 188 Critically Endangered, 449 Endangered and 505 Vulnerable. 1,677 reptiles on the IUCN Red List, 469 are threatened with extinction and 22 are already Extinct or Extinct in the Wild. 1,895 of the planet's 6,285 amphibians are in danger of extinction, making them the most threatened group of species known to date. Of these, 39 are already Extinct or Extinct in the wild, 484 are Critically Endangered, 754 are endangered and 657 are vulnerable. Of the 12,151 plants on the IUCN Red List, 8,500 are threatened with extinction, with 114 already Extinct or Extinct in the Wild". [92] "50% of world's rain forest which estimated to contain many of these species (used for plant medicine) has been destroyed and 25-30 million hectares are lost each year".[93] In recent years, demand for tropical hardwoods in world trade has grown at an alarming pace. "In 1950, the producing countries in the tropics consumed five times more tropical industrial timber than Japan, the U.S., and Europe…

[90] *Ibid*, pp.14- 21
[91] *Ibid*, pp.14- 21
[92] IUCN, *Extinction Crisis Continues Apace* (Nov. 3, 2009), http://www.iucn.org/?4143/Extinction-crisis-continues-apace.
[93] STOIANOFF.P.N, *Supra*, p.12

Between 1950 and 1973, Japan increased its imports of tropical hardwoods by nearly 2,000%, the U.S by almost 1,000%."[94]

Indeed, according to the third edition of Global Biodiversity Outlook, "the rate of biodiversity loss was one thousand times higher that the background and historical rate of extinction. If that loss rate was allowed to continue, it would soon lead to a tipping point with irreversible damage to the capacity of the planet to continue sustaining life."[95]

The above figures of degradation and loss of species explain why Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) was not sufficient to stop degradation and extinction of genetic resources. There is a need of more effective approach for conservation of GR that is one of expectations to the Nagoya Protocol.

2) Key reasons of degradation and loss of genetic resources

In theory, like other biological resources, GR may be classified into renewable resources, that means it can be replaced or replenished naturally in the same amount by itself over time. Thus, why the degradation and loss of GR happened? The reasons of the degradation and loss of GR will justify the needs for an international regime for its conservation and sustainable use.

The extinction and degradation of GR are caused by many reasons and that can be summarized as the followings:

Firstly, the increase of human population has brought about the increase in demand of animal, plant consumption. Limited plants, animal sources are unable to bear this pressure and leading to decrease of varieties and species.

Secondly, impacts of agricultural, forestry, aquaculture trade with large scope of trade, many endemic varieties and breeds have been replaced by the other that can meet immediately the human demand.

Thirdly, planning economic policies has not been estimated on the whole value of environment and natural resources. Due to pressure of economic increase, some national policies are still not paying attention to negative impacts on biodiversity and genetic diversity such as timber exploitation…

Fourthly, unfairness in ownership and benefit-sharing, most of benefits arise from GR under the group of businesses and not local communities that are conserving GR.

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94 FOWLER. C, MOONEY.P, The Threatened Gene. Food, politics and the loss of genetic diversity, Lutterworth Press, Cambridge, 1990, p.102

95 UNEP/CBD/COP/10/27, *Report of the 10th Meeting of the Conference of the Parties to the Convention on Biological Diversity*, 2010

Fifthly, lack of knowledge and restriction of knowledge using, with weak knowledge, individuals and communities exploit and destroy environment in general and biodiversity in particular unconsciously

Sixthly, legal systems and institutions have not facilitated to exploit sustainably. Violation of environment and biodiversity has not been handled timely or ineffectively.[96]

Seventhly, the cause of deforestation or biodiversity loss "rarely noted in academic works on the subject: war. The term 'ecocide' entered the English language during the Vietnam War,... Between 1965 and 1971, Indochina absorbed twice the tonnage of munitions that the U.S used in World War II. Twenty six billion pounds fell on Indochina, the equivalent of 450 Hiroshima bomb, 142 pounds for every acre of land, 584 pounds for every person. The typical five hundred pound bomb left a crater fifteen feet deep and thirty feet across. There are twenty six million of these scatters in Indochina, covering 423,000 acres. Aside from simply wasting large areas of Indochina, shrapnel from the bombs left cuts and gashes in millions of acres of forest vegetation."[97]

Lastly, recently, climate change also is mentioned as one of reasons of biodiversity or GR extinction. "Earth's biodiversity may be threatened by the worst extinction crisis in 65 million years. Mounting evidence shows that climate change is accelerating the extinction rate and could have enormous negative consequences in natural resources that sustain livelihoods and economies. The degree of climate change expected by 2050 may be enough to drive 30 % of all species to extinction. More than 20% of animal and plant species are likely to be exposed to a greater risk of extinction under a 2-3^{o}C increase in temperature[98].

Thus, there is a great urgency to protect the remaining biodiversity by legal means. The GR diversity degradation and loss urges the international community to have effective legal tools to conserve biodiversity in general and GR in particular. The insufficiency and ineffectiveness of the CITES to protect GR is proved by figures above. In nature, the CITES focuses "on protection of certain species of wild fauna and flora against over-exploitation through international trade"[99]. We understand that the protection of species also means protection of GR as they contain genetic materials of plant, animal. Thus, in some certain cases, the access and commercial utilization of GR of species under the list of appendices of the CITES should comply with both regulation of the CITES and the Nagoya Protocol. The CITES emphasis on using method of 'control" with 'strict regulation' of prohibition through import, export permits and certificates to protect species

[96] TRAN.T.H.T, *Legislation on GR conservation in Vietnam, Internalization of International Environmental Law in national legislation, and follow-up of IUCN Resolutions*, Hanoi, 2007, p.11
[97] FOWLER. C, MOONEY.P, *Supra,* p.104
[98] ENVIRONMENTAL LAW INSTITUTE, *Legal and Policy tools to adapt Biodiversity management to climate change*, 2011, p.x
[99] Preamble of the CITES

from trade. However, the Nagoya implies to support 'sustainable use' that includes sustainable trade as final results of scientific research and technology to generate benefits then share these benefits fairly and equitably for GR conservation. The difference between the CITES and the Nagoya Protocol can be explained by the time of approval of the treaties. The CITES was approved in 1973 when the development of science and technology, the level of consumption and other economic, social factors are not the same as today. The Nagoya Protocol was issued recently in the time of 'green growth' that requires minimum utilization of natural resources but maximum benefit and interest of products' utilization.

B - The ethic awareness of responsibilities to nature conservation in terms of international justice

1) "Common interest", "common concern" and "ecological debt"

The international justice aims for common interest but not individual interest. For biodiversity, its benefits should serve for common interest of all people and generations in term of equality broad meaning. This 'common interest' is different with concept of 'common heritage'. The "common heritage" might be alleged for free access and without responsibility of sharing benefit. Under the 'common heritage', the opportunities of access and getting benefit belong to some countries or individuals, who have strong abilities or own technologies for bioprospecting, then benefit from biodiversity serves the interests of some certain individuals or some certain countries but not all people and generations. However, the 'common interest', which should ensure the opportunities of access and utilization, will come to all people and generations. As ethic views, any one, who have rights, should have responsibilities correctively.[100] In other words, who benefit from bioprospecting of biodiversity and GR, who cause the degradation of biodiversity, should be responsible to recover and conserve the biodiversity. This is common principle of morality.[101] In international law, the equality calls for the ethic universal correspondence. "The ethic is assumed through and to the level of laws"[102]. Thus, it was supposed that an international legally binding treaty on access to GR and benefit-sharing would be an effort to implement international justice for country, people and generation.

When the concept of "common heritage" was no longer applied for biodiversity prospecting as establishing sovereign rights to biological resourses following the CBD, it

[100] Professor Roger Brownsword wrote "For individual human rights holders, there is the responsibility to act in ways that show appropriate respect for the rights of fellow humans wherever they are located in the global community of rights." Foreword of "*Environmental Justice and the rights of unborn and future generations, Law, Environmental Harm and the Right to Health"* by Laura Westra, Earthscan, 2006

[101] See more « ethical principles », « principle of autonomy, integrity, dignity and vulnerability », « principles of local self determination, protection of plant and ecosystems, protection of vulnerable groups, information and labelling and accessibility of food products », BYK.C (ed.) *Bioéthique et Biotechnologies, Biothics and Biotechnology*, Journal international de bioéthique – International Journal of Bioethics, Volume 17, September 2006, No 3, p.110 - p.111

[102] PAPAUX.A et WYLER.E, *L'é thique du droit international*, Presses Universitaires de France 1997, p.14

has been replaced by the concept of "common concern".[103] "Common concern" implies "a common responsibility to the issue based on its paramount importance to the international community as a whole"[104]. This relates to principle of equity between generations or judicial obligations from the present to the future. That means the present generation should take their responsibilities to protect the GR for availability of utilization of the future generation. Thus, those are common responsibilities of all people, communities and governments in present for their future generation.

Also, concerning about equity between generations, there has been an argument of consequence of biological exploitation in the past and "ecological debt". During the negotiation of the Nagoya Protocol, the term "ecological debt" was used by NGOs, developing countries to require mainly industrialized countries be responsible to biodiversity.[105] The industrialized countries would compensate for the 'ecological debt'; industrialized countries would provide sufficient funding and other support to enable developing countries to conserve and sustainably use their biodiversity[106]. Westra.L also has argued for 'ecojustice' that has moral and scientific basis and agreed that "rich countries and groups must discharge their duties intergenerationally in a direct from but also by fulfilling their intragenerational obligations to developing countries and impoverished population".[107]

The argument is based on the historical analysis. In colonial time, land and forest were with the rise of colonialism. Shiva recognizes that Europe's wealth during colonial time was "to a large extent, based on transfer of biological resources from the colonies to the centre of imperial power and the displacement of local biodiversity in the colonies by monocultures of raw material for European industry"[108].

Furthermore, for many years developing countries experienced free access to their biological and GR by foreign companies without any right to compensation until CBD. Before CBD, "it was recognized that global biodiversity as the common heritage of humanity. Companies of industrialized countries have used natural resources located in developing countries to satisfy the needs of both the national and international market, obtaining huge economic profits while developing countries witnessed the destruction of their biological diversity. While multinational companies protected their commercial product through intellectual property rights, developing countries faced free access of their GRs as these were considered the patrimony or common heritage of humanity"[109]. The

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[103] GLOWKA.L, BURHENNE-GUILMIN.F, *Supra*, p. 3
[104] GLOWKA.L BURHENNE-GUILMIN.F, Synge.H, *Ibid*, p. 3
[105] http://www.cbdalliance.org/blog/ngo-opening-statement-at-abs-5-meeting-in-montreal.html
[106] *Ibid*
[107] WESTRA.L, , *Environmental Justice and the rights of unborn and future generations, Law, Environmental Harm and the Right to Health*, Earthscan, 2006, *Supra*, p.137
[108] STOIANOFF.P.N, *Supra*, p. 2
[109] STOIANOFF.P.N, *Ibid*, p. 193

developing countries in the Global South assert "biopiracy and biocolonialism technological sophistication to develop proprietary interests in biological resources". "The multinational pharmaceutical and biotechnological corporation that are ever merging with each other to form monster corporations to control not only world access to medicines but also food and agricultural usage." "Globalization of trade through the rules of the WTO is the new mechanism by with the biological wealth of the south is being transferred to the North leaving the Third world poorer both ecologically and economically". "The third world countries have expressed concern at what they perceive as attempts by developed countries to misappropriate biological resources owned by developing countries".[110]

2) Equity for indigenous communities to protect GR and TK

In fact, most of the richest ecosystems host human populations, which have lived in harmony with nature for centuries. However, these populations are also now the poorest in the world. Their livelihood depends entirely on the natural resources that surround them. If we want to conserve nature and have access to GR, we must recognize the contribution of local and indigenous communities in maintaining GR and share with them the benefits arising from utilization.

Local and indigenous communities also have rich traditional knowledge that is valuable to conserve nature, but they have not had effective regulations to protect their valuable traditional knowledge. The classic intellectual property system is not adequate for protecting their rights and interests. Because, this is not about individual rights, but collective rights that are handed down from generation to generation in the community. Moverover, the traditional knowledge is not only varieties of economic rights, but it also should be considered as heritage and it implies the responsibility of conservation of the natural resources.

Therefore, it also requires an international treaty to ensure the equity for the indigenous communities to protect GR associated with TK**.**

§ II - Requirement of international laws to create an international legal regime

As above analysis, there are the needs and requirements to conserve GR and biodiversity through international law. These derive from the fact of loss and degradation of GR and biodiversity, from the ethic responsibilities and equity. That "constitutes a new task for humanity and an international legal system that must come over the challenges to elaborate a set of rules aiming at protection both inside borders of States' jurisdiction and outside borders".[111] Because, the CBD and other existing international instruments did not fulfill this task with their regimes; they require a new international legal regime on access

[110] STOIANOFF.P.N, *Ibid*

[111] BEURIER.J-P, *Droit International de L'environnement*, 4e edition, Alexandre Kiss, Editions A. Pedone, Paris, 2010, p. 61 – 65, p. 417 – 425

to GR and benefit-sharing under a new international treaty that the CBD set up legal background for development,

"The CBD is a framework treaty because its provisions are mostly expressed as overall goals and policies, rather than as hard and precise obligations. Moreover, it takes a comprehensive rather than a sectoral approach to conservation of the Earth's biodiversity and sustainable use of biological resources".[112] Thus, to implement Article 15 and Article 8.j to reach third objective of the CBD, it needs a protocol specializes to regulate the access to GR and benefit-sharing issues. Article 28 of the CBD is adduced as a direct legal base for development of a protocol on access to GR and benefit-sharing. This article provides that "The Contracting Parties shall co-operate in the formulation and adoption of protocols to this Convention".

Moreover, there were two legal documents related to access to GR and benefit-sharing, which are the FAO's treaty and the Bonn Guidelines. The Protocol recognizes that "international instruments related to access and benefit-sharing should be mutually supportive with a view to achieving the objectives of the CBD"[113]. The FAO's treaty is a treaty for conservation and sustainable uses of plant GR for food and agriculture. The Bonn Guidelines is a non-legally binding agreement. Therefore, there is a need of a legally - binding treaty for all sustainable uses of all GR. After the Protocol being adopted "the International Regime is constituted of the CBD, the Nagoya Protocol, as well as complementary instruments, including the FAO's treaty and the Bonn Guidelines".[114] The FAO's treaty is considered as 'a specialized international access and benefit-sharing instrument'[115] with special nature and importance for achieving food security worldwide. The Bonn guidelines "should be applied in a manner that is coherent and mutually supportive of the work of relevant international agreements and institutions. The guidelines are without prejudice to the FAO's Treaty. Furthermore, the work of the WIPO on issues of relevance to access and benefit-sharing should be taken into account. The application of the guidelines should also take into account existing regional legislation and agreements on access and benefit-sharing"[116].

An effective international access and benefit-sharing regime makes a possible guarantee for fulfillment of acquired obligations under the negotiated contractual agreements. It also assists for monitoring and enforcing the provisions of fair and equitable agreement that would also be necessary in the situation where there is still unequal power between provider and user countries.

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112 GLOWKA.L, BURHENNE-GUILMIN.F, Synge.H, *Supra*, p.18
113 Preamble of the Nagoya Protocol
114 Decision X/1, UNEP/CBD/COP/10/27, *Supra,* p. 83
115 Article 4.4 of the Protocol
116 Section D, Bonn Guidelines, COP 6 Decision VI/24 on Access and benefit-sharing as related to genetic resources

"Without international access and benefit-sharing regime for compliance of the CBD, the fair and equitable sharing of benefits could promise an utopia that deliver little or have no practical life beyond some letters on a piece of paper while developing countries still face relatively unfettered access to their GR. Experience has demonstrated that the existence of the international provisions related to the sovereign rights of the states to regulate access to their GR has not stopped the ' illegal' access to these resources to the detriment of these States and their habitants."[117] Thus, an international access and benefit-sharing regime to ensure the development of the third objective of the CBD is indispensable.

The development of an international access and benefit-sharing regime also is an objective set by the Plan of Implementation of the World Summit on Sustainable Development.[118] This is one of key tasks to reach common goal of sustainable development.

The international regime on access to GR and benefit-sharing also has been established in accordance with the principle of Declaration Rio 1992.[119] Accordingly, the equity is required for access to the GR that is known as universal principle of justice. This is the equity between the actual users and local tenure and the equity between generations. Utilization of GR is not for present generation but future generation in aspect of sustainable development.

Section 2 - Milestone of process of formation and development

§ I - The long negotiation

In 1973, the first session of the UNEP marked the starting point of international reflection on the necessity of biodiversity conservation and as its consequences of elaboration of a Convention. In 1989, the UNEP was responsible to gather a committee of experts to elaborate the CBD. In 1991, the official negotiation of intergovernmental committee had started. In 1992, the CBD was approved as the mark of the beginning of international negotiation of the Earth Summit Rio 1992 to global biodiversity. Ten years later, in 2002, at the World Summit on Sustainable Development in Johannesburg, the Nagoya protocol also decided to start with negotiation.

The process of determining the nature of an eventual international regime on access to GR and benefit-sharing and negotiating the Protocol required almost twelve years. "The prospect of potentially failing to adopt a Protocol on access to GR and benefit-sharing at COP 10 would have cast a leaden shadow on the CBD's future role in international

[117] STOIANOFF.P.N, *Supra*, p. 233
[118] Paragraph 44, point o of the Plan of Implementation of the World Summit on Sustainable Development, http://www.un.org/esa/sustdev/documents/WSSD_POI_PD/English/WSSD_PlanImpl.pdf, last accessed 13th November 2011
[119] Principle 1 of the Declaration Rio 1992

biodiversity governance."[120] Even though, the Protocol is considered by some to be 'imperfect'[121] and 'weak'[122] and there exist "some misgivings" about it,[123] its adoption should be considered an achievement of COP 10. Eight years of international negotiations, with considerable investment of time and resources, reached the goal set by the World Summit on Sustainable Development in 2002[124] and for the International Year of Biodiversity Conservation in 2010.

Implementation of Article 15 of the CBD was first put on the international agenda at the fourth Conference of the Parties (COP 4, May 1998, Bratislava, Slovakia). COP 4 Decision IV/8 on Access and Benefit-sharing established a regionally balanced panel of experts to develop "…a common understanding of basic concepts and to explore all options for access and benefit-sharing on mutually agreed terms including guiding principles, guidelines, and codes of best practice for access and benefit-sharing arrangements."[125]

From 1998 to 2008, the preparations for an international regime on access to GR and benefit-sharing made slow progress. The fifth Conference of the Parties (COP 5, May 2000, Nairobi, and Keya) established the Ad Hoc Open-Ended Working Group on Access to GR and Benefit-sharing, a subsidiary body of the COP. The sixth Conference of the Parties (COP 6, April 2002, The Hague, Netherlands) adopted the Bonn Guidelines on Access to GR and Benefit-sharing. The mandate to negotiate an international regime on access and benefit-sharing was given by the seventh Conference of the Parties (COP 7, February 2004, Kuala Lumpur, Malaysia). This COP adopted the Action Plan on capacity building for access and benefit-sharing, mandated the Working Group to elaborate and negotiate an international regime on access and benefit-sharing, and set out the terms of reference for the negotiations. The eighth Conference of the Parties (COP 8, March 2006, Curitiba, Brazil) instructed the Working Group to complete its work with regard to the international regime on access and benefit-sharing at the earliest possible time before COP 10. The ninth Conference of the Parties (COP 9, May 2008, Bonn, Germany) adopted a roadmap for the negotiation of the international regime.

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[120] CHIAROLLA.C, *Making Sense of the Draft Protocol on Access and Benefit-sharing for COP 10*, Biodiversity, N°07/2010, Institut du Développement Durable et des Relations Internationales, Paris. Available online: http://www.iddri.org/Publications/Collections/Idees-pour-le-debat/ID_1007_chiarolla_abs.pdf**.** Accessed 17 December 2011, p. 4

[121] NIJAR.G.S, *The Nagoya Protocol on Access and Benefit-sharing of Genetic Resources – an Analysis*, Centre of Excellence for Biodiversity Law (CEBLAW), Universiti Malaya. Kuala Lumpur, 2011, p.11

[122] NIJAR.G.S, *Ibid*, p.10

[123] International Centre for Trade and Sustainable Development (ICTSD), *CBD Reaches Agreement on Access and Benefit-sharing, But Some Question Its Effectiveness*, *Bridges Weekly Trade News Digest*. Volume 14, Number 38, 3 November 2010. Available online: http://ictsd.org/news/bridgesweekly/?volume=14&number=38. Accessed 3 March 2012.

[124] NIJAR.G.S, S*upra*, p.11

[125] Convention on Biological Diversity. COP IV Decision IV/8. Access and benefit-sharing. Available online: http://www.cbd.int/decision/cop/?id=7131. Accessed 17 December 2011.

The negotiations progressed from March to October 2010, during which period a series of extra negotiating sessions had to be scheduled to provide a realistic chance to adopt a Protocol at the 10th Conference of the Parties (COP 10) in October 2010 in Nagoya, Japan. The first resumed session of Working Group 9, which was held in Montreal 10-16 July 2010, for the first time agreed to formally negotiate the draft Protocol on the basis of the "Cali Annex"[126]. The second resumed session of Working Group 9, held on 16 October 2010, was to formally adopt the negotiated text and submit the draft Protocol to COP 10 for adoption.[127]

II – Adoption of the Nagoya Protocol and unsolved issues remain

A – Theoretical contexts and political impacts leading unsolved issues

There are two main theoretical contexts existing during the time of development of the regime on access to GR and benefit-sharing that could be used to explain the core of unsolved issues:

Firstly, the neoliberalisation of nature, that described particularly by privatization and marketisation. In which, "privatisation is the assignment of clear private property rights to social or environmental phenomena that were previously state-owned, un-owned, or communally owned... Marketisation is the assignment of prices to phenomena that were previously shielded from market exchange or for various reasons un-priced. These prices are set by markets that are potentially global in scale, which is why neoliberalism is often equated with geographically unbounded 'free trade'".[128] In the context of access to GR, many different stakeholders try to use, exchange intrinsic values of biodiversity and put those values in to a market.

Secondly, the concept of (subaltern) 'cosmopolitan legality', which posits law as a site of struggle and implicates a grass-roots movement that "seeks to expand the legal canon beyond individual rights and focuses on the importance of political mobilization for the success of rights-centered strategies"[129]. This leads to the second theoretical note, that "the Nagoya Protocol is the result of an ongoing struggle as a 'counter-hegemonic' movement. The Nagoya Protocol could certainly be seen as an expansion of 'cosmopolitan legality' which is leading to what could best be called new forms of 'bio-cultural

[126] Revised Draft Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity. Annex 1. Report of the First Part of the Ninth Meeting of the Ad Hoc Open Ended Working Group on Access and Benefit-Sharing (WG ABS 9). UNEP/CBD/WG-ABS/9/3. Available online: http://www.cbd.int/doc/meetings/abs/abswg-09/official/abswg-09-03-en.pdf. Accessed 17 December 2011.
[127] CHIAROLLA.C, *Supra,*
[128] BAVIKATEE.K, ROBINSON.F.D, *Towards a Peoples' History of the Law: Biocultural Jurisprudence and the Nagoya Protocol on Access and Benefit-sharing*, The Law, Environment and Development Journal, 2011, Volume 7/1, http://www.lead-journal.org/content/11035.pdf, last accessed 2nd April 2012, p.39
[129] SANTOS.B, RODRIGUEZ-GARAVITO.C, *Law and Globalization from Below, Toward a cosmopolitan Legality*, Cambridge Studies in Law and Society, Cambridge University Press, 2005, p.15

jurisprudence'." [130] Cosmopolitan legality highlights the centrality of sustained political mobilization for the success of grassroots legal strategies. It views law, rights, and elements of struggles that need to be politicized before they are legalized. Counter-hegemonic globalization fights against the economic, social and political outcomes of hegemonic globalization that challenge the conception of world development and proposes alternative conceptions. It is focused on the struggle against social exclusion. Since social exclusion is always the product of unequal power relations, counter-hegemonic globalization is animated by a redistributive ethos in its broadest sense, involving redistribution of material, social, political, cultural and symbolic resources. In this sense, redistribution is based both on the principle of equality and on the principle of recognition of difference.[131] The Nagoya Protocol provides opportunities of redistribution of benefit arising from GR's utilization in a fair and equitable manner to indigenous and local people, who are most marginalized class, who need cosmopolitanism.

Biocultural jurisprudence is defined by Bavikatee.K and Robinon.F.D as "the theory and practice of applying a biocultural rights framework to law and policy, when such law and policy affects a community whose peoplehood is integrally tied to their traditional stewardship role and fiduciary duties vis-à-vis their lands and concomitant knowledge."[132] "The biocultural rights are group rights but they differ from the general category of 'third generation' rights through their explicit link to conservation and sustainable use of biological diversity… 'Third generation' rights are called 'group rights or collective rights' which are different from the first generation civil and political rights and the second generation social and economic rights… While 'Group rights' cover all the rights required for the survival and flourishing of indigenous and ethnic peoples, a sub-set of third generation rights have emerged unnoticed as an offshoot of 'group rights'". [133] Indigenous and local communities claim their biocultural rights basing on two foundations. "The first is conservation and sustainable use of biological diversity by communities is reliant on a 'way of life', and biocultural rights must protect this 'way of life'. The second is the 'way of life' relevant for conservation and sustainable use of biological diversity is linked to secure land tenure, use rights and rights to culture, knowledge and practices." [134] Therefore, Bavikatee.K and Robinon.F.D defines "Biocultural rights' make 'the link between the communities' or refer to 'peoplehood' and 'ecosystems'.

In respect of the Protocol, "there has been a considerable push for recognition of community rights over natural resources with attempts to the recognition of forms of legal pluralism or customary/community control…A further step of formal international

[130] BAVIKATEE.K, ROBINSON.F.D, *Supra*, p.40
[131] SANTOS.B, RODRIGUEZ-GARAVITO.C, *Supra*, pp.8-28
[132] BAVIKATEE.K, ROBINSON.F.D, *Supra*, p.50
[133] BAVIKATEE.K, ROBINSON.F.D, *Supra*, pp.49-50
[134] BAVIKATEE.K, ROBINSON.F.D, *Supra*, pp.49-50

recognition of community protocols and customary laws in relation to indigenous and local communities' traditional knowledge is taken… The Protocol provides new opportunities for indigenous and local communities to assert their rights over TK" [135]. However, there are limits regarding the extent of traditional knowledge protection that the Nagoya Protocol provides.

The Nagoya Protocol is resulted by the negotiation of access to GR and benefit-sharing, which seeks to regulate bioprospecting activities internationally, to find "compromise and balance between the various ways that biodiversity can be valued, privatized and marketized, and importantly on what terms... Those are the terms of the balance and the terms of the Nagoya Protocol with an evaluation of the resistances made by some of the potentially most vulnerable groups and also potential beneficiaries to the Protocol are indigenous peoples and local communities."[136]

In fact, despite of the long, tension negotiation, the term of balance and an evaluation of the Nagoya Protocol were difficult to be reached. There are many challenges to the concepts of privatization and marketization, conditions for cosmopolitan legality that were unsolved after negotiation.

The negotiations of access to GR and benefit-sharing have characterized as 'crocodiles and anacondas'[137]. The political undercurrents might be framed in terms of two major divergences between industrialized and developing countries. There were some big unsolved concerns during the negotiation and even after the Protocol adopted.

In the first political undercurrent, the developing countries questioned to the "historical debt," with expectation to rectify the perceived injustice related to access to and transfers of GR that occurred before the CBD's entry into force. They expected that the Protocol should have a broad scope to cover GRs, derivatives, TK. Many developed countries argued against any retroactive application of the protocol's provisions. Finally, the issues of "temporal scope," with question of benefit-sharing obligations cover new and continuous uses of material acquired before the protocol's entry into force, was not solved clearly, left many arguments in the approved text. [138]

The second political undercurrent reflected the "trade and environment" debate: potential interactions between the access and benefit-sharing regime and international trade and intellectual property law. This mainly affected discussions on compliance related provisions. While disclosure requirements have been a bone of contention for a long time, a conflict occured during the negotiation of 9th Ad Hoc Open-ended Working Group over a

[135] BAVIKATEE.K, ROBINSON.F.D, *Supra*, p. 40
[136] BAVIKATEE.K, ROBINSON.F.D, *Ibid*, p. 40
[137] International Institution for Sustainable Development (IISD) "*Summary of the 9th Working Group on ABS of the CBD*", Earth Negotiations Bulletin, Vol. 9 No. 503,: 22-28 March 2010; Wednesday, 31 March 2010, p.14
[138] IISD, *Ibid*, p.14

proposal to use patent offices as checkpoints for verifying certificates of compliance and for tracking and monitoring the use of GR. While developing countries count on disclosure to fight misappropriation, developed countries aim to prefer to address the issue in WIPO or the TRIPS review process. [139]

Both of these undercurrents affected the discussion on the relationship of the Nagoya Protocol with other international agreements. It was not only the relationship with existing agreements, such as, the FAO's Treaty, the Antarctic Treaty system, the UPOV and the WIPO, but also to whether and how the protocol should be taken into account in the development and implementation of future specialized regimes on access and benefit-sharing. "This might be specialized regimes would emerge for the cases of certain GRs, such as marine or microbial GR, or for specific uses such as pharmaceuticals or animal breeding. Although, there was opposition of such a "sectoralization" of the regime, cautioning that this could allow specific user communities to "escape" the general obligations under the protocol by developing a specialized regime".[140] Finally, the "sectoralization" of the regime was adopted following Article 4.4 of the Protocol that determines "this Protocol does not apply for the Party or Parties to the specialized instrument in respect of the specific genetic resource covered by and for the purpose of the specialized instrument."

B – Some practical problems analysis

In term of formal procedures, the international negotiation on access to GR and benefit-sharing and adoption also had problems that were criticized severely. While "delegates expected to engage in text-based negotiations on a revised version of the Co-Chairs' draft, yet, text-based negotiations never took place"[141]. Moreover, "The final document that was presented for adoption came about through a rather unusual and unprecedented process. It was not arrived at through negotiations"[142]. The criticisms and suspicion increased and added more to different emphasis between developing and developed countries. Developing countries emphasized the importance of securing benefit-sharing and effective compliance measures; while developed countries stressed on access standards. Finally, in the adopted protocol, "there are rather specific and elaborate rules on access, in contrary, the compliance measures are vague, vacuous and lacking in specificity. Further, the scope of the Protocol, especially with regard to the inclusion of derivatives, and temporal scope are couched... The Protocol that emerged eliminates some key concerns of developing countries, introduces vague and indeterminate provisions, and bristles with legal uncertainty. Significantly, it does not advance the CBD text in key areas

139 IISD, *Ibid*, p.14
140 IISD, *Ibid*, p.14
141 *Ibid*, p.14
142 NIJAR.G.S, *Supra,* p.3

and, in some crucial aspects, may even be CBD-minus."[143] "Some provisions of the Protocol actually detract from the CBD's requirements. They impose obligations where none existed before under the CBD for developing countries and reducing the obligations of developed countries from the existing provisions of the CBD." [144] For example, the requirements for national law to create a special regime for pathogens; simplified access without adequate safeguards when the intent changes; reference of provisions of the Protocol to resources which are the subject of ongoing work or practices of other international organizations, subtracting obligations on technology transfer. The CBD requires Parties to provide or facilitate access and transfer of relevant technologies to developing country under fair and most favourable terms, including concessional and preferential terms. Where necessary, the financial mechanism of the CBD shall help to pay for such technology. Contracting Parties have to take the necessary legislative, administrative or policy measures with the aim that developing countries, which provide the GR, are provided access to and transfer of technology, which makes use of those resources; as well as to get the private sector to facilitate access to joint development and transfer of technology - for the benefit of both governmental institutions and private sector of developing countries (Article 16). The Protocol has reduced the obligation of developed countries to merely undertake to promote and encourage (Article 23).

The suspects and distrust between countries during and after negotiation can effect negatively to the process of integration of the Nagoya Protocol into national law for implementation later. Because, some discussed issues were not reach agreement, "While finalizing the text, some disputed provisions were simply deleted. Other disagreements were resolved by replacing clauses with general statements that leave considerable room for interpretation".[145]

The above problems of the Protocol also are common features of international law that may happen to other multilateral treaties. That is explained by 'the lowest common denominator' approach – the approach most commonly encountered in multilateral treaties of general international law. This approach indicates negotiations compromises and package-deals remove difficulties which States found in a proposed text but results in abstracts or vague wording of the text concerned. Obviously, this lays down such a low standard, that it becomes virtually meaningless. It is constantly faced with a dilemma between acceptability and effectiveness. On the one hand, interdependence requires nearly universal participation of States. On the other hand, the problems in question can not be tackled other than by norms which are sufficiently substantive and usually more weight is attached to universality than to effectiveness. This envisages to being international law

[143] NIJAR.G.S, *Supra,* p.15
[144] NIJAR.G.S, *Ibid*, p.34
[145] ICTSD**,** *Supra*,

making with the conclusion of a basic treaty (traité cadre) containing only the most fundamental rules of a more general character – both procedural and substantive.

Therefore, the problems can be found here are problems of acceptability. They are pointed out that multilateral treaties which the text having been adopted, not infrequently take a considerable period of time to acquire a sufficient number of ratifications to enter into force. It would seem that there are two grounds for the slow ratification or failure to ratify multilateral treaties on the part of a large number of States are technical inability and political unwillingness.

Conclusion of Chapter 1

Law derives from practice of life and reflects the demands of the practice, then regulates it. The fact of degradation and loss of biodiversity requires international law to have effective legal instruments for biodiversity governance. All the figures of growth of demands on GR of human kind and degradation of GR illustrate the urgent situation that requires urgent responses and actions. Before action, there is a need of awareness of responsibilities and that is a long process of development of awareness. The Nagoya Protocol is one of the results of a process of awareness development from “common interest”, to “common concern” and equity. In respect of ethic awareness, the author would like to place emphasis on common principle of morality, the ethic universal correspondence between rights and responsibilities.

The Nagoya Protocol has experienced a long international negotiation but the final text of the Protocol may cause disappointments for many concerned actors. There are many unsolved issues that will be analyzed in detail in the next chapter. Those unsolved issues can be explained by theoretical contexts and political impacts, including neo-liberalization of nature and subaltern cosmopolitan legality and bio-cultural jurisprudence. In fact, the core problem of the Protocol is the balance of interest and power. Naturally, anyone always wants to increase interest and reduce responsibility and they will use their power to attain this target within scope of common acceptable morality and legality.

CHAPTER 2 – Access to genetic resources and benefit-sharing under related treaties

During the development of the Nagoya Protocol for an international regime on access to GR and benefit sharing, many existing treaties had been studied to find the relationship, or interrelationship, with the Nagoya Protocol, including the FAO's Treaty, TRIPs under the WTO, the UPOV agreements of WIPO, the Antarctic treaty, and UNCLOS.[146] The study on the relationship between the international regime on access to GR and benefit sharing and other international instruments and forums that govern the use of GR are very important, especially to avoid overlapping or fragmentation in international law[147]. There is even the consideration on the future development of specialized access and benefit sharing arrangement [148] as prescribed by Article 4.4 of the Protocol; a balance may be possible between integrating new specialized regimes under the protocol and safeguarding the integrity and overarching nature of the protocol's principles and procedures.[149] The outcomes of the Nagoya Protocol also would be viewed as levers to open up greater gains in the long run under the CBD and related WIPO and WTO processes.

In theory and as a rule, "there is no hierarchy between treaties with the exception of *jus cogens* norms and the principle of *lex superior*"[150]. "The judicial binding nature of treaties reposes directly on the will of the sovereign states to be legally bound. It seems impossible to conceive degrees in the will to be legally bound."[151] Article 4.1 of the Protocol also recognizes "The provisions of this Protocol shall not affect the rights and obligations of any Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity. This paragraph is not intended to create a hierarchy between this Protocol and other international instruments".

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146 UNEP/CBD/WG-ABS/7/INF/3/Part.1, by BULMER.J, *Study on the relationship between an international* regime on ABS and other international instruments and forums that govern the use of genetic resources - The International Treaty on Plant Genetic Resources for Food and Agriculture and the Commission on Genetic Resources for Food and Agriculture of the Food and Agriculture Organization of the United Nations, IUCN Law centre, 2009; UNEP/CBD/WG-ABS/7/INF/3/Part.2, by MEDALIA. J. C, Study on the relationship between an international regime on ABS and other international instruments and forums that govern the use of genetic resources - The World Trade Organization (WTO); the World Intellectual Property Rights Organization (WIPO); and the International Union for the Protection of New Varieties of Plants (UPOV), 2009; UNEP/CBD/WG-ABS/7/INF/3/Part.3, by JOHNSTON.S**,** Study on the relationship between an international regime on ABS and other international instruments and forums that govern the use of genetic resources - The Antarctic Treaty System (ATS) and the United Nations Convention on the Law of the Sea (UNCLOS), UNU-IAS, 2009

147 Report of the study group on the fragmentation of international law, *http://untreaty.un.org/ilc/guide/1_9.htm*

148 UNEP/CBD/WG-ABS/9/INF/19, *Leaving room in the CBD's ABS protocol for the future development of specialized access and benefit-sharing arrangement*, 2010

149 IISD, *Supra*, p.14

150 HAUGEN.H.M, *Standard-Setting WTO Treaties: A Question of Hierarchy*? Nordic Journal of International Law 76 (2007) p.435 – 464

151 KLABBERS. J, LEFEBER. R, *Essays on the Law of Treaties*, a collection of essays in Honour of Bert Vierdag, Kluwer Law International, 1998, p.8

This paragraph can be understood as a "saving clause" of the Protocol. The "saving clause" states the relationship between the instrument and other related instruments, especially those related to international commerce and trade such as the WTO. "In accordance with international law, a State is legally bound to comply with all the treaties to which it is a party", thus, "some recent Multilateral Environmental Agreements (MEAs) contain the "saving clause" in the preamble or in the operative text". "When such a clause appears in the operative text of a treaty, it can indicate which treaty - the existing treaty or the new treaty – the Parties intended to prevail in the case of a conflict. Article 30(2) of the Vienna Convention on the Law of Treaties provides that "when a treaty specifies that it is subject to or that it is not to be considered as incompatible with, an earlier or later treaty, the provisions of the other treaty prevail". Furthermore, under the Vienna Convention later treaties between the same parties dealing with the same subject matter supersede the provisions of earlier treaties, unless wording expressing the contrary exists in the later treaty".[152]

"The first part of the paragraph re-states Article 22.1 of the CBD. In "A guide to the Convention on Biological Diversity" of the IUCN, the authors of the guide commented that "The paragraph may in practice, however, be difficult to implement because implementation depends on the circumstances of a particular case and how 'serious damage or threat' is interpreted. The notion of serious damage or threat implies that a certain threshold must be achieved before the Convention prevails. The terms will certainly require further interpretation or guiding criteria".[153] However, until now there is no official interpretation or further guiding criteria of "serious damage or threat", even the draft "An Explanatory Guide to the Nagoya Protocol on Access and Benefit-sharing" of the IUCN provides no further explanation about that. [154]

The second part of the paragraph addresses an aspect not covered by Article 22, but found in other MEAs; that is the clarification that the paragraph is not intended to create a hierarchy between the Protocol and other international instruments. It made clear that the purpose was not to "subordinate" the Protocol to other international instruments. It addresses the relationship between the Protocol with other existing international agreements, including the new agreements regulated by Article 14.2, and the situation of specialized instruments on access to genetic resources and benefit sharing, regulated by Article 14.4.

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152 GREIBER.T, MORENO.S, IUCN Explanatory Guide to the 3 Nagoya Protocol on Access and Benefit-sharing, Draft 1.1, p. 76, available at *http://cmsdata.iucn.org/downloads/iucn_explanatory_guide_to_the_nagoya_protocol_draft_1_1.pdf*, last accessed July 9, 2012

153 GLOWKA.L, BHUHENNE-GUILMIN.F, Synge.H, *A guide to the Convention on Biological diversity*, IUCN, Environmental Policy and Law Paper No.30, 1994, p.109

154 GREIBER.T, MORENO.S, *Supra*, p. 76,

However, there is a 'soft' hierarchy between treaties. This is not formal, but based on priority and more common concerns. For example, food security is normally considered to have a higher priority than conservation, so, the FAO's treaty is higher on the hierarchy than conventions on conservation such as wetland or biodiversity, including the Nagoya protocol. This soft hierarchy of treaties' law will be a challenge for the integration of the Nagoya Protocol into national law, especially in cases where there are conflicts or potential conflicts between treaties on related issues. For example, there may be conflict between the WTOs systems and the environmental regime of biodiversity.

This chapter will examine the interrelation between the Nagoya Protocol and the CBD, the Bonn guidelines and their limitation, and analyze the conflicts, and potential conflicts with FAO's treaty, TRIPs under the WTO, the UPOV and agreements of WIPO. These will be examined to determine the difficulties associated with integrating the Nagoya Protocol into national laws.

Section 1 - Access to genetic resources and benefit-sharing under the CBD and Bonn Guidelines

§ I - Access to genetic resources and benefit-sharing under the CBD

A - General introduction

The adoption of the CBD marked the end of hectic and difficult negotiations as well as efforts by many governments, international and national organizations, and individual experts over several years. This adoption also marked an exceptionally important step in an ever-continuing evolution in the legal field but generated by a profound evolution in the perception of the problems at hand and of the action required to solve them.[155] The negotiations of the CBD were similar to the Nagoya Protocol in that the difficulties of each derived from the benefits to, and interests of, developed and developing States. This includes issues such as the right to certain benefits, and obligations of States.

The CBD had been criticized as ineffective, having vague principles and engagements, the same as the Nagoya protocol. Some analysis of shortcomings of the CBD will be supplied as the basis for further analysis and comparison of the Nagoya Protocol in the next chapters.

It is said that the convention is general and has a vague principle, making the instrument less effective. While the scope of application of the CBD is very large, its provisions are vague. Legal constraints are absent, as "the engagement of the CBD is not sufficient existing because it only is the tempered conditions of application or opportunities", "a document unusually cowardly, culminating with the vague engagement", "the convention appeared the imprint of condition", "it mists the constraint – enforcement

[155] JEFFERY. I. M, QC, FIRESTONE. J, BUBNA. L. K, *Supra*, p. 27 -.28

that difficult for certain States to fill their obligations. Even though, the convention obviously is not a soft law, many articles of the convention are like "soft law" because they do not contain enforcement provisions".[156] Since the CBD was entered into effect, biodiversity has not been improved: species are continuing to disappear, and the use of chemical products continues without concern[157].

B - Problem analysis

The issue of biodiversity is a basic concept in contemporary environmental law[158], and the question of access and benefit sharing in conformity with the third objective of the CBD is also fundamental to biodiversity law. However, achieving fair and equitable sharing of benefits from the use of GR would seem very difficult through the CBD as evidenced by the following:

The first is access to GR. Article 15 of the CBD provides that access to GR should be subject to PIC of the party providing such GR, unless otherwise determined by that Party. This provision may be understood that the access under PIC is under the discretion of the Party as "the sovereign rights of States over their natural resources, the authority to determine access to GRs with the national governments and is subject to national legislation". However, under the Nagoya Protocol, this becomes a compulsory obligation of the Party with specific requirements of legal certainty, clarity and transparency of their domestic legislation or regulations on access to genetic resources and benefit sharing. Moreover, the CBD does not provide any mechanism for States to exercise their sovereignty rights. It enables them to develop their own regulatory regimes for access to GR, but the term "access to GR" is not defined by the CBD. "The CBD makes it clear that each State of origin of GR has the authority to determine questions of access".

Regarding sovereignty rights, "the GR located in the territory of a state is to be deemed subject to the sovereignty of that state. By virtue of this right, every state is free to regulate access to GR. However, this freedom is counterbalanced by the basic requirement that it be exercised in a manner so as to facilitate access to GR for sustainable development and sound environmental utilization. However, 'sound environmental utilization' is not defined or interpreted."[159]

It can be noted that "the CBD does not envisage access to GR, such as biological resources like fishing stock to the commercial value of the forest. It is not clear that the CBD applies to the products derived from GR like synthesized biomolecules, plant hybrids, etc, because it does not contain the unit of functional heredity. This does not

[156] Quoted by GUYVARC'H. A, *Les aspects juridiques de la protection de la biodiversité*, Université de Nantes, 1998, p. 386
[157] STOIANOFF. P. N, *Supra*, p. 229
[158] NAIM-GESBERT.E, *Les dimensions scientifiques du droit de l'environnement, Contribution a l'étude de rapports de la science et du droit*, Université Jean moulin –Lyon 3, 1997, p. 548
[159] FRANCESCO.F, SCOVAZZI.T, *Supra*, p. 10

prevent the party from spreading the scope of application of their legislation to product derivatives in respect of WTO regulations".

"For GR in the wild, the CBD aims to conserve domestic *in- situ* or *ex- situ*. However, the CBD's definition does not fit with the usual scientific usage which would normally restrict the term to the country where it evolved."[160] Moreover, the Article 15 of the CBD can constitue to incite the *in-situ* conservation of "only the resources situated in the zone under the jurisdiction of the State country of origin can concern the disposition. While in high sea, the access is totally free and without prejudice of application of appropriate disposition to the law of the sea."[161]

The CBD came into effect 29 December 1993, and before that the regulation of access was not applied following article 15.3 for the collection of GR. "Many GRs were accessed outside the country of origin, and were accessed without sharing benefits. The problem was presented by the spirit of the negotiation of the CBD that is necessary to find the solution for the problem of access GR before the CBD".[162]

In addition, "notwithstanding its entry into force, the CBD is ambiguous in terms of time or legal meaning because it does not define when a GR has been 'provided' by a country of origin or when it is deemed 'acquired' by a user. The closest the CBD gets to resolving these issues is in Article 2, where 'country providing GRs' is defined as "the country supplying GRs from in-situ sources ... or taken from ex-situ sources". [163]

Following the CBD, the access to GR should be in accordance with PIC. "The PIC is provided by the CBD deliberately and is similar to the mechanism which is utilized in the transfer of hazardous wastes and chemical substances, the access cannot be agreed without PIC by the provider countries". "One of the difficulties raised through the existing PIC by the State authorities is to assure the respect of this obligation when the GR is already collected by the intermediary (e.g. university or botanical garden). In defect, juridical insecurity can put weight on the utilization of the resources transfer if this transfer has not authorized itself deliberately."[164]

The second is benefit - sharing. The CBD provides in general the way for each party to take the appropriate legislative, regulatory and administrative measures, (including financial mechanisms following Article 15.7). "Benefit-sharing must be established on the MAT between the related parties (State, community, owners of the collection) and the user, whether public or private. In considering the diversity of utilization that can be made to the resources and then sharing benefits, only a case by case negotiation with the user can

[160] GLOWKA.L, BURHENNE-GUILMIN.F, Synge.H, *Supra*, p. 34
[161] SADELEER.N., BORN.H.C, *Droit international et communautaire de la biodiversité*, Dalloz, 2004, p. 116
[162] *Ibid*, p. 116
[163] GLOWKA.L, BURHENNE-GUILMIN.F, Synge.H, *Supra*, p. 95
[164] SADELEER.N., BORN.H.C, *Supra*, p. 116

be established constituted by the State of the provider as one way to establish equitable sharing." "The procedures or incitation must be established by the State to ensure the respect of the private sector in the case of negotiation and the objective of equity affected by the CBD. The regulation on sharing benefits can be applied only by the parties. The difficulty is to determine before the utilization of GR its benefit, which depends on the technical and scientific capacity of the provider countries. But this is not simple because the potential utilization is unknown and can bring less or more income than expected, especially when evaluating economic advantages of the GR from the research in advance. The GR may have more value as greater knowledge regarding their use and benefits is acquired."[165] However, "the parties normally ignore the real value of GR when negotiating their access. Even though the CBD expresses economic benefit–sharing under a form of direct finance or adequate, it does not express this in detail. It can be understood that this puts a limit on the financial obligations of developed countries."[166]

The benefit sharing can vary in function by the state of utilization (collection, researching, and commercialization). The CBD also considers the results of the scientific research on GR like benefits that should be shared. It provides that the State conducts scientific research on GR, through a party must share the final result of the works to the providers (Article 15.6). This obligation is essential to create technical capacity to a provider country which usually is a poor country. Projects and programs should be elaborated together with research and eventually, this obligation should frame the MAT to access.

For the transfer of technology utilized in the GR as the way to share benefits (Article 16.3) that is both fair and equitable, one would expect the parties to take measures to transfer. Technology includes those protected by the patent and other law of intellectual property right that must conform to intellectual property rights and the related intellectual property regime. The transfer can be facilitated as the finance mechanism under Articles 20 and 21 of the CBD. Decision of COP II/4, 1995 and COP III/16, 1996 deals with this issue. The obligation is applied independently to the grant of an access to GR and the transfer technology can be done as condition of the access. That is provided by the MAT following Article 16.4.

However, the provisions of the CBD are difficult to implement. "There is a lack of an effective international access regime and an international organization to monitor and enforce bio-prospecting agreements, and so the fair and equitable sharing of benefits from GR becomes frequently a fiction rather than a reality."[167]

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[165] STOIANOFF. P. N, *Supra*, p. 231
[166] SADELEER.N., BORN.H.C, *Supra*, p. 116
[167] STOIANOFF. P. N, *Supra*, p. 232

The third is inadequate protection of TK: "the CBD fails in its attempt to ensure the fair and equitable sharing of benefits resulting from the use of GR and TK. The value of GR is made up of two different elements: the tangible element, being the GR itself; and intangible elements or related knowledge. In addition, as the tangible and intangible elements of biodiversity cannot be separated one from the other, access to the tangible element necessarily involves access to the intangible element. TK is not protected internationally." Therefore, "the access is generally free or compensation that is made is often neither fair nor equitable in terms of the benefits for the traditional community which owns and shares the knowledge. Even though the CDB recognizes the close and traditional dependence on GR of local communities, it does not recognize intellectual property rights for TK. Article 8.j offers a potential rather than a real and useful opportunity for countries to encourage the protection of the TK. However, after nearly 20 years, it still continues to be negotiated under WIPO and TRIPs."[168]

The CBD does not establish any effective guidelines and conditions to recognize the rights of local communities. "The CBD's objective of conserving biodiversity becomes very difficult to achieve when the emphasis of such conservation in relation to the indigenous and traditional communities is not enough to protect and conserve their cultural diversity which is indispensable for environmental protection." "Most of the world's richness in biodiversity is in areas inhabited by indigenous and local communities who have used their traditional lifestyles to protect natural resources for centuries. An international regime for the protection of TK is needed."[169]

At last, "the CBD can best be described as a multilateral framework providing criteria for the development of bilateral cooperation and the concerted settlement of key aspects of access to GR and the technology based on them. Under the CBD, member states concede sovereign rights over the biological diversity existing in their territory, but are also made fully responsible for conserving it. The conservation of biological diversity and its economic utilization are thus placed on a new basis binding under international law."[170]

In my view, the relationship between the CBD and the Nagoya Protocol is a model of a framework convention and a Protocol for implementation of the convention that is quite popular in the international environmental law. The CBD provides legal base for development of the Protocol that includes objective, principles and the framework regulation. The Nagoya Protocol concretizes the provisions of the CBD for its implementation. As principle, the Nagoya Protocol should be consistent with the CBD. It is expected that the difficulties in implementing the third objective, Article 15 and Article 8.j of the CBD as a framework treaty will be addressed by development of the Nagoya Protocol**.**

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[168] http://www.wipo.int/tk/en/news/2011/news_0019.html
[169] STOIANOFF. P. N, *Supra*, p. 235
[170] SEILER.A, DUTFIELD. G, *Regulating Access and benefit-sharing, Basic issues, legal instrument, policy proposals,* BFN – SKRIPTEN 46, German Federal Agency for Nature Conservation, 2001, p.7

§ II – The Bonn Guidelines

A – General introduction

The Bonn Guidelines are considered "a complementary instrument for the CBD and the Nagoya Protocol which constitute the International Regime"[171]. The adoption of the Bonn Guidelines was an important step in the process of forming the international regime on access to GR and benefit sharing to meet the need of a guiding implementation of the CBD. They are recognized as a far reaching soft law instrument adopted by the COP of CBD at its sixth meeting in 2002 (decision VI/24 A Annex). At the Plan of implementation at the World Summit on Sustainable Development, the principle at stake has been consistently recognized in various resolutions of the UN General Assembly which, at the same time has advocated the negotiation of an international regime on benefits sharing under Res.57/260 of 20 Dec 2002, third preamble paragraph and Res 58/212 of 23 Dec 2003 forth preamble paragraph. "These voluntary guidelines offer guidance on the roles and responsibilities of the various parties involved in access to GR and benefit sharing, and were intended as a useful first step in an evolutionary process in the implementation of relevant provisions of the CBD related to access to GR and benefit sharing. In adopting the guidelines, Member States to the CBD invited Parties and Governments to use the guidelines when developing and drafting legislative, administrative or policy measures on access to GR and benefit sharing, and contracts and other arrangements under MAT"[172].

However, regarding the legal nature, the Bonn Guidelines are a voluntary instrument or non legal binding. This kind of "soft law" is considered to have weakness in theory but in fact it is argued to more effectively fulfill the goals than traditional international law and legal procedures. It is said that "nonbinding accords may be more faithfully adhered to than binding international treaties and the flexible procedures adopted for consultation regarding possible changes in the accords to meet unexpected problems may be more effective in resolving these problems than formal meetings of states parties to treaties"[173]. This choice for the Bonn Guidelines is preferred by some developed countries to follow with the CBD and for applying user's measures in their countries such as Japan.[174]

However, it is also considered a significant step with many challenges to make the Nagoya Protocol legally binding in nature.[175] This is supposed to improve and enhance compliance and enforcement of all actors.

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[171] UNEP/CBD/COP/10/27, *Supra*, p.83

[172] GUPTA. A. K., *Study on the role of intellectual property rights in the sharing of benefits arising from the use of biological resources and associated traditional knowledge*, Indian Institute of Management Ahmedabad, India, WIPO-UNEP, p. 24

[173] MURPHY.F.J, *The evolving dimensions of international law*, Cambridge University Press, 2010, p. 4

[174] See Ministry of Economy, Trade and Industry and Japan Bioindustry Association, *Guidelines on Access to Genetic Resources for users in Japan*, 2006

[175] Following CBD, COP 9 Decision IX/12- ABS, regarding Proposal on nature, there are three options of nature of international regime: 1. One legally binding instrument; 2. A combination of legally binding and non-binding instruments; 3. A non-binding instrument; ***www.cbd.int/decision/cop/?id=11655***

These Guidelines serve as inputs when developing and drafting legislative, administrative or policy measures on access and benefit-sharing with particular reference to provisions under Articles 8(j), 10 (c), 15, 16 and 19; and contracts and other arrangements under mutually agreed terms for access and benefit-sharing. The Guidelines also are intended to assist Parties in developing an overall access and benefit-sharing strategy, which may be part of their national biodiversity strategy and action plan, and in identifying the steps involved in the process of obtaining access to genetic resources and sharing benefits.

The main contents of the Guidelines include: roles and responsibilities in access and benefit-sharing pursuant to Article 15 of the CBD such as national focal point, competent national authority(ies), participation of stakeholders and their responsibilities; steps in the access and benefit-sharing process; overall strategy; identification of steps; basic principles, elements of a PIC system, competent authority(ies) granting PIC, timing and deadlines procedures for obtaining PIC; basic requirements, indicative list of typical MAT; benefit-sharing, type timelines, distribution of benefits, incentives, accountability in implementing access and benefit-sharing arrangements, national monitoring and reporting, means for verification and remedies.

The Bonn Guidelines are part of a package of complementary measures including voluntary codes of conduct, model agreements, guidelines formulated by other organizations, national access legislation, performance indicators and information exchange mechanisms such as the CBD clearing house.[176]

B – Comparative analysis

The question is that if the Bonn Guidelines are effective and concrete enough to implement the CBD, whether States need to be bound by the Nagoya Protocol or not? Especially if the Nagoya Protocol has not had any further progress in the development of the wording over the Bonn guidelines. The more detailed comparison and analysis is as following:

Regarding the scope of regulation, with 30 Articles, 1 annex, the Protocol covers almost all key issues of access to GR and benefits. With 5 provisions, 61 clauses and 2 Annexes, The Bonn Guidelines outline key steps in the access to GR and the benefit sharing process, which includes basic elements required for PIC and MAT, main roles and responsibilities of users and providers, and a list of monetary and non-monetary benefits. However, the Protocol provides a broader scope of access to GR and benefit sharing with an expansive interpretation of the definition of "utilization of GR". Following Article 2 of

[176] TULLY.S, *The Bonn guidelines on Access to Genetic Resources and Benefit-sharing*, The Review of European Community & International Environmental Law (RECIEL 12 (1) 2003. ISSN 0962 8797, © Blackwell Publishing Ltd. 2003, available at ***http://69.90.183.227/doc/articles/2003/A-00457.pdf***, p.97

the Protocol, "utilization of GR" clearly covers research and development linked to the biochemical composition of plants and other components of biodiversity. It is also clear that the Protocol covers 'derivatives' as "a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or GR." Article 3 on the scope of regulation of the Nagoya Protocol does not expressly refer to the term "derivatives," but the concept could be seen to complement the definition of "utilization of GR" by Article 2.[177] The Bonn Guidelines covers "GR" and TK and the benefits derived from the "utilization of GR and TK covered by the CBD with the exclusion of human GR that does not refer to "derivatives".

Regarding access and the PIC, the Bonn Guidelines, under Section IV.C addresses PIC including basic principles of a PIC system, elements of a PIC system, competent authority granting PIC, timing, deadlines, minimum cost, specifications of use and procedures for PIC, and the process for obtaining PIC that ensures for legal certainty and clarity. With the same targets for PIC as legal certainty, clarity and transparency, the Nagoya Protocol, under Articles 6 and 7 also sets requirements for domestic legislation on access to GR and benefit sharing. It includes fair and non-arbitrary rules and procedures on accessing GR; information on how to apply for PIC; a clear and transparent written decision by a competent national authority, in a cost-effective manner and within a reasonable period of time; issuance at the time of access of a permit or its equivalent as evidence of the decision to grant PIC and of the establishment of MAT, and notify the access and benefit sharing Clearing-House; set out criteria and/or processes for obtaining PIC or approval and involvement of indigenous and local communities for access to GR; and clear rules and procedures for requiring and establishing MAT.

The Bonn Guidelines give a list of recommendations for establishing the PIC system deliberately and effectively. One of the principles is to be obtained the PIC from the national competent agencies of the provider country, but also from related actor such as indigenous and local communities in the appropriate way without prejudice to the national law. It is expected that the PIC founded on the anticipation related resources and new PIC must be obtained each time when a new utilization is envisaged.

In relation to TK and intellectual property, the Bonn Guidelines state that Contracting Parties should take appropriate legal, administrative, or policy measures, as appropriate, to support compliance with PIC of the Contracting Party providing such resources; and MAT on which access was granted, including, *inter alia*, measures to encourage the disclosure of the country of origin of the GR and of the origin of TK, innovations and practices of Indigenous and local communities in applications for intellectual property rights. It also states that "MAT should clarify whether intellectual

[177] Maria Julia Oliva, *Nagoya Protocol on ABS* -Technical Brief, Union for Ethical Bio-Trade, ***www.ethicalbiotrade.org***.

property rights may be sought and if so under what conditions". "It also notes that the work of WIPO on intellectual property and access to GR and benefit sharing should be taken into account"[178]. "The challenge of applying existing intellectual property laws to local knowledge, innovations and practices also stems from the conceptualization of local knowledge as essentially a cultural and community construction. Having carried out a review of various intellectual property instruments together with applicability to different kinds of local knowledge, Posey and Dutfield (1996) conclude that: intellectual property right laws are generally inappropriate and inadequate for defending the rights and resources of indigenous and local communities. Intellectual property right protection is purely economic, whereas the interests of the peoples are only partly economic and linked to self-determination. Furthermore, cultural incompatibilities exist in that TK is generally shared and, even when it is not, the holders of restricted knowledge probably still do not have the right to commercialize it for personal gain." "Many people do not believe that current intellectual property regimes can provide incentives to local communities and creative individuals. They term the attempts of the large corporations, generally multinational corporations, to access biodiversity without sharing any benefits with local communities as 'Biopiracy'".[179] To this aspect, the Nagoya Protocol is very limited by general statement and referring to the other "ongoing works" of other fora and international organizations under Article 4.

Regarding benefit sharing and MAT, the benefits which are set out in the Protocol is a larger reproduction of those set out in the Annex of the Bonn Guidelines. However, the progress is that the benefits may include of those arising from the 'utilization of GR' that includes derivatives. In addition, the obligation to TK is mandatory and obliges Parties to take the appropriate measures to ensure benefits are shared upon MAT. This is also an improvement on the development of regulations on access to GR and benefit-sharing. A new international mechanism is added through Article 10, "Global multilateral benefit-sharing mechanism" which broadens the extent of the Protocol.

Regarding compliance, as a voluntary instrument, the Bonn Guidelines only suggests some measures for compliance, but the Nagoya Protocol sets out a mechanism of compliance with some basic measures, though some of these are criticized by developing countries as unclear and weak provisions for sharing benefits. Under Section IV.D.3, the Bonn Guidelines provide specifically for benefit-sharing by addressing types of benefits, and the timing, distribution and mechanisms for benefit-sharing. Appendix II provides a list of potential monetary and non-monetary benefits. The Guidelines provide basic principles and elements of (MAT), including: legal certainty and clarity; facilitating the transaction through clear information and formal procedures; reasonable periods of time

[178] GUPTA. A. K., *Supra*, p.24
[179] GUPTA. A. K., *Ibid*, p.50; p.56

for negotiations; and terms set out in a written agreement. The Guidelines also provide an indicative list of MAT, which include: type and quantity of GR, and the geographical/ecological area of activity; any limitations on the possible use of material; transfer to third parties if any; recognition of the sovereign rights of the country of origin; capacity-building; and benefit-sharing: types, timing, distributions of benefits, mechanisms for benefit-sharing.

Supporting compliance, the Guidelines provides some measures. These include incentives; accountability in implementing arrangements; national monitoring and reporting; means for verification; settlement of disputes.

A basic difference between a voluntary instrument and a legally binding instrument is about mechanisms and measures for compliance. The institutional mechanisms that support compliance include: National focal point and competent national authorities (Article 13) and Clearing House Mechanism (Article 14). Some measures also are different such as compliance with domestic legislation or regulatory requirements on access to GR and benefit sharing (Article 15), Monitoring the utilization of GR (Article 16), The designation of one or more checkpoints, Compliance with MAT (Article 18), Model contractual clauses (Article 19), Codes of conduct, guidelines and best practices and/or standards in relation to access to GR and benefit-sharing (Article 20). Especially, the new measure was decided is to use an internationally recognized certificate of compliance.

The Nagoya protocol also provides measures for capacity building and raising awareness through Articles 21, 22, 23 that significantly create a base for implementing capacity building for access to GR and benefit-sharing, but it is not much progress over the Bonn Guidelines. Under Appendix II.B and annex-draft elements, the Bonn Guidelines provide for an action plan for capacity building for access to GR and benefit-sharing.

In my opinion, the Nagoya Protocol has made a progressive development in the international regime on access and benefit-sharing, from a voluntary instrument of the Bonn Guidelines to a legally binding treaty. Even though some contents and articles on measures for capacity building and raising awareness of the Protocol are more general statement than the Guidelines, a mechanism for compliance is important. Moreover, after some years of development and negotiation, some ideas and measures have been added to the Protocol such as an internationally recognized certificate of compliance and checkpoints. Looking back into the process of international access and benefit-sharing regime development, we can say that the Bonn Guidelines were an important step towards the Nagoya Protocol. Each instrument has a role to play. As a complementary instrument, the Bonn Guidelines may be updated and amended to take it functions to guide to the Nagoya Protocol.

Section 2 - Access to Genetic Resources and Benefit-sharing under FAO'S TREATY, UPOV, TRIPs of WTO and Agreements of WIPO

§ I - International Treaty on Plant Genetic Resources for Food and Agriculture (FAO's treaty)

The decision to adopt of the Nagoya Protocol recognizes that "the objectives of the FAO's treaty are the conservation and sustainable use of plant GRs for food and agriculture and the fair and equitable sharing of the benefits arising out of their use, in harmony with the CBD, for sustainable agriculture and food security".[180] "Both the FAO's treaty and the Protocol are the only legally binding international instruments on access and benefit-sharing and it is imperative that they are implemented in a coherent and harmonious manner."[181]

A – General introduction and problems analysis

The FAO's treaty was adopted at Session 31 during FAO's conference dated 3rd November, 2001. The treaty came into force on 29th June, 2004. Up to 31th December 2008, the treaty had 119 member States[182].

The Treaty deals with access and benefit-sharing of plant GR in specific sectors of food and agriculture for conservation and sustainable use. "This treaty includes the scope of application for all national collection GR of cultivated plants and can be understood to include the collection before entering the treaty and the CBD."[183] In addition, "the treaty essentially establishes a multilateral system to facilitate access to 64 major food crops. Benefit-sharing mechanisms include information exchange, access to technology transfer, and capacity building, but the parties recognise that facilitated access to the multilateral system itself constitute the essential benefit"[184].

One of the important provisions of the Treaty is recognition of the farmer's rights following Article 9 with "the enormous contribution that the local and indigenous communities and farmers of all regions of the world, particularly those in the centres of origin and crop diversity, have made and will continue to make for the conservation and development of plant GRs which constitute the basis of food and agriculture production throughout the world". The contracting Parties agree that the responsibility for realizing Farmers' Rights, as they relate to plant genetic resources for food and agriculture, rests with national governments. In accordance with their needs and priorities, each Contracting

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[180] UNEP/CBD/COP/10/27, *Supra,* p. 83

[181] *http://www.planttreaty.org/content/policy-makers-and-senior-officials-attend-briefing-rome-coherent-implementationa*

[182] UNEP/CBD/WG-ABS/7/INF/3/Part.1, by BULMER.J, *Study on the relationship between an international regime on ABS and other international instruments and forums that govern the use of genetic resources - The International Treaty on Plant Genetic Resources for Food and Agriculture and the Commission on Genetic Resources for Food and Agriculture of the Food and Agriculture Organization of the United Nations,* IUCN Law centre, 2009, p. 4, available at *http://www.fao.org/Legal/TREATIES/033s-e.htm*

[183] SADELEER.N., BORN.H.C, *Supra,* note 138, p. 116

[184] FRANCESCO.F, SCOVAZZI.T, *Supra*, note 36, p. 10

Party should, as appropriate, and subject to its national legislation, take measures to protect and promote Farmers' Rights, including: protection of TK relevant to plant GR for food and agriculture; the right to equitably participate in sharing benefits arising from the utilization of plant GR for food and agriculture; and the right to participate in making decisions, at the national level, on matters related to the conservation and sustainable use of plant GR for food and agriculture. This is the main difference with the Nagoya protocol.

One of the main components of the treaty is a multilateral system of access to GR and benefit-sharing. The Contracting Parties recognize the sovereign rights of States over their own plant GR for food and agriculture and agree to establish a multilateral system, which is efficient, effective, and transparent, both to facilitate access to plant GRs for food and agriculture, and to share, in a fair and equitable way, the benefits arising from the utilization of these resources, on a complementary and mutually reinforcing basis.[185]

The right to access to plant GRs for food and agriculture is under the framework of multilateral system of access to GR and benefit-sharing following Article 11, Article 12 of the Treaty. The Contracting Parties also agree to take appropriate measures to encourage and agree that facilitated access to plant GR for food and agriculture under the Multilateral System. Access shall be accorded expeditiously, without the need to track individual accessions and free of charge, or, when a fee is charged, it shall not exceed the minimal cost.

The regime on access to GR and benefit-sharing is facilitated by standard material transfer agreement (SMTA) that sets forth conditions for access to GR and benefit-sharing. The SMTA standardizes access to GR and benefit-sharing. The SMTA provides a fully operational, international commercial benefit-sharing mechanism under which the recipient of a plant GR from the Treaty's Multilateral System must contribute a fixed percentage of the gross sales from a new commercial product to an international benefit-sharing trust fund under the Treaty under certain conditions. This benefit-sharing mechanism will eventually benefit farmers and agricultural priority programmes in developing countries and economies in transition.

The SMTA is already being applied worldwide by the International Agricultural Research Centers of the Consultative Group on International Agricultural Research since early 2007, and other International Institutions holding *ex-situ* collections of plant GRs for food and agriculture that have signed agreements under Article 15 of the Treaty, bringing their collections under the Treaty.[186]

It is noted that while the Treaty applies to all plant GR for food and agriculture, the Multilateral System of access to GR and benefit-sharing only covers the 35 crops and 39

[185] Article 10, the ITPGRFA
[186] UNEP/CBD/WG-ABS/5/4/Add.1, *Overview of recent developments at the international level relating to access and benefit-sharing*, 2007, p. 4

forages contained in Annex 1 of the Treaty, when they are accessed "solely for the purpose of utilization and conservation for research, breeding and training for food and agriculture, provided that such purpose does not include chemical, pharmaceutical and/or other non-food/feed industrial uses"[187]. For the GRs which are not listed in Annex 1, facilitated access following Article 12 shall be applied by the multilateral system of the Treaty. However, the state members may choose SMTA to apply following their discretion.

There is a report study shows that "the Treaty still contains some serious shortcomings. There is an urgent need to act and to overcome them – a challenge the Governing Body of the Treaty has to tackle now. If the problems are not solved, the credibility of the whole Treaty could be jeopardized"[188]. The study finds that overall implementation of the Multilateral System has been slow and identifies a need for several measures to allow for an implementation of the Multilateral System in a way that achieves the objectives of the Treaty.

The first part of the study assesses the access-part of the Multilateral System and the inclusion of plant GR into the system. "Less than one-sixth of the parties have notified which collections they are placing in the Multilateral System and provided the documentation necessary to facilitate access. No natural and legal persons that are not part of national PGRFA systems, such as private plant breeding companies, have decided to voluntarily place their collections of Annex I materials directly in the Multilateral System. No benefit-sharing payments have been received so far under the mechanism devised by the Treaty, and as of January 2011, confirmed voluntary contributions amount to only 13.7% of the agreed target between July 2009 and December 2011."[189]

I suppose that if the implementation of the Multilateral System of the Treaty has shortcomings as reported, the other agreements for other sectors may face many challenges. While the plant GR for food and agriculture have been accessed directly following SMTA, the GRs for the purposes of "chemical, pharmaceutical and/or other non-food/feed industrial uses" that can be accessed indirectly basing on biochemical compounds will be more difficult in practice.

Moreover, "the FAO system never succeeded in becoming the exclusive mechanism for ensuring the conservation and management of plant GR. Gene banks and private networks moved in to compete for the role of collectors and custodians of plants germplasm. Today the FAO is only one of the players in the worldwide business of potential providers of plant GR. Notwithstanding, this failure to make plant GR common heritage, the regulatory model significantly departs from the original concept of permanent

[187] See Article 12.3 (a) of the International Treaty on Plant Genetic Resources for Food and Agriculture.
[188] CHIAROLLA.C, JUNGCURT.S, *ITPGRFA, Out Standing issues on Access and Benefit-sharing under the Multilateral system of the International Treaty on Plant Genetic Resources for Food and Agriculture*, the Bern Declaration, Development fund, 2011, p.7
[189] CHIAROLLA.C, JUNGCURT.S, *Ibid*

sovereignty over natural resources as established in the General Assembly Resolution 1803 of 1962."[190]

B- Relationship between the FAO's treaty and the Protocol

The scope of the FAO's treaty is for the access and benefit-sharing to GRs for food and agriculture. Meanwhile, The Nagoya Protocol regulates the access to GR and benefit-sharing of remaining GRs for the purposes of "chemical, pharmaceutical and/or other non-food/feed industrial uses".

It is recognized that "all members of the FAO's treaty also are the members of the CBD, while not all Parties to the CBD are Parties to the FAO's treaty".[191] As a Protocol of the CBD, the Nagoya Protocol is only opened for the member of the CBD to sign and ratify. The States that are not Parties to the CBD, must ratify, accept, approve or accede to it, thereby enabling them also to become Parties to the Protocol. Article 4.4 of the Protocol states clearly that the Protocol is the instrument for the implementation of the provisions of the CBD on access to GR and benefit-sharing: "the Protocol does not apply for the Parties to the specialized instrument in respect of the specific GR covered by and for the purpose of the specialized instrument". Therefore, the Nagoya Protocol would not apply to a Party of the FAO's treaty. "The more complex situation would arise with the possibility of countries being Parties to some but not all of the three instruments. This patchwork of legal obligations between States could create particular challenges in the operation of any regime on access to GR and benefit-sharing."[192] For example, the USA may become a Party to the FAO's treaty but remain a non-Party to the CBD.[193] As another example, Vietnam is not a contracting party of the FAO's treaty [194] but is a contracting party of the CBD and the Protocol would potentially cover all GR to Vietnam. Thus, if Vietnam wishes to deal with issues of access to GR and benefit-sharing in relation with the USA, the Nagoya Protocol cannot be used; it needs a bilateral agreement with the USA. Vietnam and USA have also signed the US-Vietnam Bilateral Agreement on Trade in 2000, which includes trade in agriculture and intellectual property right issues.[195] In other cases, for two Parties of the Nagoya Protocol but are not Parties of the FAO's treaty, like Vietnam and South Africa,[196] the Protocol would be applied to regulate the agreement related to food and agricultural GRs between those two parties.

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[190] FRANCESCO.F, SCOVAZZI.T, *Supra*, p.10
[191] UNEP/CBD/WG-ABS/7/INF/3/Part.1, *Supra*, p.6
[192] UNEP/CBD/WG-ABS/7/INF/3/Part.1, *Ibid*
[193] http://www.cbd.int/information/parties.shtml, last accessed 10th April 11, 2012
[194] http://www.fao.org/Legal/treaties/033s-e.htm, last accessed 10th April 11, 2012
[195] THOMAS.F, *Régime de conservation et d'usage de la biodiversité au Vietnam*, de la souveraineté nationale aux mécanismes d'intégration, IDR, Programme Biotek, available at http://www.bioteksuds.org/IMG/pdf/Regime_de_conservation_et_d_usage_de_la_biodiveriste_au_Vietnam.pdf, last accessed May 20, 2012, p. 6 – p.18
[196] http://www.fao.org/Legal/treaties/033s-e.htm, last accessed 10th April 11, 2012
http://www.planttreaty.org/content/members-contracting-parties, last accessed 5th July 2012

§ II – The International Convention for the Protection of New Varieties of Plants (UPOV)

A – General introduction

The UPOV was signed in Paris in 1961 and entered into force in 1968. It was revised in 1972, 1978 and 1991. The 1991 Act of the UPOV Convention entered into force in 1998. The UPOV Convention provides a *sui generis* form of intellectual property protection specifically adapted to the process of plant breeding and developed with the aim of encouraging breeders to develop new varieties of plants.[197] To be eligible for protection, varieties have to be: (i) distinct from existing, commonly known varieties;[198] (ii) sufficiently uniform in its relevant characteristics;[199] (iii) stable; and (iv) new.[200]

The Convention offers protection to the breeder, in the form of a "breeder's right" if his plant variety satisfies the above conditions. However, the breeder's rights are limited by two kinds of exceptions. The compulsory exceptions following Article 15.1 are: the breeder's right shall not extend to acts done privately and for non-commercial purposes, acts done for experimental purposes; acts done for the purpose of breeding other varieties (breeder´s exemption). The breeder's exemption optimizes variety improvement by ensuring that germplasm sources remain accessible to all breeders. The optional exception following Article 15.2 is to restrict the breeder's rights in relation to any variety in order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting, on their own holdings, the protected variety. This exception should be done within reasonable limits and subject to safeguarding of the legitimate interest of the breeder. Therefore, the mission of UPOV is "to provide and promote an effective system of plant variety protection, with the aim of encouraging the development of new varieties of plants, for the benefit of society". Up to 2011, the UPOV has 68 members [201].

B – Relationship with the Nagoya Protocol

The UPOV Convention recognizes the importance of access to GR to ensure the development of varieties of plants. Through definition of breeder's right and exceptions to the Breeder's Right, the UPOV Convention reflects points of view of the breeders over the world that need to access to all genetic materials to maintain and develop the plant varieties

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[197] UNEP/CBD/WG-ABS/7/INF/3/Part.2, by MEDALIA. J. C, *Study on the relationship between an international regime on ABS and other international instruments and forums that govern the use of genetic resources - The World Trade Organization (WTO); the World Intellectual Property Rights Organization (WIPO); and the International Union for the Protection of New Varieties of Plants (UPOV)*, 2009, p.16

[198] Clause 1, Article 5, UPOV

[199] Article 6, UPOV

[200] in the sense that they must not have been commercialized prior to certain dates established by reference to the date of the application for protection, following Article 7, UPOV

[201] : http://www.upov.int/index_fr.html, last accessed 10th April 11, 2012

and maximize the use of GR for social benefit. The UPOV convention, therefore, is suitable with the objective of sustainable use of plant GR and other objectives of the CBD.

During the negotiation of a regime on access to GR and benefit-sharing, the Nagoya Protocol was developed by a spirit of mutual support with UPOV Convention and without impact to the CBD. However, the Protocol was adopted without mentioning in detail intellectual property rights, therefore, the relation with the UPOV convention is indirect and unclear.

The question is which are the impacts of the protection system for new varieties of plants following the UPOV on national implementation of access to GR and benefit-sharing. In addition to the principle of tax exemption for cultivators and exceptions for the right and benefit for the cultivators, other benefit-sharing may be restriction to utilization and progress on access to GR and benefit-sharing. While the UPOV requires unrestricted access to new varieties of some countries, it also requires compliance with the rights of the breeders who may be foreign individuals or organizations obtaining access to GR from providers. Those breeders have a right to define exemption to those who wish to use their protected new plant varieties following the UPOV convention and the countries cannot interfere with the rights of breeders. In this case, I suppose that there is potential conflict with the regime on access to GR and benefit-sharing. The GR providers have rights to be shared benefit following the Nagoya Protocol. However, once they provide GR to the breeders who requires unlimited and free access to GR following the UPOV convention, then their rights are under the discretion of the breeders. This means that the benefits may not be shared, because the right of the breeders are protected.

Generally, in my opinion, it may be potentially unequitable for implementation of UPOV and the Nagoya Protocol. While the UPOV focuses to promote biotechnology and science by protecting the rights of breeders who are scientists or users in general, the Nagoya Protocol implies to protect the rights of the providers who are most the local and indigenous peoples. The UPOV requires to access unrestrictly to plant varieties of some countries for the scientists to research and create the new varieties. However, it does not engage any liability of benefit-sharing to the providers, after the new varieties is created, the patent rights of the scientists will be protected by the UPOV, the legitimate benefit of the local people who supplied the primary plant varieties for the scientists is not protected. The plant varieties of the local communities which are protected from generations to generations are their heritage and guarantee their sustainable livelihood. They face with risks of degradation or loss after being accessed without benefit-sharing. I agree that the contribution of the scientist and the new research on plant varieties should be recognized and protected for promoting development of biotechnology and science, but it should be carried out in a balance with protection of the rights of the local communities who provides the plant varieties and traditional knowledge to create those new varieties.

§ III - WTO Agreements and Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs)

A- General issues

The TRIPs agreement was signed on 15th April 1994 and came into force 1st January 1995 as the establishment of the World Trade Organization (WTO). The way leading to the WTO and TRIPs had commenced from the General Agreement on Tariffs and Trade (GATT) which was established from 1st January 1948 after the Second World War in order to maintain common rules of international trade. The issues of intellectual property rights protection was firstly mentioned by the agenda of the GATT's Negotiations on Counterfeit Goods in Tokyo in 1978. The negotiation took place during 1986-1994 Uruguay Round-Group of Negotiations on Goods - Negotiating Group on TRIPs, including Trade in Counterfeit Goods [202].

TRIPS provides, inter alia, minimum standards for the protection of intellectual property rights. This includes trademarks, copyrights, geographical indications, industrial designs, patents, layout-designs (Topographies) of integrated circuits, protection of undisclosed information, and control of anti-competitive practices in contractual licences. TRIPs also deals with the procedures and domestic measures to enforcement of the intellectual property right protection and settlement of disputes between WTO's members on TRIPs. This is the first agreement that provides punishment for the members who do not ensure the minimum protection of the intellectual property rights. The agreement also provides applications of GATT basic principles, such as National Treatment, Most-Favoured-Nation Treatment for the 'nationals'[203] of any other country member of the WTOs in aspect of intellectual property right.

The expectation of TRIPs is to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property right do not themselves become barriers to legitimate trade. The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations[204].

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[202] More information at *http://www.wto.org/english/tratop_e/trips_e/trips_e.htm*

[203] When "nationals" are referred to in this Agreement, they shall be deemed, in the case of a separate customs territory Member of the WTO, to mean persons, natural or legal, who are domiciled or who have a real and effective industrial or commercial establishment in that customs territory. (footnote No 1 of the TRIP agreement)

[204] Article 7, TRIPs, *http://www.wto.org/english/docs_e/legal_e/27-trips_01_e.htm*

Regarding the relation between TRIPs and the CBD, by Doha Declaration 2001, (Paragraph 19), the TRIPs General Council considered the Article 27.3.b, 71.1 and 12 with the scope and principle at Article 7 and 8 of the Agreement. One of the solutions suggested supporting mutually the CBD and WTO's TRIPs was disclosure of origin of GRs and TK for applying intellectual property, especially patents. Some developing countries suggest amending the TRIPs Agreement to patent to GR and TK as proof of PIC and MAT. The others believe that the amendment is not necessary to implement the CBD because this issue can be done by agreements at national level and TRIPs agreement is not suitable to regulate access to GR and benefit-sharing. The 2005 Ministerial Summit in Hong Kong and meetings of the TRIPs General Council has continued to take note of paragraph 19 of the Doha Declaration. The negotiation is still taking place.

There are deepest rooted reasons for the conflicts and problems between TRIPs and CBD and other agreements of WTO

Firstly, Firstly, the TRIPs Agreement is claimed that they reflect the perception of innovation of developed countries, which hold most of the knowledge and technology. While TRIPs has protective treatment for formal innovation that satisfies the established criteria of patenting practice, the informal innovation under cumulative, incremental, and multigenerational forms, like the TK achieved by the Indigenous and local communities, which are mentioned by Article 8.j of the CBD and the Nagoya Protocol, are not covered by the intellectual property rights provisions of the TRIPs agreement, particularly with regard to patent protection.

Secondly, the conflict between the TRIPs Agreement and the CBD is the conflict between the principle of the law on development and the heart of law on patent. The objective of the law on the development is contradicted with provision of para 2, Article 16 of the CBD: "technology is objective of legal protection and access, transfer are assured following the model that the law on intellectual property is compatible, adequate and effective."[205]

Thirdly, this is also a problem related to the relationship between MEAs and WTO agreements. "All efforts undertaken so far within the WTO to reach consensus on precise rules clarifying the relationship between MEAs and WTO law (including CBD and TRIPs) have failed."[206] The MEAs which includes measures can be considered against the GATT WTO in terms of non-discrimination, national treatment and elimination of quantitative restrictions.

"The WTO rules potentially impact on the trade-related environmental measures envisaged by the CBD. At the very least, one should mention the TRIPs agreements with

[205] BEURIER.J-P, *Supra*, p. 418
[206] FRANCESCO.F, SCOVAZZI.T, *Supra*, note 36, p. 53

regard to prohibition or limits on the granting of intellectual property rights on GR and WTOs agreement relating to trade in goods (GATT, SPS, TBT agreement)."[207]

B- Conflict and overlapping in detail

There are some arguments. On one hand, it is supposed that "the CBD conforms to the TRIPs Agreement"[208]; on the other hand, it is argued that the TRIPs Agreement should be amended to conform to the CBD. One of the most contentious, emerging conflicts is that the patentability of genetic material illegally exported from the state of origin, without PIC of that state as required by the CBD and the Nagoya Protocol. "The TRIPs Agreement allows these patents while patent offices in industrialized countries, are reluctant to deny protection. This phenomenon is often stigmatized as one of bio-piracy". "In the field of biotechnology, where biotechnological inventions utilize biological and genetic resources in new, non-obvious and industrially applicable ways, such inventions may be conceived with or without the use of traditional knowledge associated with the genetic resources".[209]

However, the Nagoya Protocol left the intellectual property rights of GR and TK open, such as information supply or internationally recognized certificates that do not mention to intellectual property rights. It seems to be that the issue of intellectual property rights would be dealt with in detail by ongoing negotiations of the WTO and WIPO.

There is a concern about the internationally recognized certificate, which may become a technical barrier to trade, in case of considering the certificates are documents attached to activities of GR transfer and export in international trade.[210] This concern derives from an analysis of appropriate principles of the WTO on non-discrimination (the Most Favored Nation and National Treatment Principles, as well as the appropriate measures contained in the Agreement on Technical Barriers to Trade (TBT) which governs the elaboration and use of technical regulations, standards, and conformity assessment procedures, in a way that does not create unnecessary obstacles to international trade. "The certificate could be considered a technical regulation and it must take into account the relevant provisions of the TBT Agreement, for example Article 2.2 on technical regulations shall be no more restrictive than necessary to fulfil a legitimate objective and the requirement that technical measures shall be the less trade restrictive in light of applicable risk"[211]. Technology transfer also is one key issue of the CBD and a component of benefit sharing under the Nagoya Protocol. However, the provisions of benefit sharing

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[207] KISS.A, SHELTON.D and ISHIBASHI.K, Economic globalization and compliance with international environmental agreement, International environmental Law and Policy Series, Kluwer Law International, 2003, p. 69 – p. 73

[208] EUROPEAN COMISSION, *Nature and biodiversity cases, ruling of the European court of justice*, Office for official Publications of European communities, Luxembourg, 2006, available at http://ec.europa.eu/environment/nature/info/pubs/docs/others/ecj_rulings_en.pdf, last accessed May 16, 2012, p.27

[209] GUPTA. A. K., *Supra*, p.103

[210] UNEP/CBD/WG-ABS/7/INF/3/Part.2, *Supra*, p. 9

[211] *Ibid*, p. 10

and technology transfer of the Nagoya Protocol are general so that does not affect the intellectual property rights protection related to technology transfer following TRIPs regulation. In addition, the Protocol has no compulsory disclosure requirement for TK by the internationally recognized certificate, so that, there is no conflict between the CBD, the Nagoya Protocol and WTO, but – in the view of some countries and experts – "an opportunity to promote mutual supportiveness between intellectual property right system of WTO and the CBD international regime could be lost". However, some countries and stakeholders support this approach because "it would avoid the alleged negative consequences of new patent disclosure requirements mentioned in paragraph 56. These delegations and stakeholders support other mechanisms to address concerns regarding misappropriation."[212]

Therefore, it seems to be that the international law makers choose the normative method to deal the conflict between the CBD and GATT and TRIPs WTO. Following KISS.A and SHELTON.D, there are two kinds of methods for solutions for the conflict between the MEAs and GATT, WTO; one is interpretational and the other normative. "The interpretational method addresses the existing norms or provisions to decide which regime can prevail in general and in particular." "The normative method could result in or from the creation of international bodies which combine the difference with in the same regime, allowing any conflict between them to be resolved in a single institution. It could also mean the adoption of rules determining the priorities either practical solutions calls for amending the free trade agreements so that environmental measures may be accepted." For interpretational methods, "the Vienna Convention on the Law of Treaties established the basic rules of determine which of conflicting obligations prevails if two or more treaties are adopted at different times have 'the same subject matter' (Article 30)". "Although there are some doubt that the GR trade always has the same subject matters in conflict with the free trade regime, if the parties concerned recognize that two different obligations are within 'the same subject matter' their views will prevail. According to Articles 30.3 and 30.4.a, if the parties to the earlier treaty are also parties to the later treaty the later treaty in case of a conflict and only those provisions of the earlier treaty which are compatible with the later treaty will continues to be applicable. If one state is not a party to the later treaty the earlier treaty will govern all relevant aspects of their relationship (Art.30.4.b)". For normative methods, "one of the practical normative methods is to amend the provisions of free trade regimes or to adopt new provisions. To date numerous suggestions have been made to amend the GATT/WTO provisions, particularly in relation to Article XX. One observer suggests adding new exceptions for MEAs in general: each party affirms its respective rights and obligations with respect to measures under existing and future bilateral or MEAs to which it is or may become a party. Nothing in the WTO/GATT

[212] UNEP/CBD/WG-ABS/7/INF/3/Part.2, *Supra*, p. 20

agreement shall be construed to prevent or impede Parties from taking actions to implement or enforce existing or future international agreements. It should be noted that the above proposal excludes not only any existing MEAs but also future MEAs. Such amendment of GATT/WTO should be preferred; however, it is unlikely, because it needs approval of two-third of the parties plus formal consent by ratification. Compared to the above, as a rather easier normative method, the adoption of an understanding or guidance to be applied in the ruling of panels in case of dispute settlement may be envisaged, which would provide certain criteria to be taken into account in order to resolve the conflicts between MEAs and GATT/WTO." [213]

§ IV- World Intellectual Property organization (WIPO)

A – General introduction

Now, there are 23 international agreements regulating different aspects of the intellectual property rights protection. These agreements are suitable with the patents system for access to GR and benefit-sharing. In 2000, WIPO council established the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) as a forum for debate and dialogue on the relationship between intellectual property, TK, GR and traditional cultural expressions[214]. The scope of work of the IGC includes the possible development of an international instrument or instruments on intellectual property right and GR as well as TK.

B – Relationship with the Nagoya Protocol

In fact, the Nagoya Protocol left the issues of intellectual property rights for the negotiation within WIPO which is still taking place with aim to an international instrument for protection of TK. Therefore, all the related substantive questions related to the intellectual property raised before the Nagoya Protocol's approval, are left to be answered by the WIPO's negotiation. They include: "defensive protection of GR; disclosure requirements in patent applications for information related to GR used in the claimed invention and alternative proposals for dealing with the relationships between the patent system and GRs; and intellectual property issues in MATs including the preparation of databases and guidelines for the intellectual content in agreements on access to GR and benefit-sharing"; "non- intellectual property right-based *sui generis* forms of protecting TK; elements for *sui generis* regimes; the role of databases and registries in the protection of TK; measures for the protection of TK, elements of an ethical code of conduct to ensure respect for the cultural and intellectual heritage of indigenous and local communities;

[213] KISS.A, SHELTON.D *Economic globalization and compliance with international environmental agreement,* Kluwer Law International, 2003

[214] http://www.wipo.int/tk/en/igc/index.html, last accessed May 16, 2012

guidelines for documenting TK" [215]. In the meetings held in February and May 2011 of the IGC, negotiation documents focused on the issues of definition of TK, benefit and scope of protection, how to manage and enforce of implementation of right to TK[216], [217]

In general, all the issues related to intellectual property right aspect of GR and TK are not provided in detail by the Nagoya Protocol that avoids all conflicts and overlappings with the agreements of the WTO or WIPO. The Article 4.2 of the Protocol opens to the others agreements continue to deal with those difficult issues. However, it means that no progress had been made by the Nagoya Protocol in this aspect. In cases, the other international agreements do not provide or regulate in detail this aspect; these will create lacunas in international law system. The provisions of the Nagoya Protocol on intellectual property are likely statements and declaration rather than applicable regulation.

Conclusion of Chapter 2

In international legal system, one treaty always exists in interrelation with other relevant treaty, because demarcation of scope of regulation and object of the treaties is not always absolute. Therefore, the analysis and assessment of the Nagoya need be put in its relation with other treaties. The analysis of interrelation between the Nagoya Protocol and the CBD, Bonn guidelines FAO's treaty, TRIPs under WTO, UPOV and agreements of WIPO shows that there have not only complementary supports for the Nagoya Protocol but also limitations, gaps, overlappings or conflicts, potential conflicts.

To overcome overlappings or conflict between the Nagoya protocol and related treaties, in this chapter, the author suggests applying normative or interpretational methods. For lacuna, gaps and potential conflicts, "relevant ongoing work or practices under international instruments and relevant international organizations" should take into account to treat with the above analyzed limitations of the Protocol that will be necessary for the Protocol as well as the others relevant treaties to improve their effectiveness.

Conclusion of Title 1

The fact of biodiversity degradation, loss and awareness of responsibilities to national conservation for sustainable development shows that there is a great urgency to protect the remaining biodiversity by a more effective legal means. Concurrently, there has been a requirement of international laws to create an international legal regime on ABS. Those are the bases for elaboration of the Nagoya Protocol. However, the development of the Nagoya Protocol has experienced a long and difficult international negotiation and after adoption of the Protocol there are still unsolved issues remains. The comparative analysis

[215] UNEP/CBD/WG-ABS/7/INF/3/Part.2, *Supra*, pp.13 - 14
[216] http://www.wipo.int/portal/en/news/2011/article_0011.html last accessed May 16, 2012
[217] http://biodiversity-l.iisd.org/news/wipo-working-group-streamlines-text-on-traditional-knowledge/?referrer=biodiversity-update last accessed May 16, 2012

of the Protocol in relation with the other relevant treaties also indicates some gaps, conflicts and weakness of the Protocol itself.

When the CBD had taken only nearly one year from 1992 to 1993 to enter into force, the FAO's treaty had taken about three years from 2001 to 2004 to come into force, the TRIPs was signed in 15th April 1994 and came in to force in 1st January 1995, the Nagoya Protocol was approved in 29th October 2010, until July 2012, it has only five ratification. The slow progress of ratification of the treaty is not rare in international law such as the case of UPOV which took almost seven years from approval in 1961 to enter into force in 1968 and was being revised three times in 1972, 1978 and 1991. However, it still raises a question that when will the Protocol reach fiftieth signatures to take its effect or will the Protocol remain forever as a draft, because there are many criticism of weakness and challenges for implementation.

The number of countries members between the treaties also different in comparison with the number of signatures of the Nagoya Protocol and the division between countries parties from the North and the South (see more Annex 4). By the end of July 2012, the UPOV has 70 members[218], FAO's treaty 127 contracting parties to the Treaty (126 countries and the European Union) as of 24 October 2010[219], TRIPs under WTO that has 155 members on 10 May 2012[220]. The number of countries members of one treaty also reflects partly the nature, ideas, approach, features, scope of regulation of the treaty. The CBD became nearly universal participation treaty with 193 parties because of not only the urgent needs of global biodiversity conservation but also the characteristics of a framework convention that most of the countries can be easier to decide to ratify or accede. However, for a more concretized and difficult issues related directly to interests and rights of the countries and their citizens like access and benefit-sharing that will take their time for consideration**.**

[218] *http://www.upov.int/export/sites/upov/members/en/pdf/pub423.pdf* last accessed 12th July 2012
[219] *http://www.planttreaty.org/list_of_countries* last accessed 12th July 2012
[220] *http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm* last accessed 12th July 2012

TITLE 2 – SUBSTANCES DEVELOPMENT OF THE NAGOYA PROTOCOL

As a protocol of the CBD, the Nagoya protocol is expected to "clarify terms, add additional text as amendments, and establish new obligations. These new obligations can be quantitative targets for States to achieve"[221] the third objective of the CBD, concurrently to contribute to common goal of biodiversity conservation of the CBD.

In despites of some achievements, the Nagoya Protocol also is criticized by "weakness", generalities, and vagueness. Thus, it created 'soft' contents of law under form of a legally-binding treaty. There are different points of view of effectiveness of a 'soft' law. Namely "we had passed the order of agreement consensus and consensus is a good inverse. It is not explicitly a principle of obligations'or non-engagement. Sometimes, it also is clearly binding to ethic conscience clearly."[222] However, at the same time, "how could we respect the justice of international law if we adopt the vague text and reserved comportment if we consider the text in pure form".[223]

This part will analyse scientific and technical aspects, as well as legal aspects of the Protocol that clarify which reasons and which provisions of the Protocol are like 'soft' law and what are the problems in the integration of the Protocol into national law?

[221] See the UN explanation of how a protocol extends a treaty; *http://untreaty.un.org/english/guide/asp*
[222] PAPAUX.A et WYLER.E, *Supra,* p. 103
[223] cited by PAPAUX.A et WYLER.E, *Ibid,* p. 104

CHAPTER 1 – Analysis under scientific and technical aspects

The relation between science and the law around the paradigm of environment is reflected critically by the environmental law, driven by an essential question: why do all objects of the environment rest continuously on basic problems? “In origin, the question of justice comes finallly to the science”[224].

The science and the law about the nature are linked together. If the law preceded the science, the society would create around a social contract (or this hyphothesis) of their mutual relation resides.[225]

Similarly, the Nagoya Protocol is supposedly based on technology and science. Because, a key characteristic of GR is that its benefit or its value is revealed or realized only through technological and scientific activities. Therefore, if the technological and scientific aspects can not be treated by the Protocol, there will be problems in its application or it is not feasible.

The Nagoya Protocol recognizes the important contributions to sustainable development made by technology transfer cooperation to build research and innovation capacities for adding value to genetic resources in developing countries, in accordance with Articles 16 and 19 of the Convention (Preamble of the Protocol). Sustainable development underlies the CBD provisions on technology transfer and cooperation. The principle includes the need to distribute costs and benefits between developed and developing countries and supporting innovation in the latter. The reference to technology transfer and cooperation to build capacities for adding value is a key element for developing countries. Article 16(1) establishes goals regarding access to and transfer of technology, including biotechnology, recognizing that both access and technology transfer are essential elements for the attainment of the objectives of the CBD. Article 19(1) pertains to the handling of biotechnology and the distribution of its benefits. This includes providing for the effective participation of provider countries in research activities in those countries where feasible. Article 19(2) requires priority access to the results and benefits arising from biotechnologies based on the genetic resources provided. Article 2.d of the Protocol defines “Biotechnology” as defined in Article 2 of the Convention means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use”.

However, there are still questions: what are scientific and technical bases for all the legal regulations of the Protocol? Which difficulties are to set up legal provisions on access GR, benefit-sharing, and compliance? How does it affect the integration of the Protocol to national law? This chapter will address these questions.

[224] SERRES, *Le contrat naturel*, La rousse, 1989, p. 9
[225] NAIM-GESBERT.E, *Supra*, p. 29

Section 1 - Science, technology, intellectual property and genetic resources' utilization

§ I – Science, technology – Bases for genetic resources' utilization

A- Bases for definitions of GRs and its utilization

The bioprospecting and utilization of GR always goes together with the technology and science development. "If the concept of GR is understood only narrowly, in senses related to the original or current state of knowledge, the system with access to GR and benefit-sharing may not be able to capture the future potential value of genetic material, not least when it is used in or as a basis for synthetic biology or other new bio-economic technologies".[226] There is, however, a dilemma and a contradiction between, on the one hand, leaving a definition dynamic and flexible, and on the other hand creating legal certainty and being enforceable.

With the development of modern technology, genetic information that used for the technology and scientific research that can be obtained indirectly or researchered does not need to come to the origin country to obtain GR as tangible materials but can use this information for research. It is also a "fairly straightforward matter to read and copy long sequences of DNA or to exchange nucleotides in naturally occurring genetic material". [227] This requires the interpretation of definition of 'genetic resources' and their uses need to be dynamic as regards new technologies.

The researchers have also warned that "There is a risk that the new technology can make it easier to circumvent the obligations of the CBD. It may also prove very difficult to trace a given accessed GR once it has been altered and engineered through several technological stages. Using the protein amino acids sequence of a given protein to backtrack the RNA (and DNA) sequence is also possible today. This might also indicate that some or all forms of indirect use of genetic material and we can see the importance of keeping abreast of the many rapid changes in knowledge and technological capacity"[228]. "Through so-called 'differential' or 'alternative splicing' and other forms of m-RNA-editing after transcription to RNA from DNA, thousands of different proteins may come from one gene"[229]. This might indicate that some or all forms of indirect use of genetic materials should be part of the scope of the Protocol. "Today, we know far more about genes, gene expression and gene functioning, several species, including Homo sapiens, have had their genomes fully mapped, and there is a better understanding of what turns genes on and off and what regulates gene expression in the various cells"[230]. It is important

[226] UNEP/CBD/WG-ABS/9/INF/1, *Supra,* p. 2
[227] UNEP/CBD/WG-ABS/9/INF/1, *Ibid,* p. 19
[228] UNEP/CBD/WG-ABS/9/INF/1, *Ibid,* p. 17
[229] Shapiro, J.A. (2007), http://shapiro.bsd.uchicago.edu
[230] UNEP/CBD/WG-ABS/9/INF/1, *Supra,* , p. 16

to keep up the Protocol's provisions with abreast of the many rapid changes in knowledge and technological capacity.

Therefore, the Nagoya Protocol defines the terms of Article 2 of the CBD that reflects characteristics of the above mentioned technological and scientific bases. The Protocol repeats the definition of 'biotechnology' of the CBD that "means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use". However, the Protocol adds more two new definitions to support the definition of GRs and their use regarding technology and science. They are "utilization of GR means to conduct R&D on the genetic and/or biochemical composition of GR, including through the application of biotechnology as defined in Article 2 of the Convention". "Derivative means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or GR, even if it does not contain functional units of heredity"[231]. These definitions make the scope of application of the Protocol more broad than the satisfying requirements of being dynamic, especially the definition of derivatives to meet the requirements of covering all form of indirect use.

In which, the term "utilization" relies on R&D on genetic and/ or biochemical composition of GR. In which, R&D is known as "a well-established term, refers to creative work undertaken on a systematic basis in order to increase the stock of knowledge, including knowledge of man, culture and society, and the use of this stock of knowledge to devise new applications… R&D is a term covering three activities: basic research, applied research, and experimental development. "Utilization" covers all the R&D activities along the innovation chain i.e. the study, use and development following the collection in-situ or in situ conditions of a GR"[232].

However, "utilization" seems to be separated and not included "subsequent applications and commercialization". The wording of the Article 5 of the Protocol expresses that "utilization of GR as well as subsequent applications and commercialization". Thus, it can be interpreted "utilization", "application" and "commercialization" as distinct stages in the valuation chain.

The definition of "biochemical composition" refers to "derivatives." R&D on "biochemical composition of GR can constitutes "utilization" alone in accordance with the wording "and/or. The definition of "biotechnologies" provides explicitly inclusion of derivatives that means "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific

[231] Article 2 of the Nagoya Protocol
[232] Cited by PATERNOSTRE.R, *Supra*, p. 48-49

use"[233]. Thus, it is certain that derivatives are included in the access to GR and benefit-sharing international regime through the definition of utilization.

During the negotiations, the 'derivatives' also is understood with differently. They may be 'the results of an organism's metabolism', or 'any result of human activity utilizing a GR', as 'information on GR'. "Derivative" is the result of the utilization of a GR through human activity: a) GR used for research (research not aiming at commercialization), b) products under development (research and development aiming at commercialization) c) products (commercialization)".[234] However, the expression "naturally occurring" serves to exclude from the definition products that are derived or synthesized from genetic or biochemical resources through human intervention.

Finally, it is clear that the science and technology affects decisively to the definition of the GRs and its utilization. It also affects to determine the scope of regulation of the Nagoya Protocol through the definition of GRs and a range of related terms support the purposes of the Protocol.

B – Bases for relations between providers and users within equitable benefit-sharing

Biodiversity does not only express complexity of diversity of the living things. It is also a natural resources exploited by biotechnology like artificial genetic program. All living organism or even genetic sample, fragment can act its function. All living organisms have potential GR values and imply logically a commercialized and accessed market, and raise the question of benefits.[235] Therefore, all GR's utilization is not separated by science, technology and leads to potential benefit that is relation between users and providers in benefits sharing.

In the original CBD negotiations, the element of access to GR and benefit-sharing assumed that "users in developed countries had the technologies, infrastructure and capacity needed to benefit from GR of less developed countries".[236] In fact, most of GRs are found in the South, in particular in the mega-diversity countries, while the knowledge, the capital, the markets and organizations of research, the enterprises of the industry are found in the North.[237] It can be understood that the users' countries, which hold the technology and science knowledge and market and capitals to make GR arise benefit, need to cooperate with the provider country which owns the GRs, to access these resources. However, it also is proved that there is the decisive role of the technology and science in

[233] Article 2. d of the Nagoya Protocol
[234] UNEP/CBD/WG-ABS/7/2, *Supra*, p. 11
[235] NAIM-GESBERT.E, *Supra*, , p. 560
[236] TVEDT. M. W, YOUNG. T, *Supra*, p. 93
[237] HUFTY. M, *La biodiversité dans les relations Nord/Sud : coopération ou conflict ?* La Revue Internationale et Stratégique : *L'environment, un enjeu stratégique des relations internationales*, No 60, hiver 2005/2006, p.156

the process and the need to balance benefit between the providers and user to attain the objective of fair and equitable benefit-sharing.

The important developments of chemistry, molecular biology, and genomics provide a comprehensive menu of technologies that address supply and product development issues. "Furthermore, technologies that mutate genes in order to develop new products should raise not only monetary… but also ethical concerns among providers of GR… Scientific and technological developments should influence the negotiation of supply, benefit-sharing, monitoring, and other relevant provisions of present and future agreements on access to GR and benefit-sharing".[238] Moreover, the answers for question "Are science and technology affecting the choices made by negotiators of agreements?" can be found as follow:

The roles of technologies are in accelerating the natural product discovery process of "developments in genomics, proteome analysis, and bioinformatics that have enabled scientists to gain a better understanding of the chemical pathways and reactions in living organisms which have led to the identification of new targets for drugs". "Advances in gene technology have also allowed the speeding up of screening programs for new compounds through the development of more sophisticated in vitro assays". "There have been major advances in the field of functional genomics where whole genomes are being characterized in more detail using proteomics and microarray technologies. DNA microarrays, for example, allow for the identification of genes that are turned on or off under different environmental conditions on a genome-wide scale. Also, comparative genome hybridization (CGH) studies that employ DNA microarrays are revealing the extent of diversity across arrays of related and unrelated microbial species."[239]

In increasing the set of tools and procedures, through combinatorial chemistry, "expedite the discovery process of pharmaceuticals and agrochemicals. Combinatorial chemistry allows the generation of a huge number of chemical compounds for screening. This is based on the idea that all but the smallest organic molecules can be thought of as made up of modules which can be assembled in many ways. By going through all the possible combinations a huge number of molecules can be created from a small number of starting modules."[240]

In genetic engineering forms combinations of heritable materials by "the insertion of nucleic acid molecules produced by whatever means outside the cell into any virus, bacterial, and plasmid on another vector so as to allow their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued

[238] BHATTI. S, CARRIZOSA.S, MC GUIRE. P, YOUNG. T, *Contracting for ABS: The Legal and Scientific Implications of Bioprospecting Contracts,* ABS Series No. 4, IUCN Environmental Policy and Law Paper No. 67/4, 2007, p. 198
[239] BHATTI. S, CARRIZOSA.S, MC GUIRE. P, YOUNG. T, *Ibid,* pp.189-190
[240] BHATTI. S, CARRIZOSA.S, MC GUIRE. P, YOUNG. T, *Ibid,* p.190

propagation. In essence, gene technology is the modification of the genetic properties of an organism by the use of recombinant DNA technology. Genes are the biological software that drives the growth of organisms."[241]

Generating chemical diversity through bioprospecting and synthetic biology, "the search for plants, animals, and microbes with pharmaceutical, agrochemical, and other industrial purposes offer many opportunities for the discovery of genes coding for enzymes and proteins involved in natural product biosynthesis, many of which might be expected to have a broad substrate tolerance". [242]

Creating protein diversity through directed evolution, which is "a procedure used in genetic engineering to evolve proteins or RNA with desirable properties not found in nature. Directed evolution is usually guided toward a predetermined goal resulting largely in the accumulation of adaptive mutations, whereas natural evolution accumulates adaptive and neutral mutations. The type of properties targeted in vitro evolution often goes beyond requirements that would make biological sense"… Directed evolution can be carried out in living cells (in vivo) or directly in DNA (in vitro). Unlike in vivo directed evolution, in vitro experiments can generate large DNA libraries. Directed evolution in which as genome sequencing projects continue to grow, promises to become a principal route for search and discovery. Harvesting the potential of microorganisms through site-directed mutagenesis generates diversity by specific random or cyclic mutagenesis approaches. Thus, scientists are able to generate large information-rich libraries of unique molecules. The selection and screening possibilities are knowledge based, high throughput, and product oriented. The libraries generated are screened for the targeted properties and the best candidate is selected. Protein engineering augmented by knowledge derived from structures determined by x-ray crystallography, computational homology modeling, rapid protein characterization, and structure/function relationship analysis to create new products.[243]

Recent scientific findings and novel technologies suggest that both users and providers of GR need to negotiate agreements on access to GR and benefit-sharing that reflect these scientific developments and trends. In more detail, the roles of science and its implications for access to GR and benefit-sharing are in identifying microbes, several chemotaxonomy and DNA fingerprinting methods for the classification of microbes are available and relatively useful. In supplying biological samples, a new paradigm determined by science and technology genomic approaches has also been developed to ensure a sustainable supply of natural products. Facilitating the identification and expression of gene clusters from microbes, evolving genes that can be screened later against a desired property for a specific product screen for a diversity of enzymes in a

[241] BHATTI. S, CARRIZOSA.S, MC GUIRE. P, YOUNG. T, *Ibid*, p.191
[242] BHATTI. S, CARRIZOSA.S, MC GUIRE. P, YOUNG. T, *Ibid*, p.191
[243] BHATTI. S, CARRIZOSA.S, MC GUIRE. P, YOUNG. T, *Ibid*, p. 189 - 193

microbial community, this process, metagenomics, is a creative approach in screening for a diversity of enzymes and is close to the idea of screening a biodiversity library. The total synthesis or semi-synthesis of a drug may be possible, nevertheless the structural and stereochemical complexity of most natural compounds often preclude the development of economically feasible large-scale total syntheses.[244]

However, there are some difficulties to define the value of science research. A basic problem of valuation is that any effort to fully contract the terms and conditions of benefit-sharing is likely to be faced up with a variety of difficulties. Namely, "Non-commercial projects that will unexpected turn commercial at an unknown point in the future to commercial ventures in which it will be extremely difficult to assess the value of the collection of species to be prospected".[245] The differentiation between scientific and commercial research is not always obvious, while it is desirable to foster scientific research. Scientific research often leads to commercialisation later.[246]

"A concept holistic can answer to the judicial scientific and social existence. Because of the non-rival and/or non-excludable characteristics of plants and related traditional or genetic information, it is practically impossible for providing countries and communities to control their movement and, therefore, to secure their fair exchange."[247] In fact, the providers face with great challenges in seeking to ensure that users obtain permissions to access, and share benefits arising from GR that originated in their country. "Having sustainable supplies is critical if a chemical is to be marketed as a drug, agrochemical, or other product. Reliable production is also a necessity to support the research needed to study and understand novel compounds before commercial potential can even be evaluated"[248]. There is no longer the control point that results from the need to recollect benefits. The providers are concerned about potential income and technology transfer opportunities lost to scientific endeavors. There is also some concern that, by making this information public, these researchers are jeopardizing the ability of countries to protect the value of GR over which they have undisputed sovereign rights. The implication of this is that the free international flow of gene sequences may ultimately make control of GR irrelevant. Since these efforts will increase dramatically in the future, provider countries may want to strengthen and accelerate efforts to take advantage of opportunities to develop local capacity in order use their genetic diversity before it becomes public and looses its economic potential.[249]

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[244] BHATTI. S, CARRIZOSA.S, MC GUIRE. P, YOUNG. T, *Ibid,* pp. 193 - 198
[245] Cited by MEDAGLIA.C.J, SILVA.L.C, A*ddressing the Problem of Access: Protecting Sources, while giving users Certainty*, IUCN Environmental Policy and Law Paper No. 67/1, 2007, p. 47
[246] Cited by MEDAGLIA.C.J, SILVA.L.C, *Ibid,* p. 47
[247] JONGE.B.D, *What is fair and equitable benefit-sharing*? Journal of Agricultural and Environmental Ethics, 2010
[248] BHATTI. S, CARRIZOSA.S, MC GUIRE. P, YOUNG. T, *Supra*, p.197
[249] BHATTI. S, CARRIZOSA.S, MC GUIRE. P, YOUNG. T, *Ibid,* p.198

On the users' side, scientific and technological developments are also the core and competitive advantage of companies. "These companies are concerned that their competitive edge will be compromised if proprietary bioassays, molecular biology approaches and genomic technologies, and the nature of any specific leads, or the financial terms of an agreement are shared with parties' peripheral to the parties to agreements on access to GR and benefit-sharing."[250] Several experts noted that "if there is an obligation to return for PIC at a later stage when a use is identified, then this could involve great costs and risks to users which may have already invested considerably in the process of research and development."[251]

R&D of products is "a lengthy and risky process, involving both high investment and skilled labor." While multiple GR are typically involved in a single project, biotechnological research is, economically speaking "intensive" – that is, it depends on a number of inputs: skilled labor, capital and genetic resources. For equity, sustainability and compliane the CBD, all of these inputs need to be fairly and equitably compensated. However, it is quite difficult to separate absolutely to each individual contribution and differentiate precisely between between these three distinct inputs. While a single input can not always ultimately result in a specific profit. "Creative work needs to be rewarded, capital investments need to have an attractive return, and GR need to be recognized so that their providers receive a fair and equitable share of the benefits."[252]

Therefore, how does the Protocol deal with all these issues? The question is left to the judicial judgement and ethical behavior of scientist of scientific research, the legal framework of the scientific research in conciliation between liberty of research and constraints of ethnicity[253]. The provisions of Article 5 on benefit-sharing and other articles were elaborated to balance interest of providers and users, with an aim to fair and equitable benefit-sharing that bases on contribution of GR and science and technology.

§ II - Intellectual property

On one hand, the CBD suggests promoting development of a market by recognizing the intellectual property right of the products of biotechnology. On the other hand, it makes encouragement to different actors in the South to develop and protect their resources and knowledge of indigenous and local communities for sustainable development and a secure to facilitated access to a crucial resource for the industry[254]. Accordingly, the intellectual property issue in the Nagoya Protocol can be analysed by two aspects: A - intellectual

[250] BHATTI. S, CARRIZOSA.S, MC GUIRE. P, YOUNG. T, *Ibid*
[251] UNEP/CBD/WG-ABS/7/2, *Supra*, p. 11
[252] MULLER.R.M, LAPENA. I, *A moving Target: Genetic Resources and Options for tracking and monitoring their International Flows*, IUCN Environmental Policy and Law Paper No. 67/3, 2007, p 9
[253] NAIM-GESBERT.E, *Supra*, p. 728 –730
[254] AUBERTIN.C, PINTON.F, BOISVERT.V, *Supra*, p. 4

property rights of technology and science developed by user and B - intellectual property right for the traditional knowledge of indigenous and local communities.

A – Intellectual property rights for science and technology related to genetic resources

Intellectual property rights are linked to the biotechnology innovation. The biological resources transformed by the biotechnologies are subject to the legal protection for their inventor.[255] Intellectual property rights play an increasingly important role in the use of GR. "Intellectual property rights protect intangibles, that is to say developments or inventions expressed in the form of gene constructs, organic components, or entire organisms, subjecting them to more or less extensive exclusive rights."[256] The intellectual property right may be decisive for benefit-sharing. "For benefit-sharing to take place, there must be a legally binding system on user country measures to safeguard the realization of this objective."[257]

The regime of intellectual property is based on three factors. *First*, it is the framework for the world treaty to have worldwide validity, in which the capitalist country's people respect for the law on intellectual property, for scientific research in particular, that is adhere to the procedure to estimate the reasonableness of historical evolution that has permitted US and other countries to search the natural elements can be patented. *Second*, intellectual property was linked in the socialist countries to defend to the lack of intellectual property. *Third*, a third regime has mixed a system that permits the protection by patents of intellectual property but in a superficial way. The CBD has not established an international system but it does have sub-national protection for intellectual property for the case of search for national elements that change completely; this tri-parties regime has existed in the world, thus, it resulted an unstable equitable form in respect of the law on legitimate owner of nature.[258]

Patentability seems to become the core issue in intellectual property. There exists a question of 'can living things be patentable, or would this negate the progress linked to the GR utilization'?

Biotechnology innovation expresses the social choice of the patent law. In fact, if it appears adaptably to the all new innovation that permits adaption to the technical specificity of biotechnology invention, it will be conceivable for a distinct legal regime to obtain plant protection like "*suis generis*". It will be a new category of industrial property

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255 AUBERTIN.C, PINTON.F, BOISVERT.V, *Ibid*, p. 25

256 SEILER.A, DUTFIELD. G, *Supra*, p. 9

257 ANDERSEN.R, TVEDT.M.W, FAUCHALD.K.O, WINGE.T, ROSENDAL.K, SCHEI.P.J, *International Agreements and Processes Affecting an International Regime on Access and Benefit-sharing under the Convention on Biological Diversity, Implications for its Scope and Possibilities of a Sectoral Approach*, FNI, Norway, 2010, p. 12

258 UNIVERSITE DE LIMOGES, C.I.C.D.E, ESMPU, *Mondialisation et Droit de L'environnement, Act*es du 1er Seminaire International de Droit de l'Environnement Rio+10, Rio De Jeneiro, 2002, p 52,53, 54

to genetic creation to be justified by the difficulty linked to living things (for example description of the technique) and based on the notion of genetic information.[259]

Pasteur said "The science is not only the part, because the knowledge is the common heritage of the humanity". And the foible of the legal regime of the patentability of the living thing that formalizes a renewably of the situation of the human to nature with the pluralism of the truth"[260]. Under the legal form of the patent, the problems of the patentability of the living things imply the awareness of the monopoly reality on the creature that is created to leave the living organism exists. The problem is displaced towards to the notion of invention and its protection.[261]

There was a revolution in patent law, and the patent is the lock to the access to technology. The evolution of patent law was marked by the convention of Luxembourg of 15/12/1975 and Budapest of 28/4/1977 but the resolution engagement of the US law toward patentability of livings since 1988 that accepted a patent for the new plant varieties or micro-organisms. Outside the limit, the living things are patentable (notably micro organism) and the directive 98/44-CE of the EU dated 6/7/1998 to confirm the patentability in the limit indicated above.[262] The Marrakech Accords on the aspects of the intellectual property right in commerce 1994 and TRIPs under WTO stipulates that all patents can be obtained for all inventions without discrimination in the technology sector and it can not exclude the right to patent for an invention merely because of its living characteristics.[263]

Subject to the provisions of Paragraphs 2 and 3 of Article 27, TRIPs, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.[264] Following the WIPO, the criteria for the patentability are: new (not understood in actual state of the scientific knowledge), inventive, industrial application (can understand include agro-industry – on type of industry). Article 57 of the Convention of the Munich dated 5/10/1973 establishes the office of patents of the European, the deposit of micro organism for patent is sufficient (The Budapest Treaty dated 28/4/1977 on the international awareness on the deposit for the patent). Explicitly Article 53.b of the convention Munich on the patent provided that the European can not be granted for plant varieties and breeding animals.[265]

There were some arguments for patentability to the microorganisms or bacteria. The invention in the domain of micro-biotechnology and chemistry affects to the basic science. In fact, microorganisms imply the technical process of intervention of enzymes that can

[259] NAIM-GESBERT.E, *Supra*, p. 728 - 730
[260] NAIM-GESBERT.E, *Ibid*, p. 724
[261] NAIM-GESBERT.E, *Ibid*, p. 728 –730
[262] BEURIER.J-P, *Supra*, p. 61- p. 65, p. 417- p. 425
[263] AUBERTIN.C, PINTON.F, BOISVERT.V, *Supra*, p. 25
[264] http://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm
[265] NAIM-GESBERT.E, *Supra*, pp. 728 – 730

found by nature in the living organisms play a basic role as chemical catalyst. The essential process of the life is the chemistry, thus, the gene is a chemical. The decision of the Diamond Chakrabarty" case that granted a patent to the microorganism or bacteria that manifest to possess of noticeable different characteristics of all cells that we can find in the nature and had the potential the utility evidence. This discovery can not relay to open the nature but it self - "His discovery is not natures' handi-work, but his own". Also, the human can not create to the life, but, he can modify the material that creates the new form, he constructs properly the reality in a certain way. It is the science of the whole that can range in the order of construction.[266] This affirms that the legal model to living things expresses the certain situation of humans to nature. If the law of nature can not be patentable, they are given subject to manifestations in nature that appear to the entire human/nature relationship and can not be appropriate following whatever decision. They are the fruits of the human activity that modify the law of nature and give it a different meaning. The history of evolution of human to nature in materials can be found by briefly researching of the law.[267]

Like the CBD, the Nagoya Protocol has not regulated the issues of intellectual property correctly in the aspect of science and technology on GRs. These issues are dealt with by the others current legal systems and mechanisms of intellectual property following Article 4. However, there exist the problems with the current mechanism of intellectual property rights. More than the patents themselves, it is often their scope and procedures of application that have problems. Thus, the application of patent laws for the living things is recent times. Examiners who are familiar with inventions of the industrial world, have not always been qualified to judge whether property a plants is inventions or not that has not always been described. Meanwhile, the patents have become a way of systematic validation of scientific research.[268] If the general problem exceeds the capacity of the judicial framework, the question will ultimately depend on law writing. When living things can be patentable, debates can always be raised on this technical paradox, science will permit the patenting of living organisms.[269]

B – Intellectual property right and the traditional knowledge

The legal situation of TK of indigenous and local communities is in contrast with the situation of modern scientific knowledge. "While modern occidental intellectual efforts result in an inventions, a biotechnological product or plant variety can be protected by patent laws, the acquirer's right, industrial secrets, trademark...etc are important sectors of the intellectual output, efforts made by the indigenous and local communities are not

[266] NAIM-GESBERT.E, *Ibid*
[267] NAIM-GESBERT.E, *Ibid*
[268] AUBERTIN.C, PINTON.F, BOISVERT.V, *Supra*, p. 109
[269] NAIM-GESBERT.E, *Supra*, p. 547

protected or supported." [270] In addition, it is noted that "there is not one absolute definition of 'indigenous people' in international law…the main international law instrument that attempts to define indigenous peoples and their right is the International Labour Organization Convention on Indigenous and Tribal people".[271]

"The positive protection of TK" via the development of legal regime, recognizing the rights of indigenous peoples over their knowledge using new type of intellectual property rights is not a new idea, notably "when traditional knowledge is viewed as 'intellectual property' then some may conclude with Dinah Shelton (1994) that the best way to protect the environmental right of indigenous peoples is through intellectual property law".[272] "But none of the intellectual property rights traditional regimes fits the protection of indigenous knowledge has been recognised for years and the development of a *sui generis* system advocated for so long. A number of countries have taken steps to develop policy and some enacted specific law, like Peru, Panama. But there are limitations of the effectiveness of national action without the integration of TK protection in the international intellectual property rights system because the latter sets have basic global standards." [273]

There are also many views on the desirable content of a protection regime of intellectual property rights for the TK. It also has needs of a consistent commonality but has its limitations. "No intellectual property rights based policy and legislation of TK protection is equally if not more important in particular because knowledge cannot be viewed in isolation from the culture, the land and biological resources that it needs to evolve and grow."[274]

The TK of indigenous and local communities is unprotected. The current intellectual property right system is not suitable for the needs of indigenous and local communities for the following reasons. *Firstly*, the indigenous and local communities cannot afford the cost of registering intellectual property rights. *Secondly*, "the concession of intellectual property rights is not extended to material that is found in the public domain and much TK is already in the public domain. The criteria for obtaining patents as novelties, inventions, reproduction and industrial application or for obtaining acquirers certificate as novelties are not relevant for the protection of TK." The current intellectual property rights systems do not include the possibility of collective rights, among them past or future generation. In this sense, the possibility of conceding protection is excluded when the inventors is not identified impeding protection of the collective innovation achieved

[270] FRANCESCO.F, SCOVAZZI.T, *Supra*, p. 409
[271] WESTRA.L, *Environmental justice and the rights of indigenous peoples, International and domestic legal perspectives*, Earthscan, 2008, p.5
[272] WESTRA.L, *Ibid*, p.11
[273] JEFFERY. I. M, QC, FIRESTONE. J, BUBNA. L. K, *Supra*, p. 36
[274] JEFFERY. I. M, QC, FIRESTONE. J, BUBNA. L. K, *Ibid*

over many years by indigenous and local communities. The systems do not take into account common law already in existence in relation to property rights among indigenous and local communities. They only offer monopolistic systems for a certain period. The collective property will cease to exist when the period expires that affects the collective property of future generations. "Neither would it be possible to accept that this regulation of indigenous knowledge be carried out by means of codes of conduct as some developed countries propose since protection based totally on the willingness of states would not be effective. The protection mechanisms for this knowledge which already exist are insufficient." [275]

The Nagoya Protocol deals with the issue of TK associated with GR by Article 12, and access to TK by Article 7, compliance with law by Article 16. However, they refer to the national law without more details. Meanwhile, all the issues related to GR, TK and indigenous and local communities are being negotiated within WIPO.

Section 2 – Tracking and monitoring

§ I – The needs of tracking and monitoring and difficulties in science and technology

A – Tracking, monitoring and reporting as a system

Tracking, monitoring and reporting play an important role in access and benefit-sharing process. They are major means to ensure compliance of stakeholders with Multilateral Agreed Terms of an access and benefit-sharing relation. There is a suggestion that tracking, monitoring and reporting may simply be a system in which users of GR are required to keep minimum documentation on the GR they use. "In particular, only those that are used in connection with the conditions/permits on access to GR; transfer that information to any third parties that receive materials from them; and provide that information at specific checkpoints (e.g. intellectual property right applications and product approval processes, etc.)". [276] Moreover, the system would be a mechanism which could ensure legal interests of provider countries in regard to the materials they supply, including interests of benefit-sharing following CBD's objectives. It would contribute to the elimination of these sources of inefficiency in the current national and international law with its effectiveness. [277]

However, the value of a tracking monitoring and reporting system is limited in the absence of a coordinated response. It also needs complementary measures in order to take full advantages. Its specific design should also take into consideration several economic characteristics of access to and use of GR, otherwise, it is either impractical or too costly. It

[275] FRANCESCO.F, SCOVAZZI.T, *Supra*, p. 426
[276] MULLER. R.M, LAPENA. I, *Supra*, p. 114
[277] MULLER.R.M, LAPENA. I, Ibid, p. 7

requires time, resources, equipment, human resources and skills which may not be currently available in most developing countries, even if it is possible technically (for example through the use of DNA technology, fingerprinting and molecular markers or more common project result reports). Most importantly, "there needs to be commitment by countries and institutions providing and using resources alike. In terms of cost-benefit analysis, it seems that at least in the case of certain types of resources (GR used in plant breeding), regularly tracking and monitoring the flow of these, would not be worth the effort."[278]

Meanwhile, the CBD makes no explicit reference to tracking or monitoring the flows of GRs. However, it provides the legal foundations for developing the certification of origin and indirectly calls for tracking and monitoring by countries of origin, as a means of verifying compliance with MAT. [279]

B – Tracking and monitoring processes

In the technical aspect, tracking and monitoring can be understood as two closely related processes. "Tracking" refers to following the movement of GR (and their derived products) along the R&D chain. "Monitoring" refers to verifying that the uses being given to these resources and products are reflected in and are permitted by the original contracts on access to GR and benefit-sharing (or subsequent contracts) and national laws under which R&D are undertaken. Tracking may imply identifying what research and collected GR institutions are actually doing. Monitoring may imply verifying if research by these institutions is permitted in the light of obligations assumed in the contracts or whether research has taken a totally different route than originally planned and whether this is provided for in the contract. [280]

Therefore, a system for tracking GRs would be necessary to provide a means for providers to track the uses of the data and information derived from their GRs. Because, GRs are now being used in various forms ranging from extracted DNA to various types of sequence data that are stored in public and private databases. These derived GRs are readily copied, mobile and readily accessible globally and can be used for a variety of purposes that may have not been intended or anticipated in original agreements. The question is whether it is possible for the provider country to keep real value of their resources, especially in the environment of rapid technological innovations and global information access. "The task of tracking successive uses of information, although complex, is theoretically feasible and would require the crafting of appropriate metadata, careful utilization and implementation of a persistent identifier system and development of custom tracking applications."[281]

[278] R.M, LAPENA. I, *Supra* , p. 111
[279] MULLER.R.M, LAPENA. I, *Supra*p. 112
[280] R.M, LAPENA. I, *Supra,* p 111
[281] UNEP/CBD/WG-ABS/7/INF/2, , p. 7

"Tracking the flows of GRs could also be seen as a means of ensuring compliance of rules and principles of CBD operations and the international regime on access to GR and benefit-sharing in particular."[282]

In technical respect, there are some methods for tracking. Method of single gene based identification uses one kind of molecule which could serve as a molecular chronometer, by which the evolution of different species could be traced. Methods of whole genome sequencing include next generation sequencing technologies. Persistent identifiers as unique labels that are assigned to objects and identifiers as used in a large-scale laboratory information management system are well understood in computing systems.[283]

Monitoring focuses on effects of providing access to GR and its utilization. In particular, the benefits arising out from the use of the GR to which access was granted. Monitoring includes: assessing the compliance of providers and potential users with the provisions of legislation regarding access to GR and benefit-sharing in negotiating an agreement; assessing the scope and volume of agreed or negotiated benefit-sharing arrangements; assessing whether benefit-sharing obligations are met by the users; and assessing whether the total of agreed arrangements fulfill the objectives and the expectations of legislators and policy makers.[284]

In general, tracking, monitoring and reporting system implies to a suggestion that the Protocol should established a means of tracking, monitoring and reporting mechanism. However, the Protocol uses neither the tracking methods nor the word 'tracking'. The reason of absences of tracking may be technical complexity, impracticality and high costs. The Protocol provides some means for monitoring and reporting system only, including: Access and Benefit-sharing Clearing House, checkpoints, and competent national authority at a national level. In addition, the Protocol uses an internationally recognized certificate of compliance to assist the monitoring that has been the subject of research and debates for many years.[285]

§ II –Internationally recognized certificate of compliance

The internationally recognized certificate of compliance is a major tool to monitor the utilization of genetic resources following the Nagoya Protocol in Article 17.2, 17.3, 17.4 of the Protocol. Therefore, this sub-section analyzes the scientific and technical aspects of the international recognized certificate of compliance that should be a base for analysis of legal aspects and comparison between effective technical requirements and sufficient of provisions of the approved text of the Nagoya Protocol in the next chapter.

[282] MULLER.R.M, LAPENA. I, *Supra,* p. 114
[283] UNEP/CBD/WG-ABS/7/INF/2, *Supra,* pp.6-9
[284] R.M, LAPENA. I, A 7, *Supra,* p. 30

A – The role, important and advantages

The negotiation of the Nagoya Protocol used 'certificate of origin, source, or legal provenance" for the certificate of compliance. A group of technical experts was established to explore and elaborate possible options, form, intent and functioning of an internationally recognized certificate, to analyse its practicality, feasibility, costs and benefits.[286]

There are also studies and debates about a certificate of origin, source or legal provenance.[287] They include studies on the operation of the certificate of origin, source, or legal provenance[288] on what is to be certified, issuers of the certificate, or on who needs the certificate.[289]

The studies proved that the certificate provides a guarantee for provider country on requirements of the legal acquisition of GR. It ensures the legal certainty for users and the conformity with legal obligations for providers. It may reduce pressures in the provider countries to adopt strict legislation on access and benefit-sharing. It provides users with greater legal certainty and evidence that users have met access and benefit-sharing requirements. Thus, it builds trust among users and providers.[290] Because, the certificate traces the flows of GR and TK and attests to the legal provenance for access to such resources and knowledge under specified conditions for its use, it demonstrates compliance with CBD's requirements on access and benefit-sharing and in complying with mandatory disclosure of origin requirements.[291] Therefore, it may help to provide countries to ensure that their legal rights (including sovereignty) and economic interests in GR which flow outside national jurisdictions are effectively protected.[292]

"The basic role of the certificate is to provide evidence of compliance with national regimes on access to GR and benefit-sharing". [293] Thus, in accordance with the CBD, it is practical to refer to the certificate as a certificate of compliance with national laws. Ideally, the certificate of compliance with national laws is a public document issued by a competent national authority and reviewed as appropriate at checkpoints in user countries. Theoretically, all types of GR may have the certificate of compliance. The provider

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286 UNEP/CBD/WG-ABS/5/7, *Report of the meeting of the group of technical experts on an internationally recognized certificate of origin/source/legal provenance*, the fifth Meeting of the Ad Hoc Open Ended Working Group on Access and Benefit-Sharing (WG ABS 5), 2007, p. 1

287 For example: RICHERZHAGEN.C, *Certificates of Origin: Economic Impacts and Implications*, UNU-IAS, Working Paper No 141, July 2005; TOBIN.B, BURTON.G, UGALDE.J.C.F, *Certificates of Clarity or Confusion: The search for a practical, feasible and cost effective system for certifying compliance with PIC and MAT*, UNU-IAS Report, 2008; DROSS.M, WOLFF.F, *New Elements of the International Regime on Access and benefit-sharing of Genetic resources – the Role of Certificate of Origin*, German Federal Agency for Nature Conservation, 2005, UNEP/CBD/WG-ABS/4/INF/2, by SARNOFF. J. D. CORREA. C, *Analysis of options for implementing disclosure of origin requirements in intellectual property applications.*

288 MULLER.R.M, LAPENA. I, *Supra*, p.111

289 UNEP/CBD/WG-ABS/5/INF/4/Add.1, *Supra* p.6

290 UNEP/CBD/WG-ABS/3/5, *Supra*, p. 21

291 UNEP/CBD/WG-ABS/4/INF/2, *Supra*, p. 12

292 MULLER.R.M, LAPENA. I, *Supra*, p.111

293 UNEP/CBD/WG-ABS/5/7, *Supra*, p. 7

country may also consider including TK in the certificate. It is most appropriate to use a standardized internationally recognized format for certificates. The certificates, should, where possible, provide a link to a national database providing non-confidential information of PIC and MAT. The use of a freely available read-only access system based on a unique identifier (alphanumeric code) that links to national databases for additional information is also desirable. However, due to differences in the capacities of the countries to implement the system of the certificates, the recommendations above need to be flexible enough for the combined use of paper and electronic formats. The use of unique identifiers enables any subsequent identification of material to be traced to the certificate. Any transfers to third parties should maintain the link to the certificate and the MAT applying to the resources. Finally, measures necessary for ensure security as well as the costs of establishing the system and the security included. With implementation help from users and providers, a national certificate, with standard features recognized internationally combined with control points in user countries to monitor the use of GR and TK in accordance with national laws, including PIC, MAT would be a possible way to meet the CBD's goal.[294]

It is clear that a national legal system alone are not sufficient to guarantee benefit-sharing once GR leaves the provider country, in this respect, the certificate as part of a broader regime on access to GR and benefit-sharing, can become an important tool to reduce this limitation. A certificate can address a number of concerns of the Parties and therefore cover several other objectives such as: legal certainty; transparency; predictability; benefit-sharing facilitation; facilitation of legal access with minimal transaction costs and delay; technology transfer; preventing misappropriation; minimizing bureaucracy; supporting compliance with national law and mutually agreed terms; enabling and facilitating cooperation in monitoring and enforcement of access and benefit-sharing arrangements; facilitating development of national access and benefit-sharing frameworks; protection of traditional knowledge.[295]

An internationally recognized is advantageous when the certificate provides evidence that the GR is obtained with the PIC of the relevant authority in the provider country; facilitates the application of user measures and the verification of the certificates at check-points, and creates incentives for compliance with access to GR and benefit-sharing requirements of provider countries. Monitoring of arrangements on access to GR and benefit-sharing is facilitated through the establishment of a central registry or Access and Benefit-sharing Clearing House.[296] Therefore, depending on the model, advantages of adopting a certificate could include: ensuring greater compliance with requirements of the CBD, assisting the fair and equitable sharing of the monetary and non-monetary benefits

[294] UNEP/CBD/WG-ABS/5/7, *Supra,* pp. 7-9
[295] UNEP/CBD/WG-ABS/5/7, *Ibid,* pp. 6-7
[296] UNEP/CBD/WG-ABS/5/7, *Ibid,* p.12

from the utilization of GR and TK, facilitating cooperation among different jurisdictions, and simplifying access processes to GR. [297]

In addition, the certificate is a means to alleviate the current burdens and restrictions imposed by many existing laws on access to GR and benefit-sharing. These include: regulating access, controlling immediate and future use of GR, impeding illegal transboundary (and interinstitutional) flows of resources, safeguarding the sovereign rights of provider countries, protecting TK in some cases, among others. Giving the actual users of GR considerable responsibilities may act as an incentive to reduce the rigidity and control-type approach most of the laws on access to GR and benefit-sharing currently have.[298]

In the provider country, the studies suggest that a national authority in charge of issuing the certificate should be a designated authority. Furthermore, countries should be encouraged to streamline rather than add to current internal mechanisms for access, and issuance of permits, contracts and certificates. In the user country, one or more national authorities identified as checkpoint(s) should be appointed by the competent national authority. Identified checkpoints are registration points for commercial applications (e.g. product approval processes) or intellectual property rights offices. In the case of non-commercial uses, additional checkpoints could be further explored such as entities funding research, publishers and ex-situ collections. For reporting at checkpoints, the user should be obligated to record the certificate identifier on publication, on applications for patents and commercial product registration or on reporting to the Clearing House. User country would need to adopt measures which include and recognize certificates as a requirement and condition to commercialize certain products or, in some cases, as a condition for the granting of intellectual property rights. National authority in both provider and user country should be listed in the common international database. [299]

At the international level, an international registry containing electronic copies of the certificate or the unique identifier of the certificate might serve as a Clearing House mechanism. Countries' checkpoints could be required to notify the international registry following a simple procedure when they issue a certificate. Experts have different opinions on the amount of information stored in the Clearing House, from the unique identifier with a link to the issuing country database only to the information on the certificate.[300]

B – Challenges for implementation

The implementation of 'the internationally recognized certificate of compliance' may face costs and institutional capacity challenges.

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[297] UNEP/CBD/WG-ABS/5/7, *Ibid*, p.6
[298] UNEP/CBD/WG-ABS/4/INF/2, *Supra,* p. 12
[299] MULLER.R.M, LAPENA. I, *Supra,* p.111
[300] UNEP/CBD/WG-ABS/5/7, *Supra,* p. 10

The cost for implementation includes cost for establishing national authorities in capacity building, and in the maintenance of the international registry, additional costs such as opportunity costs, direct costs and transaction costs. Additional costs may be related to the coexistence of GR inside and outside the certificate system, the setting up and maintenance of checkpoints in user countries and the possibility of enforcement of the certificate across various jurisdictions. "The implementation and opportunity costs may escalate if, for example, the model needs substantive review of certificates on both sides, excessive tracking, monitoring and reporting, or generates more bureaucracy than required, or slows down procedures unnecessarily, or discourages research and product development." [301] The costs resulting from a growing number of uncoordinated national regimes may increase. Also, "it was considered necessary to take into account not only transaction costs but also direct costs associated with implementation. In some cases, while it is likely that an initial cost is high in the start up phase of a global regime, the transaction costs (e.g. marginal costs of each additional transaction) may under certain circumstances be relatively low." [302]

Some also may see certificates "as additional burdens on an already over-regulated scenario". Especially, there is considerable uncertainty with regard to the practical operation and implications that certificates may have. For example, "it is fairly easy to imagine a certificate traveling attached to a specimen, with some basic data on this specimen. Herbarium specimens (and parts thereof) usually travel and flow this way (with labels attached). This is standard practice for institutional trading, but it may not continue where the specimens are acquired by commercial users." Additionally, "in the case of microbial culture collections, for transfers of materials, the collections are packed and shipped with a series of documents including shipping documents and invoice and safety information. It is much less clear how the certificate would apply to the movement of a single gene, a gene sequence, a molecule, a specific protein, etc. which is also a part of a specific specimen. At the time of actual collecting (or physical access), only limited information is available". Finally, "the certificate may refer to the specimen itself or a sample, individual seed or accession in some cases and may not include any details regarding genetic resources per se." [303]

The use of the certificates also raises the substantive and procedural concerns in evaluating submitted information for the consequences of failure. In addition, the use of the certificates raises other issues regarding verification of information by certifying entities, such as errors in certification, tracking certificate validity, and misuse of certificates. Moreover, determining that entities have authority to issue certificates may require complex considerations. Like other types of certification documents, international

[301] UNEP/CBD/WG-ABS/5/7, *Supra,* p. 11
[302] UNEP/CBD/WG-ABS/5/7, *Ibid,* p. 12
[303] MULLER.R.M, LAPENA. I, *Supra,* note 216, p.117

certificates may be issued erroneously, falsified or uses improperly. Consideration must be given to what standards should apply to issuing certifications, whether to mandate or to facilitate certificates requirements, how to address errors of certification and improper uses of certificates, and what consequences should attach to false, deceptive or confusing uses of certificates. Additional consideration must be given to whether and how ownership of certificates of origin may be transferred.[304].

Conclusion for Chapter 1

Science and technology is one basic ground for developing legal provisions. The problems studied in the field of science and technology may impact the legal field and should be solved by legal provisions.

As analysed, GR utilization and issues on access to GR and benefit-sharing are not separated with science and technology development. The utilization of genetic resources, TK and process on access to GR and benefit-sharing are impacted decisively by science, technology and intellectual property rights.

However, while science and technology is changing rapidly and always progressing by nature, law is potentially stable and rigid. There exists a trend of conflict between these fields because whilst the science and technology needs flexibility for its development, law needs certainty to ensure its effectiveness of compliance. As part of international law and international biodiversity governance, the Protocol has been developed based on findings of science and technology to harmonize science, technology and the law and its governance.

304 UNEP/CBD/WG-ABS/4/INF/2, *Supra,* p. 12

CHAPTER 2 – Legal analysis of the Nagoya protocol

The Nagoya protocol has been elaborated basing on the needs of practice, the requirements of international treaties and science and technology relates to genetic resources and process of access and benefit-sharing. All of these lead to the rationality of the Protocol and lead to balance of its legal aspect and the others aspects.

This chapter will analyze the legal aspects of the Nagoya Protocol to find the problems of the integration of the Protocol into national law and solutions to address. Considering international law framework's conditions, there are questions of what does the international law provide to regulate? And what does international law ask the States to implement? These are the issues of legal obligations of the States and implementation and compliance.

This chapter, therefore, analyzes the Nagoya in two issues: Section 1 – Legal obligations for the Parties, Section 2 - Compliance with legal obligations.

Section 1 – Analysis of legal obligations

In international law, the legal obligations are usually distinguished by two kinds of obligations: mandatory or non-mandatory obligations. Mandatory obligations are direct and compulsory obligations which I would like to call 'hard' obligation. In contrary, non-mandatory obligations are indirect and voluntary obligations which I would like call 'soft' obligation, 'optional'. Some mandatory obligations can be flexible or non-flexible and they can be mixed in one article or a provision. Level of flexibility make the obligations become 'harder' or 'softer'.

Whether each legal obligation has weakness or not? It depends on the conditions of the treaties and its members. In general, the Protocol includes both 'hard' and 'soft' obligations. However, it seems to be that the 'harder' obligations are imposed to the provider country in term of 'access', the 'softer' obligations are imposed to the user country regarding 'benefit-sharing'.

The 'user country' can be defined basing on definition of 'utilization of GR' under Article 2 of the Protocol and the CBD. 'Provider country' can be interpreted by wordings of Article 5.1 and 6.1 of the Protocol as "the Party providing such resources is the country of origin of GR or a Party that has acquired the GR in accordance with the Convention". However, there is a difficulty to define "genetic resources acquired in accordance with the CBD" as the question of temporal scope of the CBD also. In fact, "the gene banks that have considerable importance that constituted since many decades or even centuries in the developed countries." [305] Moreover, "for the researcher on DNA nowadays make in vitro

[305] There are some example to demonstrate: the Institute of Vavilof of Saint Peterbourg, established in 1927, contains 250,000 plant varieties, Deutsche gen bank obst Dresde contains 35,000 varieties of fruits and cereal, or the new world bank of graines of Spitzberg, established in 2008 by 17 countries, the world trust fund for the cultural diversity, the

with the gene banks, only research new species and necessary ethnobiology need works in-situ."[306]

The balance between obligations of user countries and provider countries or between 'access'and 'benefit-sharing' is considered as the core of the Protocol. As Tvedt and Rukundo stated, "the functionality of the Protocol rests on finding an adequate balance between two imperatives. On the one hand, developing countries often advocate for strong compliance mechanisms coupled with clear benefit-sharing obligations…" On the other hand, "it is not enough to require user-side measures: the Protocol must also make those measures reasonable from the perspective of the user side. The challenge is how to create an adequate balance between these two imperatives without compromising effective compliance and without introducing undue legal uncertainty for users of genetic resources."[307]

However, the Protocol is also commented that "The former is detailed and imposes clear obligations on provider countries. The latter is vague and incoherent. The obligations it seemingly imposes leave the implementation to the absolute discretion of users' countries with in their jurisdiction."[308] Despite of the fact that,' "user-side measures' are absolutely essential to functional access to GR and benefit-sharing"[309], the phrase 'as appropriate' which used by the Protocol indicates that countries are not required to have or adopt user measures.[310]

This section will analyze to clarify 'hard' and 'soft' obligations of user country and provider country and indicate the problems of provisions on legal obligation under the Protocol that impact on integration of the Protocol into national law. The analysis is carried out following elements of the access to GR and benefit-sharing.

I – Access – harder obligation for the provider country

A – Access to genetic resources

1) State's sovereignty and legal certainty

a) State's sovereignty

State's sovereignty is one of the most important of international law principles. It is also prerequisite for provider countries accept to access to GR. By the Article 6.1, the

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foundation and private enterprises, that contains in 2010, 500.000 varieties) in addition to large numbers of botanic conservatories in the OCDE countries. BEURIER.J-P, *Supra,* note 104, p. 417 – p. 425

[306] BEURIER.J-P, *Ibid*

[307] UNEP/CBD/WG-ABS/9/INF/20, TVEDT. M. W, RUKUNDO. O, *Study on the functionality of an ABS protocol*, 2010, p. 2

[308] NIJAR.G.S, *Supra,* p. 32

[309] BHATTI. S, CARRIZOSA.S, MC GUIRE. P, YOUNG. T, *Supra*, p. 23

[310] "A legal analysis of the many uses of that phrase throughout the CBD, as well as the rules set forth in the Vienna conventions for interpreting international agreements suggests that it indicates a choice by the legislating country, among the three options, and/or underscores the fact that the particular measures adopted by a country will be unique to its own needs and system. It does not constitute a loophole in the Parties' obligation to implement each provision in good faith". Noted by BHATTI. S, CARRIZOSA.S, MC GUIRE. P, YOUNG. T, *Supra,* p. 23

Protocol reaffirms of sovereign rights over natural resources, access to GR for their utilization is subject to PIC of the providing party.[311]

Before the CBD the concept of common heritage had existed. Accordingly, "no State in particular can exercise their sovereign rights, their law on property on the common resources and can not prevent the overexploitation of these common resources, because their access must be free. The State can not oppose to the other States to utilize plant or animal GR on their territory must see the way overexploit the GR and can not engage into the activity to maintain the GR. And the same, the responsibilities are for all the States of all users. In fact, many critics of recognition of 'common heritage of mankind', it is affirmed that the concept is 'communal tragedy'".[312] "The CBD confirms sovereign rights over biological resources, while recognizing that the conservation of biological diversity is a 'common concern' of humankind".[313]

However, requirements imposed by Article 6.3 are argued that the sovereign rights of States over their GR, and their authority to determine access is limited. Because, the Article 15 of the CBD only requires Parties "to endeavor to create conditions to facilitate access to GR for environmentally sound uses", but does not require Parties have to adopt access legislation. Some Parties may choose not to put in place any measures on access, as they "exercise sovereign rights over their resources and have authority to determine access to GR and this will be subject to national legislation". The Protocol obliges provider countries "to introduce elaborate access obligations that are not required by the CBD".[314]While "the CBD does not "directly call for any kind of direct governmental measures," the Protocol requires the adoption of such specific law as a precondition to require PIC. In addition, access law of Parties requiring PIC must now also respect several general principles and requirements."[315] In addition, some obligations may not be able to implement because of discretion of user countries as requirement of legal certainty. "There is no more than a voluntary best effort provision to create conditions to facilitate access to GR for environmentally sound uses. This right now is severely curtailed by the Protocol".[316]

In contrary, there is a discussion supposes that nothing affects to the sovereign rights, Parties can decide submitting the access to their GR to PIC and they can also choose give up their rights on access to GR and benefit-sharing. As stated by Kamau.C, "It is the provider state's discretion to either require PIC or allow access without prior control

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[311] The providing party is either the country of origin or a party that acquired the genetic resources in accordance with the Convention, (Article 6.1 of the Nagoya Protocol)
[312] JEFFERY. I. M, QC, FIRESTONE. J, BUBNA. L. K, *Supra*, p. 12 – p. 32
[313] GLOWKA.L, BURHENNE-GUILMIN.F, Synge.H, *Supra*, p. 3
[314] NIJAR.G.S, *Supra,* p. 15
[315] PATERNOSTRE.R, *The Nagoya ABS Protocol: A legally sound framework for an effective regime*, Thesis for Master's degree, Utrecht University, 2011 ***http://igitur-archive.library.uu.nl/student-theses/2011-1103-200625/NAGOYAPROTOCOLABSTHESIS(RPATERNOSTRE).pdf***, p. 62, accessed at 2nd March, 2012
[316] NIJAR.G.S, *Supra,* p. 15

many states - and in particular the industrialized states which normally appear on the user side - may opt for free access to their GR and TK."[317]

b) Legal certainty

Under the Article 6.3 of the Protocol, provider States are required to provide for: 'legal certainty, clarity, and transparency' of their domestic legislation on access to GR and benefit-sharing; 'fair and non-arbitrary rules and procedures' on accessing to GR'; 'information on how to apply for PIC'; clear, cost effective and timely decision-making; recognition of a permit or its equivalent as evidence of PIC; criteria and procedures for the involvement of indigenous and local communities; and clear rules and procedures for requiring and establishing MAT.

It's clear that the Article 6 of the Protocol does a good job to provide to its Parties of what they should do and how they should do in aspect of access, but does not give any reference to what they should do in the practice.

The Protocol does not provide any criterion to assess the first requirement of 'legal certainty, clarity, and transparency' or assign any mechanism, institution to verify and determine objectively a domestic legislation on access to GR and benefit-sharing meets requirements of 'legal certainty and clarity', except the 'legal transparency' may be assessed by the Access and Benefit-sharing Clearing-House[318]. Therefore, if there is no criterion, it will be difficult to define a domestic legislation and regulatory that whether meets requirements of "legal certainty, clarity" or not. It may raise an argument that "legal certainty, clarity" is not be sure to define, there is no base to require users to comply and enforce the law of the provider countries. In other word, "Developed countries justified this requirement on the ground that only then could user countries be able to enforce the laws of the provider country".[319] There will be more challenges for provider countries to implement this provision in the current known situation, of which almost access legislation includes cumbersome application process, difficulties involving PIC, complexity of institutional mechanisms.[320], [321]

In fact, the 'legal certainty' seems to be a 'sub-objective' of all requirements for legislation and regulatory of provider countries. All the detailed requirements impose to the provider Parties are to support to reach the sub-objective of 'legal certainty'. Medaglia.C.J and Silva.L.C., cited and summarized the definition of a narrow 'legal certainty' that focuses on three elements to define. These are: 'Process certainty', 'scope and nature of the grant',

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[317] KAMAU.E.C, FEDDER.B, WINTER.G, *The Nagoya Protocol on access to genetic resources and benefit-sharing: What is new and what are the implication for provider and user countries and the scientific community?* Law and Environment Development Journal, Volume 6/3, 2010, p. 60
[318] NIJAR.G.S, *Supra,* p. 16
[319] NIJAR.G.S, *Ibid*, p.17
[320] MEDAGLIA.C.J, SILVA.L.C, *Supra*, pp. 8 - 9
[321] See more, MEDAGLIA.C.J, SILVA.L.C, *Supra*, pp. 8-9; KAMAU.E.C, FEDDER.B, WINTER.G, *Supra*, p. 248

and 'legitimate expectations and vested rights'. 'Process certainty' includes the "establishment and empowerment of competent national authorities", "specifying rights and duties of others who may be involved; clarity regarding the procedures for applying for rights on access to GR and benefit-sharing"; "clarity regarding various deadlines for processing applications; and clarity regarding the appeal of the decision by the applicant or by others". 'Scope and nature' of the grant "enhances legal certainty by clearly defining the rights granted as well as enunciating the mandatory provisions and conditions that must be included within the MAT". 'Legitimate expectations and vested rights' can be supported in several ways, including "clear and specific statutory requirements and limitations regarding subsequent challenges to the user activities after receiving rights and clear limitation of the nature of government power to alter, cancel, repudiate, amend or suspend a right, once it has been received".[322] They added that "a party would have legal certainty regarding an instrument if he was fully aware of all relevant laws and certain that they were consistently and predictably in force and enforceable" and they also gave example of "the relevance of legal certainty is evident in the position of some countries".[323] Therefore, it may be optimistic that the above explanation of the legal certainty could be used for reference in case of necessary, even though, it is unofficial and non-compulsory legal sources.

In further, 'fair and non-arbitrary rules and procedures' on access to GR provision may be understood as putting more burden of obligation to the provider countries to maintain such similar kind of principle of "most favoured nation" treatment[324]. Moreover, there is a worry that in practical term, "the user country could refuse to act against a violator within its jurisdiction if it determined that the law of the provider country was not in conformity with this requirement" of 'fair and non-arbitrary rules and procedures'. "This action could be taken if the law or practice, previous or present, of the provider is held by the user country to be unfair or discriminatory. No external criteria have been established by the Protocol as to how, and when, these situations would arise. It is in the complete discretion of the user country to establish its own basis for the determination."[325] However, the other suggests that "the fair and non arbitrary provision should not be interpreted as precluding the establishment of any kind of difference. Under the Protocol, more favourable treatments are not prohibited as long as the distinctions are operated upon objective, reasonable and legally-based grounds". 'Fair and non-arbitrary clause' should be understood that it prohibites "a long term exclusive exploitation of a genetic resource when this exclusivity runs against the environmental objectives of access to GR and benefit-sharing." [326]

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322 MEDAGLIA.C.J, SILVA.L.C, *Supra*, p. 17
323 MEDAGLIA.C.J, SILVA.L.C, *Ibid*, p. 17
324 See more at ***http://www.wto.org/english/thewto_e/whatis_e/tif_e/fact2_e.htm***, accessed at 1st April 1, 2012, for recognise similarity with this principle of WTO
325 NIJAR.G.S, *Supra*, p. 17
326 PATERNOSTRE.R, *Supra*, p. 61

Other requirements of the Protocol of procedure certainty may be a burden for institutional capacity of the provider countries which are mostly poor developing countries in the Global South. The provisions of Article 6.3 requests Parties to provide for information on how to apply to PIC and to establish clear rules and procedures for requiring and establishing MAT. The requirements of Article 6 link to Article 13 and 14. Article 13 imposes the Parties requiring PIC to create National Focal Point responsible to make available information on procedures for obtaining PIC and MAT for both genetic resources and TK. The National Focal Point has also "the task of granting access or, as applicable, providing written evidence that access requirements have been met and be responsible for advising on applicable procedures and requirements for obtaining PIC and MAT". That "a permit or its equivalent as evidence of the decision to grant PIC and of the establishment of MAT and notify the Access and Benefit-sharing Clearing House accordingly." "Once the permit or its equivalent is issued by the National Focal Point and made available to the Access and Benefit-sharing Clearing-House, it shall constitute an internationally recognized certificate of compliance" in accordance with Article 17.2 and 17.3. Thus, the creation of National Focal Point is also complemented by the establishment of an Access and Benefit-sharing Clearing-House as a means for sharing information. The Access and Benefit-sharing Clearing-House shall "provide access to information made available by each Party relevant to the implementation of this Protocol. Without prejudice to the protection of confidential information, the information to be communicated by the Parties shall include legislative, administrative and policy measures, information on the National Focal Point and the Competent National Authority(s), permits or their equivalent issued at the time of access as evidence of the decision to grant PIC and of the establishment of MAT".

The creation of National Focal Point and the Competent National Authority is a non-flexible mandatory obligation for the parties. It will be big challenges for provider countries as it leads to more cost and human to develop the institutional and legal infrastructures necessary for effective access legislation while it is uncertain that the benefit shared would be enough to cover, especially in the current context of high competition[327] and weak compliance. It is actually a 'hard' obligation even though Article 22 of the Protocol intends to support the Parties are developing countries through to "cooperate in the capacity building, capacity development and strengthening of human resources and institutional capacities to effectively implement this protocol in developing country Parties, in particular the least developed countries and small island developing States."

[327] "each specimen of a particular species, variety, or subspecies has many of the same 'genetic resources' as all others, so that even where a particular specimen is permanently located in a particular country, its genetic resources may be essentially 'shared' with every other country in which the same species is found", BHATTI. S, CARRIZOSA.S, MC GUIRE. P, YOUNG. T, *Supra*, note 208, p. 17. For instance, Vietnam shares many biological resources with neighboring countries and may want to compete with them to encourage investors to access those resources in Vietnam and not in other neighboring countries.

2) Access to GR for non-commercial purposes, emergencies, for food, agriculture

The CBD covers regulating all types of GR,[328] it includes "wild species or domesticated or cultivated species, flora/fauna, insect and microbial species".[329] "Genetic resources can be obtained from both in-situ and ex-situ sources, whether public, communally or privately owned. In-situ sources can be terrestrial, aquatic or marine".[330] All of them play an important role and have potential bioprosposting.[331 , 332] There is no distinction between these types of GR and its utilization's purposes. However, the Nagoya Protocol, by the Article 8, requires special consideration for different purposes of use. Therefore, it creates a distinction and different legal obligations for the provider countries.

In addition to the requirements of Article 6, by Article 8(a) and 8 (b), the Protocol adds more mandatory legal obligations to the provider countries. These obligations include " create conditions to promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries, including through simplified measures on access for non-commercial research purposes, taking into account the need to address a change of intent for such research" and, "take into consideration the need for expeditious access to GR…" "due regard to the cases of present or imminent emergencies that threaten or damage human, animal or plant health, as determined nationally or internationally".

'Pathogens' was one of emerging issues during the international negotiation of the Protocol,[333] but it was finally not mentioned by any word of the Protocol. However, by virtue of Article 8(b), it can be interpreted that 'pathogens' are covered by the Protocol. However, it also do clarify that "the general framework for access and benefit-sharing set

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328 See Article 2 and Article 4 of the CBD

329 GLOWKA.L, *A guide to Designing Legal Frameworks to determine Access to Genetic Resources*, IUCN, Environmental Policy and Law Paper No.34, 1998, p.33: "Insects are invertebrate animals. Micro-organisms include those groups of organisms, whether detectable with or without the aid of an electron or light microscope. They include viruses, prokaryotes such as Eubacteria (bacteria) and Archaea (archaebacteria), and eukaryotes such as protozoa, filamentous fungi, yeasts and algae"

330 GLOWKA.L, *Ibid*, p. 33

331 GLOWKA.L, *Ibid*, p.34, stated "Tropical forests and coral reefs are not the only important sources of genetic resources. For example, temperate forests and the seabed are both little explored by bioprospectors but hold enormous promise. Insects are drawing increased interest because of their biochemical defenses. Micro-organisms are also important sources of Pharmaceuticals and industrial chemicals, such as enzymes. They
play key roles in industrial fermentation processes"

332 BHATTI. S, CARRIZOSA.S, MC GUIRE. P, YOUNG. T stated "… In recent years, thousands of active compounds have been extracted from marine organisms that include bryozoans, nudibranchs, sea hares, sponges, soft corals, and tunicates. In January 2006 Marinlit, a database of marine natural products literature, reported that about 15,100 compounds had been derived from 3,088 marine species.Global estimates of marine diversity vary between 500,000 and 10 million species and with regards to drug discovery this diversity is just beginning to be examined. The oceans started to attract interest from the pharmaceutical industry only since the 1950s with the discovery of two sponge-derived lucleosides. Marine organisms also have great potential as a source of compounds for other industries that include cosmetics, agribusiness, and orthopedics. Chitin and chitosan have been used in several areas of technology for many decades…" p. 184

333 NIJAR.G.S, *Supra,* pp.6-8

out in Articles 5, 6, 15, 17 and 18 of the Protocol does not apply in the same way to [those] genetic resources (…) as it does to other genetic resources."[334]

Although, the provision relating to "expeditious fair and equitable sharing of benefits and access to affordable medicines" was proposed to balance the expeditious access provisions, "it is difficult to see how this 'expeditious benefit-sharing' may be secured" without addressing "the question of patents over these vaccines". "Further, the question of technology transfer remains unaddressed"[335].

Many concerns may arise for the cases of "emergencies that threaten or damage human, animal or plant health, as determined nationally or internationally" with question of what are emergencies? Who determines the cases of those emergencies? In common sense, "an emergency is a situation that poses an immediate risk to health, life, property or environment. Most emergencies require urgent intervention to prevent a worsening of the situation…" "While some emergencies are self evident (such as a natural disaster that threatens many lives), many smaller incidents require the subjective opinion of an observer (or affected party) in order to decide whether it qualifies as an emergency." "The precise definition of an emergency, the agencies involved and the procedures used, vary by jurisdiction, and this is usually set by the government, whose agencies (emergency services) are responsible for emergency planning and management."[336]

Following WHO, "emergency is a term describing a state. It is a managerial term, demanding decision and follow-up in terms of extra-ordinary measures (Oxford Pocet Dictionary, 1992). A 'state of emergency' demands to 'be declared' or imposed by somebody in authority, who, at a certain moment, will also lift it. Thus, it is usually defined in time and space, it requires threshold values to be recognized, and it implies rules of engagement and an exit strategy. Conceptually, it relates best to Response."[337]

The way of wording "as determined nationally or internationally" also leads to some questions of who determines the cases of those emergencies. Whether a country may determine nationally the cases of emergencies, then request provider country to access to GR under special considerations or not? Which international institution may be responsible to determine international cases of emergencies? If there is no responsible international institution, whether two organizations or authorities in two countries may determine together the international cases of emergencies or not? All assumptions are possible.

However, the use of wording "may take in to consideration the need" seems to suggest that "the provider is at liberty to decide whether a need for expeditious access exists or not. The intended meaning is of the term 'expeditious' itself implying fast or

[334] Cited by PATERNOSTRE.R, *Supra,* p. 66
[335] NIJAR.G.S, *Supra,* p. 25
[336] http://en.wikipedia.org/wiki/Emergency#cite_note-0
[337] http://www.who.int/hac/about/definitions/en/index.html

speedily. That would not make sense in connection to an already existing case of emergency. The obligation of each Party in the first part of paragraph 8.b, which is to "pay due regard to cases of present or imminent emergencies" underlines the seriousness that Parties need to accord to such cases. Whereas it is possible to consider denial of expeditious access in regard to cases of preparedness for future emergencies, it is not for a case determined as an emergency in the present, either nationally or internationally. Probably this clause is just meant to create room for providers to exercise their authority to determine access whilst at the same time".[338]

The Article 8.b also should read in combination to the Article 4.2, 4.3 regarding to the related WHO's negotiations on this issue, even though there remains controversies[339]. However, the provision of the Article 4.2 "…in a mutually supportive manner with other interntional instruments relevant to this Protocol, due regard should be paid to useful and relevant ongoing work or practices under such international instruments and relevant international organizations provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol", is facing with an argument. It supposes that "this was a relationship clause with other international instruments. Hence the reference to international organizations appeared inappropriate as these were not of the same status as international instruments." "It is also inappropriate to refer to any ongoing work and practices under such organisations. This adds to legal uncertainty. 'Ongoing work' is always in a state of flux and reflects work that has not been concluded. Further 'practices' have no status in international law as a source of law. Practices of international organisations may be 'created' in all kinds of ways: through use, custom, decisions, and such like"[340]

B – Access to traditional knowledge associated with the genetic resources

1) Traditional knowledge held by indigenous and local communities

As mentioned above, GR is characterized by two integrated aspects: tangible and intangible. The tangible aspect of GR refers to the biological resources contains them. The intangible aspect refers to information, knowledge of its utilization, including traditional knowledge associated with them. Thus, most of the case of access to GR concurrently means access to the TK. In practice, "the two elements are frequently so closely related as to be unable to be separated one from the other, as TK forms as intrinsic aspect of the biodiversity access and development equation. However, under the Nagoya Protocol, "TK has been dealt with under stand-alone provisions." [341]

[338] GREIBER.T, MORENO.S, *Supra*, p. 76
[339] For further information on controversy, see http://whqlibdoc.who.int/publications/2009/9789241547680_eng.pdf>, last accessed 6 September 2011
[340] NIJAR.G.S, *Supra,* p. 25
[341] NIJAR.G.S, *Supra,* p. 28

Therefore, The Protocol provides for two distinct situations where Parties must take measures in relation to indigenous and local communities and resources and/or TK. The first relates to access to GR. The second relates to access to TK of indigenous and local communities. In both situations, Parties are required to take measures with the aim of ensuring that the GR and/ or the TK of indigenous and local communities are accessed with their PIC. For access to TK, the measures must also aim to ensure that MATs have been established. However, the requirement is to be in 'accordance with domestic law' and the measures to be taken by each Party 'as appropriate'. "That led to interpretation of the implementation of this PIC requirement to the absolute discretion of a Party. An alternative reading of these phrases could be that the Party is obliged through its national law to take such measures as it deems appropriate"[342].

The main questions for access to TK associated with GRs are: whether are the indigenous and local communities entitled to provide access to GR? And what conditions of access to their knowledge on these resources? Both questions, according to the CBD are subject to national legislation. Both have wide implications and lead to much broader issue, both share commonalities the importance of the concept of PIC and MAT and fair sharing benefit deriving from access to that resources and knowledge together constitute for indigenous cultures.

The Protocol leaves these questions for national laws. Similarly to Article 6.2, the Article 7 states with "In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that TK that is held by indigenous and local communities is accessed with the PIC or approval and involvement of these indigenous and local communities, and that MAT have been established."

The wording "subject to domestic legislation' for access to GR, is replaced by a more temperate wording 'in accordance with domestic law'. It reinterpreted Article 8(j) in favor of community rights and created a new legal 'term of art' that could henceforth be used in other parts of the Protocol and future COP decisions instead of the Article 8(j) wording 'subject to national law'. This new term 'in accordance with domestic law' was clearly a lever that would reap big gains in the future".[343]

The reason is that it would retain the facilitative role of the State in situations where Parties argued that communities within their jurisdiction needed State protection against exploitation. This is considered as rational answer in term of national laws and sovereignty rights. Because, the issues related to indigenous and local communities are domestic matters of each State. The indigenous and local communities are member, citizens of the States and States should have law to protect their citizens and communities within their jurisdiction territory.

[342] NIJAR.G.S, *Supra,* p. 28
[343] BAVIKATEE.K, ROBINSON.F.D, *Supra*, p. 45

"It is recognized that there are two legal sleights of hand, which are worthy of note here" [344]. Firstly, "the sentence begins with 'in accordance with domestic law' thereby eliminating the 'subject to law' term and making this a facilitative provision. The obligation on Parties is a 'shall' obligation that makes it mandatory." The sentence ends with 'where they have the established right to grant access to such resources'[345]. "Note, that the words 'established right' are unqualified thereby leaving it to interpretation as to whether these rights are established in national or international law." It is a 'strategic ambiguity'- that leaves enough room for interpretation and jurisprudential growth. "The use of 'established right' may mean that communities will have to prove that they are the rightful 'owners' or 'authorities' in relation to the conservation of that GR such that it is 'in accordance with domestic law'"[346].

"While Article 7 was not perfect, it had clearly achieved what it set out to do"[347]. "Moreover, every gain in the Protocol is not an end in itself but the flat end of a lever to insert into the interstices of other negotiations to pry open community rights under TRIPS, WIPO IGC, FAO and the UNFCCC. From the perspective of negotiations, this is the fine art of cross-leveraging rights- i.e. to take rights gains from one Convention dealing with one subject matter and insist that they be respected in another Convention dealing with another subject matter." [348]

The Protocol sets up Article 12 to support to all issues related to TK. It requires Parties, "in implementing their obligations under this Protocol, shall take into consideration indigenous and local communities' customary laws, community protocols and procedures, as applicable, with respect to TK," and "establish mechanisms to inform potential users of TK about their obligations, including measures as made available through the Access and Benefit-Sharing Clearing-House for access such knowledge" and "shall endeavour to support, the development by indigenous and local communities (including women within these indigenous and local communities) of "community protocols in relation to access to TK"; "minimum requirements for MAT and model contractual clauses for benefit-sharing". The Article 12.4 provides "as far as possible, not restrict the customary use and exchange of GRs and TK within and amongst indigenous and local communities in accordance with the objectives of the Convention". This substantive content of the provision was predicted before by Glowka & Bhuhene-Guilmin that "Access policies and legislation can empower indigenous and local communities by giving them greater control over GRs located in areas that they inhabit or use and associated knowledge, innovations and practices. But policy-makers should keep in mind that imprecise and insensitive

[344] BAVIKATEE.K, ROBINSON.F.D, *Ibid*, p. 47
[345] Article 6.2 of the Nagoya Protocol
[346] BAVIKATEE.K, ROBINSON.F.D, *Supra*, p. 47
[347] BAVIKATEE.K, ROBINSON.F.D, *Ibid*, p. 45
[348] BAVIKATEE.K, ROBINSON.F.D, *Supra*, p. 49

drafting and implementation could provide the basis for further disempowerment by, for example, affecting adversely the customary use and exchange of GR within and between communities. Indigenous and local communities have customarily used and exchanged GRs for a variety of economic, cultural and religious purposes, and they still do."[349]

There is an optimistic point of view that "although there are limits regarding the extent of TK protection that the Nagoya Protocol provides, the resulting text appears to provide new opportunities for Indigenous and local communities to assert their rights over TK and to resist misappropriation or biopiracy" [350]

2) Publicly available TK

For publicly available TK, it is still a gap, even though, there were intense and prolonged negotiations that some developing countries argued that such knowledge was not freely accessible and the PIC and MAT requirements should also apply, and further, where the knowledge was diffused throughout the country, or there was no identifiable holder of the TK, PIC had to be obtained from, and MAT established with, the Party." However, the others opposed this. Some of them argued that "the State had no role; that this was outside the scope of the CBD as it only dealt with indigenous and local communities or it may fall into 'public domain'. In the end, all references to these provisions were simply eliminated in their entirety. All that remains now in the Protocol are references in the preamble paragraphs to the recognition of unique and diverse circumstances whereby TK is held."[351]

It is not easy and simple to find an intellectual property mechanism for TK held by the indigenous and local communities, then, this will be more difficult to deal with publicly available TK. One of tools to support to the TK held by the indigenous and local communities is translating TK into Trade Secrets. It is explained that "the traditional knowledge of indigenous and local communities is like many other information goods: once the information is released to others, and enters the 'public domain', virtually all control over its consumption by third parties is lost. Intellectual property rights, such as trade secrets, can help maintain control over how a community's intellectual property is used and what benefits may accrue." "Trade secrets are confidential information for which the possessors have taken demonstrable efforts to maintain as confidential".[352]

Like the other TK, it is suppose that publicly available TK should be handled by the WIPO's ongoing negotiation. As the Protocol also refers to "ongoing works and practices", the work of the WIPO on TK is to be considered, provided that "it does not run counter to the objectives of the Convention and of the Protocol". This is similar to

[349] GLOWKA.L, BURHENNE-GUILMIN.F, *Supra*, p. 16
[350] BAVIKATEE.K, ROBINSON.F.D, *Supra*, p. 47
[351] NIJAR.G.S, *Supra,* p. 31
[352] GLOWKA.L, *Supra*, p. 40

provisions of the CBD with reference to intellectual property right. However, the relationship between the Protocol and talks on TK at the WIPO is ambiguous. The silence on specific relationship between the Protocol and the WIPO created uncertainty that could make some aspects of the Protocol subject to procedures outside the CBD.

II - Benefit-sharing – softer obligation for user countries

"The living thing is not considered more as a gift of the nature". It has cost and when people exploit it, it should be paid. "The living thing turns up life, the living thing turns up to have and belong to the category of business and defined as destination to sell in the commerce."[353] This would be the base for the approach of "selling nature to save it" of the CBD and then of the Nagoya Protocol. The provisions on fair and equitable benefit - sharing is expressed of this approach.

A - Fair and Equitable benefit-sharing

1) Understanding of concept of "fair and equitable sharing"

There is no terminology interpretation for what is "fair and equitable benefit-sharing". This is the only legal standard expressed in the Nagoya protocol as the obligation that benefit-sharing must be "fair and equitable," yet interpretation of even this standard remains in doubt. It also only can be understood as the objective of the Nagoya Protocol. Thus, all the regulations, requirements under the CBD, the Nagoya Protocol are provided towards this objective. It is useful to study and analyze this concept. This sub-section will clarify the concept in two contexts**:**

a) Fair and equity principle in general context

Although, the "fairness" standard has existed in law for more than 3000 years,[354] "the "fair share" concept has not been well examined in commercial, scientific, contractual or legal terms." Because, the activities of GR's utilization mostly involve many kinds of inputs, therefore, in practice, it is difficult to determine exactly the contribution of each input to develop "a mechanism that weights all of these different types of contributions and determines what share of the profits or other results is attributable to any one input." "Legislation can provide some standards and other bases for evaluating the concept of fair sharing." "In practice, fair-share provisions will usually depend on the concrete situation between the parties, often expressed in a contractual agreement." In case, there is no agreement between the parties or that agreement was not fairly signed, equity principles can be applied to guidance for courts, arbitrators, officials and others to determine a "fair share".[355]

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353 « Le vivant n'est plus considéré comme un don de la nature », AUBERTIN.C, PINTON.F, BOISVERT.V, *Supra*, note 12, p. 14
354 TVEDT. M. W, YOUNG. T, *Supra*, p. 91
355 TVEDT. M. W, YOUNG. T, *Ibid*, p. 84

The concept of equity may provide the most useful guidance on the sharing benefits aspects. "'Equity' is a concept with many meanings and with a very specific meaning in law. In some countries based on Common Law principles, special legal rules called "equitable principles" or "equity" exist to ensure that laws are fair, as well as rigorous". The term must be viewed as an indicator of international principles. Therefore, "in some legal systems, the term "equity" refers to a well defined form of governmental action, in others, it refers to a concept of social fairness, or it is seen as a branch of morality or even divine justice. In an international legal instrument, its application is less specific but "connotes an aspect of law and legal reasoning."[356]

In domain of environmental law, there was opinion that the principle of equity to nature is essential. "The nature is one expressive reality, so, the history is constructed following one intrinsic idea".[357] The principle of equity to nature appeared not only like a basic point of the environment law, but also in its intrinsic significance. In the nature system which becomes the code of the natural history, the concept of nature - based economy was introduced by the general concept of the equity of nature. Thus, William Derham, in 1714, made a principle in his physical theory that is "balance of the nature".[358] And Adam Smith stated in politic economics that the rule of economy is the rule of nature that responds to an automatic regulation. The ecology concept raises a problem of the equity of nature which is that existing theory and practice, in its form and its capacity, produces intervention of human actions to the environment.[359]

In new area like access to GR and benefit-sharing, "equity provides an adaptive legal basis for addressing novel concepts, especially those that are more complex, less specific or less concrete than the comparable legal principles." It focuses on "fairness rather than specific valuation formulas". "In applying equity, it is necessary to move beyond "providing fair value in return for goods provided." One must also consider the factors involved in calculating and compensating formal and informal contributions, disgorging unfair profits, equalizing access to the benefits of collectively owned (or developed or provided) resources, ensuring fairness in common-resource distribution, and other aspects of "real justice." Equitable principles might address the sharing question in other ways: "Equity might call for a fair return on the historical contribution of a country or community which has, through many decades and centuries, followed practices which, although financially rewarding, resulted in a higher level of conservation and the preservation of traditional varieties". "Equity might look at the extent to which a particular product or innovation would have been developed without the GR. If the existence and

[356] TVEDT. M. W, YOUNG. T, *Ibid*, p. 84 – p. 90
[357] NAIM-GESBERT.E, *Supra*, note 135, p. 192
[358] EGERTON.F.N, Change the concepts of the balance of nature "quaterly Review biology, No 48, 1973, p. 333, cited by NAIM-GESBERT.E, *Supra*, note 135
[359] E.KANT, Critique du jugement (1790) Paris, Vrin, 1965, p 238, cited by NAIM-GESBERT

properties of the GR are the reason that the innovation or product was developed, then its contribution to the final product may deserve a higher share". "Equity may look at the wider biological contribution that enabled the particular GR to exist – at the need to protect the entire ecosystem over a long time, against many threats, in order for the GR to be available today. This is one of the apparent theoretical underpinnings of the entire CBD framework, and a major justification for its inclusion of access to GR and benefit-sharing."[360]

Within the CBD and the Nagoya Protocol "the use of the term "equitable" cannot be guided solely by one country's legal tradition or even one category of legal systems. Rather, it must be guided by a broader standard, beginning with the Convention's terms, the Bonn Guidelines," the Protocol and "principles of international law". However, in the CBD and the Protocol, "the requirement of equity is encompassed primarily through the use of the word "equitable" in describing the objective". However, for purposes of implementation, the Protocol gives little guidance on how the term "equitable" affects the system on access to GR and benefit-sharing. Equitable principles that have already been accepted as principles of international law can provide a partial guide. "In international law, many principles of equity have been formally recognized, through an ongoing process that considers the relevance of legal concepts across the range of countries, and identifies "general principles of international law." "It is clear that international practice includes the application of equity, particularly where it is specifically incorporated into the text of an international instrument."[361]

For purposes of applying the "equity" component of access to GR and benefit-sharing, it is useful to consider the following examples of equitable principles which are applicable to individual actions that have been recognized in international law, in terms of their application to access to GR and benefit-sharing:

Firstly, the recognition of 'historic contribution': "One aspect of equity is the recognition of historic contribution: Legal and contractual practices should recognize and recompense one who has engaged in a long pattern of actions that have contributed to the value of a property, right or other goods. In the context of access to GR and benefit-sharing, this principle suggests that States that have historically succeeded in preserving their biodiversity are recognized as having achieved something concrete." "The biological diversity was attained at a historic cost that can now be recognized and compensated under equitable principles. Therefore, when conserved biological and genetic resources are converted to individual commercial benefit, concepts on access to GR and benefit-sharing and equity may suggest a basis for recompense of that historical contribution."

[360] TVEDT. M. W, YOUNG. T, *Supra,* p. 84 – p. 90
[361] TVEDT. M. W, YOUNG. T, *Supra,* p. 89

Secondly, 'unjust enrichment – quantum meruit': "This principle says that one person should not be able to unfairly take advantage of another's situation to earn a benefit that should belong, at least in part, to that other person". "Increasingly in the area of GR, arguments of fairness are based on the idea that companies should not be allowed to profit from products based on resources derived from providing countries and local communities without paying or providing other recognition of this contribution."

Thirdly, 'Clean hands': "The 'clean hands' doctrine states that a person who has failed to 'do equity' cannot use equity as a basis for a claim against another. In the context of access to GR and benefit-sharing, this concept raises an interesting possibility – that the access country's compliance with the "access" side might be conditioned, either legally or equitably, on other conditions necessary to support access, in addition to specific commitments of the specific user. For example, the contract on access to GR and benefit-sharing might include a condition that the user must use the resources only in a country that has fully complied with its obligations on access to GR and benefit-sharing – i.e., a country that has adopted user-side measures."[362]

b) "Fair and equitable benefit-sharing" under view of sustainable development

In addition to the definition of 'fair and equitable sharing" within legal general context, how can we define "fair and equitable" in broad perspective of sustainable development?

'Fair' and 'Equity', now, is not only objective between the parties or stakeholders who evolves into the certain contracts on access to GR and benefit-sharing or between provider countries or user countries, the Global North or the Global South countries, but also between the present and future generation under the point of view of sustainable development. If the future generation has the rights that means the present generation have the responsibility to the conserve better the natural and cultural heritage and they have to store or save. However, the equitable position is not easy to formulate because it need a prospective evaluation of the necessity of the future and sometimes it is difficult to know and measure at present.

The problem of "the essence of the question that give much ethic to the law, including the meanings of reflection of the system of value that guide and must guide suitably the behaviour of the human to ensure the equity between the generations". "The concept of the future generation becomes substitute of concept of common heritage of humanity in particularly in aspect of the idea to share equitably and sustainably the natural resources. This basic idea is suitable with the different traditional jurisdiction of international community. It links the terms judicial obligations from the present to the future". Westra.L has "argued that these obligations should be viewed as *erga omnes* and

[362] TVEDT. M. W, YOUNG. T, *Supra*, pp. 84 – 90

they should also be considered as founded on *jus cogens* norms".[363] In this option, Edith Brown Weiss in her thesis 'Justice for the future generation' proposed to make equitable intergeneration. The satisfactory of the present generation does not compromise the need of future generation, it must be accepted the traditional culture and different political, socio-economic system.[364]

In certain context of legislation on access to GR and benefit-sharing, in broader equities to achieve objective of the Protocol, equity interrelate with economic value and public interest principles. The concept of access to GR and benefit-sharing "finds its justification and basis in three often-opposing concepts: equity, valuation and the public interest." "In order to build the foundation for the system on access to GR and benefit-sharing, it is essential to examine the nexus of these three principles. Together they pose a legislative challenge – to design a commercial or contractual legal system that can function while still serving the public interest. Stated alternatively, countries need to create public interest legislation that is implemented through commercial concepts based on valuation, while reflecting equitable principles." In term of valuation, in aspect of economic, commerce, "they must require and enforce compliance with the contract on access to GR and benefit-sharing; but also create mechanisms, motivations and incentives to encourage users who have not obtained such an agreement. In terms of equity, they must create a framework that ensures that access to GR and benefit-sharing is applied on the basis of equitable principles. They must also enable or ensure that the system compensates source countries and providers not only for the specific value of the GR, but for its role in the ecosystem and for their historic and current contributions and rights. In terms of international public interest, the measures must attempt to ensure the link between the system of access to GR and benefit-sharing and the objectives of promoting conservation and sustainable use, as well as integrating with national and international efforts to achieve Millennium Development Goals. None of these objectives can be considered without integrating the others."[365]

Most important, the contribution to preservation of the entire ecosystem and the physical factors that allowed it to thrive, suggests that "equitable principles must consider the conservation of the entire ecosystem, in evaluating the equity side of benefit-sharing. This may necessitate a broader scope of valuation of the source country's contribution."[366]

Under the Protocol, Article 10 seems to be one provision has been characterized by sustainable view, because "the benefits shared by users of genetic resources and traditional knowledge associated with genetic resources, shall be used to support the conservation of biological diversity and the sustainable use of its components globally". Those benefits

[363] WESTRA.L, 2006, *Supra,* p.136
[364] NAIM-GESBERT.E, *Supra,* p. 456
[365] TVEDT. M. W, YOUNG. T, *Supra,* p. 84 – p. 95
[366] TVEDT. M. W, YOUNG. T, *Ibid,* p. 90

"derived from the utilization of GR and TK that occur in transboundary situations or for which it is not possible to grant or obtain PIC" and through "modalities of a global multilateral benefit-sharing mechanism to address". However, this is opened provisions that put the first step for further negotiation and development of mechanism of organization and operation.

2) Ensuring fair and equitable benefit-sharing

Fair and equitable benefit-sharing emerges as the cornerstone of the regime on access to GR and benefit-sharing. It is the other side that keeps balance with "appropriate access". It also is referred as the objective of the Protocol "fair and equitable sharing of the benefits arising from the utilization".[367] The Article 5 of the Protocol elaborates this objective. This will answer the main questions: what benefits shall be shared and how these benefits will be shared fairly and equitably?

a) What benefit shall be shared?

Article 5.1 stipulates that "benefit-sharing arising from the utilization of GR as well as subsequent applications and commercialization shall be shared in a fair and equitable way with the Party providing such resources," in accordance with Article 15.3 and 15.7 of the CBD. Therefore, the benefits to be shared are those arising from the 'utilisation of GR' that includes 'derivatives' as discussed earlier. The Protocol also states that the benefits include those arising from "subsequent applications and commercialization". This is implicit in Article 15.7 of the CBD.

Therefore, it is clear that the benefits are able to be shared are broad. These derive from a large range of activities: "utilization" and/or "subsequent applications and commercialization". The nature of the benefits also is different. It can be tangible or intangible value, countable or uncountable value or it is classified as monetary and non-monetary following the Annex to the Protocol.

The Article 5.4 provides "Benefit may include monetary and non-monetary benefits, including but not limited to those listed in the Annex", that are largely a reproduction of those set out in the Annex II to the Bonn Guidelines.

Regarding monetary benefits, "payments of money often occur in the form of up-front payments, milestone payments, royalties, license fees, "special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity" (a limited form of monetary payment), research fundind,". Some of monetary benefits can come from determinable commercial values, such as "joint ventures; joint ownership of relevant intellectual property right, joint ownership of relevant intellectual property right." [368]

[367] Article 1 of the Nagoya Protocol
[368] TVEDT. M. W, YOUNG. T, *Supra*, p. 86

In practice, a specific share in the user's profits, especially up-front payment, 'royalty' or similar kinds "can be relatively difficult for users, who will be required to undertake very strict accounting processes, in order to provide accurate and auditable records of all of the factors that must be considered in determining the share to be paid. Such limits may restrict the ability of the user to engage in other contracts". In addition, "larger user companies and institutions are often willing to postpone results – where for example the research results create a usable/patentable discovery or innovation, but the company feels that other technical innovations in future will improve the profitability or effectiveness of its practical application. In those cases, although a patent may be filed, little or nothing may be done to utilize the patented concept for many years." "As a consequence, it is common for contracts on access to GR and benefit-sharing to "liquidate" the benefit share, by identifying other forms of payment which, when made, will constitute a current substitute for the direct sharing of benefits which would otherwise come over a long and unpredictable term, might not be sharable at all, or might be delayed by the company's strategic decision making."[369]

A number of benefits are entirely outside of the monetary commercial analysis and listed as non – monetary benefits. For example, sharing of R&D results; other access to scientific information; "collaboration, cooperation and contribution in scientific R&D programs;" a general right to "participate in product development, education and training, access to GR facilities and databases;" capacity building of various types. There are a number of less direct or tangible benefits under the list that only are conditions (general improvement of the provider country's situation) may be counted among the means of paying for access or liquidating GR, including contributions to the local economy; research directed towards priority needs, such as health and food security, taking into account domestic uses of GR in provider countries; institutional and professional relationships that can arise from an agreement on access to GR and benefit-sharing and subsequent collaborative activities; food and livelihood security benefits; and social recognition.[370]

In common, "non-monetary benefits can be significant, especially with regard to the building of scientific and technical capacity."[371] However, there is an argument that "'Non-monetary benefits' – this provision is only a list of different non-monetary ways that the user may pay under a contract. This does not answer the real question: If the users of GR are supposed to equitably share the benefits arising from their utilization, then don't the sources countries need to know what the benefits arising from utilisation of resources are?"[372]

The other important question is "When and how do the benefits arise?" "This question can be difficult, both theoretically and practically." "Theoretically speaking, the

[369] TVEDT. M. W, YOUNG. T, *Ibid*,, p. 86
[370] Annex I to the Nagoya Protocol
[371] YOUNG.T, *Supra*, p. 50
[372] YOUNG.T, *Ibid*, p. 34

creation of a benefit happens in many incremental steps, from the creation of data through the marketing of a product." For example, the biochemical or genetic properties of a species, "is determined through a number of different texts and processes. While these activities are ongoing, users have an interest in protecting their data, so that it can be analyzed and presented or used as an integrated whole. At the same time, source countries have a strong interest in having a share in this information." "Many kinds of benefits (data, processes, formulas, etc.) are protected by institutional secrecy – supported by laws affording privacy, freedom from unwarranted search, and the right to protect "trade secrets" even in documents which they are required by law to file. In some cases, the existence of a benefit simply cannot be externally discovered." "In addition, it may not be possible for a source country or other external entity to discern the linkage between a known benefit (a new product) and the ingredients and processes by which it was created or is manufactured." "In general, the most effective aproach to this question is to focus on determining when GR utilization activities result in capture of the "actual or potential value." "This will occur in commercial development when a commercially valuable commodity is created (whether a product on the market or an intellectual property right or other marketable right). In non-commercial development, this could be defined as the point at which the research, analysis, cataloguing or other activity is completed and ready for publication. At this point, where a benefit exists, it will be possible to rationally determine the amount or nature of the benefit-sharing obligation."[373]

Further, sharing benefit as research results is also challenged. Despite of recognition of research results are a benefit to be shared by the Protocol, the obligation to share research results has not yet been discussed in sufficient legal detail. Actually, this is relates to the user's interest in exclusivity of the obtained information. "A researcher forced to share preliminary results loses the trade-secret protection of those results, and may lose the ability to generate commercial benefits". "On one hand, it is inequitable to require the researcher to completely devalue his results (and his ability to obtain appropriate return on his efforts) by sharing them in an unrestricted way with the source country. On the other, it may be inequitable to allow him to dispense information (research results) of potential commercial value in a way that prevents the provider country from obtaining any share in future benefits derived."[374] Moreover, the results of research and analysis – may be non-commercial and intangible. "Like the GR themselves, once they have been shared outside of the research institute in which they are developed, research results and analytical conclusions are non-excludable."[375]

It is suggested that "the sharing of benefits must strike a balance or find a compromise between these various needs." "These dilemmas emphasize the importance of

[373] TVEDT. M. W, YOUNG. T, *Supra*, p. 70
[374] TVEDT. M. W, YOUNG. T, *Supra*, p. 72
[375] TVEDT. M. W, YOUNG. T, *Ibid*, p. 84

including a clear benefit-sharing obligation in user-side measures, as a "background" law that can prevent inappropriate uses of this type by users who are not acting on the basis of MAT. A user-side mechanism to ensure benefit-sharing can enable such balancing while closing the potential loopholes"[376]. However, with provisions on MAT not clearly and detail, the Protocol does not fix the problem.

b) How these benefits shall be shared and who should be shared benefits?

The Article 5.1 stipulates that "Such sharing shall be upon MAT." This confirms that the sharing of benefits should be carried through MAT. 'MAT' is not only the principle element of the access and benefit sharing process but also is an unique legal means to proceed fair and equitable sharing of the benefits arising from the utilization of GR. MAT becomes a precondition for sharing of benefits. "Only the conclusion of a MAT entitles the provider to enforce the rights of the provider. If no contract is signed with the user, the provider can not go to court to proceed to a fair and equitable sharing of the benefits".[377]

However, there is a concern about the link between MAT and PIC. "In the Protocol the link between access and benefit-sharing is not explicit." "If benefit-sharing is delinked, it could imply that so long as benefits are shared, even for unauthorized access or where access is not possible for some reasons, the Protocol is complied with" and "…. no PIC is required for derivatives. Only benefit-sharing is required … would violate the general tenor of the CBD and the Protocol. The spirit and thrust of these two instruments are to provide for benefit-sharing that ensues upon the grant of access. Hence legal access under these two instruments is upon PIC and benefit-sharing through MAT. If access is not obtained, any subsequent dealing with GR, derivatives or TK would be a violation of the Protocol."[378] In contrary, the other research emphasies the importance of MAT as "provider may be helped by the user country in concluding a MAT with non-compliant user. Importantly, the latter provision does not impose a "self-standing obligation of user states to ensure benefit-sharing."[379]

Who should be shared benefits?

The Protocol does not mention to "owners" or "beneficiaries". It only regulates "...the benefit …shall be shared with the party providing such resources that is the country of origin of such resources or a Party that has required the genetic resources". There is also no argument of such subjects to be benefited. However, the Protocol emphasis to indigenous and local communities who held GR and TK with "regarding the established rights of these indigenous and local communities over these GR are shared in a fair and

[376] TVEDT. M. W, YOUNG. T, *Ibid,* p. 72
[377] PATERNOSTRE.R, *Supra,* p. 71
[378] NIJAR.G.S, *Supra,* p. 27
[379] PATERNOSTRE.R, *Supra,* p. 71

equitable way with the communities concerned based on MAT".[380] Moreover, "that the benefit arising from the utilization of TK is shared in a fair and equitable way with indigenous and local communities holding such knowledge".[381] The provision is really a "progress in recognizing the right of the indigenous and local communities to GR and TK. This secures rights of Indigenous and local communities over their GR in the Protocol thereby creating a precedent of dynamic interpretation of the CBD in the light of the UN Declaration on the rights of the indigenous people (UNDRIP)" [382].

It needs to explain that why "the indigenous and local communities insisted in acquire their rights over GR while this right had to be strictly restricted to national discretion especially since there were no CBD obligations to recognise such a right and the UNDRIP is a UN General Assembly resolution and therefore non-legally binding had the moral authority that obliged countries to take it seriously"[383]. In fact, in some cases, we know that the State territory is always conflict with the ndigenous and local communities on the nature jurisdic of land and livings on the land that like heritage of the nation. In most case that are supposed in problem of resolution of how the indigenous people participate but not make the cultural loss to the living population.[384] The moral responsibility of the internatonal community is engaged by the CBD, the Bonn guidelines, the Protocol for the necessity of the indigenous population in participation in negotiation in PIC. The ECOSOC acknowledged under the report of expert of 18/5/200 (DH/4921) on the situation of the indigenous people right also alarmed and by message 9/8/2007, the General Director of the UNESCO (DG/ME/ID/2007/010) has called for the implementation of the Convention on Protection of Cultural Expressions that understood to protect cultural goods and services. Although, there is no independent convention on the protection of TK of the indigenous and local communities, the Declaration of the UN on the Right of indigenous people, adopted by Session 61 of the General Assembly of the UN 13/9/2007, is considered as legal base to protect their technique (Article 24) and their sciences (Article 31)[385]. There are also several international instruments support to protect issues of indigenous people rights such as "Convenant on Civil and Political rights and the Convenant on Economic, Social and Political Rights, Convention for the Protection of the World Cultural and Natural Heritage, International Labour Organization Convention concerning Indigenous and Tribal Peoples in Independent Countries"[386] and "future trends of influence of soft law and NGOs"[387].

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380 Article 5.2 of the Nagoya Protocol
381 Article 5.4 of the Nagoya Protocol
382 BAVIKATEE.K, ROBINSON.F.D, *Supra*, p. 45
383 BAVIKATEE.K, ROBINSON.F.D, *Ibid*, p. 45
384 See more the case of the Awas tingni v. Nicaragua, case of Ivan Kitok v. Sweden, case of Mabo v. Queensland, Aboriginal land rights in Australia, New Zealand, the trail Smelter arbitration on environmental harms, WESTRA.L, 2008, *Supra*, pp. 71 – 83, case of Sparrow v.The Queen, and others pp. 127- 158
385 BEURIER.J-P, *Supra*, p.p 61 – 65, pp. 417 – 425
386 WESTRA.L, 2008, *Supra*, p.242
387 *Ibid*, pp. 255 - 259

B – Challenges of ensuring fair and equitable benefit-sharing

1) Measures of ensuring fair and equitable benefit-sharing

The Protocol obliges each Party to "take legislative, administrative or policy measures, as appropritate" to share benefits in a fair and equitable way with the Party providing the resource.[388] The exact regulatory content of this provision is unclear: "it seems to confirm more specific obligations of Parties under the Protocol rather than to establish additional ones."[389]

There are various questions raises with difficulty of answers: What are legislative, administrative or policy measures? What is difference between 'legislative measures", "administrative measures" and "policy measures"? Why are they not legal measures? How can they support to each other? Why do not all of those measures can be applied together, but only each of them can be applied following word "or"? In general explaination, obligations of taking "legislative, administrative or policy measures, as appropriate" [390] has weak legal impact. This phrase is used popularly in the text of the Protocol.

Lack of user-side measures in detail and mechanism to ensure benefit-sharing may make the Protocol ineffective. "There are virtually no user-side measures, and a large number of users have concluded that they are not obligated to comply with access to GR and benefit-sharing. If the lack of user-side measures continues, the current situation will probably continue – that is, benefit-sharing will continue to be nearly non-existent."[391] There was conclusion that, "although all CBD Parties are required under Article 15.7 to adopt user-side measures, in fact, to date, no country (developed or developing) has adopted any legislation that requires national implementing legislation to impose a binding legal obligation on all users of foreign GR. Currently, no law or other incentive in the user - side national legislative frameworks creates any motivation for companies, researchers and others to confirm that this assumption is correct."[392]

There may have solution for this situation of lacking concretized provisions for "legislative, administrative or policy measures" that is "the application of the principles of legal analysis and interpretation".[393] Tvedt and Young supposed that "even in carefully negotiated international legal instruments, it is frequently necessary to engage in the process of legislative interpretation – to study the language, content and intention of the instrument to obtain a legally specific understanding of the meaning and intent of particular provisions." In addressing this issue, the authors have undertaken a legal analysis in accordance with the rules promulgated by the Vienna Convention on the Law of Treaties,

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388 See Article 5.3
389 Cited by PATERNOSTRE.R, *Supra,* p. 73
390 Following Article 5.2, 5.3 and 5.5
391TVEDT. M. W, YOUNG. T, *Supra,* p. 99
392 TVEDT. M. W, YOUNG. T, *Ibid,* p.100
393 TVEDT. M. W, YOUNG.T, *Ibid,* p. 52

1969, regarding the manner in which international binding instruments should be interpreted, where there are issues of unclarity or insufficient understanding, or where the treaty is to be applied to a situation or question not directly answered in the language of the treaty[394]. Therefore, in case of the Nagoya Protocol, it "it is necessary to engage in the process of legislative interpretation" for "unclarity or insufficient" issues of "take legislative, administrative or policy measures, as appropritate".

Because of the wording 'or' in the text of Article 5.2, 5.3, it raises question of how to distinguish and evaluate 'legislative measures' and 'administrative measures' from 'policy measures' and what is the legal meaning and content of policy measures? In my opinion, while 'legislative measures' may be distinguished as formal instruments from the parliament, 'administrative measures" may be understood as formal instruments from the Government, 'policy measures' may be any formal and informal instruments that are issued and recognized for implementation by any authorities or politics bodies of country. The legal meaning of the policy measures is flexible and the content is wide. The difference between those measures can be seen by the origin of wordings 'law' and 'policy'. The 'legislative measures' imply enforcement, compliance with compulsion, the 'policy measures' may be wider that include voluntary and non-mandatory implementation. Therefore, obligations under Article 5.2, 5.3 are mandatory implementation but flexible.

2) Determining temporal scope for benefit-sharing

One of the most ambiguous restrictive issues of scope of the Nagoya Protocol is "temporal scope" with question of application to "new" and "continuing uses" of GR, including those acquired before its entry into force. In fact, this was not expressly resolved. "This issue of continued utilization of GR and TK acquired before the entry into force of

394 TVEDT. M. W, YOUNG.T, at note 227, p. 52, sets forth the Vienna Convention's eight components of interpretation process, in order of their legal effect: *(i)* Direct application of the language of the Convention itself (Vienna Convention, Art. 31, paras 1 and 2). *(ii)* Direct application of the language of other documents that are part of the same treaty, such as, in the current analysis, the Cartagena Protocol and relevant annexes to the CBD (see Vienna Convention, Art. 31, paras 2 and 3). *(iii)* Direct application of the language of separate instruments between the same parties "which establishes the agreement of the parties regarding its interpretation." (Vienna Convention, Art. 31.3(b)) Such "agreed interpretations" have not yet been used in the CBD, where COP decisions are not executed by national plenipotentiaries. *(iv)*Subsequent practices which help to establish the agreement of the parties (Vienna Convention, Art. 31.3 (b)). In the context of the CBD, this category describes "COP decisions." *(v)* International customary law (included by generic reference in Vienna Convention at Art. 31, para 3, and defined by Statutes of the International Court of Justice, Art. 38.1(b)). *(vi)*Information gleaned from study of "the preparatory work of the treaty and the circumstances of its conclusion" (Vienna Convention, Art. 32). *(vii)* Broader analysis of the objectives or intention of the instrument (authorized under Vienna Convention, Art. 32). *(viii)* Determination of the meaning from contemporaneous information regarding the intention of the parties (Vienna Convention, Art. 32.) The order of precedence is clearly set by Vienna Convention at Art. 32. If the first method (linguistic analysis) yields a clear interpretation which answers all relevant legal questions, then the remaining steps are not needed, however, they may still be used to confirm the meaning that has been determined by the interpretation.

the Convention and new utilization of GR and derivatives arising from the date of entry into force of this Protocol were eliminated"[395]. This creates legal uncertainty.

Following principle of retroactivity under international law, provisions of an international instrument are not binding to any act or fact that took place before or any situation that ceased to exist at the date of entry into force of the treaty[396]. Therefore, access that had already taken place and benefits that have already been accrued without new and ongoing act, all its duration ceased before the entry into force of the Protocol, would not be covered by the new requirements for sharing benefit arising in accordance with the principle of retroactivity. However, new uses of GR entail new instances of access that would thus be covered new benefits arising from prior or ongoing uses may also be considered as new situations for benefit-sharing requirements, without violating the principle of retroactivity in international law.

There also has a concern that: Will only the benefit-sharing requirements apply if the rules for access are not possible to apply as the resource has been accessed long before the entry into force of the Protocol? How will this be practically affected? It is difficult to see how this provision can be tracked, let alone enforced, whether with regard to access or benefit-sharing. Article 10 on global multilateral benefit-sharing mechanism may aim to deal with these cases where "the utilization of GR and TK which it is not possible to grant or obtain PIC". In such cases, "The benefits shared by users of GR and TK associated with GR through this mechanism shall be used to support the conservation of biological diversity and the sustainable use of its components globally". The problem is that it is unpredictable to determined whether, how and when, this provision will be realized. The vagueness of temporal scope of the Protocol also may effect to the other articles of the Protocol.

Section 2 – Analysis of compliance with the legal obligations

The term "compliance" is part of a range of terminology used to describe patterns of conformity with legal norms.[397]

Compliance has important meaning, decisive role in effectiveness and successful MEA. Without compliance, the fair and equitable sharing of benefits "could promise a

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[395] IUCN, *Meeting report of Convention on Biological Diversity Tenth Meeting of CBD COP10*, Nagoya, Aichi Prefecture, Japan, 18-29 October, 2010, p. 5

[396] Article 28 of the Vienna convention on the Law of Treaties, 1969 deals with non retroactivity of treaties states "*Unless a different intention appears from the treaty or is otherwise established, its provisions do not bind a party in relation to any act or fact which took place or any situation which ceased to exist before the date of the entry into force of the treaty with respect to that party*."

[397] The CBD, ICNP, *Cooperative procedures and institutional mechanisms to promote compliance with the Protocol and to address cases of non-compliance*. UNEP/CBD/ICNP/1/6/Rev.1, 9 June 2011, p.2. Available online: http://www.cbd.int/doc/?meeting=icnp-01. Accessed 4 March 2012.

utopia that deliver little having no life beyond some letters on a piece of paper, while developing countries still face relatively unfettered access to their GR." [398]

"For developing countries, compliance was at the 'core of the core' of the Protocol. Recurring reports of cases of biopiracy underlined their concern of the continuing expropriation of their resources without any sharing of benefits. At all stages of the negotiations, developing countries maintained that weak compliance provisions would mean an insignificant and unacceptable Protocol." "The Group of Latin American and Caribbean Countries expressed commitment to a Protocol that would be "... significant in stopping biopiracy and efficient in benefit-sharing, therefore, a Protocol that includes derivatives, and a Protocol with strong compliance measures."[399]

This section analyzes two aspects of compliance: I - compliance of the parties with the national legislation to fulfill the legal obligations following the Protocol; II - procedures and mechanism on compliance with the Protocol.

§ I – Compliance with the national legislation on access and benefit-sharing

Specific obligations to support compliance with domestic legislation under PIC and contractual obligations reflected in MAT are a significant innovation of the Nagoya Protocol. These compliance provisions will contribute to ensuring the sharing of benefits when GR leave territory of the provider Party. Also, the Protocol's provisions on access to TK held by indigenous and local communities will strengthen the ability of these communities to benefit from the use of their knowledge, innovations and practices.

In this sub- section, "compliance" refers to ensure that users of GR comply with domestic legislation on access to GR and benefit-sharing (Article 15 and 16 of the Protocol) and with the MAT they conclude with the provider (Article 18 of the Protocol) and measures to support compliance that include monitoring the utilization of GR (Article 17 of the Protocol).

A – Compliance with PIC and MAT requirements

Ensuring "user compliance" consists in making sure that user fulfil their obligations, namely that GR utilized are legally accessed through PIC authorization and a MAT is concluded with the provider and the compliance of the user to the terms and conditions set out in the MAT.

1) Compliance with PIC

Following Article 15 the Protocol, parties are obliged to take measures to ensure that GR utilized within their jurisdiction have accessed the resource in accordance with PIC and MATs have been established as required by the domestic access and benefit-

[398] STOIANOFF.P.N, *Supra*, p. 233
[399] NIJAR.G.S, *Supra,* p. 18

sharing legislation or regulatory of other Party. These must be 'appropriate, effective and proportionate legislative, administrative and policy measures'. However, there is also no criterion established for determining what constitutes such measures. It is entirely in the discretion of the user countries to decide these.

In addition to Article 15.1, Article 15.2 also requires the Parties to take appropriate, effective and proportionate measures to address situation of non compliance. Article 15.3 obliges the user country to cooperate, as far as possible and as appropriate, to collaborate in cases of alleged violation of domestic legislation referred to in paragraph 1. All those provisions of Article 15 supplement to Article 15.7 of the CBD. However, they do not insist on the user country to ensure benefit-sharing. Therefore, "the user country may not proceed or be requested to proceed to fair and equitable sharing of the benefits if a user is utilizing a genetic resource for which no MAT was concluded at the time of access." Article 15.1 emphasizes that the implementation of user measures is largely dependent on decisions adopted at the time of access, especially the issuance of a permit or its equivalent. "The verb "provide" in Article 15.1 also seems to lay the emphasis on the results to achieve rather than the manner employed to reach them." [400] In Article 15.2, the exact meaning and regulatory content of Parties' obligation to "address situations of non-compliance" is unclear with again no criteria established for ascertaining how the measures may be considered 'appropriate, effective and proportionate. Following Article 15.3, the obligation "as far as possible" and "as appropriate" to cooperate in case of alleged violation must also be viewed in the perspective as striving for the successful conclusion of the MAT. Therefore, all provisions of Article 15.2 and 15.3 are supported to Article 15.1 to ensure GR accessed basing on PIC and MAT "as required by the domestic legislation or regulatory requirements of the other Party".

There is a concern about the legislation or regulatory requirements that must be adhered to 'the other Party'. 'The other Party' may be not "the countries of origin of such resources or the Parties that have acquired the resources in accordance with the CBD" based on Article 15.3 of the CBD. Therefore, "the language in the Protocol condones the legitimacy of access from countries that are not such countries. Hence if resources have been accessed illegally from a country of origin X, by another country Y, and a user accesses these from country Y in accordance with the provisions of country Y, the user country does not have to ensure compliance with the requirements of the country of origin X. This legitimizes biopiracy"[401].

Moreover, there is a fact that "the users often express a strong motivation to avoid any compliance with access to GR and benefit-sharing. This desire may also appear indirectly, in the form of corporate statements that does not apply. Companies making

[400] PATERNOSTRE.R, *Supra,* pp.76-77
[401] NIJAR.G.S, *Supra,* p.18

these statements may not have researched the issue, but simply concluded that if they acquire their specimens in the user country – from an ex-situ collection, another user, a researcher or some other person – then, by definition, they are utilizing domestic GR, regardless of the actual origin of the GR acquired."[402]

"Until now, hardly any user state has introduced legislation, administrative or policy measures ensuring compliance with access conditions and the duty to share benefits. The new provisions on compliance of Protocol now call them to task". "Four problems had to be solved: What agency should be in charge, at what point in the valorisation stream of GR shall the checking occur, what documents shall count as evidence, and what substantive issue shall be checked". "As for the responsible agencies, the Protocol only requires that user states must designate them". [403]

It is clear that obligations of compliance with domestic legislation or regulatory requirements provided by Article 15 are mandatory but flexible. No criterion established for determining what constitutes "legislative, administrative and/or policy measures" which user countries must approve, as long as, the measures are "appropriate, effective and proportionate". These are really qualitative standards that can not be assessed by exact quantative criteria. However, one argument supposes that "this flexibility is justified by the necessity of Parties to adopt the measures they estimated best suited to their national realities. These can be mandatory and/or incentivized. In addition, such modularity will allow to better coping with the specificities of the wide range of economic activities covered by the new framework…effective measures for one sector may be clearly inappropriate for another…This kind of 'tailor-made approach' and favouring the use of soft law instruments is also underscored by Article 20 of the Protocol."[404] In diffirent view, the other supposes that "the enforcement of benefit-sharing duties is left to contractual means, with all the difficulties of forum, litigation costs, and prosecution of titles. The fact that the Protocol does not go further in that direction constitutes a major disappointment for the provider side."[405]

Article 16 of the Protocol provides on compliance with domestic legislation or regulatory requirements on access and benefit-sharing for TK as "user country measures". This article is elaborated similarly to Article 15. Thus, it is critized as "a mirror image of those provisions. The same comments made for Article 15 apply to this article as well. What is a significant omission, however, is that the monitoring provisions make no reference to associated TK."[406]

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402 TVEDT. M. W, YOUNG. T, *Supra,* p.102
403 KAMAU.E.C, FEDDER.B, WINTER.G, *Supra*, p. 257
404 PATERNOSTRE.R, *Supra,* p. 77
405 KAMAU.E.C, FEDDER.B, WINTER.G, *Supra*, p. 257
406 NIJAR.G.S, *Supra,* p. 29

Notably, patent offices as designated checkpoints in the draft versions of the Protocol, this has not been included in the final version. "This is somewhat disappointing because it could have helped increase pressure in forums such as the WTO TRIPS Council towards an internationally binding disclosure of origin patent requirement that could help mitigate the many cases of patent-related biopiracy. For several years, since the CBD COP 4, there have been bio-diverse countries raising calls for a disclosure of origin requirement. It has also been mentioned in the Bonn Guidelines that user country should take into account measures to promote the disclosure of origin of GR and TK, innovations, and practices in intellectual property right applications (16.d.ii). This leaves the Nagoya Protocol falling significantly short in dealing with intellectual property and biopiracy concerns, with the text remaining a compromise that would allow delegates in other forums such as the WIPO IGC, and the WTO TRIPS Council to pick up concerns from many countries about the need for a disclosure of origin patent requirement."[407]

Finally, in my opinion, all obligations to compliance with PIC are mandatory with wording "Parties shall…" but flexible for implementation without specific determination of what are "legislative, administrative and/or policy measures" and critieria to determine "appropriate, effective and proportionate" measures. Therefore, these provide 'softer' obligations to the user countries. It is not easy to conclude the link between 'soft' obligations with 'ineffective' implementation of legal obligation under the Protocol because there are arguments on 'soft' measures supposes that are best suited to national realities and can be effective in combining implementation with other obligations. However, the wording of Article 15 of the Protocol is vague that implies different interpretation that is not the good way for implementation**.**

2) Compliance with MAT

Regarding to compliance with MAT, there is a need to enforce the contract for any breach of the terms in the jurisdiction of the other party or 'access to justice' and 'utilization of mechanisms regarding mutual recognition and enforcement of foreign judgments and arbitral awards', especially in the user countries in their jurisdiction. The question of access to justice in a foreign jurisdiction is at the core of the negotiation of an international regime on access to GR and benefit-sharing. The key concern underlying the question of access to justice is to ensure agreements on access to GR and benefit-sharing and legislation of the provider country adhered to is recognized and observed in the user countries.

In addition, based on a theory that international law assumes that "national courts can be instrumental in enforcing international obligations upon recalcitrant governments. Lacking centre enforcement, agencies, international law relies heavily on the action of national agencies. A judiciary that is independent of the national Government, that

[407] BAVIKATEE.K, ROBINSON.F.D, *Supra*, p. 48

employs international standards by resorting to technical, non-political, legal discourse, promises indeed to be a perfect forum to interpret, apply and develop international norm"[408].

Therefore, Article 18 of the Protocol provides the obligations to ensure the availability of administrative and legal remedies enabling the provider to protect the rights on access to GR and benefit-sharing acquired in a MAT, by encouraging provider and users to include MAT to cover dispute resolution and by ensuring opportunity to seek recourse "in cases of disputes arising from MAT". It seems that Article 18 only deal with situation of which "the user may also have legally accessed a GR through PIC and MAT but may not be compliant with the implementation of the said contract, but not for situation of non-compliance of which the user utilizes a foreign-origin GR for which no PIC was granted and no MAT established at the time of access. In addition, there are not only Article 18 but also Articles 15 and 16 of the Protocol, "are silent on jurisdiction and access to justice standards in cases of non-contractual disputes".[409]

Following Article 18.2, "each party shall ensure that an opportunity to seek recourse is available under their legal system, consistent with applicable jurisdictional requirements". And, Article 18.3 provides that "each Party shall take effective measures, as appropriate". Those provisions supplement to Article 18.1 to ensure the availability of administrative and legal remedies enabling the provider to protect the rights he acquired in a MAT. In theory, "it is legally feasible to proceed to the cross-border enforcement of a contract and different remedial options might be suited to address claims brought by providers. However, in the context of access to GR and benefit-sharing, the provider claiming user non-compliance will be surely faced up with difficulties to access to justice in user country", if there is no any facilitation. Those difficulties are explained by the fact that, at present "no country has adopted any law which requires users of foreign-origin GR to comply with source country requirements, including PIC and MAT. This means that a user will not be subject to legal action in the user country, unless he has obtained a contract"[410]. Despite having contracts, "the providers, who seek enforce the contract, will face with many challenges, such as the challenge of making certain that the contract is sufficiently clear and specific to enable a court, arbitration or other remedial action to come to an unambiguous decision; challenge of costs, access to information and evidence gathering, unfamiliarity with legal system, judicial institutions, while many of those lack the funds, expertise and ability to engage in a protracted action in another country seeking

[408] BENVENISTI.A, *Judicial Misgivings Regarding the Application of International Law: An Analysis of Attitudes of National Courts*, EJIL, 1993, p. 159 – p. 183

[409] CHIAROLLA.C, *Biopiracy and the Role of Private International Law under the Nagoya Protocol*, *working paper*, N°02/12 FEBRUARY 2012, BIODIVERSITY, IDDRI, available at http://www.iddri.org/Publications/Collections/Idees-pour-le-debat/WP0212_Chiarolla_PIL%20Nagoya.pdf, last accessed May 31, 2012

[410] YOUNG.T, *Supra*, p. 181

redress from an entity which is probably better funded, more familiar with the relevant legal system; and better positioned to participate in legal action"[411]. Therefore, this issue shall be reviewed by the COP/MOP and improve its feasibility of implementation[412].

The fact that "the enforcement of the benefit-sharing is left to contractual means, with all the difficulties of forum, litigations costs, and prosecution of titles (…) constitutes a major disappointment for the provider side.[413] There is an opposite argument that even if the contract certainty aspect of the MAT is improved, it will remain very challenging to proceed to their cross-border enforcement. The provider should clearly be assisted in ensuring that the enforcement of their rights is possible and it is unclear whether or not this is the case under the Protocol. Nevertheless, it would have been unrealistic to require user countries to ensure the due implementation of all MAT transactions. It must be acknowledged that it is practically unfeasible and excessively onerous to oblige user country to assess each individual transaction, determine whether the terms are fair and equitable and eventually force users to comply with their obligations. The clear definition of limited but implementable obligations has a better potential for effectiveness than excessively broad and ambitious requirements that are impossible to realize in practice.[414] This opinion seems to go further than proposal during negotiation that "would include granting access to courts or other impartial adjudication bodies in the jurisdiction, based on procedures that are fair and provide effective remedies; and where possible, appropriate assistance mechanisms to remove or reduce financial or other barriers to such access".[415]

In addition, there is an opinion supposes that following Article 18.2, "the obligation to ensure that an opportunity to seek recourse is available seems not to imply an obligation of assistance. And Article 18.3 (a) 'access to justice' is said "to refer to the UNECE Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters ('Aarhus Convention'). The legal consequences of this reference in the Protocol are still to be explored. More specifically, it has yet to be seen whether and to which extent Article 18.3 could be interpreted as requiring Parties to provide legal, technical and/or economical assistance in order to enforce compliance with MAT."[416]

Generally, it is suggested that if measures are adopted in accordance with Article 15 to Article 18 do not succeed in ensuring the fair and equitable sharing of benefits through MAT, other measures may be necessary to implement this overarching obligation. There are various measures for implementing obligations of benefit-sharing. For example, first,

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[411] YOUNG.T, *Ibid*, p.181
[412] Article 18.4 of the Nagoya protocol
[413] KAMAU.E.C, FEDDER.B, WINTER.G, *Supra*, p. 257
[414] PATERNOSTRE.R, *Supra*, p. 81
[415] NIJAR.G.S, *Supra*, p. 20
[416] PATERNOSTRE.R, *Supra*, p. 83 – p. 84

voluntary measures, thereof, "commercial and non-commercial user communities could cooperate with provider States by providing financial and other resources for enabling activities in the areas of planning, legislation and institutions. Legislation could provide indicative criteria for developing a policy. Economic incentives could be provided to support this. Measures on subsequent use could be contemplated which ensure PIC. Other legal measures might require potential users of GR operating within the jurisdiction of a State, whether they are legal or natural persons, to obtain PIC to acquiring GR". [417] "Penalties and remedies for importation and subsequent use without PIC could be provided. More complicated measures might include legal requirements for importers to demonstrate export has been pursuant to the PIC of the exporting State. Import controls could coincide with existing customs and biosecurity controls (such as quarantine regulations for plants and animals)." "Bilateral or multilateral agreements could be negotiated between States to establish the basis for cooperation in this area. The existence of PIC could also be established through application processes to grant intellectual property rights or product approval and licensing. Ideally, an application would not be accepted, or an approval would not be granted, until PIC and MAT had been confirmed. There would be at least three practical effects from this". Finally, "the effectiveness of all of these proposed measures would depend on the States from which GR are provided, or the legal and natural persons within their jurisdiction, having access to the court system of the State in which the GR are used."[418]

Some opinions suppose that an incentive would be created for GR users to comply with the spirit of the CBD and the letter of existing access laws. "The international regime should however not impose excessive regulatory burdens on user countries and allow for the creation of an incentive based paradigm". In general, for "user compliance", "Parties will need to adopt laws requiring the user of foreign GR to respect the benefit-sharing obligation and authorizing the provider of a foreign GR to seek remedies against non-compliant users operating within their jurisdiction. The adoption of user side measures is pivotal for the functionality of the international regime on access to GR and benefit-sharing, especially since it often has the most direct impact on the users' behaviour."[419]

Finally, my general comments to this analysis are the same to comments to the legal obligations of compliance with PIC. Although, the Article 18 provides some obligations activitites in more details than obligations with PIC but they are still flexible for the implementation of the user countries. Some recommendations to implementation of obligations with MAT still are to adopt law or need guidance. Especially, there is an expectation that "the COP/MOP could improve its feasibility of implementation".

[417] GLOWKA.L, *Supra*, p. 10
[418] GLOWKA.L, *Ibid*, p. 10 – p. 12
[419] PATERNOSTRE.R, *Supra*, p. 75

B – Measures to support compliance: monitoring the utilization of genetic resources

Under Article 17, the Protocol provides to use check points and internationally recognized certificate on compliance as major measures for monitoring the utilization of genetic resources. This subsection will analyze this provision.

1) Designation of check points

To support compliance, Article 17.1 requires Parties to take measures, as appropriate, to monitor and to enhance transparency concerning the utilization of genetic resources. The measures shall include the designation of one or more checkpoints (Article 17.1.a), encouraging parties to a MAT to include provisions to share information on the implementation of such terms, including through reporting requirement (Article 17.1.b), encouraging the use of cost-effective communication tools and systems (Article 17.1.c). It is clear that the Article 17 does not impose an obligation of tracking the resources utilized or to report on the utilization activities within its national jurisdiction, as proposed in previous drafts.

Following Article 17.1.a, there shall be 'one or more' checkpoint, but "there is no obligation to inform the secretariat or the Access and Benefit-Sharing Clearing-House of the designation of the proposed checkpoint"[420]. In addition, the functions of the checkpoints are not clear imposed as suggestion of the Technical Group "These checkpoints may be established to monitor compliance in relation to a range of possible uses" and "Checkpoints identified were: Registration points for commercial applications (e.g. product approval processes); intellectual property right offices (in particular patent and plant variety authorities). In the case of non-commercial uses, additional checkpoints could be further explored such as entities funding research, publishers and ex-situ collections".[421] In fact, designated checkpoint now just "would collect or receive" relevant information. The two separated activities "collect or receive" seems to give a limited role to checkpoint to fulfill their obligations of Article 17. In addition, under the use of conditional tense 'would' that introduce the flexibility on how the checkpoints would operate? These indicate that "there is no obligation for designated checkpoint to verify that the relevant information that it would receive or collect". It means that "Parties are not obliged to meet their monitoring obligation by checkpoint(s)". Accordingly, "a checkpoint solely enhancing transparency fulfils the requirements of Article 17 of the Protocol and Parties may decide to achieve their monitoring duties in totally different ways"[422].

[420] NIJAR.G.S, *Supra,* p. 20
[421] UNEP/CBD/WG-ABS/5/7, *Supra*, p. 10
[422] PATERNOSTRE.R, *Supra,* p. 81

It is clear that "there is no mandatory obligation to disclose information at these checkpoints."[423] "The text purposefully avoids the use of the words 'disclosure' or 'disclosure requirement' and suggests rather indirectly that a disclosure requirements at designated checkpoints could play a role in the implementation of Article 17.1 (a). This is left to the discretion of Parties."[424]

The information collected or received by the checkpoint (s) just are "relevant information related to PIC, to the source of the genetic resource, to the establishment of MAT, and/or to the utilization of GR". They exclude any information of TK associated to GR, while "most cases of bio-piracy or violation of legislation on access to GR and benefit-sharing"[425], now relate to the unlawful use of such TK. Moreover, following Article 17.1.a.iii, "Such information, including from internationally recognized certificates of compliance where they are available, will, without prejudice to the protection of confidential information, be provided to relevant national authorities, to the Party providing PIC and to the Access and Benefit-sharing Clearing-House." That means, in case of "the protection of confidential information", they will not be provided. But, the protocol does not provide who decides the case of "the protection of confidential information" or which situation will become this case. "There are also no sanctions prescribed for failure to disclose the information at the designated checkpoints" [426], but "each Party shall take appropriate, effective and proportionate measures to address situations of non-compliance". These wordings are the same with the Article 15.2.

Article 17.1.a.iv states that the checkpoints 'must be effective and should have functions relevant to implementation of this subparagraph' that is as vague as language can be. What is a checkpoint that has functions relevant to the implementation of a paragraph that speaks of the role of checkpoints to collect/receive information, the obligation to optionally require providing information, the protection of confidential information and the supply of the information to various authorities? As observed by Buck and Hamilton, "the notion that checkpoints 'must be effective' already flows from the chapeau of Article 17.1 and 17.1 (a) (i) of the Protocol. Furthermore, the non-obligatory list of stages to collect 'relevant' information goes beyond the substantive scope of the obligation in the chapeau to Article 17.1 ('utilization of GR'), which suggests that some of the collected information might indeed be irrelevant for implementing Article 17 of the Protocol."[427]

At last, Article 17.1.a.iv set out a general criteria is set out for such checkpoints by these terms: They should be "relevant to the utilisation of GR, or to the collection of relevant information at, inter alia, any stage of R&D, innovation, pre-commercialisation or

[423] NIJAR.G.S, *Supra,* p. 20
[424] Cited by PATERNOSTRE.R, *Supra,* p. 81
[425] NIJAR.G.S, *Supra,* p. 20
[426] NIJAR.G.S, *Ibid*, p. 20
[427] Cited by PATERNOSTRE.R, *Supra,* p. 82 (note 24)

commercialization". "The formulation is rather obtuse. Are the intellectual property right offices relevant to the collection of information at the stage of innovation or pre-commercialisation? What is more worrying is that developed countries studiously fought to exclude any text that directly named these offices or bodies as checkpoints." [428] In fact, other than the Draft Protocol which had envisaged a list of checkpoints such as research institutions, financial institutions, patent offices and regulatory agencies, the agencies are not specified any more. This is probably wise because states may decide to nominate just one agency for this purpose. "With regard to the point of disclosure the Protocol is very broad including 'any stage of R&D, innovation, pre-commercialisation and commercialisation'. Using a 'should' the provision leaves discretion for user states to identify strategic points. The mandatory disclosure requirement at the state of patenting of inventions from GR which had widely been discussed in the run-up to COP10 was not included in the Protocol."[429]

2) Internationally recognized certificate of compliance

The scientific base, the role and necessary of internationally recognized certificate of compliance has been already analyzed in Section I, Chapter 1, Title 2, Part 1 of this thesis. Pursuing with these bases, this sub-section analyzes actual provisions on this certificate under the Nagoya Protocol.

Article 17.2 of the Protocol states that "a permit or its equivalent issued in accordance with Article 6, paragraph 3 (e) and made available to the Access and Benefit-sharing Clearing-House, shall constitute an internationally recognized certificate of compliance". It is unclear that "whether the simple act of registration in the Access and Benefit-sharing Clearing House elevates a domestic permit or equivalent to the status of an internationally recognized certificate of compliance or whether the registered information itself constitutes the internationally recognized certificate of compliance. In the latter case, the internationally recognized certificate of compliance would be distinct from the domestic permit or equivalent."[430]

Article 17.3 stipulates that "an internationally recognized certificate of compliance shall serve as evidence that GR which it covers has been accessed in accordance with PIC and MAT have been established as required by the domestic legislation or regulatory requirements of the Party providing MAT" that shows nature of the legally binding effect of the certificate. It precludes States from tracking the GR back to the 'Other Party' and protects the user in its possession from being accused of biopiracy, because, the certificate of compliance is the evidence of which GR has been accessed legally.

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[428] NIJAR.G.S, *Supra,* p. 20
[429] KAMAU.E.C, FEDDER.B, WINTER.G, *Supra*, p. 256 – p. 257
[430] Cited by PATERNOSTRE.R, *Supra,* p. 82

Article 17.4 contains a list of minimum information which must be included in the certificate. As Buck and Hamilton states it "contingent to the interpretation of Article 17.2, this list will either result in a minimum harmonization of domestic permits or equivalents or it could be implemented by providing a common format for registering information on domestic permits or equivalents in the Access and Benefit-Sharing Clearing House."[431] The internationally recognized certificates of compliance with minimum information following Article 17.4, may not meet objectives raised by group of technical experts on an internationally recognized certificate of origin/source/legal provenance and the 8th Working Group on Access and Benefit-Sharing. It lacks details of the rights holders of associated TK, link to MAT, conditions of transfer the certificate to third parties. The certificate now contains most information of PIC, only "Confirmation that MAT was established" but it does not ensure that MAT, including the sharing of benefits will be met; the certificate does not substitute the need to develop national legislation on access to GR and benefit-sharing."[432]

In general, "Article 17 of the Protocol reflects a delicate political compromise between developing and developed countries. The approach of "checkpoints", "certificate of compliance" is conserved but the Protocol introduces significant flexibility and does not contain any reference to "disclosure requirement" or "patent office."[433] Although, sole disclosure requirement will not be sufficient to achieve the benefit-sharing obligations, it will have to form a part of a more complete enforcement system which can resolve the difficult technical legal issues of GR outside the provider country.

There are many concerns and questions remains for Article 17: which is further guidance on how exactly situations of noncompliance should be managed? Whether or not genetic resources utilized for which no certificate is presented are within the scope of the Protocol? And which are potential sanctions for non-compliance or non-disclosure of the origin of the GR utilized? These are crucial for the integrity by the fact that "one of the most important gaps that prevent further progress towards functionality is the loophole by which users who do not know or disclose the source country of the resources they are using are not required to engage in any benefit-sharing or substitute activity. Even more than the practical unenforceability of contracts, the failure to adopt user measures to close this gap has rendered access to GR and benefit-sharing a very ineffective system, and closed many options for increasing its effectiveness."[434]

In general, there are also different views about provisions on compliance with PIC and MAT and support to compliance of the Protocol. One supposed that: "clear obligations by countries with users in their jurisdiction to take effective measures against

[431] Cited by PATERNOSTRE.R, *Supra,* p. 83 (note 226)
[432] UNEP/CBD/WG-ABS/5/7, *Supra,* p.6
[433] PATERNOSTRE.R, *Supra,* p. 79
[434] TVEDT. M. W, YOUNG. T, *Supra,* p. 130

misappropriation; a specification of the measures", "the establishment of monitoring and tracking measures in support of compliance, designated checkpoints to monitor and track the use of GR", "derivatives and TK", "patent offices as one such checkpoint, and finally sanctions for non-compliance", but "in the end, a co-engineered final text made possible a Protocol that contains compliance provisions of dubious value to developing countries."[435] In addition, more views indicate that "Similarly elusive are those provisions addressing situations of non-compliance, and in cases of alleged violations, parties have a weak obligation to cooperate. These shortcomings will be addressed at the next COP though."[436] In contrary, "In terms of results, the obligations 'to monitor and enhance transparency' are clear and sufficiently precise to be implemented. The system of checkpoints and internationally recognized certificate of compliance remains rather undetermined. In particular, the exact role and features of the latter is still largely undefined…this is nevertheless not so problematic. Indeed, only the practical implementation of the whole regime will show how the certificate can best operate."[437]

Most importantly, suggestions and solutions need to be explored to improve effective compliance with national legislation. In the view of "the Nagoya is not a single magic bullet addressing all the problems in one shot",[438] "discussion will need to be pursued under other forum …with various framework of international law." "At international level, Parties should closely collaborate and share knowledge, experience and best practices. At national level, Parties should start reflecting as soon as possible on how user measures could best operate." "Parties dispose of all necessary discretion to focus their action on creating the conditions to favour compliance and develop incentive for economic operators to enter into relationships on access to GR and benefit-sharing."[439]

In my opinion, there is a progress of the Protocol in development of compliance obligations by newly introduced compliance measures such as establishment of checkpoints and the internationally recognized certificates of compliance. Although, they have some limits as outlined above, they still play an important role in implementation in the beginning of a new international regime on access and benefit-sharing. Thus, they should be recognized and promoted by the Parties and furtherly facilitiated by the COP/MOP. It is clear that the flexible obligations for the user countries will be challenges for implementation of the Protocol. However, each country also needs to improve their national legislation and regulatory requirements on the access and benefit-sharing to protect their own rights and benefit, concurrently, to have stronger bases to requires implementation obligations of others country. There are difficulties but also many solutions to address.

[435] NIJAR. G.S, *Supra*, p. 18 – p.19
[436] KAMAU.E.C, FEDDER.B, WINTER.G, *Supra*, p. 252
[437] PATERNOSTRE.R, *Ibid*, p. 86
[438] PATERNOSTRE.R, *Ibid*, p. 81
[439] PATERNOSTRE.R, *Supra*, p. 89

§ II – Procedures and mechanism on compliance with the Protocol

At present, the most concerned question to the Nagoya Protocol would be about procedures and mechanism on compliance as: what will come when the Protocol into force? The Protocol only has one Article 30 refers to the responsibility of the first COP/MOP of the Protocol to "consider and approve cooperative procedures and institutional mechanism to promote compliance with the provisions of this Protocol and to address of non compliance". This raises many questions and options for setting an effective and significant procedures and mechanism on compliance.

This sub-section will check definition and scope of procedures and mechanism on compliance and analyze actual provisions and questions on elements of procedures and mechanism, as well as, options for consideration on these.

A – Definition and scope of procedures and mechanism

In the context of Article 30 of the Nagoya Protocol, compliance means "the fulfilment by the contracting Parties of their obligations under a multilateral environmental agreement (MEA) and any amendments to the multilateral environmental agreement".[440]

MEA's compliance regimes have typically included "requiring Parties to report on implementation and the provision of dispute settlement mechanisms to be used in the context of a breach of the treaty. These have had limited efficacy in the first instance and very limited use in the second." [441] As a result, "new approaches for compliance regimes have evolved. These have been based on recognizing the collective nature of the interests of the Parties in the successful implementation of MEAs, while recognizing, as well, that the typical reason for a party's non-compliance is not so often intentional disregard of its obligations, but rather a lack of capacity, awareness or resources to comply with them." [442]

There is a new approach towards compliance characterized by the development of procedures and mechanisms premised on cooperation and partnership rather than confrontation "with the view to assisting Parties having compliance problems and addressing individual cases of non-compliance". "A preventive dimension was therefore emphasized providing a vehicle for identifying non-compliance at an early stage."[443]

It is quite clear that Article 30 of the Protocol takes closely with this new approach with provision that "cooperative procedures and institutional mechanism to promote compliance with the provisions of this Protocol and to address of non-compliance". The

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[440] UNEP/CBD/ICNP/1/6/Rev.1, *Supra*, note 349, p. 2

[441] BEYERLIN.U, STOLL.P-T, WOLFRUM.R, *Ensuring Compliance with MEAs: A dialogue between Practitioners and the Academia*, Conclusions drawn from the Conference on Ensuring Compliance with MEAs: A dialogue between Practitioners and the Academia", 2006.

[442] UNEP, "*Manual on Compliance with and Enforcement of MEAs*" UNEP Division of Environmental Conventions (2006) (UNEP Compliance Manual), p. 144.

[443] http://www.unep.org/dec/onlinemanual/Compliance/NegotiatingMEAs/ComplianceMechanisms/tabid/429/Default.aspx http://www.cbd.int/abs/submissions/em-compliance/japan-en.pdf last accessed 10th April 2012

scope of operation of procedures and mechanism is determined by two main activities, which also are objectives: promote compliance and address of non-compliance.

These may be some of the reasons why non-compliance procedures are established in treaties. An alternative explanation; however is that "States prefer non-compliance procedures because-instead of leaving decisions to a third party in the form of a court or an arbitral tribunal – they allow States more control over the process and its outcome. Furthermore, a decision resulting from a non-compliance procedure is not final in the form of *res judicata* and may therefore be seen as less intrusive on State sovereignty"[444].

The term compliance is also to be distinguished from related terms, such as 'effectiveness', 'enforcement' and 'implementation'. Especially, there may be exist view supposes carrying out "implementation" of a treaty that means fulfilling "compliance" with the treaty. The "implementation" as defined "inter alia, all relevant laws, regulations, policies, and other measures and initiatives that contracting Parties adopt and/or take to meet their obligations under a MEA…" "The mere fact that an implementation measure is taken does not mean that it is adequate to meet a treaty obligation. Alternatively, the State is necessarily in compliance with its treaty obligations. Implementation is understood to occur in three phases: first, by adopting national legal, policy and administrative measures or actions; second, by enforcing them; and third, by reporting on implementation measures to the governing body of a MEA."[445] The adoption of compliance mechanism should be at the first meeting.

B – Elements of procedures and mechanisms on compliance

1) Questions and options on each element

Most of the procedures and mechanisms on compliance have similar elements and structure as well as many common features, though there are also some substantial differences among them depending on the characteristics of the MEA and the nature of its obligations. They commonly provide for: "a) objectives, nature and underlying principles, b) institutional mechanisms, c) functions of the compliance body, d) procedures, e) information and consultation, f) measures to promote compliance and address cases of non-compliance, and g) review of the procedures and mechanisms."[446]

a) Objective and nature:

Article 30 of the Nagoya Protocol indicates that the objective of the compliance procedure is "…to promote compliance with the provisions of this Protocol and to address cases of non compliance. These procedures and mechanisms shall include provisions to offer advice or assistance, where appropriate…" "The Nagoya Protocol emphasizes two

[444] ULFSTEIN.G, *Making treaties work*, Cambridge University Press, 2007, p. 14
[445] UNEP, "Compliance Mechanisms under Selected MEAs (UNEP Compliance Mechanisms) p 19-22
[446] UNEP/CBD/ICNP/1/6/Rev.1, *Supra*, p. 4

facets of the procedures and mechanisms to be developed. The first is to promote compliance with the Protocol. The second is to address cases of non-compliance. These two facets are not always explicitly differentiated in the procedures and mechanisms of other MEAs, and in practice the compliance bodies are normally triggered to address cases of non-compliance and not so often to promote compliance."

Assuming Article 30 already specifies the objectives of the compliance procedure and mechanisms, the questions are: "What should be the nature of the compliance regime established? What principles should underpin the operation of the compliance procedure? How can these objectives be achieved?"[447]

b) Institutional mechanism:

"Compliance procedures and mechanisms normally establish a compliance body with a defined size, composition and function."

Number of members of the compliance body may range from 8 to 15 members (like the Aarhus and the Espoo Conventions, the Cartagena Protocol and the Basel Convention). And the member are only nominated by Parties and elected by the governing body, in the exception Committee members can also be nominated by signatories and NGOs (like Aarhus Convention). Members serve on compliance bodies in their personal and individual capacity (the Cartagena Protocol or the FAO's treaty). Members are elected based on their competence in the relevant field and on their legal, scientific and/or technical expertise, as appropriate. Equitable geographical representation is a common criterion for determining the composition of the body. Members are elected by the COP-MOP for a period of four years (like the Cartagena Protocol). Members do not serve for more than two consecutive terms. Generally, the compliance bodies analysed meet once or twice a year, unless otherwise decided. Flexibility in the sequence of meetings would be able better to adapt to the circumstances and submissions received (like FAO's treaty). Normally, the compliance bodies submit their reports and recommendations to the governing body for consideration. The compliance body normally develops its own rules of procedure and additional rules that may be needed.[448]

However, the questions arise: "Should the compliance body be a standing or an ad hoc body? What should its size and composition be? In what capacity should members serve? What expertise should be represented in the membership of the body? What procedure should be used to select members? Should the procedure foresee a system for replacing members? How often should the compliance body meet?" [449]

[447] UNEP/CBD/ICNP/1/6/Rev.1, *Ibid*, pp.4- 5
[448] UNEP/CBD/ICNP/1/INF/1**,** *Overview of compliance and procedures and mechanism established under other multilateral environmental agreements*, 2011, p. 2 – p.24
[449] UNEP/CBD/ICNP/1/6/Rev.1, *Ibid*, p. 7

One requirement of Article 30 of the Protocol is recognized that "they shall be separate from, and without prejudice to, the dispute settlement procedures and mechanisms under Article 27 of the Convention"

c) Functions of the compliance body:

Article 30 of the Nagoya Protocol points to the objectives of the compliance procedures and institutional mechanisms shall be adopted. Therefore, the functions of the compliance body would be elaborated with a view to promoting compliance with the Protocol and addressing cases of non-compliance.

"The functions of the compliance bodies under other MEAs may be refered, including: Offer advice and/or facilitate assistance on matters relating to compliance; Seeking and considering information related to the submissions; Identifying the facts and possible causes of non-compliance; Undertaking, upon invitation, information gathering in the territory; Reviewing general issues of compliance by Parties with their obligations under the MEA; Taking measures or make recommendations to the governing body, as appropriate; Seeking the service of experts, as appropriate; Preparing reports on compliance; Reporting to the governing body; and Carrying out any other functions as may be assigned by the governing body."[450]

The Article 30 indicates one function at least should be included by the compliance mechanism, which is provided as "these procedures and mechanism shall include provisions to offer advice or assistance, where appropriate".

The questions are: "What functions should be assigned to the compliance body? Should this include the review of the monitoring and reporting of the implementation of the Nagoya Protocol under Article 29?"[451]

d) The compliance procedures

They include: "the procedure is initiated or triggered, the submission triggering the procedure is subsequently processed and the ability of the party who is the subject of a submission to participate in the deliberations of the respective compliance body."

For triggering, "the compliance procedures under the different MEAs include a range of triggers to initiate the respective processes. These include submissions by a party with respect to itself; a party regarding the compliance of another party; (iii) the Secretariat; (iv) the compliance body; the governing body of the MEA; members of the public; or experts."

"The lack of submissions hinders the achievement of the objectives of the compliance procedures. Consequently, review processes and discussions have been

[450] UNEP/CBD/ICNP/1/6/Rev.1, *Ibid*, p.7
[451] UNEP/CBD/ICNP/1/6/Rev.1, *Ibid*, p. 8

initiated in several fora to improve the performance of the compliance procedures. Most of the issues raised and shortcomings highlighted are related to the trigger of the compliance procedure." [452]

Submission by a Party, the practice shows that relying only on the initiative of Parties to initiate the compliance procedures may not be sufficient to make the procedure effective. In addition, most cases of non-compliance do not result from intentional disregard for treaty obligations, but rather from a lack of awareness, capacity or resources, promoting self submission by Parties with difficulties to comply is essential if the nature of the compliance procedure is to be facilitative and preventive.

"Referrals by the Secretariat, in some compliance regimes, the Secretariat is given the possibility of triggering the procedure through referrals to the compliance body".

"Referrals by the compliance body, only the Espoo Convention compliance regime includes referrals by the compliance body. In addition, during the review of their compliance procedures, both the Cartagena and the Kyoto Protocol examined the possibility of enhancing the role of the compliance body." [453]

"Communications by members of the public, the compliance procedures under the Water and Health Protocol and the Aarhus Convention foresee a trigger by any member of the public, whether it be a natural or a legal person, or a NGO."

For processing the submissions, generally, they received by the Secretariat. Sometimes different processes are foreseen depending on who invoked the procedure. In the case of a self-trigger, the usual practice is that that the Secretariat transmits the self-submission to the compliance body for its consideration. In the other cases, the Secretariat sends a copy of the submission to the concerned party. The submission, together with the response and information from the concerned party, are then transmitted to the compliance body. In most cases, when the procedure was initiated by another party or by members of the public, the compliance body is first directed by the procedure to consider the admissibility of the submission and afterwards to gather information to assess the possible measures to be taken.[454] This procedure seems to be similar for most of treaties.

e) Information and consultation

"Consultation through the entire process with the party that is the subject of a submission is essential to guarantee due process. The party is normally entitled to participate in the deliberations of the compliance body, but not in the elaboration and adoption of recommendations to the governing body."

[452] UNEP/CBD/ICNP/1/6/Rev.1, *Ibid*, p. 8
[453] UNEP/CBD/ICNP/1/6/Rev.1, *Ibid*, p. 10
[454] UNEP/CBD/ICNP/1/6/Rev.1, *Ibid*, p. 8 – p. 13

"The compliance body in its consideration of the submissions made normally receives information from the party which is the subject of the submission and from the submission's author, but it can also seek information from other sources including, for example, the governing body, the Secretariat and other subsidiary bodies, international organizations, experts and NGOs. Many compliance procedures foresee the possibility of gathering information in the territory of a party upon its invitation. In some instances confidentiality of the communications is required."

The Questions are: "which sources of information should the compliance body rely upon? Should confidentiality be maintained?"[455]

f) Measures to promote compliance and address cases of non-compliance:

"The governing body and the compliance body can play different roles on compliance matters. In certain compliance procedures, the governing body is the only institution that can make the final decision regarding compliance on the basis of the recommendations and reports of the compliance body". "Both the compliance body and the governing body have the capacity to take measures to address compliance, but in the case of the measures taken by the compliance body these are normally of a facilitative nature".

"When considering taking measures to promote compliance and to address cases of non-compliance, the competent body takes several factors into account. The most common factors are the capacity of the party concerned and the cause, type, degree and frequency of the non-compliance."

"Measures to promote compliance and address cases of non-compliance are usually applied in an order of increasing severity. Response measures can include incentives, assistance, and/or sanctions." "This is usually without prejudice to the prerogative of the competent body to decide to apply the measures in the order it may consider appropriate taking into account." "A response can also be tailored to the underlying reason for non-compliance. For example a lack of financial or human capacity would suggest a facilitative response, and a lack of political will or negligence would suggest a stronger response." "In practice, the measures taken within the compliance regimes examined usually focus on assistance rather than the suspension of rights and privileges under the treaty and other stronger measures. This is consistent with the general recognition that the common reason for non-compliance is lack of capacity."

"The measures taken within other compliance regimes to promote compliance and to address cases of non-compliance include: Providing advice or assistance to the party concerned in the following areas: financial; technical, legal, technology transfer, and/or training and other capacity-building measures; Requesting or assisting, as appropriate, the

[455] UNEP/CBD/ICNP/1/6/Rev.1, *Ibid*, p. 13

party concerned to develop a compliance action plan within an agreed timeframe and indicators to assess satisfactory implementation; Inviting the party concerned to submit progress reports on its efforts to comply; Issuing a caution or warning; Issuing declarations of non-compliance; Distributing to all Parties a public notification through the Secretariat; Publishing cases of non-compliance; Suspending, in accordance with the applicable rules of international law concerning the suspension of the operation of a treaty, of specific rights and privileges; and/or applying economic or trade consequences; Responses to non-compliance can be combined, for example, it is usual to request the development of compliance actions plans and the submission of progress reports when both facilitative and stronger measures are taken."

The questions are: "What roles should the compliance body and COP/MOP have in relation to the measures taken to promote compliance and to address non-compliance? What considerations should be taken into account during the procedure? Article 30 of the Nagoya Protocol specifies that "these procedures and mechanisms shall include provisions to offer advice or assistance, where appropriate…." What other measures should be included in the procedure?"[456]

g) Review of procedures and mechanisms

"Review of the compliance procedures and mechanisms is explicitly foreseen in the regime itself only under the Cartagena Protocol, CITES and the FAO's treaty. Under other MEAs, reviews are conducted within the context of the general evaluation of the effectiveness of the particular instrument or developed by practice."

The questions are: "Should the review of the compliance procedures and mechanisms adopted for the Nagoya Protocol be explicitly provided for? Should it be scheduled?"[457]

2) Some relevant considerations for options

Some reviews below should be considered for development of procedures and mechanism on compliance:

Firstly, "many MEAs have developed similar compliance procedures and mechanisms, and valuable practical experience has been gained. Compliance procedures have similar elements and features, but there are also some substantial differences among them depending on the characteristics of the MEA and the nature of its obligations."[458] Therefore, options on procedures and mechanism for compliance with the Nagoya Protocol also should be based on the characteristic and nature of its obligations; these may take consideration as appropriate to some characteristics which are analysed in previous sections of this chapter.

[456] UNEP/CBD/ICNP/1/6/Rev.1, *Ibid*, p. 13 – p. 15
[457] UNEP/CBD/ICNP/1/6/Rev.1, *Ibid*, p. 15
[458] UNEP/CBD/ICNP/1/6/Rev.1, *Ibid*, p. 15 – p.16

Moreover, two treaties, which seems to be close to the Nagoya Protocol, are Biosafety Protocol and the International Treaty on Plant Genetic Resources for Food and Agriculture their experiences and outcomes of the compliance procedures, "if adapted to the circumstances of the Nagoya Protocol, either or both could provide a possible basis to begin developing draft elements and options." In addition, "the compliance procedures recently adopted under the FAO's treaty, while building on the compliance procedures of the Cartagena Protocol, incorporate some of the lessons learned from previous experiences, giving a stronger emphasis to promoting compliance and the facilitative aspects of the procedures."[459]

Secondly, in determining objective, nature and principle of the compliance procedures and mechanism, reference can be made from the compliance mechanisms under the Basel Convention, Cartagena Protocol, CITES, the FAO's treaty and the Water and Health Protocol, with wording as "simple", "facilitative", "non-adversarial", "cooperative", "cost-effective", "non-judicial", "supportive", "non-confrontational", "transparent", "preventive", "flexible" and "legally non-binding". "The wordings "simple, cost-effective, facilitative, non-adversarial and cooperative in nature" may be considered as they are used in most referred treaties and also are apply to Article 17.1.c on monitoring genetic resources utilization."[460]

Thirdly, the principles of transparency, accountability, fairness, expeditiousness, predictability, consistency good faith, and reasonableness should be considered to apply because they can prevent possible accusations of partiality and arbitrariness. "Fairness is guaranteed through due process, enabling Parties to present information regarding submissions against them and to engage fully in the process. To ensure measures taken to address non-compliance are reasonable, some instruments require their compliance body to take into account certain considerations when examining submissions".

The principle of common but differentiated responsibilities also should be applied. This principle is provided by the Cartagena Protocol on biosafety, the FAO's treaty, Basel Convention, Water and Health Protocol. It should be considered that "It shall pay particular attention to the special needs of Contracting Parties that are developing countries and Contracting Parties with economies in transition, take into full consideration the difficulties they face in the implementation of the Protocol". [461]

This principle may be argued that compliance obligations apply equally to all Parties, and that this consideration could only be drawn when it comes to applying measures to address non-compliance. [462] However, it is clear that the obligations of compliance with national legislation under the Nagoya protocol also are different, in

[459] UNEP/CBD/ICNP/1/6/Rev.1, *Ibid*, p. 17
[460] UNEP/CBD/ICNP/1/INF/1, *Ibid*, p. 2 – p. 24
[461] UNEP/CBD/ICNP/1/6/Rev.1, *Ibid*, p. 5
[462] UNEP/CBD/ICNP/1/6/Rev.1, *Ibid*, p. 5

which, “softer” or flexible obligations are for user countries, “harder” or more elaborated obligations are for provider countries. Therefore, international mechanism could consider particular needs of provider countries to assist them compliance. Although, “in fact, any Party can be both a provider and user of genetic resources , often “user country” is equated with “developed country,” and “provider country” is equated with “developing country” because, “the most complex and potentially valuable forms of utilization of GR usually occur in developed countries.”[463]

Fourthly, in setting up institutional mechanisms, it could consider establish a standing compliance body. Because, all the regimes under MEAs mentioned above establish a standing body to administer the compliance regime.[464] It is more necessary for the Nagoya Protocol as a standing compliance body could play a role of ‘international control’ to implementation. This may response to the situation of the Nagoya Protocol with many of its provisions require to the national implementation, namely “‘Each Party shall take legislative, administrative or policy measures, as appropriate’, ‘in accordance with domestic legislation”, “subject to its domestic legislation or regulatory requirements” “in accordance with domestic law, each Party shall take measures, as appropriate”, “Parties shall take appropriate, effective and proportionate measures as required by the domestic legislation or regulatory requirements.”

Lastly, some practical problems should be considered in establishing and operating of the compliance body such as attendance-related problems and subsequent lack of quorum to take decisions; delays replacing members who resign inter-sessionally; level of expertise and engagement of members, no submission relating to compliance has been put forward by a Party for consideration by the Compliance Committee, sufficient budget for meeting.

Generally, in my view, we can learn a lot experiences from the others treaties to develop procedures and mechanism on compliance for the Nagoya Protocol. The Protocol also had two meetings of Open-ended Ad Hoc Intergovernmental Committee of the Nagoya Protocol (Montreal, 5-10 June 2011 and New Delhi, 2-6 July 2012) and development of procedures and mechanism of compliance is one of key issues in their provisional agenda[465]. However, it should consider the peculiarities of the Protocol in the specific nationals and international practice context, the principle of the international frameworks and other relevant factors to set up an effective mechanism. This procedural and institutional development of the Protocol is especially significant to ensure reaching the objectives of the Protocol, when, the substantive text and provisions on legal obligations for compliance of the Protocol still have limited.

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[463] TVEDT. M. W, YOUNG. T, *Supra*, p.10

[464] UNEP/CBD/ICNP/1/6/Rev.1, *Supra*, p. 5

[465] See more UNEP/CBD/ICNP/1/1, UNEP/CBD/ICNP/2/1/Rev.1, UNEP/CBD/ICNP/1/6/Rev.1, UNEP/CBD/ICNP/2/12

Conclusion of Chapter 2

The core challenge of international treaty always is a balance between rights and interests of Parties, namely for the Nagoya protocol, it is the balance between user countries and provider countries. In logically interpreted way, the rights and interests of one Party that correspond with responsibilities of the others and it is nature for the parties strive for reaching highest rights and interests for them. Thus, provisions of the Protocol are results of compromise of each party. In optimism, consensus between Parties for approval of the Protocol was a trade-off. Each party has their own status to require the trade-off. The user party holds science and technology for GR utilization as analysis in the Section 1. The provider party owns GR or has sovereignty rights as analysis in the Section 1 and in first sub-section of the Section 2. While user Party requires for legal certainty for access to GR through PIC and MAT, provider Party claims for fair and equitable sharing benefits arise from GR's utilization as analysis under ther Section 2. The legal obligations have been elaborated for each party. However, there are different ways to interpret the provisions on legal obligations and compliance of the Nagoya Protocol. As being indicated by Section 2, some supposed that there is flexibility for Parties to comply with the Protocol, some opposed that these are unclear and vague provisions lead to weak effectiveness.

It seems to be appropriate with a statement of Klabbers.J: "It is a truism to say that actions may often be explained in more than one way and it similarly goes without saying that words or texts may lend themselves to varying different interpretations. The question then becomes of course, how to assess the various acts or words; how to give meaning to them." [466] Therefore, the most important thing is to make the achieved results of the Nagoya protocol effective in practice. It is recognized that the Protocol is a "first step", so, we need to prepare to continue to go. This also could be considered seriously for States during integration of the Protocol into national law for its implementation and compliance.

[466] KLABBERS. J, *The concept of treaty in International law*, Kluwer Law International, 1996, p. 123

Conclusion of Title 2

There are many approaches to assess achievements or shortcomings of one treaty. The Nagoya Protocol also has been assessed and analyzed by different approaches in different aspects, such as in aspect of economics of information[467], biocultural rights[468], implication for major actors[469], private international law[470]. In this thesis, the author assesses the Nagoya Protocol in two basis aspects: scientific and technical aspects, and legal aspects. Under the scientific and technical aspects, the strong and weak points of the Protocol are assessed by analysis of the bases for development of the Nagoya Protocol, the scientific and technical requirements for the Protocol and existing provisions of the Protocol. The legal aspects are essential for assessment of the Protocol with both legal obligations and legal compliance to the obligations. Under the legal aspects, the author finds lacunes, gaps, vaguness and weakness of the Protocol that may impact on the integration of the Protocol in to national laws. The author suggests that integration of the Protocol and improvement of implementation of national laws on access and benefit-sharing may overcome weakness of provisions of the Protocol to achieve the objective of the Protocol and the CBD.

[467] See more VOGEL.H. J et al., *'The Economics of Information, Studiously Ignored in the Nagoya Protocol on Access to Genetic Resources and Benefit-sharing'*, 7/1 Law, Environment and Development Journal, 2011

[468] See more BAVIKATEE.K, ROBINSON.F.D, *Towards a Peoples' History of the Law: Biocultural Jurisprudence and the Nagoya Protocol on Access and Benefit-sharing*, Law, Environment and Development Journal, 2011

[469] KAMAU.E.C, FEDDER.B, WINTER.G, *The Nagoya Protocol on access to genetic resources and benefit-sharing: What is new and what are the implication for provider and user countries and the scientific community?* Law, Environment and Development Journal, Volume 6/3, 2010

[470] See more CHIAROLLA.C, *Biopiracy and the Role of Private International Law under the Nagoya Protocol*, working paper, N°02/12 February 2012, BIODIVERSITY, IDDRI,

Conclusion of Part 1

"No law can exercise an unreasonable way, because unreasonable way is not the law".[471] No one can predict when the Nagoya Protocol will have fiftieth ratification of the CBD's Parties to come into force, and officially become a part of international law to be exercised. However, deriving from actual needs of the fact of biodiversity conservation governance, experiencing the long history of strained negotiation, with "much hard working time, resources, containing hope and high expectation", Protocol has been started its own reasonable way as analysis in Chapter 1, Title 1. Reasonableness exists both internally and externally. Externally, the Nagoya Protocol has been impacted by interrelationship with other related international treaties in environmental, social, intellectual property right and commercial sectors. It was found a reasonable way to be elaborated in a harmonization of effectiveness and validity of those treaties within international law system. This external aspect is analysed by Chapter 2 of this Part 1. Internally, the Nagoya Protocol was developed basing on the reasonable background of science, technology and intellectually rights. The analysis of Chapter 1, Title 2 clarifies that GR's utilization can not be separated from science and technology and the substantive development of the Protocol also affected by the development of science and technology. This is also the bases for legal analysis of Chapter 2 of Title 2. There are many arguments of the balance of legal obligations between user Party and provider Party. All reasonableness of the Nagoya Protocol should be considered comprehensively and prudentially when States decide to ratify or adhere to the Protocol and integrate it into national law for implementation.

Being recognized as "a product of all knowledge and wisdom" and resultful negotiation, the Protocol is mentioned by some major achievements. These are: the binding nature, a clear definition of 'utilisation of GR', obligations to ensure legal certainty for access, facilitation of noncommercial research, obligations to ensure compliance measures on increasing capacity and awareness, additional obligations on technology transfer, the establishment of an Access to GR and Benefit-sharing Clearing House, and encouragement of multilateral approaches in transboundary situations. Nevertheless, there still exists "some misgivings about the agreement that had just been reached" [472] with inarguable drawbacks such as temporal scope of regulation, no self-standing obligation of user states to ensure benefit-sharing, disclosure TK, unclear points in measures to support compliance. Therefore, in some aspects, the Nagoya Protocol was not resulted as expected.

"Fair and equitable benefit-sharing" actually is a struggling objective that can not reach in a short time. Moreover, it seems to be impossible that all problems related to

[471] PERELMAN. C, *Les notions à contenu variable en droit. Essai de synthèse. Le reasonable et le déreasonable en droit. Au de là du positivism jurisdique*, Paris, L.G.D.J, vol 29, 1984, cited by NAIM-GESBERT.E, *Supra*, p. 418
[472] ICTSD, *Supra*,

access and benefit-sharing could be addressed by the Nagoya Protocol in one hit. There are more works needed to continue to pursue. The first meeting of the intergovernmental Committee of the Nagoya Protocol also had the suggestion "Further review and develop the elements and options for compliance procedures and mechanisms on the basis of the foregoing analysis". The effectiveness of provisions on compliance with MAT shall be reviewed by the COP-MOP.[473] It is also necessary to consider to development of model contractual clauses[474], codes of conducts, guidelines and best practices and/or standards[475] that will play a crucial role for the successful implementation of the Protocol. Awareness raising[476] and capacity building[477] are elaborated comprehensively, especially, technology transfer, collaboration and cooperation[478] are very important measures, those need to be considered and followed up seriously. Each country that becomes a Party to the Nagoya Protocol will need to develop national legislation on access and benefit-sharing to meet its obligations under the Protocol, filling in gaps with national legislation in accordance with its particular situation. "Once access and benefit-sharing is implemented as intended by the Protocol, fair and equitable sharing will become a significant motive for biodiversity conservation, as well as contributing to poverty reduction and improving livelihoods of local communities."[479]

[473] Article 18.4 of the Nagoya Protocol
[474] Article 19 of the Nagoya Protocol
[475] Article 20 of the Nagoya Protocol, EU published a range best practice on ABS in the EU, it includes: 1) ABS measures by European Botanic Gardens (Principles on access to genetic resources and benefit-sharing for participating institution; The Code of Conduct and Access and Benefit-Sharing System for Botanic Gardens; PlantNet conservation policy); 2) ABS measures by European culture collections; 3) ABS measures by European germplasm banks; 4) The Novo Nordisk/Novozymes ABS policy; 5) GlaxoSmithKline public policy position on the CBD (approved February 2002); 6) ABS agreements for non-commercial research (The Millennium Seed Bank at the Royal Botanic Gardens, Kew, UK enters into full ABS Agreements); 7) Collaborative research and benefit-sharing by the Royal Botanic Gardens, Kew; 8) GlaxoSmithKline and Extracta Laboratories, Brazil; 9) Use of San traditional knowledge in the commercialisation of *Hoodia; 10)* Benefit-sharing by the International Locust Control Programme, *Lutte Biologique contre les Locustes et les Sauteriaux* (LUBILOSA)**.** See more EUROPEAN COMISSION, *Nature and biodiversity cases, ruling of the European court of justice*, Office for official Publications of European communities, Luxembourg, 2006, p.30 – p.47; available at *http://ec.europa.eu/environment/nature/info/pubs/docs/others/ecj_rulings_en.pdf***,** last accessed May 16, 2012
[476] Article 21 of the Nagoya Protocol
[477] Article 22 of the Nagoya Protocol
[478] Article 23 of the Nagoya Protocol
[479] SUNEETHA.M.S, PISUPATI.B, *Learning from the Practitioners: Benefit-sharing Perspectives from Enterprising Communities*, UNEP - UNU-IAS, 2009, p. 6, Available online: *http://www.ias.unu.edu/resource_centre/UNU-UNEP_Learning_from_practitioners.pdf*. Accessed 17 December 2011.

PART 2 – INTEGRATION OF THE NAGOYA PROTOCOL INTO NATIONAL LAW - THE CASE OF VIETNAM

Part 1 of this thesis proves that the Nagoya Protocol contains some characteristics of generalities, vagueness, flexibility, non-self executing obligations under form of a legally-binding agreement. In other words, the Protocol is only a starting point and the remains depend on the domestic implementation with 'domestic legislation'. It is recognized that **"**the adoption of the Protocol, whatever its shortcomings, can be welcomed - so long as policy-makers (and those who hold them accountable) bear in mind that much depends on the eventual domestic implementation, future review processes and in some cases other negotiating fora."[480] "A Party needs to assess whether its interest is best served by being a Party to the Protocol. An assessment needs to be made whether the benefits outweigh the burdens imposed by the Protocol or vice versa."[481] All of these clearly effect to integration of the Nagoya Protocol into national law.

Moreover, international law only determines responsibilities of the countries to fulfill in good faith the legal obligations in accordance with the international treaties following the principle of *Pacta Sunt Servanda* that codified by Article 26 of the Vienna Convention on The Law of International Treaties, 1969 and recognized by the Charter of United Nation, 24 October 1945.[482] However, it does not define process and methods to apply the international treaties. "The State decides the principle to open to the international law can apply directly in their territory.[483]

Basically, there are two main points of view of application of international treaties within national law system: Monism and Dualism. Both points of view have been criticized by their problems impacted on the process which international treaties become part of the national law of a sovereign state. However, distinction between the two points of views and their controversy seems to exist in theory research only. In fact, in many countries are in "points d'accord entre les deux theories".[484] Moreover, Dupuy indicates "pontaux-ânes" of problem of analysis and exegesis in long time to oppose the doctrine into two camps with irreducible opposition for defending dualism or taking advantage of monism.[485] This seems to be true with the current situation of non-self executing of most MEAs. Despite of monist or dualist view, they require activities of States to adopt national legislation to fulfill national obligations. And improvement of national implementation of the treaties becomes more important than defining which point of views for application of international law. Each State has different conditions of economy, society, politics and international diplomacy that impact on process by which international law becomes part of

[480] ICTSD, *Supra*,
[481] NIJAR.G.S, *Supra,* p. 32
[482] Available at http://untreaty.un.org/ilc/texts/instruments/english/conventions/1_1_1969.pdf, last accessed 11th April 2012
[483] DUPUY.P.M, KERBRAT.Y, *Droit international Public*, 10 e Edition, Dalloz, p. 447 – p. 506
[484] DUPUY.P.M, KERBRAT.Y, *Ibid*, p. 447 – p. 506
[485] DUPUY.P.M, KERBRAT.Y, *Ibid*, p. 447 – p. 506

national law and its implementation. Each State finds the suitable way to fulfill their obligation complying with international treaty

This part of the thesis, therefore, comprises of two titles. Title 1 – The legal issues, analyzes vagueness of international law within two main doctrines of monist and dualist, problems of non-self executing treaties that impacts on the integration of the Nagoya Protocol into national law. Title 2 – Access to GR and benefit-sharing in national laws of selected countries and the case of Vietnam, analyzes laws on access to GR and benefit-sharing and/or related issues of some selected countries to prove findings of analysis the Title 1 in specific national contexts and solutions to address the problems. This Title also pays more attention to analze in more detail the practice of legislation of Vietnam on access to GR and benefit-sharing..

TITLE 1 - THE LEGAL ISSUES

When saying about incorporation or transformation of a treaty into national law that means we say about the relation between international law and national law in one way by which international norms become part of national law or national law receives international norms into its legal system for compliance and implementation.[486] This relation firstly impacted by the weakness of international law itself with problems of treaty in contrast with non-treaty (or non legally binding or so-called 'soft law'). This is also featured by two traditional doctrines of monist and dualist with their long debates over centuries. Also, this is affected by problems of non-self executing treaty. This relation would consider principles of law, methods and modes/ways of incorporation or transformation. This Title analyzes these mentioned legal factors impact directly on the integration of the Protocol into national law.

It is noted that many research works and précis on international law usually mention to 'application of the international law in national law'[487] that provide analysis of full process from the time States ratify/adopt/adhere treaties and/or incorporation/ transformation, then compliance, implementation and enforcement in national practice. However, in the case of the Nagoya Protocol, there still has no practice of implementation of this treaty as it is still a new approved Protocol and has not come into force. Therefore, this Title of the thesis only aims at analysis of the process by which international law becomes part of national law or the integration of Nagoya Protocol into national law in particular.

Accordingly, Chapter 1 analyzes legal points of views on the integration of international law into national law. Chapter 2 analyzes principles, methods and ways of the integration of the Nagoya Protocol into national law.

[486] It excludes to mention about the other direction of the relation that national law impacts and transform into international laws

[487] See DUPUY, P. M., *Droit international public*, 9e édition, Dalloz Sirey, Paris, 2008 ; DUPUY.P.M, KERBRAT.Y, Droit international Public, 10 e Edition, Dalloz, 2010 ; DAILLIER.P, PELLET.A, *Droit international public*, 7e Edition, NGUYEN Quoc Dinh, LGDT, 2002, p 217-292 ; COMBACAU.J, SUR.S *Droit international public*, 5e Edition, Monthrestien E.JA, Paris, 2001, p 177 – 178, BERNSTORFF.V.J. *The Public International Law Theory of Hans Kelsen, Believing in Universal Law*, Cambridge Studies in International and comparative law, Cambridge University Press, 2010 ; BEURIER.J-P, *Droit International de L'environnement*, 4e edition, Alexandre Kiss, Editions A. Pedone, Paris, 2010

CHAPTER 1 - Legal points of views on the integration of international law into national law

The relationship between the international law and national law becomes core of many arguments and controversies. It includes status of international law, its hierarchy with influences of two main doctrines: monist and dualist.

In general, some common points may be introduced that "international law both influences and has independent status in domestic legal systems, and (conversely) domestic law affects international law".[488] "International law leaves certain questions to be decided by national law".[489] However, the general rule of international law is that a state can not plead a rule of or a gap in its own national law as a defense to a claim based on international law as provided by Article 27 of the Vienna Convention "A party may not invoke the provisions of its internal law as justification for its failure to perform a treaty." "States are required to perform their international obligations in good faith, but they are at liberty to decide on the modalities of such performance within their domestic legal systems. Similarly, there is a general duty for states to bring national law into conformity with obligations under international law. But international law leaves the method of achieving this result (described in the literature by varying concepts of 'incorporation', 'adoption', 'transformation' or 'reception') to the domestic jurisdiction of states. They are free to decide how best to translate their international obligations into national law and to determine which legal status these have domestically. On this issue, in practice there is a lack of uniformity in the different national legal systems"[490].

There are also many question of the relationship between international law and national law can give rise to many practical problems, especially if there is a conflict between the two; "which rule prevails in the case of conflict"? "How do rules of international law take effect in the internal law of states"?[491] This question of hierarchy or question of subordination theory between international law and national law normally alleged to explanation of monist and dualist. However, it raises the problems of insufficiencies of monist and dualist in relationship between international law and national law. It always opens itself a gap separated between theory and application: the superiority theory of international law and inferiority practice of national law.[492] As noting in the general introduction of the thesis, this chapter does not pursue controversing, defending two doctrines. However, this chapter analyzes the weakness of the international law and

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[488] KISS.A.C quoted by GUYVARC'H. A, *Les aspects juridiques de la protection de la biodiversité*, Université de Nantes, 1998, p. 394

[489] 'Municipal law' is the technical name given by international lawyers to the national or internal law of a state, explained by MALANCZUK. P, *Supra*, note 65, p. 64. Therefore, in the thesis, when a quote mentions to 'municipal law' 'national law' 'internal law' 'domestic law' that are understood as the same word, the same meaning with 'national law',

[490] MALANCZUK. P, *Supra*, p. 64

[491] MALANCZUK. P, *Ibid*,p. 64

[492] PAPAUX.A et WYLER.E, *Supra*, p. 123

problems of two doctrines that impacted on the integration of the Nagoya protocol into national law. This chapter also focuses on the problems of non-self executing treaties as the common problems of many MEAs and the Nagoya Protocol. After that, this chapter analyzes principles and methods that can be available for application during the process by which the Nagoya Protocol becomes part of national law

Section 1 – Weakness of international law and two main points of view impact on the integration

The thesis is implicitly agreed that there are roles, importance and strong points of international law but they are not objective of analysis of this research. The thesis, through this section, focuses only on analyzing certain recognized weakness of international law that impacts on the integration of the Nagoya Protocol into national law. It also analyzes weakness of two main points of view: monist and dualist in relationship between international law and national law.

§ I – Weakness of international law

A – Analysis of intrinsic weakness of international law

1) Institutions, jurisdiction and subjects matters in international law

International law can be argued that "it is not 'real law",[493] or whether international law is true 'law'[494]. Although, the discussion may be only a moot point, the following reasons, which derive from nature and characteristics of international law, may expose weakness of international law.[495]

Firstly, "international law is predominantly made and implemented by states".[496] This is supported by recognition that "the free will of the State is as the formal ground of all law".[497] Only the State–which established law as the 'sovereign will of all' was a candidate for a law-creating organ. Thus, "the very reality of international law is sometimes open to challenge on the grounds that there can be no hierarchy of governing sovereign states or because states obey 'law' only when it is in their interest to do, so clearly some definitions of law would exclude international law."[498]

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[493] SLOMANSON.R.W, *Fundamental Perspectives on international law*, 6th editions, Wadsworth Cengage learning, 2010, p. 13

[494] MALANCZUK. P, *Supra*, p. 5

[495] MALANCZUK.P, *Ibid*, supposed the old discussion is a moot point. Because, the general concept of 'law' itself and its relative status in society is subject to quite divergent views throughout the world, as has been shown by the modern discipline of comparative legal studies. It is based on different ideas, methods and traditions, as a consequence of historical and cultural diversity. For him, the real question is which interests does international law now serve in a much more expanded, diverse, but increasingly interdependent world, and the answer requires a closer look at various branches of the 'law in action' in international relations.

[496] MALANCZUK. P, *Supra*, p. 63

[497] BERNSTORFF.V.J. *The Public International Law Theory of Hans Kelsen, Believing in Universal Law*, Cambridge Studies in International and comparative law, Cambridge University Press, 2010, p. 28

[498] SLOMANSON.R.W, *Supra*, p. 13

Secondly, as regards international law as 'law', the arguments of the critics centered "upon the absence of a legislature and, more recently, upon the topic of sanctions and compliance without recognizing the historical, structural and functional differences between legal systems within states and the international legal system". "A horizontal system of law operates in a different manner from a centralized one and is based on principles of reciprocity and consensus rather than on command, obedience and enforcement. A system of law designed primarily for the external relations of states does not work like any internal legal system of a state."[499] "Thus, international law is a horizontal legal system, lacking a supreme authority, the centralization of the use of force, and a differentiation of the three basic functions of law-making, law determination, and law enforcement typically entrusted to central organs. The United Nations General Assembly is not a world legislature, the International Court of Justice in The Hague can operate only on the basis of the consent of states to its jurisdiction, and the law-enforcement capacity of the United Nations Security Council is both legally and politically limited." It is also true that international law, "due to the lack of central institutions, is heavily dependent on national legal systems".[500]

Thirdly, in comparison, "domestic law is addressed to a large number of governmental bodies and private individuals and groups of individuals". International law "is primarily concerned with the legal regulation of the international intercourse of states which are organized as territorial entities, are limited in number and consider themselves, in spite of the obvious factual differences in reality, in formal terms as 'sovereign' and 'equal'".[501] Moreover, "unlike domestic legal systems, international law lack a constitution and has no central authority that can determine the common concern of the international community or adopt a general international legal code that would be mandatory for all the states.[502]

2) Compliance and enforcement

The enforcement of international law is different with national law and always becomes a big question. Especially, it is stated that 'the law without enforcement is nothing'.[503]

Perhaps no greater problem bedevils international law than the problem of enforcement or ensuring compliance with its norms. The fact that international law is often not integrated into national legal systems poses a strong challenge to its effectiveness. National enforcement is an essential means of increasing respect for and effectiveness of international law. With the increased acceptance of international law by national courts, and the direct application of international law within national legal systems, private

[499] MALANCZUK. P, *Supra*, p. 6
[500] MALANCZUK. P, *Ibid*, p. 4
[501] MALANCZUK. P, *Ibid*, p. 5
[502] KISS.A, SHELTON.D, ISHIBASHI. K, *Economic globalization and compliance with international environmental agreement*, International environmental Law and Policy Series, Kluwer Law International, 2003, p. 6
[503] PAPAUX. A, WYLER. E, *Supra*, p. 101

individuals may be able to make claims founded on it. This will enhance the effectiveness of international law. The extension of the doctrine of legitimate expectation by the courts to unincorporated treaties may afford substantive rights to individuals in litigation before national courts. By constitutionally making international law a part of domestic law, international law becomes a relevant consideration in decision-making. International law is clearly weaker than national law from the viewpoint of independent enforcement,[504]

In addition, "it must be admitted that sanctions work less effectively in international law than in national law. States are few in number and unequal in strength, and there are always one or two states which are so strong that other states are usually too weak or too timid or too disunited to impose sanctions against them. But this does not mean that international law as a whole works less effectively than national law - only that it works in a different way. In international law there is considered to be collective responsibility of the whole community of a state which has committed an internationally wrongful act". "Nevertheless, a state which violates an international obligation is responsible for the wrongful act towards the injured state, or, under certain circumstances, to the international community as a whole. The injured state can raise an international claim which it may pursue on the basis of special remedies, if available, or by resorting to third-party mediation or conciliation, arbitration or judicial proceedings". However, in the end, "the role of self-help by states in cases of a violation of their rights is predominant in international law, as compared with there strict admissibility of self-help of individuals in national legal systems. If one state commits an illegal act against another state, and refuses to make reparation or to appear before an international tribunal, there is (or was until recently) only one sanction available to the injured state: self-help".[505]

B – Problems in procedure of international law making

Issues of representation and accountability appear not to have been wholly accounted for arrangements and for receiving international law. These raise questions of a potential and actual democratic deficit at two levels

1) Democratic deficit in treaty making at international level

One scholar stated that "international law-making processes are not democratic...the democratic deficit that characterizes the international legal system".[506] One may query the propriety of entrusting 'national law making powers' to international institutions that are not directly accountable to the people who are often affected by the decisions. For example, "treaty making often takes place behind close doors with little outside input". As Daintith puts it "international law is formed in an inherently non-democratic way…by

[504] MALANCZUK. P, *Supra*, p. 63
[505] MALANCZUK. P, *Ibid*, p. 5
[506] SCHRIJVER.N, WEISS.F, *International law and sustainable development, Principles and Practice*, Martinus Nijhoff Publisher, Leiden/Boston, 2004, p. 12

conclaves of treaty negotiators collectively responsible to no representative body." [507] This seems to be true with situation of making the Nagoya protocol that "everybody else present condemned the undisclosed process leading to the text as nontransparent and non-inclusive… 'The way this was done is unacceptable. We did not know all this was going on behind our backs".[508]

Despite of insisting on non general public participation in treaty making power, more and more NGO participation in the spirit of Almaty Declaration (by Aarhus COP), but only for NGO specially accredited for existing treaties. For new treaties, it would be only initiative of U.N Economic and Social Council with the NGOs having consultative status following for consultative status following Article 71 of Chapter 10 of the United Nations Charter.[509]

International law leaves the procedures by which a treaty is negotiated to the will of the State Parties. States are still principle actors in treaty making; this is illustrated by their central role in the negotiation and ratification of treaties. In so far as the State performs this preponderant role in treaty making, individuals might not feel adequately represented by the decision taken. "Democracy is a concept that entails the idea that all citizens have a right to participate in the decision-making process that leads to the adoption of policies that are applicable in their society. It also involves the idea that there are some limits on majority decision making. The fact that treaty making lies essentially on the executive branches of the government, that predominant role of the executive in the international arena makes the whole process of treaty making less transparent to the public, with the immediate consequence that decision may be taken without open discussion, disregarding the views of the various sectors of society."[510] "There is typically little or no opportunity for parliamentary or public input at international level. Once the terms of a treaty are agreed upon, international law does require the treaty text to be adopted, authenticated as correct and final (usually by signature or initials), and then made available to be accepted as binding by the parties (although there is no prescribed procedure by which to accomplish these three tasks)."[511] All the problems are exacerbated if international rules are ascribed supremacy and direct effect within national legal system.

Another aspect of the international legal system that contributes to this democratic deficit is the principle of sovereign equality of States. Although very often this principle is

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[507] DAINTITH.T, *Is International Law the Enemy of National Democracy?* in THOMAS.A.J.A VANDAMME, REESTMAN.J-H, *Ambiguity in the Rule of Law: The Interface Between National and International Legal Systems:* Proceedings of the Annual Colloquium of the G.K. Van Hogendorp Centre for European Constitutional Studies, 2001, p. 115

[508] NIJAR.G.S, *Supra,* p. 4

[509] Currently there are 3382 NGOs in consultative status with the Economic and Social Council, and some 400 NGOs accredited to the Commission on Sustainable Development (CSD), following ***http://en.wikipedia.org/wiki/Consultative_Status***, ***http://esa.un.org/coordination/ngo/new/index.asp?page=intro***, last accessed 1 August 2012

[510] SCHRIJVER.N, WEISS.F, *Supra,* p. 13

[511] HARRINGTON. J., *Democratic deficit in treaty law making,* McGill Law journal/Revue de droit de McGill, vol.50, 2005, available at *http://lawjournal.mcgill.ca/documents/1225244248_Harrington.pdf*, last accessed 16th April 2012, p. 471

waived, "the general idea is that each State is legally equal to others, despite, sometimes obvious, differences in territorial extension, number of population, military capacity, diplomatic power and so forth. It is not clear that a system, in which each state has one vote, may be described as really democratic. If democracy is understood as the citizen's right to political participation, one has to concede that the voting system of General Assembly of the UN does not promote the idea."[512]

Another factor that contributes to the democratic deficit in international law is that "sovereign equality in treaty making is not immune to economic and political differences between States. It is evident that in particular fields of international law, industrialized countries have more decision making power than developing countries. Differences in powers have also an impact on international law making, after all 'the capacity to determine the international agenda has rightly been identified as a particularly effective form of power".[513]

Paragraph 76 of the Resolution A/RES/66/288 of the General Assembly of United Nations (Draft A/66/L.56 dated 24 July 2012), "The future we want" has made a small progress for democracy for international fora. It has contributed to the international treaty making a progress with statement: "Enhance the participation and effective engagement of civil society and other relevant stakeholders in the relevant international forums and in this regard promote transparency and broad public participation and partnerships to implement sustainable development"[514]

2) Democratic deficit at national level

The problem always is who gets represented and by whom. "Various interests groups such as women, investors and traders are all significantly affected by international law. Ensuring a voice for them in the creation of international law represents a formidable challenge. The fact that these interests are often not represented, coupled with the increasing application of international law in the national legal system. Mechanisms, such as question times in parliament, and the use of the parliamentary committee system, would be put in place to ensure legislative involvement in the processes leading to the conclusion of international agreements."[515]

Although, there is some form of democratic participation in the process of introducing treaties into domestic law,[516] the problem may be found in Commonwealth

[512] SCHRIJVER.N, WEISS.F, *Supra*, p. 14
[513] SCHRIJVER.N, WEISS.F , *Ibid*
[514] http://daccess-dds-ny.un.org/doc/UNDOC/GEN/N12/436/88/PDF/N1243688.pdf?OpenElement, last accessed Augus 1, 2012
[515] RIESENFELD.S.A, ABBOTT.F.M, *Parliamentary participation in the making and operation of treaties*, University of Michigan, 1995, p. 67
[516] SHELTON.D, *International law and domestic legal systems, Incorporation, transformation and persuasion,* Oxford University press, 2011, p. 8, stated that "legislative approval has increasingly become a precondition for the internal effect of treaties…In most states, the head of state or government concludes treaties that then must be approved by all or part of the legislature prior to ratification. Practice differs about whether it is sufficient for one part

states, where the decision to make a treaty clearly rests at common law with the executive branch of the government that represents the state abroad. "The common law imposes no legal obligation on the executive to secure the consent or approval of Parliament prior to treaty ratification, despite the fact that Parliament is the ultimate law-making authority in a Westminster-style democracy. There is a lack of a legal requirement for consultation of parliamentary approval for treaty actions prior to ratification supports complaints that a 'democratic deficit' exists in the treaty-making process given the executive's ability to engage the nation in legal commitments without involving the institution responsible for making law." "Deficit can be found in federal Commonwealth states, where there is also no legal requirement for the executive branch of the central government to involve the elected regional assemblies, or their executive bodies, in the treaty-making process."[517] "With respect to the scrutiny of treaties given the other matters competing…as for the passage of enabling legislation prior to ratification, there are "rare occasions" when this is not done".[518] It is stated that "Conventional international law has increased in domestic importance to the point where leaving it solely in the hands of the executive creates - it is said - a 'democratic deficit'."[519]

All above weakness of international law impact on integration of the Nagoya Protocol into national law. Although, such integration also is various from countries to countries, it is described traditionally by two main points of views in international law.

§ II – Two main points of view in international law

A – General understanding on dualist and monist view

1) Monist view

Monist view assumes that national and international legal system forms a unity. Both national legal rules and international rules are accepted by the state, the legislature or part of the legislature, participates in the process of ratification, so that ratification becomes a legislative act, therefore, international law does not need to be incorporated into national law. The act of ratifying the international law immediately incorporates it into national law. Provisions of international law are parts of national law and take direct effect of implementation in the countries' territory. A national rule can be declared as invalid if it contradicts international rules. The countries with the monist view are predominant such as Germany, Holland, France, United States, Russia…

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of legislature to approve or whether in state with bicameral legislature, both bodies must consent. …Some constitutions provide for pre-ratification judicial review of the conformity to the constitution of a proposed treaty.

[517] HARRINGTON. J., *Supra*, p. 471

[518] HARRINGTON. J., *Ibid*, p. 479

[519] MONKS.S.S, "*In Defence of the Use of Public International Law by Australian Courts*" Australian Year Book of International Law , AUYrBkIntLaw 6; (201) 2002, available at http://corrigan.austlii.edu.au/au/journals/AUYrBkIntLaw/2002/6.html, last accessed 17 April 17, 2012

The most radical version of the monist approach was formulated by Kelsen. In his view, "the ultimate source of the validity of all law derived from a basic rule ('Grundnorm') of international law. Kelsen's theory led to the conclusion that all rules of international law were supreme over municipal law, that a municipal law inconsistent with international law was automatically null and void and that rules of international law were directly applicable in the domestic sphere of states."[520]

Kelsel argued a norm of international law determined by the spatial and temporal sphere of validity of State's order, but also the material validity of State's legal orders was delimited by international law. With regard to the temporal, territorial and material validity of its norms, a national law was thus merely a 'sub-order' that was subordinated to international law.[521]

Kelsen's theory derives its origin from the law of nature which binds equally the States and individuals. Thus, "they are intrinsically the same and form part of that science of law which binds all human beings alike. Accordingly, both national law and international law ultimately regulate the conduct of individuals immediately or mediately, though in the sphere of international law, the consequences of such conduct are attributed to the State. In other words, this theory regards law as a single unified of knowledge consisting of rules, whether binding on States, individuals or on entities other than States and the decisive point is whether or not international law is true law. One it is accepted as true law then there is no intrinsic difference between the two."[522]

According to Kelsen, "the individual could be authorized or obligated either indirectly or directly by the norms of universal law. Universal law is a dynamic system of integration".[523] Other supporters of this theory are Lautepacht Fizmaurice and Starke. According to them, "since the behavior of States is reducible to the behavior of individuals representing the State, the alleged difference in subject matter between the two systems can not be considered a difference. Consequently, there is no dichotomy between international law and national law and they operate without any conflict in their assigned spheres of action. Therefore, the question of superiority or primacy of one system over the other does not arise."[524]

However, Kelsel maintains that in accordance with his hierarchical, "each rule is conditioned by a superior rule for it validity and thus in turn, it devices validity form the fundamental postulate, the *grundnorm* which might belong either to international law or State law". Without taking his thesis to its logical conclusion, he has ascribed primacy to State law because the choice between system could not be made in a strictly scientific way.

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[520] MALANCZUK. P, *Supra*, p. 63
[521] BERNSTORFF.V.J, *Supra*, p. 94
[522] VERMA.S.K, "*An Introduction to Public International Law*", Eastern Economy Edition**,** PHI Learning, 2004 p. 49
[523] BERNSTORFF.V.J. *Supra*, p. 39
[524] VERMA.S.K, *Supra*, p. 49

[525] According primacy to State law has its own set of problems. "It would be tantamount to according primacy to legal system of almost all the independent nations of the world with its attendant confusion and anarchy. This proposition also fails in the final analysis on other grounds as well". *First*, "if it is accepted that the international law derives its validity from the State law it would necessarily mean that the disappearance of State law the rule of international law should also disappear. But the State practice has invariably established that international law operates independent of internal changes or revolution in a State or repeal or abolition of its constitution. On the contrary, international law exerts a definite check upon national law and holds the state responsible internationally for its delinquent behavior towards other State". *Second*, "when a new state is admitted to the family of nations, the international law binds it without it consent. Furthermore, the State practice has established the duty of each State to adopt not only its laws but also its constitution in accordance with international law and most of the State has reiterated this position in their constitution by accepting the supremacy of international law". According to Starke, "primacy lies with international law, in his view, the state sovereignty the basis logic for according primacy to State law, represent no more than the competence, however wide which States enjoy within the limits of international law… the analogy of model of federal countries".[526]

However, "monist" systems do differ in their approach. Under some Constitutions direct incorporation of international obligations into national law occur on ratification. In other States direct incorporation occurs only for self-executing treaties.[527]

2) Dualist view

Dualist view recognizes the distinction between national and international law. Legal norms of international law cannot be applied directly in national law. To be applicable in national legal order, international law must be transformed into national law. Only through transformation, legal norms of international law are applied as national law and then individuals within the state may benefit from or rely on the international law. The transformation of international agreement is procedure stipulated by national legislation with purpose of fulfilment of international agreement in the signatory countries.

If it assumes that international law and national law are two separate legal systems which exist independently of each other. The central question is which system will be prevailed in case of conflict or which system is superior to the other. To the dualist, international law could not claim supremacy within the domestic legal system. Thus, in case national law is contrary to international law, it remains in force. But, a State accepts international law but does not adapt its national law in order to conform to the international law or does not create a national law explicitly integrating into the national law;

[525] VERMA.S.K, *Ibid*, p. 49
[526] VERMA.S.K, *Ibid*, p. 49
[527] http://www.peaceandjusticeinitiative.org/implementation-resources/dualist-and-monist, last accessed April 17, 2012

consequently, it violates international law. The international law requires contradict national law must be modified or eliminated in order to conformity. The countries with the dualist view are predominant, are the UK and Commonwealth countries.

The theory of dualism grew out of 19th century positivist philosophy which emphasized on the « will » of the state as the sole criterion for the creation of rules of international law. According to this doctrine, the difference between international law and national law is fundamental, the former bases on the common will of States and operating between States solely and the later bases on the will of the state itself and binds the individuals within its jurisdiction. The chief exponents of this theory are Triepel and Anzilotti.

Triepel, among Germany's most renowned scholars of international law until the 1930s, likewise sought to construct the law of nations as an objective legal order without having to give up the subjective principle. According to Triepel, "state law and international law must be traceable to different sources because of their invariably different object of regulation."[528] "International law is made of mainly customary and treaty rules and the national law consists for the most part legislative enactment and judge made law. The difference between international law and national law lies in their subject matter and juridical origin. Whereas subject of international law are states exclusively, while those of national law are individuals, the sources of international law is the "common will' (Gemin wille) of the States and that of national law is "state will" will be of State itself. This consideration led him to posit the existence of a 'common will' of the states that was independent of the will of the individual state. This 'common will' did not arise from treaties of a contractual nature, which represented only the respective wills of the individual states, but only from 'agreements' that carried objective obligation."[529] Triepel concluded that "international law and state law were separate legal orders. This falls with the assumption that the objects of regulation in international law and national law are necessarily separate and distinct. International law regulated relations among states and national law regulated the life of individuals on the territory of the state." [530]

Anzilotti tried to explain "the differences between two systems in terms of the fundamental principles by which each system is conditioned. According to him, the fundamental principle of State law is that should be obeyed whereas the fundamental principle of international law is *pacta sunt servanda* agreements between states are to be observed in good faith. Thus both are entirely distinct systems though there may be certain cross references of each other".[531]

[528] BERNSTORFF.V.J. *Supra*, p. 39
[529] BERNSTORFF.V.J. *Ibid*
[530] BERNSTORFF.V.J. *Ibid*, p. 94
[531] VERMA.S.K, *Supra*, p. 49

B – Analysis of problems of two points of views to integration of the Nagoya protocol into national law

1) Controversy between two points of views

The controversy between 'monist' and 'dualist' view has lasted for many decades in term of the theoretical relationship between national and international law. Even though, this controversy "is more academic than real",[532] it is necessary and useful to overview theoretical background to assess reality.

A 'monist' debates versus Triepel's view that "doubt has been expressed against this approach of a 'common will' of the states. The subjects of modern international law are not only States but international organizations, individuals and other non-State entities are also bound by it. Further, to contribute to the will to State and to say that the 'common will' is the sources of international law is totally misleading and fails to provide answer as to under what circumstances an expression of the 'common will' can become decisive. Common will of the State is nothing but the will of the people who compose it. Further, there can be certain fundamental principles of international law and considerations which make the international law binding on the States against their will. It also fails to explain the existence of general international law which becomes binding upon States to contribute it with tacit agreement would be at variance with reality."[533]

There was also an argument against explanation of Anzilotti of the differences between two systems in terms of the fundamental principles *pacta sunt servanda*. "It can not be denied that *pacta sunt servanda* is an important postulate of international law but it is not a partial illustration of much wider principle lying on at the root of international law. It does not explain the binding forces of customary rules to which the States have not given their consent."[534] Moreover, "*pacta sunt servanda* constitute an axe which permits to give a body and coherence of the judicial system. If we take the point of starting with the objective of validity of the international law, it will appear like a judicial order of the national laws is subordinate and in this way we have an universal juridical system founded on primate of international law"[535].

In contrary, dualist states that "As a rule of thumb, it may be said that the ideological background to dualist doctrines is strongly coloured by an adherence to positivism and an emphasis on the theory of sovereignty, while monist schools are more inclined to follow natural law thinking and liberal ideas of a world society. It is also notable that the controversy was predominantly conducted among authors from civil law countries. Authors with a common law background tended to pay lesser attention to these

[532] VERMA.S.K, *Ibid*, p. 49
[533] BERNSTORFF.V.J. *Supra*, p. 94
[534] VERMA.S.K, *Supra*, p. 49
[535] H. KELSEN, « Théorie du droit international public », RCADI, 1953, III, t. 84, p. 191-192.

theoretical issues and preferred a more empirical approach seeking practical solutions in a given case."[536]

To support the emphasis on the theory of sovereignty, the others supposed that "to allow the rules of international law to operate directly in national law unjustifiably concedes that international law is superior to, and detracts from the authority of national law."[537] "This was something a sovereign State, with its legal system, could not countenance. Traditional understanding of sovereignty relates to the relationship between the international and national legal systems, represents a significant shift, even if in theory, on the part of countries that were once characterised as "reluctant to incorporate international law directly into their national constitutions and thereby make it an integral part of their municipal law."[538]

In addition, "the laws of different countries vary greatly in this respect. If one examines constitutional texts, especially those of developing countries which are usually keen on emphasizing their sovereignty, the finding is that most states do not give primacy to international law over their own national law."[539] "Constitutional texts can form a starting point for analysis. What also matters is national legislation, the attitude of the national courts and administrative practice, which is often ambiguous and inconsistent. The prevailing approach in practice appears to be dualist, regarding international law and national law as different systems requiring the incorporation of international rules on the national level. Thus, the effectiveness of international law generally depends on the criteria adopted by national legal systems."[540]

Some scholars argue that the dualism is a starting point for fundamental principle of sovereign equality of states. "It is for each state to organize its legal system and determine the process for giving its consent to be bound by norms of international. Treaties generally contain final clauses that specify for purposes of international law how a state's consent should be expressed, usually by ratification or accession, but the domestic process required to obtain ratification or accession is not set out, because that is a domestic legal matter for each state." There is similar division between international and national law once a state has become party to a treaty, it must comply with the obligations it has accepted. However, the treaty will often leave to the state the determination of how that compliance is to occur. Many treaty provisions set out only the result that must be achieved, sometimes adding 'by legislation if necessary'. Such provisions seem to support a dualist notion in respect to the

[536] MALANCZUK. P, *Supra*, p. 63
[537] MONKS.S.S, *Supra*, p. 201 – p. 222
[538] MALUWA.T, *International Law in post-colonial Africa*, Kluwer Law International, 1999, p. 52
MALUWA.T, *The incorporation of international law and its interpretational role in municipal legal systems in Africa; an exploratory survey*, South Africa Year Book International, vol 23, 1998, p. 57.
[539] MALANCZUK. P, *Supra*, p.64
[540] MALANCZUK. P, *Ibid*, p. 64

relationship between international and national law.[541] There is more argument that "international law did not need to establish its primacy in relation to national law, given the interdependent, rather than hierarchical, relationship between these integrated legal systems".[542]

2) Problems impact on the integration of the Protocol into national law

Contrary to the debate above, there are some opinions suppose that the controversy is unreal, contains problems. It did not reflect actual state practice, not produce a conclusive answer on the true relationship between international law and national law. In fact international law and national law "are not comparable since both have their own sphere of operation and neither can termed as subordinate to the other". "The supremacy of international law in the international sphere is unchallenged in the same way as of national law in the state matters. They are mutually independent and normally do not come into conflict with other…. International law simply does not purport to govern the contents of national law in national sphere." [543]

While academic discourse on the relationship between international law and national law continues, "it is rare to find a system that is entirely one or the other" [544] or even "no national legal system is entirely at one with the norms of international law, nor is any national legal system entirely insulated from the norms of international law". In actual practice, "most relationships between international law and national law occur at points between the polar extremes of monism and dualism, these points varying both across and within different national legal systems".[545] For example, one 'dualist' country may be 'monist' in point of treating customary international law as automatically incorporated into domestic laws, or one 'monist' country may be 'dualist' in point of jurisdictions requirement of the intervention of the legislature before a non-self- executing treaty can be transformed into domestic law. As Eisemann.P.M states that "the traditional monist/dualist dichotomy has limited value in the majority of the legal systems considered here. What is more important in most systems would seem to be the degree of integration into the domestic legal system that required by the treaty's obligation of the State…"[546]

The monist/dualist debate is also unsatisfactory in many respects. The debate focuses on the source or pedigree of norms, and ignores the substance of the norms. By creating a dichotomy between norms on the basis of their source, "we risk being blinded from assessing the merits of the contents of the norms at issue". Moreover, international

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[541] SHELTON.D, *Supra*, p. 3
[542] SLOMANSON.R.W, *Supra*,
[543] VERMA.S.K, *Supra*, p. 49
[544] SHELTON.D, *Supra*, p. 4
[545] ROSE.L.G, National and Global environmental laws: Dichotomy and interlinkages as examined through the implementation of multilateral environmental agreements, Paper for firs preparatory meeting of the World congress on justice, governance and law for environmental sustainability, UNEP, October 2011, Malaysia, p. 4
[546] EISEMANN.P.M, *L'intégration du droit international et communautaire dans l'ordre juridique national, etude de la pratique en Europe, The integration of international and European community law in to the national legal order*; A study of the practice in Europe, Kluwer law international, 1996, p.63

law has it subject, objective and condition of regulation is different with national law. International law has traditionally addressed different issues with national law. It concentrates on the relationship among States. National law concentrates on relationship among persons within its jurisdiction. Even though, there is now increasing interaction between national and international law, they share a lot in common, but the difference of its nature can not be changed.

However, putting the theoretical problems with the monist/dualist paradigm aside, it finds that the relationship between international law and national law is practically important for both systems and their subjects. "It determines the extent to which individuals can rely on international law for the vindication of their rights within the national legal system; this has implications for the effectiveness of international law, which generally lacks effective enforcement mechanisms. It is precisely because of the inadequate enforcement facilities that lie at the disposal of international law that one must consider the relationship with national law as more than of marginal importance."[547] "The relationship between the two systems may also determine the extent to which there is cross-fertilisation of norms generated in both systems. The extent to which international law can compel or induce reform in national law hinges on this relationship. The respect accorded a legal system is enhanced when it is able to influence normative developments in other legal systems". Moreover, "there are numerous possibilities encompasses both monism and dualism in theory and in practice. For example, "peremptory norms (*jus cogens*) is automatically binding, irrespective of a state's consent or domestic legal order-creating a sub- category of monist norms even for dualist system. These peremptory norms may exist along side other international norms that only become binding after they are adopted by the state according to its domestic constitutional processes, either through direct incorporation or through transformative legislation." "As logic of international law and national laws, the importance for the law of people is no doubt that it can not functionate without go up stream and go down stream from a national law."[548]

One practical question is: if there is a conflict between the two. Which rule prevails in the case of conflict? How do rules of international law take effect in the national law of states?[549] The answer usually is found in constitution of each country. The constitution provides the position of the treaties whether they are superior to national legislation or they are equivalent to national legislation. There are different situations that States grant treaties supremacy over legislation or not. "States with common law systems generally rank treaties as equivalent to national legislation meaning that the later in time prevails in case of conflict."[550] However, the answer is not easy to find in case of "a few constitutions

[547] SHAW.M.N, *International law*, Cambridge University Press, 2003, p. 161.
[548] PAPAUX. A, WYLER. E, *Supra*, p. 123
[549] MALANCZUK. P, *Supra*, p. 64
[550] SHELTON.D, *Supra*, p. 6

appear to leave the issue of hierarchy between treaties and national law unresolved, either failing to mention the topic or doing so in terms that are ambiguous about the place of international law in the domestic legal system. Some constitutions simply make reference to the principles and norms of international law or to international obligations."[551]

If the answer cannot be found, difficulty will arise in case of a national legislation issued after the date of the Nagoya Protocol takes effects has conflicts with the norms of the Protocol. The question of how to deal with this national legislation will remain. The worry of the question has a real potentiality that the Protocol is a non-self-executing treaty. Most provisions of the Protocol are open and refer to national legislation.

Section 2 – Problems of binding agreements non-self-executing treaties

In international environmental law, the term "MEAs"[552] becomes predominant source that includes legally binding agreements – treaties, which are regarded as 'hard law' and non-legally-binding which are regarded as 'soft law'. Treaty with different names but comparable legal effect includes conventions, protocols, agreements and legally binding exchanges of letters. However, "'soft law' instruments, such as memoranda of understanding, declarations, action plans and guidelines are not covered by the term 'treaties'".[553] There are many arguments on advantages and reasons why concluding legally binding agreements or non - legally binding agreements. In addition, many environmental treaties are non-self-executing. The questions arise: Which features of non-self-executing treaty are problems in respect of the Nagoya Protocol? What are differences between self-executing treaty and non-self executing treaty at the roots of problems and their impacts on integration of the Nagoya Protocol into national law? The analysis in this section aims at clarifying these questions and arguments.

§ I – General understanding of treaty: legally 'binding' agreement

As being analysed by Part 1, the Nagoya Protocol is characterized as a legally binding agreement. The question still remains in international law "what constitutes a legally binding agreement"[554]? There are some arguments of nature and characteristics of treaty as legally binding agreement. It may be useful to prove some certain particular features of 'a legally binding agreement' to understand why international community choose the form of treaty for international regime on access to GR and benefit-sharing and why the nature and characteristics of a legally-binding agreement of the Nagoya Protocol affects to integration in to national law.

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[551] SHELTON.D, *Ibid*, p. 6

[552] See more on UNEP website http://www.unep.org/DEC/OnlineManual/Compliance/PreparingforNegotiations/tabid/59/Default.aspx

[553] ROSE.L.G, *Supra*, p. 7

[554] FITZMAURICE. M, ELIAS.O, *Contemporary issues in the law of treaties*, Eleven International Publishing, 2005, p.3

A- Definition of treaty

1) Definition of treaty following the Vienna Convention on the Law of treaties

Article 2.1.a of the Vienna Convention defines: "Treaty" means an international agreement concluded between States in written form and governed by international law, whether embodied in a single instrument or in two or more related instruments and whatever its particular designation".[555]

It is impossible to consider treaties without reference to the Vienna Convention however, it must be said that the Vienna Convention is limited. The definition of treaty in Article 2.1.a lays down a number of positive formal rules as to what constitutes a treaty. "The Vienna Convention is essentially silent with respect to the substantive issue as to which "agreement" which meet the positive formal requirements as set out in the Vienna Convention are to be upheld by international law and which are not. It simply refers to an 'international agreement' but gives no further indication of what is meant by the expression."[556]

Given the wide variety of instruments used in modern international relations, the question is whether the formal definition of a treaty in the Vienna Convention is adequate or not?

Definition of a treaty is formed by two main terms "'international agreement'…and 'governed by international law'". This is one of the more problematic issues of the definition of the treaty in international law. "This term is meant to imply that in order to constitute a treaty, an agreement must be legally binding in international law and create legally binding rights and obligations: it is enough that it falls within the ambit of international law or that international law is applicable to it. In other words for an agreement to constitute a treaty, not only must international law (as to opposed to any other legal system) be applicable to it, but international law must also designate the agreement as one that is legally binding on the parties (as opposed to an agreement which is merely morally binding or merely political in nature)."[557]

2) Definition of treaty in different aspects

Firstly, in term of formality, a treaty is "an official, express written agreement that States use to legally bind themselves". "A treaty is that official document which expresses that agreement in words. It is also the objective outcome of a ceremonial occasion which acknowledges the parties and their defined relationships". In difference with customary international law, "treaties are principal means of international law-making, whose

[555] The Vienna Convention 1986 extends the definition of treaties to include international agreements involving international organizations as parties. There are no consistent rules when state practice employs the term 'treaty' as a title for an international instrument.
[556] FITZMAURICE. M, ELIAS.O, *Supra*, p. 7
[557] FITZMAURICE. M, ELIAS.O, *Ibid*, p. 8

characteristics offer several self-evident advantages over customary international law".[558] The first advantage of treaty is that "custom emerges only after a long, rather mysterious process". [559] "The process of treaty making is relatively quick. Probably because the whole process of negotiating a law-making treaty is directed exclusively towards the end of creating rules of international law, results come rather fast. Still, the drafting, negotiation and conclusion of a treaty may take several years or even a decade, if multilateral treaties dealing with complex and/or controversial issues are concerned…Even extreme cases like these, however, present a quite rapid process of law-making if compared to the usual pace of custom"[560]. The use of language treaties makes it possible to avoid too general and vague standards which seldom result from the process of custom. Treaty may provide a more precise regulation which is likely to be more effective that makes it suited for those new tasks which international law has been taken on as a result of its horizontal expansion and vertical penetration.[561] Therefore, "no wonder that today international law is mainly developed by bilateral or multilateral treaties". [562] "Most of new tasks of international relations are suitable to be regulated by treaty, although both treaty and customary international law are the sources of international law. For example, the search for the common concerns of mankind should be conducted primarily through an examination of provisions in treaties."[563] Those characteristics of treaties are appropriate for international regime on access to GR and benefit-sharing in form of the Protocol. The development of the Nagoya protocol is explained by analysis of the negotiation of the Protocol in Part 1of the thesis.

Secondly, in terms of international legal obligation: "treaties are one of the sources which give rise to international legal obligations."[564] "An international obligation may arise from provisions stipulated in a treaty that may be applicable to a State by reason of its unilateral act and so on."[565]

However, the nature of treaty obligation remains difficult problems in the law of treaties. "The notion that there is a clear and ordinary meaning of the word 'treaty' is a mirage". The problem has been the subject of much writing and has been considered by the International Court of Justice (ICJ) in a number of cases. It has been remarked that "although the definition of an international treaty seems at first sight to be a purely academic question, judicial experience shows that the determination of whether a certain instrument constitutes a treaty has important practical consequences. The lack of

[558] FITZMAURICE. M, ELIAS.O, *Ibid*, p. 2
[559] KISS.A, SHELTON.D, ISHIBASHI. K, Economic globalization and compliance with international environmental agreement, International environmental Law and Policy Series, Kluwer Law International, 2003, p.6
[560] G.J.H.VAN HOOF, *Supra*, p. 117
[561] G.J.H.VAN HOOF, *Ibid*, p. 118
[562] G.J.H.VAN HOOF, *Ibid*, p. 118
[563] KISS.A, SHELTON.D, ISHIBASHI., p.6
[564] FITZMAURICE. M, ELIAS.O, *Supra*, p. 4
[565] UN Doc.A/56/10. The Report of the International law commission, p 126, available at http://www.un.org/law/ilc/report.htm, last accessed 18 April 2012

differentiation as regards the legal origin of an international obligation is evident in cases of breach of that obligation". Article 16 Document A/CN.4/L.574 [and Corr.1 and 3] of International Law Commission states: "there is a breach of international obligation by a State when an act of that State is not in conformity with what is required of it by that obligation, regardless of its origin or character".[566] Thus, "treaties as a source of international obligations and of responsibility arising from a breach of such obligations are not distinct from other sources of international law. In absence of any specific provisions to the contrary breaches of treaty entail the general consequences that derive from the law of State responsibility".[567]

In the Nagoya Protocol, many obligations of a State are not clear that depends on discretion of the State. Furthermore, those obligations are not distinct from other obligations in other international agreements. Thus, there may have problems to define whether the State breaks the Protocol or it may be alleged to the other international agreements because all the obligation are treated in the same "regardless of its origin or character"

Moreover, there is absence of tools for analysis of the substantive nature of agreements. "International law makes very little use of analytical tools in effect basing the substantive distinction between international agreements that are binding and those that are not almost entirely on the 'intention' of the parties as a legacy of its volutarist origins"[568]. The problems of the Nagoya protocol is formally as 'binding' agreement, but in substantive distinction following analytical tools, it seems to be inclined to voluntary of the Parties.

B – The problems of legally binding agreement

Kiss.A and Shelton.D recognized that "non-binding international agreements sometimes are criticized as ineffective; compliance with such instrument may reach high rates".[569] However, they also gave reasons for the increasing use of non – legally binding instruments or the role of 'soft law' in international environmental law. This point can be used to clarify shortcomings of treaty as legally – binding agreements.

1) Legally binding in distinction with non-legally binding agreement

Distinction between legally binding and non-legally-binding agreements can be explained basing on some of their own characteristics, nature, features and even roots of reasons.

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[566] Document A/CN.4/L.574 [and Corr.1 and 3] – State responsibility extract from the yearbook of the International Law Commission, 1999, vol. I, available at http://untreaty.un.org/ilc/documentation/english/a_cn4_l574.pdf, last accessed July 31, 2012

[567] FITZMAURICE. M, ELIAS.O, *Supra,* p. 5

[568] UN Doc.A/56/10. The Report of the International law commission, p 126, available at http://www.un.org/law/ilc/report.htm, last accessed 18 April 2012

[569] KISS.A, SHELTON.D, *Guide to international environmental law,* Martinus Nijhoff Publisher, 2007, p. 11

In nature, as Van Hook proved that "law has binding character and indeed the words 'law' and 'binding' are most often considered being synonyms. 'Binding' has to be understood here as to mean that by law human behaviour is made non-optional in some sense. When they speak of law they mean binding rules. When they mean non-binding rules or at least legally non-binding rules they refer to them as political rules, rules of morality usage or some other kind of rules of conduct".[570]

'Legally binding' is explained as 'the intention to be bound' by 'a compulsory judicial dispute settlement clause" that contains in the treaty. "In the absence of such a clause, a document could also be considered legally binding if all its parties had accepted the compulsory jurisdiction of the international court in some other way without making too far reaching reservation or had voluntarily submitted themselves to any other form of compulsory judicial dispute settlement"[571]. Further, "anything not clearly legally binding must be deemed non-legally binding". In respect of 'intention to be bound', it has to be clearly shown and driven to conclude that any instrument does not meet this requirement simply does not rise to legal rights and obligations. "Agreements are only legally binding to the extent that their authors so intended, however, the binding force of other agreements does not depend on their authors' intentions but rather on the exigencies of world order. Agreements may be legally binding only if their authors so intend but are politically binding regardless of such intentions."[572]

Anyway, it is supposed that "to establish legally binding ties between its partners any such commitment must be based on a *Grundnorm*… The judicial binding nature of treaties reposes directly on the will of the sovereign states to be legally bound. It seems be impossible to conceive degrees in the will to be legally bound."[573]

"Non-legally binding" is explained by the absence of any international legislative body in international law. "Not binding at all" is an argument: "only agencies and department themselves become legally bound without the State becoming bound" because "the conclusion of administrative agreements may lead to only individual agencies being bound either as the result of the separate personality of those agencies, or as the result of the agencies possessing their own international legal order." [574]

However, there is the development of non-legally binding rules in new branches of international law, such as international environmental law for the emergence of multifaceted forms of cooperation. They procuded new forms of international instruments which are not intended to be legally binding at all but have a certain political or moral

[570] G.J.H.VAN HOOF, *Supra*, p. 20
[571] KLABBERS. J, *Supra*, p. 106
[572] KLABBERS.J, *Ibid*, p. 107,
[573] KLABBERS. J, LEFEBER. R, *Supra*, p. 8
[574] KLABBERS. J, *Supra*, p. 106

forces, those are so-called "soft law".[575] Kiss and Shelton defines "soft law: non-binding international instruments expressing emerging norms and political commitments; often the precursor to treaty negotiations."[576] "Soft law can enable States to take on commitments that otherwise they would not, because they are non-binding or to formulate them in a more precise and restrictive form that could not at the point be agreed in treaty form. The soft law approach allows states to tackle a problem collectively at a time when they do not want too strictly to shackle their freedom of action. On environmental matters this might be either because scientific evidence is not conclusive or complete, but nonetheless a precautionary approach is required or because the economic costs are uncertain or over-burdensome."[577] It is noted that "soft law instruments are clearly not law in the sense used by Article 38.1 of the ICJ statute". However, they do not lack all power; they are carefully negotiated and drafted, and intended in many cases to have some normative significance. "They may provide good evidence of juristic opinion or constitute authoritative guidance on the interpretation or application of a treaty. Their adoption has a legitimizing effect on policy and practice and may lead eventually to the negotiation of new treaties. The fact that a great deal of environmental soft law is subsequently transformed into binding treaty commitment or is otherwise incorporated by reference into binding treaties."[578] This point can be proved by the establishment of the Bonn Guidelines with its effects and the development of the Nagoya Protocol.

2) Shortcomings of treaties - legally binding agreement

Van Hook proves that there are many shortcomings of treaties with various problems. Some of problems may be appropriate to clarify what are the shortcomings of the Nagoya Protocol also that would be considered in integration of the Protocol into national law.

Firstly, it is problems of acceptability. Multilateral treaties have the text adopted, not infrequently take a considerable period of time to acquire a sufficient number of ratifications to enter into force. "A comparable but certainly more serious problem is that many multilateral treaties of a general character (i.e. dealing with subject-matters affecting the interests of all or nearly all States in the world) never seem to obtain anything close to universal acceptance on the part of the States."[579] As Birnie recognizes that "this is especially true of environmental issues, whose regulation may require modification of economic policies and be perceived as inhibiting development and growth". "Treaties may be a more useful medium for codifying the law or for concerted lawmaking, but many

[575] FITZMAURICE. M, ELIAS.O, *Supra*, p. 2
[576] KISS.A, SHELTON.D, 2007, *Supra*, p. 300
[577] BIRNIE.P, BOYLE.A, REDGWELL.C, *International Law and Environment*, Third Edition, Oxford University Press, 2011, p. 35 – p. 36
[578] BIRNIE.P, BOYLE.A, REDGWELL.C, *Ibid*, p. 34
[579] G.J.H.VAN HOOF, *Supra*, note 64, p. 120

either do not enter into force, or more frequently, do so for only a limited number of parties which do not necessarily include the states whose involvement is most vital. Treaties thus present problems as vehicles for changing or developing the law".[580]

There are two grounds for the slow ratification, even failure to ratify multilateral treaties on the part of a large number of States are technical inability and political unwillingness. In industrialized countries, "the national legal rout of getting a treaty ratified is often very long and cumbersome. The national legal systems of these States usually require the involvement of various instances through elaborate procedures before a treaty can eventually be approved."[581] Developing countries presents special problems. The main technical reason why these States usually delay ratification is their lack of sufficient manpower. "Developing countries often experience difficulties in staffing their missions to international organizations and other international gatherings where treaties are to be drawn up. This in itself already hampers the efforts to deal with such a treaty on the national level, once it has been concluded. In addition, both the national legal systems and bureaucracies are generally ill-equipped to cope adequately with the problems this engenders". [582]

This is what has happened with the Nagoya Protocol. It had experienced a long negotiation, and now, no one knows when it acquires fiftieth ratifications to enter into force.

'The lowest common denominator' approach – the approach most commonly encountered in multilateral treaties of general international law seemed happen during negotiation of the Nagoya Protocol. This approach indicates that seldom during negotiations compromises and package-deals remove difficulties which States found in a proposed text. This usually results in a quite abstract and/or vague wording of the text concerned. Obviously, this entails that the ensuing text becomes so abstract and/or vague, or lays down such a low standard, that it becomes virtually meaningless. However, facing with dilemma between acceptability and effectiveness: one is interdependence requires nearly universal participation of States in many international issues, the other is problems in question can not be tackled other than by norms which are sufficiently substantive and usually more weight is attached to universality than to effectiveness. In this case, it needs a device to tailor the abstract or vague norms to the requirements of effectiveness that is a procedure of so-called "delegated legislation' in matters which are of a comprehensive nature, but at the same time present considerable technical aspects. This suggestion envisages to international law making with the conclusion of a basic treaty (traité cadre) containing only the most fundamental rules of a more general character – both procedural and substantive.[583]

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[580] BIRNIE.P, BOYLE.A, REDGWELL.C, *Supra*,
[581] G.J.H.VAN HOOF, *Supra*, p. 120
[582] G.J.H.VAN HOOF, *Ibid*, p. 121
[583] G.J.H.VAN HOOF, *Ibid*, p. 123

Secondly, this is the problems of adaptation and change. The problem of open texture of treaties is not completely safeguarded. "If the national legal system has developed various techniques to cope with or at least to neutralize as much as possible the negative effects of open texture of law, international law is concerned such techniques can be applied to a very limited extent only. The main impediment to effectively deal with cases of open texture is therefore, constituted by one of the basic features of international law as the absence of a hierarchical/organizational structure."[584] "In such case, most natural approach is to start from general principles or guidelines, which constitute the point of departure for regulating the subject-matter concerned. Particularly with respect to rules addressing issues of general interest, the problem of the generality and vagueness of international law has grown in recent years and is still growing". [585]

The above shortcomings of treaty as 'hard law' are in contrast to advantages of 'soft law' or non - treaty agreements as outlined above.[586] However, the advantages of soft law are beyond scope of analysis of this section. They do not imply any disadvantages to effects and meanings of the Nagoya protocol in development of international regime on access to GR and benefit-sharing. As described in the Part 1 of the thesis, the process of development of international regime on access to GR and benefit-sharing was remarked by one soft law instrument that is the Bonn Guidelines on access to GR and benefit-sharing. This was considered an important, progressive step for the Nagoya protocol. Adoption of the Nagoya Protocol as a 'hard law' or legally–binding agreement has been recognized as an achievement, although this achievement is featured by common shortcomings of any environmental treaty. In general, as Birnie states that "many environmental treaties do not necessarily contain clear, detailed or specific rules. Sometimes, they lay down only a framework of general principles or requirements for states 'to take measures' or 'all practicable measures." [587]

§ II – Problems of a non-self executing treaty

A – Distinction between self – executing treaty and non-self executing treaty

There is no official definition of self-executing treating or non-executing treaty under the Vienna Convention or other multilateral treaties. However, some researchers describes nature and characteristics of the self-executing treaties to define this concept and obligations of States parties of the treaties. Following Kiss.A and Shelton.D "A self-executing treaty is automatically part of domestic law and enforceable by courts, but treaties that require further legislation to implement them are non-self-executing and are

[584] G.J.H.VAN HOOF, *Ibid*, p. 125
[585] G.J.H.VAN HOOF, *Supra*, p. 125
[586] See more comparative analysis of Birnie in *International Law and Environment*, Third Edition, Oxford University Press, 2011, p. 34 – 37.
[587] BIRNIE.P, BOYLE.A, REDGWELL.C, *Supra*, p. 17

therefore not justifiable until implementing legislation has been adopted. Courts look to the intent of the parties and to the language of the agreement to make determination."[588] A non-self-executing treaty needs to be distinctive with a self-executing treaty for national implementation. However, it is not always clear to divide treaties into two explicit types to apply. Some characteristics of self-executing and non-self-executing treaty are reflected below as distinction between them that may be proper to consider the Protocol as a non-self-executing treaty.

1) Self – executing treaties

Based on synthesis of key characteristics from research documents, self-executing treaties are understood as those treaties that can be applied directly their norms to persons in national law without the need of further legislative or administrative actions.

Self-executing treaties are sufficiently clear and precise to confer rights or obligations on individuals in national law without need implementing legislation, thus they have to satisfy two conditions. First, "personal criterion that means the rights and obligations created by the treaty must be enforceable by individuals directly before national courts. The persons entitled to the right or subject to the obligation must be specifically targeted by the international treaty". Second, "material criterion that means the rule must be sufficiently precise and clear not to require national implementing measures. There should be minimal scope for different interpretations of the implementation of the international rule."[589]

Self-executing obligations should be capable of immediate judicial enforcement without the need of further legislative or administrative action.[590] In this point, one treaty may have both self-executing obligations and non-self executing obligations. Therefore, it is rare to have treaties are totally self-executing obligation. "A small number of international instruments are "self-executing" that is, they include all of the relevant provisions of national law in the international instrument itself. The countries that become parties to such an instrument may instantly apply it, from the day that the country formally ratifies it."[591]

Self-executing obligations can be defined by direct application of international norms. Following that, a norm created in international law can be applied directly in national law to the private, physical and moral persons. This permits the person demand himself application of international law to the national public organs, court, tribunal within the national legislation. This application is directly and the national legislation defines the

[588] KISS.A, SHELTON.D, *Guide to international environmental law,* Martinus Nijhoff Publisher, 2007, p. 16

[589] http://www.peaceandjusticeinitiative.org/implementation-resources/dualist-and-monist/self-executing-treaties, last accessed April 20, 2012

[590] KISS.A, SHELTON.D, 2007, *Supra*, p. 300

[591] TVEDT. M. W, YOUNG. T, *Supra*, p.2 - 3

conditions of application.[592] For example, the new reference of French Conseil d'Etat, Assemblée 11 avril 2012 n° 322326, Gisti, gives a new definition of "direct effect" more in favor of direct application of international treaties.[593]

However, in my view, the concept of self-excuting treaty only exists in monist countries. Because, as analyzed above, in dualist countries, legal norms of international law cannot be applied directly in national law, it must be transformed to be applicable national law or always required further legislation. Further, nothwithstanding monist or dualist doctrine, I suppose that it is difficult for international negotiators to reach a self-executing treaty, especially in international environmental governance, because each country has different conditions, strategy of development in influence of principle of 'common but differentiated responsibilities'. Moreover, as outlined above, difference in nature between international law and national law such as subject of regulation, objective and conditions of application that makes a norm of international law difficult to be applicable directly in national law.

2) Non - self - executing treaties

A non - self - executing treaty can be distinctive by defined characteristics and nature of self-executing treaties. "It is noted that the distinction made between self-executing treaties and non-self executing treaty are the self-executing treaties have their provisions are precise and detailed sufficiently for them to be applicable directly by the courts, non-self executing treaties have general obligation is contracted but it acts as a political engagement and can not apply directly its text."[594] In addition, it argues that the term "non-self-executing has been used to describe treaties that are not enforceable in the courts without prior legislative implementation for a variety of distinct reasons."[595] Therefore, some matters should take into account as following:

Firstly, it is matter of adopting relevant national legislation to apply international rules. Becoming self-executing or non-self executing treaties, the treaties can be applied directly to States parties without needs of accomplishing constitutional procedures after ratification or approval and do not need to have legislative measures corresponding. Thus, treaty can or can not be executive corresponding entirement to a reality that always the

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[592] DUPUY.P.M, KERBRAT.Y, Droit international Public, 10 e Edition, Dalloz, 2010, p. 447-506

[593] see comments of Denys Simon, Europe, Lexis Nexis, Mai 2002, p. 1 and conclusions Dumortier and note of Gautier in Revue Française de Droit Administrative, N° 3, 2012, p.547

[594] BASTID.S, Les traités dans la vie internationale, Paris, Economia, 1985, p 124, quoted by SALMON.J, *Dictionnaire de droit international public*, Universités Francophones, Bruylant Bruselles, 2001, p 413. However, it is noted that this expression sometimes would not be used by francophone doctrine, it must be consulted when using it, considering the uncertainty on its definition and its understanding outside the law of country knowing this concept and the existence of an appropriate terminology of French language for translating difference significance. "Traité self-executing: expression compose partiellement de mots de langue anglaise. L'expression anglaise complète est « self-executing treaty ». Traduction littéral: « Traité auto-exécutoire ». p 1089

[595] VAZQUEZ.J.C, *Treaties as law of the land, the supremacy clause and the judicial enforcement of treaties*, Havard Law Review, 2008, Vol. 122:599, p. 628

same instrument can be undertood and disposed in one time that it can or can not be applied directly.[596]

Secondly, it is to be distinguished from the technique of incorporation of a treaty into the national law. "The treaty may well be the law of the land …and still be considered non-self- executing in this sense. There are no clear rules for courts in assessing the effect of specific treaties, but this is a matter of treaty interpretation for the courts that will look to the nature of the treaty and to the complete and precise nature of rule". Therefore, "a treaty may well be considered self-executing for the courts of one State but not for another. On the other hand the concept of 'direct applicability' has been seen as a question of international law, depending on whether the treaty under international law was intended by the parties to be directly applicable as such in their national law".[597]

For example, the countries, which are considered monist such as France, Japan, Holland or United States, where international law is declared 'the law of the land" hence where no transformation of duly ratified treaties is required and promulgation is usually the condition for international effect, the result may not be the direct applicability of trearties. "In such countries, a distinction is usually made between self-executing treaties which are sufficiently precise and complete and intended to become immediately operative against individuals on the domestic level and those which are non-self-executing and therefore require the enactment of implementing legislation to be enforceable by municipal courts."[598] It suggested that "only self-executing treaties were to be regarded in the courts as equivalent to acts of the legislature. What exactly makes a treaty non-self-executing has long been a matter of great uncertainty".[599]

Therefore, "the direct application of a treaty properly adopted is by no means automatic. This is also true of other so - called 'monist' states, whose courts may invoke doctrines like self-execution or political question to limit the domestic legal effect of ratified treaties. Dualist states, on the other hand, courts sometimes find that even implementing legislation is not self-executing, because it is insufficiently precise to allow the court to apply the norms incorporated from a treaty".[600]

Thirdly, it is the distinction between monist and dualist in the question of self-executing. "The countries where the ratification of a treaty following legislation approval gives it *ipso facto* the status of national law may be described as monist States". By

[596] BEURIER.J-P, *Droit International de L'environnement*, 4e edition, Alexandre Kiss, Editions A. Pedone, Paris, 2010, p. 417- 425
[597] GOWLLAND-DEBBAS.V, National implementation of United Nations Sanctions, The Graduate Institute of International Studies, HEI, Martinus Nijhoff Publishers, the Hague, Leiden, 2004, p. 39- 40
[598] BUERGENTHAL.T, *Self –executing and non-self executing treaties in national and international law,,p 314*
[599] VAZQUEZ, 2008, *Supra*, p. 628
[600] SHELTON.D, *Supra*, p. 4

contrast, "dualist States require some further legislative action."[601] There are some assumed characteristics between monist States and dualist States in distinctions of non-self executing treaty that can be clarified:

First, all treaties could be said to be non-self executing in dualist States, where a duly ratified treaty is not a formal sources of law and always requires implementing legislation. That is different with monist States where a non-self executing treaty has the same domestic legal effect and it becomes domestic law when it has been duly ratified. Although a court may not be able to apply the treaty in a specific case to establish the legal right or obligation being asserted by one of the Parties, the treaty is law to the same extent as a non-self-executing legislative provision.

Second, non-self-executing treaties enjoy the same normative status in many monist States. They are law or a source of law although in a particular case they may not be capable of creating directly enforceable legal rights or obligations. In dualist States, by contrast, where all treaties require implementing legislation to become domestic law, the treaty is not a source of law. Here it usually has no legal force despite it was duly ratified. In dualist States, we should either avoid describing such a treaty as non-self because in dualist States they have no formal domestic legal status. However, they still have some effects or consequences that are legally significant. For example, the courts might take such a treaty into account in interpreting ambiguous domestic legislation dealing with the same subject. "They will often do so on the theory that parliament by adopting a law later in time or by not changing its domestic law upon the Government's ratification of the treaty". This should not be presumed to have intended to violate the State's international obligation or the contents of the unincorporated treaty can be a relevant factor to be taken into account in interpreting and applying domestic law.[602]

Lastly, environmental laws are recognized that are not self-executing and they cannot function in the absence of effective implementation. They require "extensive and expensive administrative capacities, detailed regulatory mandates responsive to particular national circumstances, strong government commitments in the face of competing economic and social interests, and influential public constituencies supporting environmental protection."[603] Environmental treaties aim on impact upon substantive governmental obligations and often impact indirectly upon the rights of individual businesses. Therefore, "it is most likely that an environmental treaty would be classified as non-self-executing."[604]

B – Problems of non- self- executing treaties and of the Nagoya Protocol

[601] BURGENTHAL.T, *Self-executing and non-self executing treaties in national and international law,* Recueil des cours, 1992-IV, the Hagues Academy of International law, Kluwer Academic Publishers, p. 313-319
[602] BURGENTHAL.T, p. 313-319
[603] See more http://ecovitality.org/badlaw.htm
[604] ROSE.L.G, *Supra*, p. 6

1) General problems

Problems of non-self-executing treaties derive from their nature of non direct applicability and the need further national legislation, administration that depends heavily on discretion, willingness, even capacity and awareness of State members. Because the states are free to determine the way to execute their obligations of the convention, this liberty may lead to the possibility of the certain abuse, without sanction. It is difficult to find clear criteria without ambiguity to determine characteristics of non-self execution or not of a treaty.[605] It means there are many obstacles to integration those treaties into national law.

a) Problems of depending on political will.

As Bastid defines "non-self executing treaty acts as a political engagement and can not apply directly its text."[606] It is admitted that "if delay in, or failure of ratification are the result of unwillingness on the part of the States concerned the problem, of course, is first of all of a political nature."[607]

In fact, "law is politics, the distinction between law and politics is only a half-truth", and "law is made by political actors (not by lawyers) through political procedures, for political ends".[608] In other words, law depends on politics, impacted by politics and results of political activities. As political engagements, "non-self-executing treaties need national law for its application".[609]

In addition, "it is often politicized in disagreements within a government over a treaty, since a non-self-executing treaty cannot be acted on without the proper change in domestic law". "If a treaty requires implementing legislation, a state may be in default of its obligations by the failure of its legislature to pass the necessary domestic laws."[610]

The impact of political matters also is proved by debates on doctrines of treaty non-self-execution[611]. It is recognized that the issue in this doctrine was one with significant foreign policy implications, and "the Court recognized that such decisions were within the discretion of the political branches. Although the political branches had staked out a position, the diplomatic dispute was live, and the Court left enforcement of that position to the political process, consistent with the political branches' understanding that the treaty was to be implemented legislatively".[612] The doctrine ensures that the "political branches

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[605] EISEMANN.P.M, *Supra*, p.25
[606] See note 111, SALMON.J, *Dictionnaire de droit international public*, Universités Francophones, Bruylant Bruselles, 2001, p. 413.
[607] G.J.H.VAN HOOF, *Supra*, p. 122
[608] SLOMANSON.R.W, *Supra*, p. 3
[609] DUPUY.P.M, KERBRAT.Y, p. 447-506
[610] http://en.wikipedia.org/wiki/Treaty
[611] MOORE.D.H, Law (Makers) of the land: the doctrine of treaty non-self-execution, Havard Law Review, Vol. 122:32, 2009, p. 32
[612] MOORE.D.H, *Ibid*, p. 38

exercise lawmaking discretion, the judgment that a treaty is more likely non-self-executing; if a finding of self-execution would effect troubling consequences again arise from recognition of political branch primacy in foreign affairs and lawmaking". [613]

b) Problem of depending on domestic law with challenges of change law.

Non-self-executing treaty is usually to require the contracting Party to adopt legislation relevant to the national law to implement. In other words, the application of the international treaty into the interiors of the State requires legislative correspondent are taken that requires ratification or approval and other procedures taken place, if not, the treaties can not be executed to correspond entirely the reality.[614]

This requirement of 'implementing legislation' means a change in the domestic law of a State Party that will enable it to fulfill treaty's obligations. The problem is that the change is always difficult and provisions of the treaty may have conflicts with existing national law. As Triepel noted that all the modification of the law for applying objective of international law, exclude the notion of judicial reception. It is impossible absolutely to know exactly the true situation of things that call 'acceptation' or 'appropriation' or 'incorporation' of the norm of the international law by the national law. The process of a national law obeys an obligation of international law or fulfils responsibility are free determination. [615]

Especially, for developing countries, they struggle with problems of weak capacity, such as lack of sufficient manpowers, weak capacity. Both the national legal systems and bureaucracies are generally ill-equipped to cope adequately with the problems. [616]

c) Problem of interpretation of whether a treaty is self-executing or non-self-executing.

In a strict sense, a treaty is self-executing if no legislation is necessary to authorize executive action pursuant to its provisions. The question of whether a treaty is self-executing is a matter of interpretation for the courts when the issue presents itself in litigation.

This question is perhaps one of the most confoundings in treaty law. Theoretically, a self-executing and an executory provision should be readily distinguishable. However, in practice, it is difficult. Treaties cannot affect certain subject matters without implementing legislation and be self-executing to the extent that it involves governmental action. Apart from the language of the treaty expressly calls for legislative implementation or the subject matter is within the exclusive jurisdiction of Congress, the question is purely a matter of interpretation. In carrying out interpretive task, the history of the treaty, the negotiations,

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[613] MOORE.D.H, *Ibid*, p. 42
[614] BEURIER.J-P, *Droit International de L'environnement*, 4e edition, Alexandre Kiss, Editions A. Pedone, Paris, 2010, p. 62
[615] TRIEPEL. Henrich, *Supra*, p. 167
[616] G.J.H.VAN HOOF, *Supra*, p. 121

and the practical construction adopted by the parties should be considered. In the specific context of determining whether a treaty provision is self-executing, several factors should be preferred such as the purposes of the treaty, the objectives of its creators, the existence of domestic procedures, the institutions appropriate for direct implementation, the availability and feasibility of alternative enforcement methods.[617]

Moreover, there is the lack of mutuality between countries that do not recognize treaties as self-executing. A self executing interpretation may weigh against any of the treaty provisions conflict with existing legislation that requires supplementary and new implementing legislation. [618]

d) Problems of arguments on doctrines of non-self-execution[619]

There are different doctrines of non-self-execution that reflect instrinsic problems of non-self-executing treaty. One doctrine assumes that a treaty may be itself that means the treaty requires legislative implementation. However, other scholars suppose that strain of this doctrine of non-self-execution is invalid,[620] and untenable view that non-self-executing treaties lack the force of domestic law.[621] They argue that treatymakers can create a non-self-executing treaty by providing a clear statement of that intent or by negotiating and ratifying an instrument that is sufficiently vague. As Vazquez states that "the treatymakers have the power to limit the domestic effects of treaties through declarations of non-self-execution".[622]

The debates hinge on the status of treaty as law of the land under Supremacy Clause[623]. "This clause, designed, principally to assure the supremacy of treaties over state law, has been interpreted to mean also that treaties are the law of the land of their own accord"[624]. Some questiones whether the issue of non-self-execution is primarily governed by the Supremacy Clause's designation of treaties as law of the land or by the constitutional delegation of lawmaking and foreign affairs authority to the lawmakers of the land. It is recognized that "The concept of a non-self-executing treaty fits uneasily with

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[617] http://iilj.org/courses/documents/Self-executingandnon-setreaties.pdf, last accessed 22th May 2012

[618] *Ibid*

[619] See MOORE.D.H Law *(Makers) of the land: the doctrine of treaty non-self-execution*, Havard Law Review , Vol. 122:32, 2009; CURTIS.A.B, *Intent, presumptions and non-self-executing treaties*, The American Journal of international law, Vol.102;540; YOO.C.J, *Treaties and Public Lawmaking: A Textual and Structural Defense of Non-Self-Execution*, 99 Columbia Law Review, 1999, 2218, 2227VAZQUEZ, *The four doctrines of self-executing treaties*, American Journal of international law, Vol 89, No 4, 0ct, 1995, p. 695-723, VAZQUEZ, *Treaties as law of the land, the supremacy clause and the judicial enforcement of treaties*, Havard Law Review, 2008, Vol. 122:599, p. 601-694,

[620] MOORE.D.H, *Law (Makers) of the land: the doctrine of treaty non-self-execution*, Havard Law Review, Vol. 122:32, 2009, p.32

[621] VAZQUEZ, *Treaties as law of the land, the Supremacy Clause and the judicial enforcement of treaties*, Havard Law Review, Vol. 122:599, 2008, p. 600

[622] VAZQUEZ, 2008, *Ibid*, p 600

[623] The Clause in Consitution defines the status to international treaties in national law (most monist countries). In US'Constitution Article VI, clause 2, Vazquez, 2008, *Supra*, p 613-614. Professor Vazquez also stated that "By virtue of the Supremacy Clause, treaties became enforceable in court without the need for prior legislative implementation or incorporation into domestic law."p. 618

[624] Edited by PRIEUR.M, DOUBE-BILLE.S, *Droit de l'Environnement et Développement Durable*, Press Universitaires de Limoges (PULIM), 1994, p. 30

the Supremacy Clause…lack the force of domestic law."[625] The dissent emphasized the role of the Supremacy Clause in the self-execution question.

The other supposes that the Supremacy Clause does not limit the treatymakers' discretion to exercise their authority in ways to produce a treaty that does not qualify for judicially enforceable, preemptive effect. "If the Supremacy Clause did, the courts arguably should strike treaties that require action constitutionally committed to other actors. However, the accepted wisdom is that such treaties are merely non-self-executing. All this suggests that attempting to answer the self-execution question by placing primary emphasis on the Supremacy Clause is misguided."[626] As Findley.R explained that "…not all treaties are, in fact, law of the land of their own accord, treaties designed to have domestic consequences…can be either 'non-self-executing' requiring an act of Congress to carry out the international obligation or 'self-executing', so that without any legislative intervention, the Executive and the courts will accord to claimants the benefits promised by the treaty"[627].

By contrast, the others do not focus on the Supremacy Clause and endorsed the view that non-self-execution derives from the authority to make treaties. In defending its reliance on the treaty's text, they argue that the political branches, not the courts, should have "the primary role in deciding when and how international agreements will be enforced." They ultimately conclude that "nothing in the text, background, negotiating and drafting history, or practice among signatory nations suggests that the President or Senate intended the improbable result of giving judgments of an international tribunal preemptive effect over state procedural rules that apply even to constitutional rights". "The dissent was likewise unwilling to conclude that the Supremacy Clause mandates automatic enforcement of all treaties, acknowledging some authority in the treatymakers to assume non-self-executing obligations."[628]

The conclusion that the treaty does not apply to the land whose ownership is disputed. National lawmakers apparently understand the treaty requires future legislative acts for authorized boards of commissioners and courts to review land claims covered by the treaty. Consequently, the Court could not apply the treaty to disregard the existing laws on the subject in absence of implementing legislation

The debate also includes matter of treaty language. There is a broader separation of powers analysis of which the treaty language is one part. The doctrines look to separation of powers considerations beyond the treaty's language in deciding whether they have. These separations of powers considerations may be present even when a treaty does not

[625] VAZQUEZ, 2008, *Supra*, p. 600
[626] MOORE.D.H, *Ibid*, p. 35
[627] Edited by PRIEUR.M, DOUBE-BILLE.S, *Supra*, p.30
[628] MOORE.D.H, *Ibid*, p. 35

address domestic implementation. The language differential is not the only basis for interpreting the treaty differently. [629]

Arguments also focus on status of the treaties in national law whether they are different with the Constitution and statutes. One scholar states that "The Constitution is, of course, superior to federal statutes and treaties. Under current doctrine, treaties and federal statutes are regarded as having equivalent stature, so that the last in time prevails in the event of a conflict. The last-in-time rule has been disputed by scholars, some of whom claim that treaties are superior to statutes and others the reverse."[630] This can be explained by some reasons. First, "it is not clear that the Supremacy Clause requires equal treatment of the three sources of law it describes, the Supremacy Clause does not give the Constitution law and treaties in the same statues". Constitution is different from statutes and treaties. Treaties are different from the constitution and statutes. They serve an external role that the constitution and status do not and give rise to obligations to and from coequal sovereigns. But, the Constitution assigns treaties a domestic function. Second, it is not clear that "the doctrines of treaty non-self execution necessarily results in unequal treatment".

The doctrines are differentiated by the base of separation of powers concerns and employs separation of powers–based presumptions to guide the self-execution analysis. "The 'private right of action doctrine' reflects the separation of powers judgment." "The 'non-justiciability doctrine' similarly rests on the recognition that lawmaking discretion of a certain scale generally belongs to the political branches." "The 'constitutionality doctrine' is likewise based on separation of powers concerns that based on the separation of powers between the political branches and the courts as evidenced by the fact that courts do not strike as unconstitutional a treaty that assumes obligations other political actors must fulfill". "Rather, the courts designate the treaty as non-self-executing, effectively presuming that the political branches did not intend for the treaty to be immediately effective and respecting the limits on the judiciary's ability to compel domestic lawmaking." [631]

The use of separation of powers presumptions raises two additional issues. One, in certain case, the separation of powers presumptions employed make it more likely that courts will find treaties to be non-self-executing when the treatymakers do not expressly indicate otherwise. This makes the question of the constitutionality of declarations of self-execution all the more important. Second, the separation of powers presumptions lead to a conclusion that a treaty is self-executing in one situation but not in other treaties have a fixed character that character may depend on the context in which the question of a treaty's

[629] *Ibid*
[630] *Ibid*
[631] MOORE.D.H, *Ibid*, p. 47

self-executing character first arises. "The treatymakers might avoid this problem by attaching declarations of non-self-execution or self-execution. Of course, forcing treatymakers to do so may hamper their foreign affairs discretion."[632]

In sum, in my view, all these problems of non-self executing treaty should be considered in case of the Nagoya Protocol integrated into national law. They include 'external' problems such as political will, changes of law, interpretation or 'intrinsic' problems such as nature, status of the non-self executing treaty, relationship with Constitution, and status or separation of power in national context. There are many diffirent points of view, arguments and debates, but I would wish to emphasize on the role of political will of State to approve and implement a non-self executing treaty like the Nagoya Protocol with understanding that this political will depends on many factors and conditions to realize it.

2) Some problems of the Nagoya Protocol as non – self executing treaty

It is rarely an environmental treaty has self-executing obligations. There is a few examples that can bring obligation to the State parties the disposition of legislative or regulatory precise, like Article 3.5 of Bonn convention 23/6/1979 on the conservation of migrated species, like Article 8 of Washington Convention 3/3/1973 on the international trade of saving fauna and flora management. The provisions of the convention that engage the contracting State to take penal sanctions against the person who violates the provisions.[633]

It is usually to require the contracting Party to adopt legislation relevant to the national law to implement the treaties. Like most others environmental treaties, the Nagoya Protocol is characterized by language of a "non-self executing treating". As analyzed in Part 1 of this thesis, it uses common phrases such as "each Party shall take legislative, administrative or policy measures, as appropriate"; 'in accordance with domestic legislation"; "subject to its domestic legislation or regulatory requirements"; "in accordance with domestic law, each Party shall take measures, as appropriate", "parties shall take appropriate, effective and proportionate measures as required by the domestic legislation or regulatory requirements". Therefore, it has no arguable possibility of whether the Protocol is self - executing or non-self-executing treaty. There is unnecessary for distinction between monist and dualist States to define which kind of treaty is the Protocol that needs transformation or incorporation. It requires all State Parties to take measures to implement. The Protocol is confirmed that it is a non-self executing treaty with all definitions, characteristics and nature or exactly 'political engagement in true meaning. The problems of the Nagoya Protocol are how State Parties integrate norms of the Protocol

[632] MOORE.D.H, *Ibid,* p. 47
[633] BEURIER.J-P, *Droit International de L'environnement*, 4e edition, Alexandre Kiss, Editions A. Pedone, Paris, 2010, p. 62

into national law or make them executable with vague language of the Protocol, political will, and actual situation of existing national legislation.

The substantive language of the Protocol is analyzed by Part 1 that will be problem to integrate the protocol in to national law. The political will to ratify/adhere the Protocol and apply the Protocol is very difficult to predict and it is various from State to State. Looking back negotiation and development of the protocol, the problems become more severe because of interest conflict between user countries and provider countries.

The actual situation of existing national legislation will be analysed in more detail by Title 2 of this Part, but a small number of countries adopted legislation on access to GR and benefit-sharing with limited application. All of these with the problems of a non-self executing treaty will become challenges for the Nagoya protocol integrated into national law.

Conclusion of Chapter 1

This chapter emphasizes on findings of weakness of international law that impact on the integration of the Nagoya Protocol into national that includes intrinsic weakness such as institutional subject, jurisdiction, compliance and enforcement, as well as problems of procedures in international law making like democratic deficit.

This chapter also has analysis on the relationship between the international law and national law, process of application of international law into national law with two doctrines: monist and dualist. Whenever legal scholars have started to analyze the relation and application of international law into national law, the two doctrines monist and dualist always are mentioned. However, the author supposes that there is difference between theory and practice of application. Despite of a long controversy between two doctrines, the controversy has not impacted much on practice. No nation entirely bases on monist or dualist but varying from both. The relationship between national law and international law is mutual influenced.

This chapter also has found problems of legally binding treaties and non- legally bindings treaties (hard laws and soft laws). It defines that the Nagoya Protocol is non-self executing treaty. However, the author agrees that this concept of ‘non-self-executing treaty’ exists in ‘monist’ country where a treaty enjoys the same normative status and legal effects in national laws but not for ‘dualist’ country where all treaties need a process of domestic legislation for executing or they have no formal domestic legal status. The characteristics of the Nagoya Protocol as a non-self-executing treaty are the same with those of most the other environmental treaties. The problem here is the dependence on political will and changes of national law and interpretation of the treaty.

CHAPTER 2 – Principles, methods and ways of the integration of the Nagoya protocol into national laws

Many people concern about legality and effectiveness of international law. There is "scepticism about the legality of international law that international law is not law, it is a series of political and moral arrangements that stand or fall on their own merits, any other characterization is no more than 'theology and superstition masquerading as law'. Skeptics thus, assume that States act only in their own best interests with no regard for expectations imposed by international law." [634] While, "law is the normative expression of a political system. To appreciate the character of international law, it is helpful… to invoke national law as an analogue. National law is an expression of a domestic political system in a domestic national society."[635]

"There is no universal uniform practice stipulating how states should incorporate international law into their domestic legal system and it is the State's perception of international law that determines the way in which international law becomes part of national law."[636] In fact, "Treaties generally leave the question of domestic implementation to the domestic laws of the states-parties."[637] In addition, implementation of national law which we called as '*jus naturale*' or '*jus gentium'* is different with international law, because it acts with private law or public law in its nature that is not characteristics of international law. It never has integration of international law by a State if the content of national law does not response exactly to content of the regulation of international law.[638]Moreover, "non-self executing treaties need national legislation for its application while international law has no rules for how of realization of the international rules in the states. The state decides the principle to open to the international law can apply directly."[639]

In the above context of international law, many questions arise: How do States integrate the Protocol into national law for implementation? Are there any principles, methods, measures suggested for integration? Are there any problems of those principles, methods and measures? This chapter aims at providing answers for these questions.

Section 1 – Principles for the integration of the Nagoya protocol in to national laws

The law can not exist without the principle that is necessary to notice an essential situation to identify features characteristics of quality of law that lighten toward the justice. The integration the Nagoya protocol into national law can not avoid the general principles of law.

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634 SLOMANSON.R.W, *Supra*, p.10
635 SLOMANSON.R.W, *Ibid*, p. 3
636 BILDERBEEK. S, *Biodiversity and international law: the effectiveness of international environmental law*, Netherlands National committee for the IUCN, IOS Press, Netherlands, 1992, p. 172
637 VAZQUEZ, 2008, *Supra*, p. 601
638 TRIEPEL. Henrich, *Supra*, p. 167
639 DUPUY.P.M, KERBRAT.Y, p. 447-506

§ I – Some basic principles of international law

A – Generalities

There is a continuing debate on general principles of their existence as a source of international law. Article 38 of the Statute of ICJ enumerates "the general principles of law recognized by civilized nation" this last 'full-fledged" source contained in the Court's Statute probably is the most controversial one." [640] In reality, the matter is more complicated. "Not all general principles applied in international practice stem from domestic legal systems and have been transplanted to the international level by recognition. They may include principles recognized by international law itself such as prohibition on the non-use of forces, basic principles of human rights and the freedom of the seas."[641] Some are based on 'natural justice' common to all legal systems (such as the principles of good faith *Pacta Sunt Servanda*, *Estoppe*l and proportionality, others simply apply logic familiar to lawyers (such as the rules *lex specialisderogat legi generali*, *lex posterior derogat legi priori*). "General principles of law have proved most useful in 'new' areas of international law when the modern system of international law was beginning to develop".[642] There are some recognized principles of law such as the principle of equal treatment or non-discrimination, the principle of proportionality, the principle of legal certainty, and principle of the protection of legitimate expectations, the protection of fundamental rights and the rights of defence.[643] Therefore, this section recognizes these general principles of law that affects to the integration of the Protocol into national law, but it can not cover analysis in detail of all these principles as going far beyond of its scope. It will focus on some basic principles that impact directly and clearly on the integration of the Protocol with their problems and limitations.

B - Some foundation principles of international law

1) Sovereignty

"State sovereignty is one of the oldest principles of international law means that each state has exclusive legislative, judicial and executive jurisdiction over activities on its territory. Sovereignty is exercised subject to international law however and is not absolute. States may enact or accept limits on their own freedom of action in order to protect common interests or the interests of other states."[644]

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[640] G.J.H.VAN HOOF, *Supra*, p. 131
[641] BIRNIE.P, BOYLE.A, REDGWELL.C, *Supra*, p. 26
[642] MALANCZUK. P, *Supra*, p. 63
[643] http://fds.oup.com/www.oup.co.uk/pdf/0-19-826012-1.pdf
ALPA.G, "*General Principles of Law*," Annual Survey of International & Comparative Law: Vol. 1: Iss. 1, Article 2, 1994
[644] KISS.A, SHELTON.D, 2007, *Supra*, p. 11

"Treaties to which a state becomes a contracting party result in self-imposed limits on sovereignty." The States conclude the CBD and the Protocol that containing obligations must be executed in their territories. "Consequently, states are obliged to exercise broad control over public and private activities and this necessarily places legal limits their freedom of action."

This principle is applied by the principle 21 of Stockholm Declaration that affirms "states have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies"[645]. The principle 2 of the Rio Declaration also uses the same wording but enlarges its scope by referring to 'environmental and development policies'.[646]

The principle of sovereignty is repeated by Article 3 of the CBD. Deriving from national sovereignty, each country has separate and comprehensive right to exploit natural resources in their own territory. However, in the field of biodiversity, jurisdiction of the nations is restricted by the compulsory for the nations should be responsible to the other nations as well as international communities when the nations exploit and conserve in scope of their jurisdiction. Because, the components of biodiversity have interaction relationship in an overall unity, the nations implement their national sovereignty of GR do not cause damage to the environment of the other nations and must be respect the sovereignty of the other countries.

Following the sovereign of nations over GR, countries have right to use, exploit, dispose GR their own territory. The principle of sovereign right over natural resources is reaffirmed by Article 6 of the Nagoya Protocol.

2) Cooperation

"An obligation to cooperate with other states emerges from the very rational for international law and finds reflection in the proliferation of international agreements and institution. In the field of environmental protection, equitable use of shared resources depends on international cooperation." The general need to cooperate is expressed by principle 24 of the Stockholm declaration and referred by UN General Assembly Resolutions, the 1982 World Charter for Nature and the Rio Declaration on Environmental and Development.

"The principle of cooperation underlines all treaty obligations but several texts specify the aims of state cooperation. Principle 5 of Rio Declaration calls for cooperates to eradicate poverty. Principle 27 adds that cooperation shall be conducted in good faith and

[645] ABBOUR.J-M, VAVALLEE.S, *Droit international de l'environnement*, Editions Yvon Blais, Une Société, Bruylant, 2006, p.44
[646] KISS.A, SHELTON.D, 2000, *Supra,* p. 258

shall include further development of international law in the field of sustainable development."[647]

The Nagoya Protocol recognized this principle through Article 11 on trans-boundary cooperation; Article 22.1 on cooperation in the capacity-building, capacity development and strengthening of human resources and institutional capacities; Article 23 on technology transfer, collaboration and cooperation.

3) Common concern of humanity

"The cohesion of every society is based upon and maintained by a value system. The system may demand respect for the human person, propriety, patriotism, cultural values, or a particular social order. The protection of such fundamental values is generally recognized as common concern of the community and is ensured through law, especially constitutional law."

"The international recognition of human rights and fundamental freedoms was a first step in developing the concept of an international community build on the fundamental values of humanity. Similarly if somewhat later, protection of the human environment became accepted as a common concern of humanity. The ecological processes of the biosphere such as climate change, necessitated protection at the global level while trans-boundary and many domestic environmental issues cannot be managed effectively by national efforts alone. The modalities of protection and preservation are formulated in international law and policy and enforced by national and international institutions."[648]

In fact, "'common concern' is not a concept previously employed in international law and it presents legal implication remains unsettled. The choice of language was itself the outcome of political compromise, agreed after initial proposals using the term 'common heritage of mankind for global climate and biological diversity encountered predictable opposition. Nonetheless, 'common concern' indicates a legal status both for climate change and biological resources which is distinctively different from the concepts of permanent sovereignty, common property, shared resources or common heritage which generally determine the international legal status of natural resources."[649] The CBD affirms that the conservation of biological diversity is a common concern of humankind.[650]

"'Common concern' is neither common property nor common heritage and it entails a reaffirmation of the existing sovereignty of states over their own resources. Its main impact appears to be that it gives the international community of states both a legitimate interest in resources of global significance and a common responsibility to assist in their

[647] KISS.A, SHELTON.D, 2007, S*upra* p. 13
[648] KISS.A, SHELTON.D, 2007, *Ibid,* p. 13 – p 14
[649] BIRNIE.P, BOYLE.A, REDGWELL.C, *Supra*, p. 130
[650] Preamble of the CBD

sustainable development." "Moreover, insofar as states continue to enjoy sovereignty over their own natural resources and the freedom to determine how they will be used, this sovereignty is not unlimited or absolute, but must be now be exercised within the confines of the global responsibilities set out principally by the CBD, Rio Declaration and other relevant instrument. [651]". "The international concept of common concern does not connote specific rules and obligations, but establishes the general basis for the concerned community to act. Designing a matter as one of common concern removes the topic from states exclusive domestic jurisdiction and makes it a legitimate matter for international regulation".[652]

"The right and duty of the international community to act in matters of common concern still must be balanced with respect for sovereignty. States retain exclusive jurisdiction subject to the obligations international law creates to assure the common interest. The notion of common interests shared by the international community may have procedural implications". "The traditional international law, only an injured state could bring a claim against the state which caused the injury in violation of international law. Where the common interest is infringed, all states may be considered to have suffered a legal injury with the obligations designated as obligations owing to all sates as obligation *erga omnes*."[653] "The *erga omnes* obligation is understood as legal obligations owed to the whole international community of states, which can be enforced by or on behalf of that community that traditionally is distinguished by legal obligation owed to the state, which can be enforced only by that state." [654]

This principle should be considered in process of integration of the Nagoya protocol in to national law together with principle of sovereignty and principle of cooperation as GR is part of the biological diversity that is defined as 'common concern' of human kind.[655] The obligations under Article 8 on special consideration, Article 9 on contribution to conservation and sustainable use, Article 10 on global multilateral benefit-sharing mechanism of the Protocol imply towards this principle.

II – Common legal principles of international environmental law

In addition to apply the general principle of international law, it is necessary to apply principles of international environmental law during the integration of the Nagoya Protocol into national law as its nature of a MEA. While general principles can be found in the 1992 Rio Declaration, other soft law instruments and certain treaties, some basic sustantive principle of environmental law have all been endoresed by states such as the prevention principle, precautionary principle, the polluter pays principle and the principles

[651] BIRNIE.P, BOYLE.A, REDGWELL.C, *Ibid*, p. 130
[652] KISS.A, SHELTON.D, *Supra*, p. 13 – 14
[653] KISS.A, SHELTON.D, *Ibid*
[654] BIRNIE.P, BOYLE.A, REDGWELL.C, *Supra*, p. 131
[655] Preamble of the CBD

of common but differentiated responsibility in this form. They need to be integrated in treaties and reflected in national law.

A - Substantive principles

1) General principles of environmental law

The author considers four basic principles, including: the principles of prevention, polluters pay, precautionary and non-regression to study to apply for integration of the Nagoya Protocol. These are the principles are recognized and applied by countries. They are mentioned as key principles of environmental law[656],[657], [658] or have significance of need to be recognized as key principle of environmental law, such as a new principle of non-regression[659].

a) Principle of prevention

"The general duty of prevention clearly emerges form the international responsibility not to cause significant damage to the environmental extra-territorially, but the preventive principle seeks to avoid harm irrespective of whether or not there are transboundary impacts. The rationale derives from the interdependence of all parts of the environment and the fact that it is frequently impossible to remedy environment injury". The CBD lists the measures that should be taken to ensure conservation and sustainable use of biological resources within States parties. Article 3 expresses the principle of prevention. The Principle 2 of the 1992 Rio Declaration sets the terms of the obligation "to ensure that activities within their jurisdiction or control do not cause damage to the environment of other states or of areas beyond the limits of national jurisdiction".[660]

"States find themselves bound by a due diligence requirements. Preventive principle is infact an external element of the general obligation to 'due diligence' or 'due care' with respect to the environmental and natural wealth and resources." It has some certain consequences for liability. The preventive principle strengthen the core of the general obligation of due diligence that makes it easier to engage state liability for unlawful acts. For example, "environmental impact assessment (EIA) may serve as a secondary standard for determining whether or not a State has complied with due diligence requirement to prevent transboundary harm." The requirements to prevent harm are complex following

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656 See more HUNTER.D, SALZMAN.J, ZAELKE.D, International environmental law and policy, University Casebook series, Newyork foundation Press, 1998, p. 318 – p. 382

657 See more GOSSEMENT.A, *Le principle de precaution, Essain sur l'incidence de l'incertitude scientifique sur la decision et la resposabilite publique*, L'Harmattan, 2003, 527p

658 See more ABBOUR.J-M, VAVALLEE.S, *Droit international de l'environnement*, Editions Yvon Blais, Une Société, Bruylant, 2006 p 46-84 ; ROMI.R, *Droit et administration de l'environnement*, 6th Edition ; Montchrestien, 2007, p.43, and p.111-p146, ROMI.R, *Droit de l'environnement*, 7th Edition ; Montchrestien, 2010, p.115-p.158; NEURAY.J-F, *Droit de l'environnement, Bruylant Bruxelles*, 2001, p.74 - p.88; VAN LANG. A, *Droit de l'environnement*, Presses Universitaires de France, 2007, p.70 -141

659 PRIEUR.M, SOZZO.G, *La non-régression en droit de l'environnement*, Bruylant, 2012, p.5-46

660 SADELEER.N, *Environmental Principles, from political slogans to legal rules*, Oxford University Press, 2002, p. 63

various the legal instruments contain it. Some due diligence requirements should be considered such as: prior assessment of environmental harm; procedures to license or authorize hazardous activities; conditions for operation and the consequences of violations; the use of best available technique; elaboration and adoption of overarching strategic and policies.[661]

Infact, most MEAs require States to comply with EIA, monitoring, notification and exchange of information. Because, the objective of almost MEA is to prevent environmental degradation terioration that is suitable with the positive side of prevention is protection and conservation. 'Protection' 'preservation' or 'conservation' are the core term for the principle but there is no treaty definition. Article 192 of the UNCLOS suggests the first two terms have different meanings. "Protection" can be seen as abstaining from harmful activities and taking affirmative measures to ensure that environmental deterioration does not occur. The concept of protection includes comprehensive ecological planning and management, with substantive regulations, procedures and institution on a national scale. 'Preservation' could be considered as including long time perspective that take into account the rights and interest of future generation for whom natural resources should be safeguarded. The term 'conservation' has a narrower scope but falls under the heading of 'protection'. It generally is used in the field of living resources and is based upon the *status quo*, mainly demanding maintenance of the conditions necessary for continued resource existence at present level". When applied to exploit GR, 'conservation' often means the exploitation without exceeding the limits that guarantee its renewal and its sustainability. In recent texts 'conservation' has been supplemented or replaced by reference to 'sustainable development' assuring the ongoing productivity of exploitable natural resources. "A related concept is the 'favorable state of conservation, 'based not on the idea of exploitation or of yield but on that of maintaining living resources at optimum levels. The detail is found in various international convention aimed at protecting living species threatened with extinction and those concerned with natural resources in general such as RAMSAR convention on wetland, UNESCO convention on protection of World Cultural and Natural heritage."

However, "it is unclear whether or not a legal obligation to assist a state in an environmental emergency falls within the duty to prevent environmental harm. Assistance usually implies operations on the territory of a foreign state and traditionally necessities specific arrangements between the states requesting and supplying assistance. States may hesitate to permit assistance because while it is sometime necessary, it is also inherently instrusive of state sovereignty."[662]

[661] KISS.A, SHELTON.D, *Supra*, p. 92
[662] KISS.A, SHELTON.D, *Ibid*, p. 94

This principle can be applied in the context of the Nagoya protocol by setting threshold, requirements of best available technology and impact assessment. States can provide threshold for access to GR and use best available technology to minimize environmental harms. The access of GR as well its utilization should have EIA report.

b) Precautionary principle

Precautionary principle is also described as 'principle of caution', 'principle of prudence'. Principle 15 of the Rio Declaration 1992, states "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation". The Preamble of the CBD also provides that "where there is a threat of significant reduction or lost of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize such a threat".

In general, "precautionary principle can be considered as the most developed form of prevention that remains the general basis for environmental law". "Precaution means preparing for potential, uncertain or even hypothetical threats, when there is no irrefutable proof that damage will occur. It is prevention based on probabilities or contingences, but it can not eliminate all claimed risks, because these are claims that lack any scientific basis. Precaution particularly applies when the consequences of non action could be serious or irreversible. Policy makers must consider the circumstances if a given situation and decide whether scientific opinion is based on credible evidence and reliable scientific methodology."[663]

Although "subject to varying interpretations in international treaties and declarations, the precautionary principle becomes a fundamental principle of environmental law. Its purpose is to make greater allowance for uncertainty in the regulation of environmental risks and the sustainable use of natural resources."[664] However, "the principle has also becomes a major point of controversy in the strained relationship between trade and environment with the EU pleading for its expansion while the US calls for trade measures to based on 'sound science'". "The principle often led to conflicts between the supporters of the softer 'precautionary approach' and the supporters of a more legalistic 'precautionary principle'. The principle was the cause of Cartagena Protocol on Biosafety under the CBD."[665]

There are critics of the principle often set precaution and scientific knowledge against one another. "The implication of this opposition is that the adoption of the principle

[663] KISS.A, SHELTON.D, *Ibid,* p. 95
[664] BIRNIE.P, BOYLE.A, REDGWELL.C, *Supra,* p. 136
[665] SADELEER.N, *Supra*, p. 98

might somehow be seen a priority as being antithetical to the principles of scientific rigour in the regulation of risks (systematic methodology, skepticism, transparency, emphasis on learning…) Within such a perspective, implementation of the precautionary principle essentially becomes a politically determined compromise with has nothing to do with 'sound science'".[666] However, "it is proved that the precautionary principle and the principles of scientific rigour are not antithetical, but rather mutual reinforcing". On one hand, "it would reaffirm the primacy of political decision making in determining the contents and timing of preventive measures, thereby limiting the role of scientist." On the other hand, "although arising from a lack of scientific information, precaution calls for ever increasing scientific knowledge, thus serving to reinforce the power of experts, initially rejected as insufficient would thereafter be sought to balance the scope of anticipatory measures." It is demonstrated in consideration "the articulation between risk assessment and risk management, these two tendencies can operate in a complementary fashion". In other words, "the problems of precaution come within the competence of engineers and toxicologist working to assess a particular type of risk as much as that of the decision maker, it is a question of knowing how to arbitrate between two fields when knowledge is uncertain and imperfect, so that no single party can make a decisive case to convince others, obtain their agreement."[667]

For the Nagoya protocol, this principle should apply for access to GR, this comes out as related to the bioprospecting sector which corresponds to legitimation of the right of states to adopt with PIC, environmental protection requirements and even though there is substantial scientific certainty. For instance, the access of GR causes what effects to the environment, biodiversity, human health? All these effects require a prior risk assessment. A clausible risk of harm is a no-derogable requirement of precautionary measures, including relevance and appropriateness. It should also define temporal scope of precautionary measures. They can be adopted for an indefinite period of time and on a continuous basis. There are needs of risk assessment and risk management. Another legal implication frequently associated with the precautionary principle is a reversal of the burden of proof in relation to the risks that pertinent measures aim at averting.

c) 'Polluter pays' principle

"The polluter pays principle holds the polluter who creates an environmental harm liable to pay the costs to remedy that harm". The principle 16 of Rio Declaration states that "National authorities should endeavor to promote the internationalization of environmental costs and the use of economic instrument taking into account the approach that polluter should, in principle, bear the cost of pollution, with regard to the public interests and

[666] SADELEER.N, *Ibid*, p. 174
[667] SADELEER.N, *Ibid*, p. 174

without distorting international trade and environment". Chapter 20 of Agenda 21 calls on states to apply this principle in their policies regarding the problem of waste.[668]

At this point of Agenda 21, it seems to be that this principle does not directly affect to natural resources management and access to GR and benefit-sharing issues under the Nagoya Protocol. However, this principle can be interpreted in different way depending upon the extent of prevention and control or/and whether compensation for damage is included in the definition of reduction. Accordingly, there may have assumption that a user of GR, during access or use GR caused any damage, he would be applied this principle to compensate the damage caused by him. This responsibility of compensation under this principle should be distincted with the responsibility of sharing benefits under MAT. When granting PIC the National Competent Authorities can consider including this principle within PIC.

In practice, many problems and questions should be taken consideration. They include: who is the polluter? How much must the polluter pay? even what constitutes pollution or damage?

It is also necessary to consider "user pays' principle. There is a question of the relevance of recourse to the concept of 'polluter' to ensure the implementation of sustainable development policy. "Acts of pollution are not the only cause of today's ecological harm: the unbridled consumption of natural resources is also a problem, even if it is not a source of pollution properly speaking. The official positions of the OECD indicate a growing awareness of the need for prices to reflect 'true' 'cost of natural resources use'. According to the OECD, a 'user-pay' principle should complement the polluter-pays principle in order to guarantee more prudent resources management. By attributing a price to the consumption of natural resources, such a principle could contribute to sustainable development." "The main difference between these two principles is that the 'user pay' principle would apply to resources and their users, while 'polluter-pays' principle applies entirely to discharges of pollutants and consequently only to polluters. Other than that, these two principles arise from a single economic logic of internalizing external cost."[669]

Therefore, it is clear that the principle of 'user pays' can be applied to the Nagoya protocol as its nature. Concurrently, it is clarified that the principle of 'polluter pays' also can be applied in case the user of GR, during access or use GR caused any damages to environment and he must compensate the damage caused by him.

d) Principle of non-regression of environment

All current international environmental conventions, whether universal or regional, and most national environmental legislation, provide that States commit themselves to the

[668] KISS.A, SHELTON.D, 2000, *Supra*, p. 266
[669] SADELEER.N, *Supra*, p. 42

continuous improvement of the environment and of the well being of citizens along with social progress and poverty eradication. Therefore, there is an international consensus on the need for legal measures to attain a high level of environmental protection and improvement in environmental quality. Human society has a collective responsibility not to harm the rights of future generations to life, dignity, health and sound environment, which includes a responsibility not to backslide on existing levels of environmental protection in policy and law. Non-regression is a prerequisite for effectiveness of all sustainable development policies and laws. The need for measures prevents all backsliding or regression of the level of environmental protection attained by each State according to its development status.

The principle of non-regression aims "to improve the environment that means all activities should not reduce levels of environmental protection." The objective of the principle is to affirm interdiction of any opposite measure. This is a precise of the principle 7 of the Rio Declaration 1992 "to conserve, protect and restore the health and integrity of the Earth's ecosystem".

If the environmental politics reflect progress, they must interdict all regression. The environmental law is devoted as a new humanright law by a great number of constitutions, but at the same time, it has substantive threats. The international humanrights law applies constantly a progress of right's protection through two international Pacts 1966. This can be interpreted as an interdiction of regression. Thus, the environmental law can benefit this theory for a progress of social rights. The Lisbon Treaty in the EU law also applies a new high protection and an improvement of environmental quality that acts as a principle to support the theories acquired by the Community.[670] The European Parliament Resolution of 20 September 2011 on a common EU position for the United Nations Conference on Sustainable Development (Rio+20), also calls for the recognition of non-regression in the context of environmental protection as well as fundamental rights.

This principle may be considered to apply for development of national legislation on access to GR, especially, during the process of integration of the Nagoya Protocol. This principle ensures that the access of GR meets all the environmental quality improvement; the benefit-sharing includes the right of future generation.

2) Principles for natural resources law

a) Conservation and sustainable use of natural resources

The World Charter for Nature called for "all areas of the earth, both land and sea to be subject to principles of conservation."[671] Article 2 of the CBD defines sustainable use "means the use of components of biological diversity in a way and at a rate that does not

[670] PRIEUR. M, *Droit de l'environnement*, Dalloz, 6e Edition, 2011, p. 88 - 89
[671] BIRNIE.P, BOYLE.A, REDGWELL.C, *Supra*, p. 199

lead to the long-term decline of biological diversity, thereby maintaining its potential to meet the needs and aspirations of present and future generations".

"The precautionary principle endorsed by Principle 15 of the Rio Declaration considers an important element of sustainable utilization because it addressed the key question of uncertainty in the prediction of environmental effects. Underlying all these agreements is a concern for the more rational use and conservation of natural resources and a desire to strengthen existing conservation law". However, "there remains a question of how far it can be assumed that international law now imposed on states a general obligation of conservation and sustainable use. The CBD impose little by way of concrete obligation." "The evidence of treaty commitment coupled with indication of supporting state practice, might be sufficient to crystallize conservation and sustainable use of natural resources in to an independent normative standard of international law. However, it is clear that states retain substantial discretion in giving effect to the alleged principle, unless specific international action has been agreed." [672]

Therefore, the Nagoya Protocol can be considered one of more concrete commitments contribute to principle of conservation and sustainable use of natural resources. Article 1 of the Protocol determines "objective of the protocol is the fair and equitable sharing of the benefits arising from the utilization of GRs…thereby contributing to the conservation of biological diversity and the sustainable use of its components." It is clear that the principle of conservation and sustainable use is integrated in the whole text of the Protocol. Especially, the Protocol has one separated article to provide on contribution to conservation and sustainable use. Article 9 of the Protocol provides "The Parties shall encourage users and providers to direct benefits arising from the utilization of GR towards the conservation of biological diversity and the sustainable use of its components." This article seems like a declaration and in form of a principle guiding for access and benefit-sharing activities. Article 8 of the protocol on special consideration requires Party in development and implementation of its domestic access and benefit-sharing legislation or regulatory requirements shall "create conditions to promote and encourage research which contributes to the conservation and sustainable use of biological diversity."

Article 10 of the Protocol on global multilateral benefit-sharing mechanism determines the objective of this mechanism is to support the conservation and sustainable use with provision of "The benefits shared by users of GR and TK through this mechanism shall be used to support the conservation of biological diversity and the sustainable use of its components globally."

[672] BIRNIE.P, BOYLE.A, REDGWELL.C, *Ibid*, pp. 199 - 200

b) Reasonable use

"The principle that common spaces are open for use by al nationals entails an obligation not to abuse this right or to interfere unreasonably with the freedom of others." "Reasonableness is essentially a basis for resolving competing claims where otherwise lawful activities conflict. It is not as such a principle of substantive environmental protection. While as a last resort it may enable States to argue that the exploitation of natural resources are illegal if so excessive that the interests of other states are disproportionately affected, it is not a substitute for other, more concrete rules limiting the right of states requiring sustainable use of resources."[673]

This principle is ideal to apply for access and utilization of GR found in places beyond national jurisdiction following principle of common heritage of mankind such as marine GR in the high sea - deep seabed or in Antarctic, "where the access is totally free and without prejudice of application of appropriate disposition to the UNCLOS" ,[674] or treaties forming the Antarctic treaty system, including the 1991 Protocol to the Antarctic Treaty on environmental protection. There still has question of "what is the applicable legal regime to determine the status of GR found therein and no explicit answer is provided to this question in existing treaties."[675] The Resolution A/RES/66/288 (Draft A/66/L.56) of the General Assembly of United Nations for Rio + 20 "The future we want", also refers in general of utiliziation of marine resources from para 158 to 177.[676] However, discussion of the reasonableness principle in the aspect of GR as common heritage of mankind seems to be far from the scope of this section which focuses only on principles for integration of the Nagoya Protocol into national law.

Nevertheless, the reasonableness principle may support for Article 10 of the Protocol regulates 'GR and TK that occur in transboundary situation or for which it is not possible to grant or obtain PIC.' The reasonableness seems to be relevant to apply "for benefits derived from the utilization of those GR and TK and support for the objective of the global mechanism. In this aspect, this principle could be considered during process of integration.

c) Abuse of rights

Birnie, Boyel and Redgwell stated "it has been said that it is not unreasonable to regard 'abuse of rights' as a general principle of international law, but that it is a doctrine which must be used with 'studied restraint". Some versions of the principle are more relevant to environmental questions than others." [677] Thus, this is reasonable to consider this principle for integration of the Nagoya Protocol into national law.

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[673] BIRNIE.P, BOYLE.A, REDGWELL.C, *Supra,* p. 201
[674] SADELEER.N., BORN.H.C, *Supra*, p. 116
[675] FRANCESCO.F, SCOVAZZI.T, *Supra*, p. 10 – p. 13
[676] Outcome of Rio +20 "The future we want" ***http://www.uncsd2012.org/thefuturewewant.html*** last accessed August 1, 2012
[677] BIRNIE.P, BOYLE.A, REDGWELL.C, *Supra,* p. 204

"The concept can be treated as one which limits the exercise of rights in bad faith, maliciously or arbitrarily. In this form, it is found in the UNCLOS and above principles including the duty to negotiation and consult in good faith. This is nothing about the content of legal rights and duties but is essentially a method of interpreting them." [678]

The legal base for this principle can be found by Principle 21 of the 1972 Stockholm Declaration and Principle 2 of the 1992 Rio Declaration. "Principle 21 and Principle 2 is to prevent the abuse of rights over natural resources management."[679]

However, there are some arguments that 'abuse of rights' is simply another way of formulating a doctrine of 'reasonableness' or a 'balancing of interests' or 'regard the *Trail smelter* arbitration and other formulations of the *sic utere tuo* principle[680] as indicative of an implicit 'abuse of rights' doctrine in this form. Therefore, some writers deny this principle and raise a question of whether is it correct. In contrary, "there is a view of the interpretation of the principle adds something useful to the elaboration of substantive rights and obligation concerning transboundary relations or the conservation and use of resources. In the relative absence of concrete rules and prohibitions of international law, abuse of rights offered a general principle from which judicial organs might construct an international tort law in accordance with the needs of interdependent states."[681] In addition, "Ago's conclusion that international illegality is constituted by a failure to fulfill an international obligation and that 'abuse of rights would be nothing else but failure to comply with a positive rule of international law thus enunciated".[682] Then, "any wider use of the doctrine is likely, as Birnie observes to encourage instability and relativity."[683]

Although, "in a certain view, abuse of rights is not an independent principle, but simply an expression of limits inherent in the formulation of certain rights and obligations which now form part of international law".[684] This is relevant to consider as one principle apply to access and benefit-sharing issues in the context of the Nagoya protocol. Therefore, during integration of the Nagoya Protocol into national law, it could be referred, but consider and mitigate limitations on "abuse of rights" like the generality of nascent rules of law which have subsequently acquired much greater particularity through codification and elaboration, primarily in treaty form. Present rules of international environmental law require a balancing of interests or incorporating limitations of reasonableness.

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[678] BIRNIE.P, BOYLE.A, REDGWELL.C, *Ibid*
[679] SADELEER.N, *Supra*, p. 64
[680] The *sic utere tuo* principle is the long-settled principle that persons must use their property so as not to harm that of others, *http://en.wikipedia.org/wiki/Vaughan_v_Menlove*
[681] BIRNIE.P, BOYLE.A, REDGWELL.C, *Supra,* p. 204
[682] BIRNIE.P, BOYLE.A, REDGWELL.C, *Ibid,* p. 204
[683] BIRNIE.P, BOYLE.A, REDGWELL.C, *Ibid,* p. 205
[684] BIRNIE.P, BOYLE.A, REDGWELL.C, *Ibid,* p 204

3) Equitable principles

In most national legal systems, "equity has played a major part in determining the distribution of rights and responsibilities in conditions of scarcity and inequity. The general value of equity is largely accepted in this context but debate exists on the appropriate principles to determine equitable allocation, for example, whether decisions should be based on need, capacity, prior entitlement, and the greatest good for the greatest number, or strict equality of treatment." "Equity also may provide a basis for decision in the absence of law or when it is necessary to fill in gaps in existing norms, such as when new issues emerge that give rise to disputes". "International tribunals have applied equity in this way, but usually on the basis that the equitable principle being invoked is a general principle of law."[685]

"Equity has been utilized most often in environmental agreements to fairly allocate and regulate scare resources and to ensure that the benefits of environmental resources, the cost associated with protecting them and any degradation that occurs (that is all the benefits and burdens) are fairly shared by all members if society". In this respect, "equity is an application of the principles of distributive justice, which seek to reconcile competing social and economic policies in order to obtain the fair sharing of resources". It does this by "incorporating equitable principles in legal instruments to mandate just procedures and results".[686] Therefore, it can be said that the Nagoya Protocol bases on equity under this meaning as its overall objective is fair and equitable sharing.

However, there still has controversy of the role of equity in international environmental law. Some writers see "most of problems as requiring 'equitable solutions', in which more created rules of law are displaced or interpreted in favor of an ad-hoc balancing of interests. Used in this general sense equity is little different from concepts of reasonableness or abuse of rights and suffers the same objection of encouraging instability and relativity in the legal system. There is of course nothing to stop states agreeing to settle disputes on an 'equitable' basis but political accommodation should not be confused with determinations of international law." [687]

Generally, All aspect of equity or equitable principles are necessary to consider during integration of the Nagoya protocol into national law. This sub-section examines equity in three particular equitable principles as following:

a) Intergenerational equity

"The theory of inter-generation equity has been advanced to explain the optimum basis for the relationship between one generation and the next. The theory requires each

[685] KISS.A, SHELTON.D, 2007, *Supra*, p 105
[686] KISS.A, SHELTON.D, 2007, *Supra*, p 105; TVEDT. M. W, YOUNG. T, *Supra*, p. 87- p. 88
[687] BIRNIE.P, BOYLE.A, REDGWELL.C, *Supra*, p. 202

generation to use and develop its natural and cultural heritage in such a manner that it can be passed on to future generation in no worse condition than it was received".

"The essential point of the theory that inter-generation equity is an inherent component of sustainable development that is defined 'development that meets the needs of the present generation without compromising the needs of future generation'". "Inter-generational equity is explicitly referred to in Principle 3 of the 1992 Rio Declaration, which provided for the right to development to be fulfilled 'so as to equitably meet development and environmental need of present and future generation and is reiterated in the same terms in the 1993 Vienna Declaration on Human rights". [688] However, the question is implementation. "Representation of future generations in legal proceedings before international courts is a less well-developed possibility. What is lacking is a theory of representation before international tribunals capable of according standing to future generations independently of the states and international institutions which are at present the only competent parties in international litigation."[689]

Intergeneration equity as a principle of international justice is based on the recognition of two key facts: one, "human life emerged from, and is dependent upon, the earth's natural resources base, including its ecological process and is thus inseparable from environmental conditions"; two, "human beings have a unique capacity to later the environment upon which life depends". "From these facts emerges the notion that human who are alive to day have a special obligation as custodians or trustees of the planet to maintain its integrity to ensure the survival of human species. Those living have received a heritage from their forbears in which they have benefit rights of use that are limited by the interest and needs of future generations". "This limitation requires each generation to maintain the corpus of trust and pass it on in no worse condition than it was received. Another way to consider the issue is to view current environmental goods, wealth and technology as owing to the progress of prior generations. This debt can not be discharged backward so it is projected forward and discharged in the present on behalf of the future." [690]

Three implications emerge from the principle of inter-generational equity. *First*, "each generation is required to conserve the diversity of the natural and cultural resource base so that it does not unduly restrict the options available to future generation to satisfy their own values and needs". *Second*, "the quality of ecological process passed on should be comparable to that enjoyed by the future generation". *Third*, "the past and present cultural and natural heritage should be conserved so that future generations will have access to it. These rights and

[688] BIRNIE.P, BOYLE.A, REDGWELL.C, *Ibid*, p. 120
[689] BIRNIE.P, BOYLE.A, REDGWELL.C, *Ibid*, p. 121
[690] KISS.A, SHELTON.D, 2007, *Supra*, p. 106

obligations derive from a notion of human society that extends beyond the totality of the current planetary population, giving it a temporal dimension."[691]

However, "the apparent simplicity of the theory of inter-generational equity is deceptive. It provides an essential reference point within which future impacts and concerns must be considered and taken into account by present generations, as well as a process by which these and other concerns can be addressed". Nevertheless, "inter-generation equity as an element of sustainable development does not resolve the argument for stronger generational rights nor does it determine the optimal balance between this generation and its successor". Moreover, "it fails to answer the question how we valuate the environment for the purpose of determining whether future generation will be worse off. Nor does concentration on relations between one generation and the next convincingly answer the equally pressing question of how benefits and burden should be shared within each generation". Thus, "although the content of the theory of inter-generational equity is well-defined, it rests on some questionable assumptions concerning the nature of economic equity".[692]

Moreover, the theory of inter-generational equity can be criticized for neglecting intra-generational equity consideration although it is more novel. Unlike inter-generational equity, "intra-generational addresses inequity within the existing economic system". The Rio Declaration does not refer by name to any concept of intra-generational equity. Some provisions of the CBD imply intra-generational concerns. "A part from principle 5, which calls for cooperation to eradicate poverty, intra-generational equity is served mainly by recognition of the special needs of developing countries.[693] Meanwhile, following Westra.L, "These two forms of protection are inseparable and their interface, we shall argue, forms the basis for 'ecojustice' that is both intragenerational and intergenerational at the same time".[694] "Brown-Weiss quite correct as she links intergenerational obligations with intragenerational duties: rich countries and groups must discharge their duties intergenerationally in a direct from but also by fulfilling their intragenerational obligations to developing countries and impoverished population".[695] In addition "Paul Barresi acknowledges that …these should be more than just moral obligations: they should be codified as law"[696]. In addition, "by ensuring now that eco-justice should prevail by supporting it in both its aspects intra-generational and inter-generational equity, both these aspects should be codified in appropriate law regimes of course and both should be enforced".[697]

In this respect, the CBD and the Nagoya Protocol with establishment and development of international regime on access and benefit-sharing that allows developing

[691] KISS.A, SHELTON.D, 2007, *Ibid*, p. 106
[692] BIRNIE.P, BOYLE.A, REDGWELL.C, *Supra*, p. 122
[693] BIRNIE.P, BOYLE.A, REDGWELL.C, *Ibid*, p. 123
[694] WESTRA.L, 2006, *Supra*, p.3
[695] WESTRA.L, 2006, *Supra*, p.137
[696] *Ibid*
[697] *Ibid*

countries are entitled to "a fair and equitable sharing benefit arising from the use of GR' found in their territory. A trade-off between conservation and economic equity is at the core of the CBD and the Protocol that is mentioned in Part 1 as 'selling nature to conserve it". This can be understood that some aspects of intra-generational equity principle are implied by the Protocol. It is clear that inter-generational equity is integrated in the Protocol.

b) Equitable utilization

"Equitable utilization is a widely accepted principle applied in apportioning shared resources, firstly, such as watercourses, fish and other exploited species. It finds expression in Article 2 of the 1997 UN Convention on the law of non-navigational use of international watercourses and affirmed by ICJ in some certain cases."[698] "The notion of equitable utilization is one that attempts to make a 'reasonable' allocation or reach a fair result in distribution of a scare resource, based on what are deemed to be relevant factors, such as need, prior use or entitlement and other interests. On a substantive level, each party is held to have an equal right to use the resource but since one party's use can impact the beneficial uses of others and not all uses can be satisfied, some limitation are necessary".[699] In this view, equitable utilization principle seems to be only suitable with GR as common heritage of mankind that is similar situation with the principle of reasonable use analysed above, thus it is inappropriate with aspects of legal status of GR under sovereignty of states of the CBD and the Nagoya protocol. In broad view, following Westra.L, "the principle of equitable resources use can be therefore understood in this way: rather than exacerbating a conflict between North -West preferences and South – East basic needs,…if we combine the two under the Kew Garden principle it ensures that both intergenerational and intragenerational basic rights are met and the correlative obligations are discharged"[700].

In addition, "Apart from its generality and limited capacity for describing predictable outcomes, equitable utilization is sometimes also deficient in addressing environmental problems only form the perspective of those states sharing sovereignty over the resource or engaged in its actual exploitation. It is thus less well suited to accommodating common interests or the protection of common areas since these requires a wider representation in any process for determining a balance of interest." [701] "The 'equitable' utilization of shared or common property natural resources entails a balancing of interests and consideration of all relevant factors. What these factors are and how they should be balanced depends entirely on the context of each case. No useful purpose can be served by attempting generalized definitions of what is essentially an exercise of discretion, whether by judges or other decision-makers. This discretion can be constructed,

[698] KISS.A, SHELTON.D, 2007, *Supra*, p. 108
[699] KISS.A, SHELTON.D, 2007, *Ibid*, p. 108 - 109
[700] WESTRA.L, 2006, *Supra*, p.137
[701] BIRNIE.P, BOYLE.A, REDGWELL.C, *Supra*, p. 202

however, and rendered more predictable, by careful analysis of international practice or by explicit recognition of relevant criteria in treaties or other instruments." [702]

However, in view of defining priority in purpose of GR's use, either international level or national level, this principle of equitable utilization should be applied, that effects to access and benefit-sharing management. It is recognized that "the idea of equitable utilization is the past had as a corollary that no use had inherent priority over any other. To day, there appears to be a move towards recognizing that some resource uses do have priority over others. In the use of freshwaters, emphasis is being placed on the satisfaction of basic human needs-that is the provision of safe drinking water and sanitation. The Watercourses convention provides that in the event of a conflict between the uses of an international watercourse, special regard is to be given to the requirements of vital human needs (Article 10)… The substantive human rights considerations help determine appropriate allocation".[703] Similarly, the priority should be given to use of GR for food and health. Therefore, the Article 8 of the Nagoya protocol expresses this aspect of the equitable utilization principle that special considerations for utilization of GR for food security and imminent emergencies that threaten or damage human, animal or plant health.

c) Principle of common but differentiated responsibilities:

"Law gives the favour to the common interest and common goods. The law operates through commands, through conformity to the regulatory according to logic of obeisance and no more justice. There emerged the recognition of common but differentiated responsibilities among states, incorporated in all global environmental conventions since the end of the 1980s, although it does not affect the obligations deriving from common concern it introduces the notion of equity into its implementation".[704]

"Common but differentiated responsibilities can be seen to define an explicit equitable balance between developed and developing states in at least two senses: it allow for different standards for developing states and it makes their performance dependent on the provision of solidarity assistance by developed states".[705]

Principle 7 of the 1992 Rio Declaration expresses this principle "States shall co-operate in a spirit of global partnership to conserve, protect and restore the health and integrity of the Earth's ecosystem. In view of the different contribution to global environmental degradation States have common but differentiated responsibilities. The developed countries acknowledge the responsibility that they bear in the international pursuit of sustainable development in view of the pressures their societies place on the

[702] BIRNIE.P, BOYLE.A, REDGWELL.C, *Ibid,* p. 202
[703] KISS.A, SHELTON.D, 2007, *Supra,* p. 109
[704] JEFFERY. I. M, QC, FIRESTONE. J, BUBNA. L. K, *Supra,* p. 27 – p. 28
[705] BIRNIE.P, BOYLE.A, REDGWELL.C, *Supra,* p 202

global environment and of the technologies and financial resources they command". [706] Therefore, there are two distinct ways to define this. First, "it imputes differentiated responsibility to states in accordance with their different levels of responsibilities for causing the harm". Second, "it ties differentiated responsibility to the different capacity of States by referring to the differentiated responsibility for sustainable development, acknowledged by developed countries in view of the technology and financial resources they command". Together, "these two elements of differentiated responsibility provide the beginnings of a philosophical basis for international cooperation in the fields of environment and development. It is a basis that allows the characterization of the transfer of resources from developed to developing countries as obligation rather than as 'aid' or 'assistance'."[707]

The principle of common but differentiated responsibilities is widely incorporated in MEAs. It calls broadly for developed countries to take the lead in solving existing global environmental problems. Thus, "even though the responsibility for protecting the environment is to be shared among all nations, countries should contribute differently to international environmental initiatives depending on their capabilities and responsibilities".[708]

Although, the CBD and the Protocol does not repeat phraseology of Principle 7 and has explicit differentiation between the responsibilities of developed countries and developing countries, but there are frequent references to what is "possible and appropriate". Article 6 of the CBD allows account to be taken if the 'particular conditions and capabilities' of each party that imply the different burden in different context.

Grounds for principle of 'common but differentiated responsibilities' also are explained by two elements: First, 'common responsibilities' element stems clearly from 'the integral and interdependent nature of the Earth, our home' and the consequent recognition of global partnership.[709] As a consequence of common responsibilities, all states concerned, especially developing countries are required to participate actively in the formation and implementation of international law for sustainable development in accordance with paragraph 39.1.c of Agenda 21. Paragraph 39.3.c of Agenda 21 also recognized the necessity to promote and support the effective participation of all countries concerned in particular developing countries in the negotiation, implementation, review and governance of international agreements or instruments. Second, 'differentiated responsibilities" element stems from two grounds: one is 'the different contributions of global environmental degradation' namely the pressures the developed countries societies place on the global environment' and the other is 'the technologies and financial resources

[706] BIRNIE.P, BOYLE.A, REDGWELL.C, *Ibid*, p 202; ABBOUR.J-M, VAVALLEE.S, *Droit international de l'environnement*, Editions Yvon Blais, Une Société, Bruylant, 2006, p.86-87
[707] MALANCZUK. P, *Supra*, p. 6
[708] KISS.A, SHELTON.D, 2007, *Supra*, p. 107
[709] Preamble of the 1992 Rio Declaration

they command. The fact that "the largest share of historical and current global emission of greenhouse gas has originated in developed countries and that per capita emissions in developing countries are still relatively low".[710]

"The broader version of the principle would oblige the developed world to pay for past harms, as a form of corrective justice, as well as present and future harms. For both climate change and depletion of ozone layer, the global community finds itself because of the conduct of developed world. It is precisely because of this conduct that the marginal environmental costs of industrialization of developing nations today are high. Developed nations thus should pay for any reduction or modification of developing world has to make in the process of industrialization because developed industrialization has unfairly circumscribed the ability if the developing world to pass off the negative externalities of development on the environment. The true social and environment costs of developed-nation industrialization were never accounted for in the past, so unfairly obtained windfall should now be redistributed."[711] For biodiversity loss and degradation, it was admitted that "Europe's wealth during colonial time was "to a large extent, based on transfer of biological resources from the colonies to the centres of imperial power".[712] Therefore, it seems to be principles of equity applied for developed world be responsible for degradation of environment and natural resources that "is reflected in those provisions referring to the historic responsibility of developed countries for the problem of climate change and the loss of biodiversity"[713]

The principle of 'common but differentiated responsibilities' is now being referred in negotiation for development of procedures and mechanisms on compliance for the Nagoya protocol.[714] This principle also should be considered during integration of the Nagoya protocol into national law.

B - Principles of process

Several values are reflected in the emphasis on procedural prinples in biodiversity conservation. Access information can assist both providers, users to perform better their obligation. Early and complete data assists national competent authority to make informed choices.

In addition, "the process by which rules emerge, how proposed rules become norms and norms become laws, is highly important to the legitimacy of law and legitimacy in turns effects compliance. When those governed have and perceive that they have a voice in

[710] SCHRIJVER.N, WEISS.F, *Supra*, p. 78
[711] KISS.A, SHELTON.D, 2007, *Supra*, p 107
[712] STOIANOFF, *Supra*, p. 2
[713] SANDS. P, *Principles of international environmental law*, Volume 1, 1995, frameworks, standards and implementation, p 213, cited by Matsui.Y, in Chapter 4, edited by SCHRIJVER.N, WEISS.F, *International law and sustainable development, principles and practice*, Martinus Nijhoff Publisher, 2004, p. 79
[714] UNEP/CBD/ICNP/1/6/Rev.1, *Supra*, p. 5

governance, they may see the decisions taken as ones in which they are stakeholders and which they will uphold."[715]

The provisions of institutional establishment access and benefit-sharing Clearing House mechanism and requirements for National Focal Point, National Competent Authorities and a range of related provisions like monitoring, reporting under the Nagoya Protocol aim at promote principles of process

1) Duty to know and "research"

Knowledge of environmental conditions and biodiversity state is necessary to have proper action of conservation and prevent harm to the environment. The basic information on the relevant area is essential for evaluating proposed activities. Thus, the implementation, formulation of law and policies require the collection of reliable information and continuous assessment. The techniques to support principle duty to know usually adopted in international and national environmental laws are surveillance, reporting and monitoring.

The CBD requires the acquisition of data through inventories, mainly a scientific activity on which further action, such as monitoring. Following that, the parties of the CBD are obliged to identify important component of biological diversity and monitoring them through sampling or other techniques. "Inventories concerning biological biodiversity aimed at conserving or managing living resources". "It can be done by individual enterprises, by associations or by local or national authorities. Once the information is obtained, it must be assembled, organized and analysed by an appropriate agency or institution to which the information is sent. It is common to find environmental laws requiring reporting by enterprises or state institution." [716]

"Monitoring is the continuous assessment of information, comparing it to mandated parameters". "Monitoring is necessary foundation for giving effect to all environmental obligations. Generally, a monitoring organ can propose legal changes based on reports and information that makes it possible to assess the effectiveness of existing measures". Monitoring provides constant feed back for decision making from long term protection to rapid guidance in emergencies. To ensure progress, the effectiveness of surveillance and monitoring must itself be assessed." [717]

The duty to know imposes a further procedural obligation related to the principle of prevention – prior assessment of potential harmful activities. This duty is expressed in the texts of the Rio Declaration through Principle 17, in Agenda 21 in Chapter 21 and the CBD in Article 14. In the Nagoya Protocol, this principle is supported by Article 13, 14, 17, 29,

[715] KISS.A, SHELTON.D, 2007, *Supra*, p 98
[716] KISS.A, SHELTON.D, 2007, *Ibid*, p. 99
[717] KISS.A, SHELTON.D, 2007, *Ibid*, p. 99

30. The States parties could consider this principle during integration of the Nagoya Protocol into national law.

2) Duty to inform and consult

"A state that plans to undertake or authorise capable activities of having significant impact on the environment of another state must inform the later and should transmit to it the pertinent details of the project, provided no national legislation or applicable international treaty prohibits such transmission". The 1992 Rio Declaration formulates the obligation as follows: "States shall provider prior and timely notification and relevant information to potentially affected States on activities that have a significant adverse transboundary environmental effect and shall consult with those States at an early stage and in good faith" (Principle 19). [718]

The CBD and the Nagoya Protocol also set "prior informed consent" (PIC) as a key component of access and benefit-sharing. This principle requires access to GR shall be subject to PIC of the contracting Party providing such resources, unless otherwise determined by that Party. The principle is provided by paragraph 5, Article 15 of the CBD and Article 6, 7 and related articles.

Parallel to the interstate duty to inform and consult, "an emerging international obligation suggests duties towards the residents of the potentially affected state. Norms requiring equality of information and access to administrative or judicial procedures are contained mainly in non-binding international texts and in some judicial opinions. Information is required on projects, activities and new development that could engender a risk of damage to the environment of non-residents. Non-residents may also seek access to information that the competent national authorities make available to their own interested local persons."[719] This is affected decisively by principle of access information; this is a precise of the Principle 10 of the Rio Declaration 1992 "each individual shall have appropriate access to information concerning the environment that is held by public authorities, including information on hazardous materials and activities". This principle should be considered during integration of the Protocol into national law.

By virtue of Principle 10 of the Rio Declaration, Article 13 of the Nagoya Protocol requires "Each Party shall designate a National Focal Point on access and benefit-sharing. The National Focal Point shall make information available for applicants seeking access to GR, information on procedures for obtaining PIC and establishing MAT, including benefit-sharing; for applicants seeking access to TK, where possible, information on procedures for obtaining PIC or approval and involvement, as appropriate, of indigenous and local communities and establishing MAT including benefit-sharing; and information on National

[718] KISS.A, SHELTON.D, 2007, *Ibid*, p. 101
[719] KISS.A, SHELTON.D, 2007, *Ibid*, p. 101

Competent Authorities, relevant indigenous and local communities and relevant stakeholders." Article 14 of the Protocol provides that access and benefit-sharing Clearing House "shall serve as a means for sharing of information related to access and benefit-sharing. In particular, it shall provide access to information made available by each Party relevant to the implementation of this Protocol."

3) Public participation

"Public participation is based on the right of those who may be affected to have a say in the determination of their environmental future". Principle 10 of the 1992 Rio Declaration stated that "access to information, public participation and also access to effective judicial and administrative proceedings, including redress and remedy, should be guaranteed, because 'environmental issues are best handled with the participation of all concerned citizens at the relevant level." Participation may take place through election, grassroots action, lobbying, public speaking, hearings, and other forms of governance, whereby various interests and communities participate in shaping the laws and decisions that affect them. The major role played by the public in environmental protection is usually through participation in environmental impact assessment or other permitting procedures.[720]

The most comprehensive international agreement on the role of the public is the regional Convention on Access to Information, Public participation and Access to Justice in Environmental Matters (Aarhus, 1998). The treaty builds on prior texts, especially Principle 1 of the Stockholm Declaration, which it incorporates and strengthens. The preamble forthrightly proclaims that "every person has right to live in an environment adequate to his or her health and well being and the duty, both individually and in association with others, to protect and improve the environment for the benefit of present and future generations." "The Aarhus convention is also important for procedural rights because the States parties have established a compliance procedure that accepts individual complaints and is the first environmental agreement to do so."[721] Its procedure has some distinctive features such as "NGOs and Convention signatories can nominate Committee members. Contrary to other compliance procedures, the rules of procedure of the Committee do not need to be approved by the Meeting of the Parties". The compliance procedure can be triggered in four ways: by a self-submission, by one or more Parties regarding another Party's compliance, by the Secretariat through referrals to the Committee and by members of the public concerning a Party's compliance. In addition, the Committee may examine compliance issues on its own initiative.[722] The compliance committee of Aarhus Convention was established in 2002, by first COP decision I/7 on

[720] KISS.A, SHELTON.D, 2007, *Supra*, p. 103
[721] KISS.A, SHELTON.D, 2007, *Ibid*, p. 104
[722] UNEP/CBD/ICNP/1/INF/1, *Supra*, p.11

Review of Compliance.[723] The UNECE 1999 Protocol on Water and Health to the 1992 Convention on the Protection and Use of Transboundary Watercourses and International Lakes also include a trigger by any member of the public.[724]

The Nagoya Protocol also provides requirements on public participation as "Where applicable, and subject to domestic legislation, set out criteria and/or processes for obtaining PIC or approval and involvement of indigenous and local communities for access to GR" under Article 6 and 7. Article 21 on awareness-raising and Article 22 on capacity of the Protocol provides a list of activities that promote public participation. Both two meetings of Open-ended Ad Hoc Intergovernmental Committee for the Nagoya Protocol (Montreal, 5-10 June 2011 and New Delhi, 2-6 July 2012) put in their provisional agenda the issues of cooperative procedures and institutional mechanisms to promote compliance with the Protocol in consideration of aspects of public participation.[725]

Section 2 - Methods, measures and other factors impact on the integration of the Nagoya protocol in to national laws

International law seldom stipulates how a State should implement its provisions, leaving it up to the State to choose the appropriate procedure for the execution. As mentioned by the thesis's general introduction, integration[726] of the Protocol is the process by which the Protocol becomes part of national law of sovereign states. A country integrates the Protocol bypassing domestic legislation that gives effect to the Protocol within its own national legal system. To make the Protocol function, no national order is required to convert it into the national one. The Protocol operates automatically within the national legal system. This process of integration is required because the Protocol has no effect on individual in national legal systems.

Therefore, questions are: How the Protocol is integrated into national law? What are needs for integration? Which affects to the integration? The answer for these questions is the need to clarify methods, measures and other factors during the process by which the Protocol becomes part of national law.

§ I - Methods and measures

A non-self-executing treaty always requires 'implementing legislation' - a change in the domestic law of a State Party that will direct or enable it to fulfill treaty obligations, thus, it becomes unnecessary to analyse in detail the two general methods in theories:

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[723] http://www.unece.org/fileadmin/DAM/env/pp/documents/mop1/ece.mp.pp.2.add.8.e.pdf last accessed August 2, 2012

[724] UNEP/CBD/ICNP/1/INF/1, *Supra*, p.19

[725] See more UNEP/CBD/ICNP/1/1, UNEP/CBD/ICNP/2/1/Rev.1, UNEP/CBD/ICNP/1/6/Rev.1, UNEP/CBD/ICNP/2/12

[726] or also expressed by many terms: 'incorporation', 'transformation', 'application', 'legitimation', 'reception', 'parallel law-creation', 'unification', 'conversion', BUTLER.W, - translator, editor, ZIMNENKO.L.B. writer, *International law and the Russian legal system*, Utrecht: Eleven Publications, 2007, p 46

incorporation and transformation following two doctrines of monist and dualist.[727] It rather is more necessary to analyze direct methods/approaches, which is necessary for process by which the Protocol becomes part of national law.

As indicated above, State Parties have freedom to choose methods, measures to make a treaty to become part of national law for compliance with their obligations, application and implementation. Therefore, there are different approaches of how to make a treaty become part of national law.[728]

A – Methods (or approaches)

There are various methods for integration of an international treaty into national law.[729] The author synthesizes to analyze three methods which are useful and effective for integration of the Nagoya Protocol into national law, even though, their wordings and names are different[730]. They are methods of interaction for the proper ensuring of the Protocol's obligations in each specific instance that make changes and/or additions to the system of law of the country**.**

1) Re-enactement

This method includes enactment of different legislative measures in the civil, criminal and administrative laws to give effect to the rights and obligations recognized by the Protocol or so-called national law-creation. It connects with juridical measures and

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[727] Incorporation was simply the method by which the liability was transferred from one system to the other. On the other hand, transformation doctrine, stipulates that rules of international law do not become part of international law until they have been expressly adopted by the state. It is often said that the doctrines of incorporation and transformation match up to monism and dualism respectively. However, it is clear that whether any state adopts the incorporation or transformation doctrine by its own national law, usually its constitution that tell use only what method that state has chosen as its way of giving effect to international law in its national courts, 15. DIXON.M, Textbooks on International law, 6th Edition, Oxford University Press, 2007, p 94-97

[728] Some view that it includes further steps: application and implementation of the treaty at national leve

[729] See more PRIEUR.M, *La mise en oeuvre national du droit international de l'environnement dans les pays Francophones*, Pulim, CRIDEAU, 2001

[730] UNEP manual provides Methods for Incorporating International Environmental Law into National Law: 1- *by re-enactment*. Incorporation by re-enactment translates institutional, administrative, regulatory and penal measures required by the MEA into domestic law at the time when the legislation is passed. 2- *by reference*. Incorporation by reference has the advantage of speed and simplicity. Incorporation by reference does not necessarily create the required institutions or administrative arrangement in domestic law. 3- *Adaptively Developing Implementing Legislation*, when developing legislation and institutions to implement MEAs, States often consider the approaches of other States (particularly those in the same region and with similar legal systems).
http://www.unep.org/DEC/ONLINEMANUAL/Enforcement/NationalLawsRegulations/tabid/75/Default.aspx
Or three main methods are available to implement international legal instruments in domestic law (1) Direct incorporation of rights recognised in the international instrument into what may be termed a "bill of rights" in the national legal order. (2) Enactment of different legislative measures in the civil, criminal and administrative laws to give effect to the rights recognised in international legal instruments. (3) Self-executing operation of international legal instruments in the national legal order.
http://www.un.org/esa/socdev/enable/disovlf.htm
See more COMBACAU.J, SUR.S *Droit international public*, 8e Edition Monthrestien E.JA, Paris, 2008, p 178 - p 187. " l'application des règles internationals dans l'ordre interne n'est pas toujours nécessaire à leur mise en oeuvre. Elles peuvent simplement réglementer les compétences internationales des États, sans directement concerner les sujets internes. De plus en plus toutefois ces règles, surtout les règles conventionnelles et les actes qui en sont dérivés, sont appelés à produire des effets interns, c'est-à-dire créer pour les particuliers des droits et des obligatión qu'ils puissent directement... »

administrative measures to effectuate changes of the system of law of a State, including its legislation. To apply this method, some factors should be considered as following:

Firstly, this method connects with a change of law of country but not of the legal system of a State. In fact, State adopts norms of national law to realize norms of the Protocol, in other words, engages in law-creation activities to which the system of law of the State are consequently changed or added. Under 'law creation', material and procedural legal norms form the system of law.

The concept of 'law-creation' may be considered in both its narrow and broad meanings. Narrow 'law-creation' is understood as activities of a State connect solely with a change of the system of law; in turn, broad 'law-creation' encompasses activities of a State concerning a change of both the system of law and of the legal system of the country.

This method re-enactment encompasses solely 'narrow' national law-creation. To characterize this method, it does not necessarily borrow, converse, or transit of norms of the Protocol into norms of national law. In this method, norms of the Protocol continue to remain and these norms continue to form the Protocol in international law system. However, the State adopts its legal norms for proper performance of the Protocol's obligations in its territory. The specific norms of the Protocol may be realized that can not be of a general character.[731]

Secondly, when creating national legal norms for the purpose of the realization of norms of the Protocol; it seems not effectuate the interaction between norms of the Protocol and national law.[732]

The legal norms adopted for the purpose of the realization of norms of the Protocol do not depend on the legal fate of the Protocol containing the legal norm. In fact, "norms of national law are issued in execution of norms of the international law always are other norms in their legal and… social nature than norms of international law".[733]

Indeed, when a State creates legal norms whose formulations wholly or partially is identical to the formulations consolidated with the Protocol, it is possible and realistic to speak of transformation. However, a State also may realize its Protocol's legal obligations by adopting other norms in which their content do not correspond to the formulations provided by the Protocol's norms but whose adoption is essential for the effectuation of proper implementation.

For example, to realize Article 6 of the Protocol on access to GR, we can speak in this instance about the conformity of the language text of national access and benefit-

[731] http://www.bju.nl/system/uploads/22060/original/9789077596203_voorbeeldhoofdstuk.pdf?1300458850
[732] http://www.bju.nl/system/uploads/22060/original/9789077596203_voorbeeldhoofdstuk.pdf?1300458850
[733] BUTLER.W, - translator, editor, ZIMNENKO.L.B. writer, *International law and the Russian legal system*, Utrecht: Eleven Publications, 2007, p. 52 and seq

sharing law and Article 6 is possible relatively. It is impossible to speak of any transformation in its classical understanding irrespective of whether this concept is derivative or generic. In principle, "transformation", having regard to its conditional character, may be regarded as a special instance of national law-creation. We can assume a situation of which the State adopts a national legislation fully or partly are identical to provisions of the Protocol, but it would not be advisable to regard transformation as an autonomous method.

Thirdly, there may be in "parallel law-creation" the models of behavior maximally coincide. This is in event a national law is adopted not in execution of the Protocol, but autonomously, in parallel, by proceeding from the domestic access and benefit-sharing requirements of the State. The legislator, in forming national access and benefit-sharing law of the country, has the right in his activity to use rules of the Protocol, to change the appearance of law with taking into account the peculiarities of the national legal system. He can also adopt a completely different rules of behavior connected with its Protocol's obligations. All these are technical means of effectuating national law creation in each specific instance. However, a State has to create legal norms which should not be contrary to norms of the Protocol. National law creation does not always facilitate the effective realization of norms of the Protocol. Therefore, a State is obliged to adopt legal norms which would regulate the effective procedure.

Fourthly, it should be noted that the Protocol does not accept reservation.[734] Therefore, a State has not the right to make conservation, by expressing consent with respect to the Protocol and not wish to change its legislation. The State must change its legislation. Thus, national 'law-creation', being an autonomous method that consists of the adoption by a State or sanctioning legal operation of other social norms for the purpose of the proper realization of norms of the Protocol. Norms adopted or sanctioned by a State may wholly or partially repeat rules consolidated in the Protocol and also contain other rules facilitating the realization by the State of its obligations.

Fifthly, this method may advocate using legal economic instruments. When realizing the Protocol's obligation by national law, in consideration of country specific conditions, it should not be only 'command and control' method, but also a normative framework for economic planning and market instruments. Such methods can also be useful for the implementation of obligations resulting from the Protocol.

It is suggested that the government should regularly assess the laws and regulations enacted and the related institutional and administrative machinery. "Governments and legislators should establish judicial and administrative procedures for legal redress and remedy of actions affecting environment and development that may be unlawful or infringe

[734] Article 34 of the Nagoya Protocol

on rights under the law and should provide access to individuals, groups and organizations with a recognized legal interest."[735]

2) Incorporative norm

The peculiarity of this method is that the Protocol's norm can be incorporated into national law. A national court or other law-application agency directly has recourse to the Protocol's provisions but this is not a self - execution. This method can be explained as following:

Firstly, the essence to apply this method is that a rule[736] which contains principal rights and obligations as subjects of national law may be regulated by the Protocol' norms. The norm is not introduced by new documents in national law but merely is allowed with application of the Protocol's norms to regulate a specific relation arising within a State. In this method, the legislator does not reproduce the Protocol's norm, but refers to a Protocol's prescription to achieve the absolute concordance of the norms of the two systems of law.

Secondly, possibilities to incorporate the Protocol's norms and its legal consequences can be explained by structure of a legal norm. Any legal norm has its own objectively conditioned logical structure which includes three elements: hypothesis, disposition, and sanction. "The hypothesis represents an indication of the conditions under which subjective rights and duties arise that are, in turn, the content of relations regulated by a norm". "The disposition contains directly an indication of the subjective rights and duties". "The sanctions are those unfavorable consequences which the subject of the right undergoes in the event of the failure to comply with the disposition and hypothesis." [737] The presence of these elements also is characteristic of the Protocol's norms. However, specific individual sanctions are not formulated in the Protocol in the absolute instance of legal norms, because, the Protocol only take its effect to States but not to individual citizen or legal entity of the State.

I would wish to take an example to clarify the above structure of the legal norm by analyzing legal structure of Article 5.2 of the Protocol. Article 5.2 defines that "Each Party shall take legislative, administrative or policy measures, as appropriate, with the aim of ensuring that benefits arising from the utilization of GR that are held by indigenous and local communities, in accordance with domestic legislation regarding the established rights of these Indigenous and local communities over these GR, are shared in a fair and

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[735] KISS.A, SHELTON.D, *International Environmental law*, Second Edition, Transnational Publishers, Inc, Ardsley, New York, 2000, p .73

[736] BUTLER.W and ZIMNENKO.L.B, in *International law and the Russian legal system*, Utrecht: Eleven Publications, 2007, used the original term 'renvoi'norm, "Renvoi constitutes the content of the transformed norm according to which the rules and prescriptions that are international legal norms in determined instances begin to be regarded as municipal norms". p. 45

[737] BUTLER.W and ZIMNENKO.L.B, *Supra*, p.67

equitable way with the communities concerned, based on MAT". Thereof, the hypothesis is the entry of the Article "Each Party shall take legislative, administrative or policy measures, as appropriate"; and the disposition is "ensuring that benefits arising from the utilization of GR … are shared in a fair and equitable way with the communities concerned, based on MAT". The sanctions are absent. Aso, the difficulty of distinguishing and evaluating 'legislative measures' and 'policy measures' in the hypothesis as indicated by Part 1 of this thesis will make difficult to implement the disposition.

Thus, to incorporate of a Protocol's norm to make this norm operate within nation law system, a national complex norm will be created which also contains a hypothesis, disposition, and sanction. This national complex norm regards to relations with the participation of national subjects of law.

However, the Protocol's norm regulates inter-State relations which determine the subjects, rights and duties of subjects, the object of the relations, and the legal facts (such as condition, origin, change, and/or termination of the respective relations). A national legal norm (or legal complex norm), in regulating national relations, also determines the subjects of relations, subjective rights and legal duties, object of the particular relations, and also legal facts (condition, origin, change, and/or termination) of relations being regulated. The content of the elements of relations being regulated in the Protocol and national law do not coincide. Thus, a Protocol's provision (but not a norm) with regard to national relations contains a list of empowered subjects, their subjective rights, legal duties, the object of relations, and legal facts. However, the Protocol provisions do not provide a sanction in the event of the failure to fulfill the respective duty. This is to confirm that the Protocol's norm is impossible to operate directly in the sphere of national relations. Accordingly, substantiated position of the national norm or complex norms arises as a consequence of the operation of the Protocol's norm within the framework of the national legal system.

Thirdly, the inclusion of the Protocol's norms in the national legal system creates complex legal norms that emerges the legal duty of State agencies and private persons whose activities guided by those norms. In other words, subjects of national law receive the possibility to realize the mutual rights and duties provided by any legal norm. In this respect, the Protocol's norms provide rights and duties of subjects of the Protocol for an international access and benefit-sharing relation. The right of subject or 'subjective right' is a possibility of a subject ensured by norms of law (and respective duties) to act and thereby to effectuate the prescriptions of an objective right. When the Protocol's provisions become part of a national legal system; the relations regulated by the new complex norms will include other subjective rights and duties than the rights and duties contained in the norms of Protocol's provisions. The different character of subjective rights and duties is conditioned not only by the existence of other subjects of law, but also by the content.

A situation is not excluded that a State agency, while complying with, executing, using, and applying complex norms, will be guided solely to fill gaps in the national system of law. A conflict may arise between the provision of the Protocol's norm and the national norm of national law that may be guided by principle of priority for application, including the principle of *lex posterior* (the law latest in time governs) or *lex specialis* (replaces a general law). Thus, State agencies should indicate the procedure to settle this conflict.

Fourthly, the national provision does not incorporate the Protocol's norms into the national legal system, but states that the fact of social relations regulated by national norms is in conformity to the Protocol's norms. In other words, the consolidation of a legal presumption on the conformity national law and the Protocol's norms is determined by social relations. (e.g, state of national access and benefit-sharing legislation of some countries has been promulgated before the Protocol) This presumption must be borne in mind when effectuating an interpretation of legal norms. That is, when the provisions of Protocol's norms become part of the legal system of a country, State agencies must precede any conflicts between the Protocol's norms and provisions of national norms law.[738]

It is noted that the method of re-enactment and incorporative norm are closely linked with one another. In the first instance national legal norms are adopted by the State, and in the second, complex norms arise within the framework of the legal system of a State, the forms of existence of which are simultaneously both sources of the Protocol and national law of a State. There is manifest a dialectical unity of the methods connects to national law creation. Moreover, incorporation of norms of the Protocol is the possibility of realizing protocol's provisions in the sphere of national relations. "The implementation of an international treaty within a national legal regime cannot be made by the direct incorporation of its rules to the national legislation through a simple administrative or legislative act. It is widely determined by the degree of evolution of the national legal and institutional framework." [739]

3) Interpretation

Legislation of State and national practice give us the possibility to speak about another necessary method of ensuring the realization of provisions the Protocol in the sphere of national relations. We refer to interpretation of norms of national law by taking into account the Protocol's norms, and also norms of the Protocol's provision which have become part of the legal system of a State.

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[738] BUTLER.W and ZIMNENKO.L.B, *Supra*, p. 52 and seq

[739] CARRIZOSA.S, BRUSH.S.B, WRIGHT.D.B, MC GUIRE.E.P, *Accessing Biodiversity and sharing the benefits: Lessons from Implementing the Convention on Biological Diversity*, IUCN Environmental Policy and Law Paper No. 54, 2004, p. 229

Through interpretation, "it seeks also conciliation between international law and national law"[740].

a) The necessity of the method of interpretation

First, obligation of States is not always capable of reflecting the essence of the Protocol's norm in execution, thus, it needs interpretation as an autonomous method of national-legal implementation which is essential. In principle, if one speaks solely about the interpretation of national-legal norms adopted by the method of national 'law-creation', the interpretation of such norms should not be singled out as an autonomous method of national legal implementation. However, a national legal norm may emerge not by way of the realization of particular the Protocol obligations. "The State takes all interpretation in harmonies 'interpretation conforms' to avoid violation of treaty in the case of the application contrary internal norm, except the internal rule has been adopted in the same contradiction with obligation of the treaty".[741]

Second, a law-creation does not maximum coincide with the Protocol or not simultaneously with execution of the Protocol's obligations. The greater part of national law does not coincide with the issuance of a law and the Protocol. The creation of legal norms for the purpose of the realization of norms of the Protocol may not always further the achievement of this purpose. Therefore, it is essential to devote great significance to the procedure of interpretation as legal norms adopted by the State to effectuate national law.

It is important in any legal system not only to create a legal norm, but also to ensure the realization thereof. An interpretation is a necessary stage of any form of the realization of law: compliance, execution, use, and application. Interpretation has special significance for the application of legal norms by judicial and arbitral agencies operating both on the international and national levels. The peculiarity of this method is that subjects of national law participate in the realization" and, consequently, interpretation of already created national legal norms and/or formed complex legal norms that make up the legal system of the State concord to the Protocol.[742]

Third, the language of the Protocol, like that of any law or contract, must be interpreted, because the wording does not seem clear or it is not immediately apparent how it should be applied in a perhaps unforeseen circumstance. It is recognized that "the need for interpretation, doctrinal writings emphasize, arises because of the fact that frequently treaty provisions (or norms) are too general, insufficiently definite. This makes difficult their realization in a particular situation. One has recourse to interpretation when there is

[740] EISEMANN.P.M, *Supra*, p.19
[741] EISEMANN.P.M, *Ibid*, p.21
[742] BUTLER.W and ZIMNENKO.L.B, *Supra*, p. 52

indefiniteness, lack of clarity, ambiguity (or multiple meanings) of words, terms, expressions, or the failure of some provisions to conform to others, their lack of coordination".[743]

In addition, resort to norms of the Protocol when interpreting national legislation is admissible not only in instances of ambiguity arising with respect to a national normative act, but also for the purpose of revealing such ambiguity. That is, it is necessary to turn to the Protocol at the very outset of applying the respective implementing legislation. "If the legislator, in adopting implementing legislation, precisely and explicitly proceeds from the position that the rules in this legislation will differ from the rules formulated in the Protocol, in other words, we speak of the "establishment" of an intentional" conflict, the judicial system should be guided by the rules formulated in the implementing legislation." [744]

However, it is criticized that "the process of interpretation reposes wide discretionary powers in the judge. Voltaire's misgivings would not be altogether misplaced in a judicial environment where methods of interpretation of legal norms were lax, applied subjectively, or simply exploited to justify a desired end. Then there would be a real likelihood that in some cases the courts would cut the functions of the legislature and call in question their own legitimacy."[745] "The judges are not always in the positition to know clearly to interpret a national norm in international origin that is not important to respect the rules of interpretation of applicable treaty."[746]

b) The purpose of the interpretation

Murray states that "when one considers that first, there is the law; then there is interpretation. Then, interpretation is the law".[747]

"The purpose of the interpretation of any legal norm is eliciting the meaning and content of the respective legal norms and terms in which the respective legal norm found expression. In turn, a legal norm is an ideal model of a social relation. A juridical norm – is the initial elementary unit, the 'brick' of law of a particular country as a whole, a norm of law is a general rule of behavior, it is a model, an etalon, of a typified, then – official, publicly obligatory decision of life situations of a determined nature". A "norm as a model of legal relation in general form determines the possible behavior of one party of a future relation and the legal bindingness of any actions or refrain from actions of the other party to this relation." "To properly construe a legal norm means to determine not only the structure of a specific norm, but also the basic elements of the social relation regulated by law which find, in turn, consolidation in the structure of the norm."[748]

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[743] BUTLER.W and ZIMNENKO.L.B, S*upra,* p.110
[744] BUTLER.W and ZIMNENKO.L.B, *Ibid,* pp. 98-99
[745] MURRAY.L.J, *Methods of interpretation – comparative law method,* Actes du colloque pour le cinquantième anniversaire des Traités de Rome, 2ème session: Le système juridictionnel, p. 40
[746] EISEMANN.P.M, *Supra,* p.24
[747] MURRAY.L.J, *Methods of interpretation – comparative law method, Supra,* p. 39
[748] BUTLER.W and ZIMNENKO.L.B, 2007, *Supra,* p. 97

When the provisions of norms of the Protocol which have become binding upon a State "contain a different normative content of concepts or terms than provided in sources of national law, a subject of law taking part in the realization of national law norms does not simply have the right", but is obliged to turn to the content of the respective norms of the Protocol. "In other words, when effectuating the interpretation of national legal norms and identifying the content of particular legal terms and concepts it is essential to take into account the normative content of analogous terms" and concepts existing in the Protocol's provisions which have become binding upon a State. [749]

c) Modes and ways of the interpretation

The interpretation of any legal norm is an integral stage of the realization of a norm in the sphere of social relations. Following Lukashuk, there are some ways for interpretation as following: "(a) establishment of the factual circumstances of the case; (b) legal qualification of the factual circumstances; (c) determination of the legal characteristics relevant to the case of norms, their operation with respect to the particular subjects or that is special-legal interpretation of norms; (d) establishment of the content of norms, that is general interpretation; (e) adoption of a decision concerning the application of norms to particular factual circumstances; (f) actions with regard to ensuring the realization of the decision adopted".[750] Following Combacau, there are three modes: "unilateral interpretation", "concrete interpretation" and "jurisdictional interpretation". [751]

In considering the peculiarities of interpreting provisions the Protocol which have become an integral part of the legal system of the State, the interpretation of norms of the Protocol as part of the law of a country is a rather complex problem having many specific features and acquiring ever greater practical significance. "In international relations States and international agencies, including judicial, explain the meaning of norms as elements of the international legal system." [752] Agencies of a State interpret the Protocol's norm so that it might be applied as part of the national legal system.

One of the important questions here is who makes the interpretation? It should have to distinguish between national interpretation, the international interpretation and the academic interpretation by authors and professors of 'la doctrine'. For national interpretation, depending on specific conditions and provisions of each country, the authority and responsibility of interpretation of Protocol shall be assigned to the Government or Foreign Minister or Ministers or judge. For the international interpretation, it can be made by the secretariat, the COP, the compliance committee that depends on each treaty and purposes and requirements of interpretation

[749] BUTLER.W and ZIMNENKO.L.B, 2007, *Ibid*, p. 98
[750] Cited by BUTLER.W and ZIMNENKO.L.B, *Ibid*, p. 110
[751] COMBACAU.J, SUR.S *Droit international public*, 8e Edition Monthrestien E.JA, Paris, 2008, p. 178 – p. 182
[752] Cited by ZIMNENKO.L.B, S*upra*, p. 110 – p. 111

When effectuating the interpretation of provisions of the Protocol as part of the legal system of a State, it is necessary to use principles, means, and rules in force within the framework of the international legal system and principles and means of interpretation characteristic of the specific national legal system.

Certain principles of interpreting international treaties that can be applied for the Protocol are contained in the 1969 Vienna Convention on The Law of Treaties. The Vienna Convention states that treaties are to be interpreted "in good faith" according to the "ordinary meaning given to the terms of the treaty in their context and in the light of its object and purpose" and the basic principles of international law. "Interpretation should not prejudice the rights of the parties" that means no one party to a treaty can impose its particular interpretation of the treaty upon the other parties. Consent may be implied, however, if the other parties fail to explicitly disavow that initially unilateral interpretation, particularly if that state has acted upon its view of the treaty without complaint. Consent by all parties to the treaty to a particular interpretation has the legal effect of adding an additional clause to the treaty – this is commonly called an 'authentic interpretation'. There are also some principles which interpretation should be followed. "'Principle of maximum effectiveness,' interprets treaty language as having the fullest force and effect possible to establish obligations between the parties." "Principle of lawfulness, by virtue of which, the interpretation of norms of international law should not lead to a violation of other international legal norms, including imperative". "The principle of the unity of interpretation guarantees a uniform interpretation of the legal norm for each instance without allowing a different interpretation of particular norms in particular situations." "The principle of respect for the rights of subjects does not allow an unsubstantiated expansion of the rights of some subjects at the expense of impinging the rights of other subjects and, accordingly, an expansion of their duties". "The principle of justness promotes the interpretation of a legal norm by taking into account the circumstances of a certain matter. Terms contained in a norm should be understood in their ordinary meaning by taking into account the context of the treaty; special meaning is imparted to a term only when this clearly follows from the intentions of the parties; and the priority of a special norm over a general norm." "The rule of the unity of the text in different languages for concerning the interpretation of multilingual texts, consisting in the fact that a treaty has a single content expressed in different language texts; the rules of the equal legal force of different language texts (equal authenticity). Attention should be drawn to the fact that the parties to a treaty having different language texts possessing equal authenticity may provide for the possibility of granting priority in interpretation to a certain text."[753] "The

[753] ZIMNENKO.L.B, *Ibid,* p. 115

interpretation of some provisions provided for in sources of international law, should be effectuated uniformly without violation the principle of "legal certainty".[754]

Zimnenko considered the methods of interpretation of international treaties which basically come down to the following: grammatical, logical, systematic, and historical, this list of methods not being exhaustive considered the special means of interpretation of international treaties. In particular, he noted, "the peculiarities of languages should be taken into account in which the treaty is drawn up, the historical peculiarities of its conclusion, the link of parts of the treaty between themselves, and also whether the treaty, including the preamble, comprises and single and legal whole. The results of interpretation should not be contrary to the basic principles of international law, nor violate the sovereignty of the State, nor lead to the treaty not operating, nor to a loss of meaning. Special articles have priority over general provisions of a treaty. The practice of application is important for the interpretation of a treaty". [755]

"The types of interpretation depend on the agencies effectuating the interpretation. Unilateral interpretation of a treaty does not bind the other participants. In turn, such an interpretation which is agreed by all the participants of the treaty is binding." "A detailed analysis of the basic principles, rules, and means of interpretation of international-legal norms are effectuated."

The means of interpretation are in existence. "Special legal interpretation, consisting of the elucidation of legal characteristics of an international legal norm – whether the norm operates, whether it is lawful, the group of subjects of international law to which the operation of the norm extends". "Systematic interpretation, being the interpretation of norms of law within the system of other legal norms operating within the framework of the respective legal system". "Grammatical interpretation, being the elucidation of the meaning of a norm by means of an analysis of the words and terms, and also the text thereof from the standpoint of etymology, lexicon, syntax, and style of the language". "Logical interpretation subjects the text of a norm to an analysis based on the laws and rules of logic". "Historical interpretation assumes an interpretation effectuated by taking into account the historical conditions of the creation of the norm". "Political interpretation, in turn, is effectuated by taking into account the political conditions which operated at the moment of the creation of the norm". "Teleological interpretation is an interpretation taking into account the object and purpose of the legal norm being interpreted."[756]

It is distinguished as means literal, expansive, and limited interpretation. "Literal interpretation is used in those instances when the text sufficiently precisely expresses the intention of the parties". "Expansive interpretation applies when the real meaning of the

[754] ZIMNENKO.L.B, *Ibid,* p. 131
[755] ZIMNENKO.L.B, *Ibid,* p. 114
[756] ZIMNENKO.L.B, *Ibid,* p. 116

norm is broader than the literal form". Accordingly, "limited interpretation is when the sense of the norm already has word form". "Lukashuks especially emphasize that these last two means of interpretation should not lead to a limitation or expansion of the real content of the legal norm." [757] In addition, there are some criticisms that "While the meaning of 'literal interpretation' is fairly obvious the teleological method of interpretation is also sometimes called the purposive and often difficult to distinguish from the schematic or the harmonious methods of interpretation, notwithstanding a certain ambiguity in the nomenclature of methods of interpretation it could be said that the literal, teleological and comparative law methods comprise a primary group of such methods."[758]

"The other authors also note normative and casual interpretation". "The first is elucidation of the content of the legal norm with regard to all instances falling under the regulatory operation of the norm". "Casual interpretation, in turn, presupposes interpretation with respect to a certain situation of an event which is the subject of consideration by a State agency, including a national court. International agencies and organizations effectuate a normative-recommendatory interpretation, the essence of which lies in the elucidation of the content of a norm of law with regard to all instances, but such an interpretation is solely recommendatory in character". "Depending on the subject of interpretation, it is distinguished also by authentic and doctrinal interpretation, and depending on the possibility thereafter to use the results of the interpretation – normative and casual." [759]

"A complex interpretation may be regarded as a basic principle of interpretation of a complex norm formed in the legal system of the State. Conflicts may arise between a complex norm and a norm of national law or between two complex norms. When interpreting provisions fixed in international law, it is important to bear in mind that this interpretation should be effectuated according to the foundations of legal order (or public policy) existing in the particular State. An interpretation of the aforesaid provisions should not lead not only to a situation when the interpretation is contrary to imperative norms of international law, but also not to lead to a violation of the foundations of the constitutional system of the State." [760]

"A complex norm formed as a consequence of the operation of international legal norms is, above all, within the system of norms regulating national relations. Simultaneously, this norm does not lose a legal link with other norms of international law which are binding on this State." "When interpreting a complex norm, by the conception of a friendly attitude towards international law, the essence is to take into account municipal

[757] ZIMNENKO.L.B, *Ibid,* p. 116
[758] MURRAY.L.J, *Methods of interpretation – comparative law method,* Actes du colloque pour le cinquantième anniversaire des Traités de Rome, 2ème session: Le système juridictionnel, p. 40
[759] ZIMNENKO.L.B, *Ibid,* p. 116-117
[760] ZIMNENKO.L.B, *Ibid,* p. 121

normative-legal acts; the legislation had no intention to violate norms of international law. Accordingly, the situation could be considered the presumption operates of the absence of a conflict between complex norms and norms of municipal law. But if as a consequence of interpretation a clear and unambiguous conflict arises between the complex norm being interpreted and other complex norms, or between a complex norm and norms of national law, the person participating in the realization of the respective norm must be guided by the principles of hierarchy or priority of application in this work." [761]

"A peculiarity of systematic interpretation of norms of international law is linked with the fact that a State or other subject of international law interprets norms of international law within a system of other already existing social norms. If a treaty norm of international law or a norm fixed in a decision of an international organization is the object of interpretation, special problems do not arise, as a rule, for the law-applier connected with establishing the content of the respective norm". "According to Article 31.3.b of the Vienna Convention, when interpreting treaties in addition to the context the subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation is taken into account." This Article denies the possibility of this point encompassing unilateral practice. It is emphasized that "unilateral practice, the more so unlawful, of the application of an international treaty may not serve as grounds for its proper construction". [762]

In the course of the application in the sphere of national relations of provisions contained in the international law which have become part of the legal system of the State, "there are no protests on the part of interested subjects of international law, the respective application and, thus, interpretation must be regarded as an obligation constituting agreement established as a consequence of subsequent practice of the application of a specific source of international law."

"To be sure, a State is free in the choice of means, methods, and ways of the realization of norms of international law in the sphere of relations with the participation of subjects of national law. However, if in the view of the interested subject of international law a State, in realizing respective provisions, violates international legal norms, to declare a protest in this respect is not only a right, but under equal circumstances, also the duty of the interested subject of international law". "As emphasized above, in the course of the realization in the sphere of national relations of norms of national law and/or provisions contained in sources of international law, State agencies have the right to take into account, including to do so during interpretation, decisions of international organizations which have become a source of international law for a State and decisions of international

[761] ZIMNENKO.L.B, *Ibid,* p. 126
[762] ZIMNENKO.L.B, *Ibid,* p. 129, 130, 131

organizations which are not a source of international law but which may be used by a law-realizing agency". [763]

"It should be noted that to avoid 'legal uncertainty', agencies of executive power should refrain from giving any explanations with regard to an understanding of provisions which have become part of the legal system of this state. Legislative agencies, in turn, should refrain from unilateral 'interpretative statements', except for instances of necessity which the national interests of the State require this. When effectuating justice under the general rule an interpretation of provisions contained in sources of international law should be within the competence of judicial power. As noted above, the judicial system should not allow an equivocal, ambiguous interpretation of the same norms of an international treaty." One must note that "the possibility of effectuating the interpretation (both complex and systematic) of a norm formed is conditioned by the possibility of the direct operation within the framework of the legal system of a State of a source of international law. However, the direct operation of an international treaty or other source of international law in the sphere of national relations does not mean the direct operation of a norm of international law. Naturally, the respective sanction of a State is required for a source of international law to operate directly in the sphere of national relations."[764]

B – Measures

Many articles of the Protocol suggest and require State Parties to use various measures to achieve the objective of the Protocol. They include not only "legislative, administrative or policy measures" but all "appropriate, effective and proportionate measures". Following the guidelines of UN suggest, there are technical, economical and social measures feasible to implement, monitor and enforce effectively and provide standards that are objectively quantifiable to ensure consistency, transparency and fairness in enforcement.[765]

This section will examine all measures support for integration of the Protocol into national law. Most of measures are analyzed by reference to the measures introduced by KISS.A and SHELTON.D in 2000 for the environmental law in general.[766] These measures are improved by consideration and wordings of the author to maximize their effectiveness and harmonization for the integration of the Nagoya Prototocol. Those measures are provided as follow:

[763] ZIMNENKO.L.B, *Ibid,* p. 132
[764] ZIMNENKO.L.B, *Supra,* p. 137-138
[765] http://www.unep.org/DEC/ONLINEMANUAL/Resources/Guidelines/tabid/70/Default.aspx?targets=40#high
[766]. Therefore, the quotation marks are difficult to put exactly in each sentence.

1) Regulatory measures

Access and benefit-sharing processes is assumed to cause harm to biodiversity and the environment. The duty to prevent environmental harm implies the application of measures to avoid harm and reduce or eliminate the risk of harm. Therefore, it is required adoption of implementing laws and regulations and specifying measures.

"The CBD suggests use the best practices. This requirement can be seen as deriving in part from the customary international obligation of 'due diligence' to prevent environmental harm. The protocol also suggest to use best practices defines the term"[767]

a) Standard setting[768]

Establishing standard is required during access GR that impact on environment. In the context of access and benefit-sharing, standard are prescriptive norm that govern process or limit on the amount of GR exploited. Some categories of standards may be distinguished according to the subjects they regulate as follows:

Process standards specify design requirements or operating procedures applicable to fixed installations, such as designate permissible means and methods of activities like collecting samples of plants or animals.

Product standards are used for items that are created or manufactured for sale or distribution. Product standards may regulate: the physical or chemical compositions of items such as pharmaceuticals, for examples: biochemicals extract from or use GR information as derivatives. Labeling requirements are used to ensure that consumer aware of the contents and permissible use of product that includes the GR and TK utilization. The product standards can be used in different industry such as pharmacy, biotechnology,…

b) Restriction and prohibitions[769]

The strict measures can be imposed to limit over exploitation of GR and reduce the harm to environments from the activities of GR access and utilization. When the likelihood of risk is too great, the measure may call for a ban. The numbers are types of restriction are almost unlimited but certain ones are availably used.

Limits or bans: controlled activities of GR access and utilization are named in easily amended lists appended to the regulation of access and benefit-sharing, such lists permit individualizing situations and give the regulation some flexibility. Lists also avoid too much technical detail being included in the basic legislative or regulatory text. The use of lists is very common in protection wild flora and fauna, especially species, such as limits and ban in exploiting GR of some species.

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[767] KISS.A, SHELTON.D, 2000, *Supra*, p. 192 – 193, read
[768] KISS.A, SHELTON.D, 2000, *Ibid,* p 194
[769] KISS.A, SHELTON.D, 2000, *Ibid,* p. 200

Taking and trade measures: this is the common measure of treaties for the protections of biodiversity that mandate the use of trade restriction or require the imposition of limits on taking specimens of protected living or non living resources. The types of restriction vary and include: hunting and collecting restrictions. These protective measures may restrict injury to and destruction or taking of, some wild plant and animals. Taking restrictions and prohibition may apply to non-living as well as living resources, although they are imposed the more frequently for the flora and fauna. Principle 5 of the Stockholm Declaration states that 'the non-renewable resources of the earth must be employed in such a way as to guard against the danger of their future exhaustion and to ensure that benefits from such employment are shared by all mankind.

Import and export restrictions, both temporary suspensions and permanent limits are commonly utilized for the protection of wild flora and fauna. The access and benefit-sharing national legislation can issue list of GR of wild flora and fauna that is virtually prohibited or required present export or import permits issued under stringent conditions. Prior informed consents of GR access and utilization could also cover import and export restriction.

2) Administrative and judicial measures

The Protocol requires implementation and enforcement at the national level. It calls on States to take appropriate action in domestic legal systems to enforce the laws that enact pursuant to the Protocol's obligations.

a) Administrative proceedings[770]

The breach of a statutory access and benefit-sharing duty, even without measurable harm, can result in sanctions or remedies, just as infraction of speeding law can result in a traffic citation and fine even if no accident occurs. Proceedings usually can be initiated either by the authorities, concerned individuals or companies or by associations. In some states, administrative procedures of a quasi-judicial character are the primary means of enforcing environmental laws and access and benefit-sharing law. Environmental laws also may permit agencies to impose fines on violations

The range of remedies may includes fines, closure or the installation, prohibitions on exercise of a profession or activity and deprivation of company or individual rights to public competition. There also exists an obligation to restore the environment that can be undertaken by the state and charged to the company if the latter fails to carry out its duty. Other sanctions may include a denial of government contracts or blacklisting of harmful products. Lending institutions may refuse loans of other benefits to projects failing to meet environmental standards or those scheduled for establishment in areas not attaining quality

[770] KISS.A, SHELTON.D, 2000, *Ibid,* p. 224

objectives. For example, a bank might reject project which are not fulfill obligation following legislation and the Protocol.

b) Civil liability[771]

Civil liability refers to the liability of any legal or natural person under rules of national law adopted pursuant to international treaty obligations which establish harmonized minimum national standards. Even though, the Protocol does not provide directly, it is useful and common to apply civil liability for environmental damage.

The concept of liability generally implies that damage or harm has occurred to something. Normally, civil actions are commenced by those who have suffered harm to themselves or their property. They seek to halt further damage and repair that which has been done. Liability is most often imposed on the principle of owner. Remedies can be sought if the damage results from the breach of law and the damange are not too remote from the wrongful action. Some national laws permit consumers or even those with no direct injury to sue. In case of access and benefit-sharing with most of international relation, the fundamental problems exist in establishing causation, identifying causer and providing damage. To these difficulties are added four issues particular to the field of private international law: jurisdiction, choice of law, assessing damages and executions of judgments.

c) Adjudicative jurisdiction[772]

Adjudicative jurisdiction can exist in the state of the victim or the state of the provider of GR. As a general rule, private international law favors jurisdiction in the defendant's domicile. Several factors support this approach: the accused is able to defend itself in local tribunals, the evidence of harmful activity is more readily available, witnesses more easily may be called and execution of a judgment in favor of the plaintiff will be more easily enforced. Conversely, it can be argued that the victim should have benefit of local courts to obtain compensation, especially because evidence of damage is more readily available in plaintiff's domicile where experts can evaluate and establish the scope of jury. Moreover, the innocent victim should not have to bear the additional expenses of litigation in a foreign country.[773] Whatever solution is taken the basic principle of equality of access and equal treatment of aliens and nationals applies in all cases.[774]

Choice of law

Choice of law in the demand for compensation is determined by the court with jurisdiction. Generally, tribunals apply local law, but public policy concerns and the principle of non-discrimination may affect the choice. The latter rule requires that in no

[771] KISS.A, SHELTON.D, 2000, *Ibid*, p. 226
[772] KISS.A, SHELTON.D, 2000, *Ibid*, p. 227
[773] See more UNEP/CBD/WG-ABS/7/INF/4, COLAS. B, *Comparative study of the real and transactional costs involved in the process of access to justice across jurisdictions*, 2009
[774] KISS.A, SHELTON.D, 2000, *Supra*, p. 227

case may the plaintiff's complaint be judged according to rules less favorable than those which would be used to judge the matter in the state where the activities took place. [775]

Assessing damage

Providing a remedy of compensation for environmental harm requires consideration of the amount of damage that has occurred. The concept of harm to the environment is often viewed as a property concept, where economic value is placed on the lost or damaged object. This may include market value, loss of income and damage to mral, aesthetic and scientific interests. The economic approach poses problems for protection of species and wild fauna and flora that are not exploited and thus have no market value, as well as for ecosystem or landscapes the economic value of which can not be assessed exactly. Evaluating the economic value of the intangible aspects of the environment, such as biological diversity and balanced ecosystems, is difficult. The situation is similar for areas that are under common ownership and even more for those areas that are for common use but not capable of ownership. Measurement or evaluation of harm for the purpose of damage awards also involves important questions of the threshold or diminish level of harm, proximity of harm, especially long-term, long distance, multiple-authored actions and, finally the possible irreversibility of the harm caused. The last issue is something that is thus far largely ignored in law. The last issue is something that is thus far largely ignored in law.

One of the most difficult issues in environmental litigation is the scope of damage. In access and benefit-sharing case, the difficulty is to define the scope of benefit arised which should be shared as being analysed by Part 1, Title 2, Chapter 2, Section 1.II.A.2.a of the thesis.

Execution of foreign judgments

Execution of foreign judgement in tort matters is not guaranteed absent treaty protection, although the state of the uses may consent to respect the judgment on the basis of comity. Uncertainty on this question may induce plaintiffs to choose the courts of the state where user is found rather then their own national courts (with assumption now is that most plaintiffs are provider).[776]

Liability and compensation

Compensation as one kind of remedies for harms caused (payment of 'damages' or 'restitution' calculated based on the value of the injury, damage or financial loss suffered by the claimant), including: "compensatory" remedies (i.e., the direct value of the harm suffered), and "punitive" remedies;[777]

[775] KISS.A, SHELTON.D, 2000, *Ibid,* p. 228

[776] See more CBD website on ABS

[777] UNEP/CBD/WG-ABS/5/INF/3, YOUNG. S. T, *Analytical study on administrative and judicial remedies available in countries with users under their jurisdiction and in international agreements,* 2007, p. 5

The problem is that general remedies are broadly available only when a claimant is able to bring a legal action in the courts of the user country. This means that to obtain a remedy, it requires the claim (whether it is brought through a court, in an administrative agency, as an arbitration award, or using some other path) must meet the substantive requirements of law of the country in which the claim is filed or enforced. The claimant must comply with that country's procedural and jurisdictional rules. The claim must be supported by evidence and arguments in a form and content that is recognised and useable in those courts, the claim must seek one of the above remedies, and that remedy must be authorised for use with the particular kind of claim involved. However, access and benefit-sharing complicates the picture in that most claims for remedies will be brought by foreign claimants. In addition access and benefit-sharing necessarily involves a re-conceptualisation of several critical aspects of conventional law. As a legal matter, it creates a special legal interest or right in the "genetic resources" of a species, which is not automatically obtained by legal possession of a specimen of that species. In other words, one may legally own the biological specimen, but not have a right to "utilise" its "GR."

"In identifying national remedy legislation, it is important to note that we currently have not developed an understanding about how each country's standard forms of law (civil and equitable court claims, administrative actions, arbitrations, etc.) should apply to access and benefit-sharing. It is likely that, should such cases be brought, they will be decided in very diverse ways. Since every access and benefit-sharing claim or remedy involves transboundary litigation, this diversity of approaches suggests that additional principles of "private international law" may be needed to help clarify the precise nature of these claims and the procedures and processes that apply." "So long as the law has not clarified the critical concepts underlying the access and benefit-sharing framework, it may be very difficult to know whether/how an access and benefit-sharing claim can fit within the normal substantive requirements of contract law, tort law or other laws to meet the basic requirements above. In access and benefit-sharing, the existing ambiguities have generally prevented claimants from seeking legal remedies under access and benefit-sharing authority." [778]

d) Penal law[779]

The function of penal law is to protect the most important values of society by creating and enforcing penalties, including those involving deprivation of liberty. Increasingly, national law is imposing criminal liability on those who perform acts damage to environment.

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[778] UNEP/CBD/WG-ABS/5/INF/3, YOUNG. S. T, *Supra,* p 31,
[779] KISS.A, SHELTON.D, 2000, *Supra,* p 243

States also criminalize the offences when committed with gross negligence. Jurisdiction over offences can be based on territory, flag and nationality. Penal sanctions can range from fines for petty offences to imprisonment for more serious offences. Criminal liability may be primary, accomplice or conspiracy. In many countries, accomplice liability is imposed on whose who give help, support, or assistance to a person committing an offence, or who incite, encourage, or counsel such a person. The lesser offence of conspiracy involves a decision by two or more parties to perpetrate an unlawful act.

For remedies, "penalty provisions are not normally considered to provide remedies, however, many national submissions and other documents suggest that the primary legal measures that can be used in the case of an access and benefit-sharing violation may be penalties. Where penalty provisions appear in existing legislation, it appears to be focused only on penalties against users of the GR of the legislating country. This means that, if the user, some of the resources being used, or other property is found in provider country, or some other basis for jurisdiction is claimed a penalty may be sought. Although, penalties are not remedies or compensation to the claimant, there are some remedial consequences to the use of these penalties."

"Penalty provisions and other rights may operate as a remedy for a source country. For example, consider a provider country that is seeking remedies in its own courts against a user who has used that country's GRs in violation of the provider country's access and benefit-sharing law. If that provider country can get jurisdiction over the user or some assets of the user – i.e, if the user is operating or owning property within the borders of the provider country – it may be possible to bring a criminal action against the user in the provider country courts." "That action could result in fines and confiscation of equipment, in addition to other possible penalties. Since these fines and confiscated properties a paid to the source country, the net effect of these financial penalties would be very similar to a financial remedy." The differences would be: "the amount of the fine may be different, (penalties are often calculated differently from remedies, or the value of seize-able property may not be significant)". "Most criminal/penalty suits actions are brought at a single point in time, so that the fine will not satisfy the longer term benefit-sharing obligation, if any". "Penalties are generally paid to different accounts – hence where access and benefit-sharing payments (and remedies) might be owed to a specific agency or ministry or subject to specific distribution rules, a penalty will typically be paid into the country's general fund and allocated under national budget processes". "Courts deciding penalty and criminal actions often are not empowered to order the non compliant user to comply in future, especially a user operating in another country." "Their decisions are not as easily enforced across borders as civil and arbitration awards. At most, however, these provisions provide a "pseudo-remedy" only for the legislating country itself, as to its own resources. "The "remedy" aspect of these laws is limited to the situation in which the provider

country brings a domestic action against a foreign user of the provider country's own GR. As these laws are phrases, a domestic company or researcher is utilising GR of another country, this law will not provide any remedy or other return to that other country or provider." [780]

3) Technical measures[781]

a) Environmental impact assessment (EIA):

That can be required to apply for the process of access to GR and utilization of GR. EIA is a procedure that seeks to ensure the acquisition of adequate and early information on likely environmental consequences of projects on possible alternatives and on measures to mitigate harm. It is generally a prerequisite to decisions to undertake or to authorize designated construction, process or activities. EIA procedures require that user submit a written document to a designate agency or decision making body, describing the probable or possible future environmental impact of intended action. The procedures may be integrated into licensing schemes. EIA can require risk assessment, a specific application of the precautionary principle. Precaution dictates a comprehensive approach to risks access sources and media. Risk assessment looks not only at likely or known impacts but all the probabilities of possible harm from a proposed activity of access to GR or utilization.

The Nagoya Protocol does not have any provision that requires directly implementing EIA when accessing to GR and utilization of GR. The Protocol leaves this issue for national legislation to provide as one respect of "sovereign rights over natural resources" and "subject to domestic… legislation or regulatory requirements". In my opinion, basing on nature and objective of the EIA procedures, certain risks to environment of access and utilization of GR, the national legislaton should provide to require EIA as conditions to grant a permit to access.

b) Licensing and permitting

This is one of the most widely used techniques to prevent environmental harm is government authorization through permits, certification or licensing. The purpose of licensing and permiting is to ensure the sustainable use of GR. Following the Protocol a license or permit granted by national competent authority, through access and benefit-sharing Clearing- House mechanism, creates the internationally recognized certificate.[782]

4) Economic measures

As an alternative to the regulatory approach, they are recommended that states make efforts to influence the decisions of individual state and non state actors who choose their activities by comparing the benefits and costs of the available and perceived options. Decisions can be influenced by limiting the options, altering the cost or benefits or altering

[780] UNEP/CBD/WG-ABS/5/INF/3, YOUNG. S. T, 2007, *Supra,* p 29
[781] KISS.A, SHELTON.D, 2000, *Supra,* pp. 202 - 211
[782] KISS.A, SHELTON.D, 2000, *Ibid,* pp. 211-213

the priorities and significance agents attach to environmental change of access and benefit-sharing process. Economic measures can act as incentives or disincentives to behavior. This relies on education, information and training, as well as social pressure, negotiation and moral arguments.

The use of economic measures is an application of the polluter pays principle. The environmental law shows a trend toward use of economic instruments. Principle 16 of the Rio Declaration calls on national authorities to promote internalization of environmental cost and the use of economic instruments. The CBD also calls for effective use of economic instrument, in which, the parties undertake to provide financial support and incentives for national activities intended to achieve objectives of the CBD. However, there is no definition of what is 'economic instruments'. The Organization for Economic Co-operation and Development addressed the subject of economic instrument in their use in environmental policy. The regulation recommends that member countries make greater and more consistent use of economic instruments such are charges and taxes, marketable permits, deposit refund systems and financial assistance to complement other policy instrument. There are some sets of criteria for the use of economic instruments. They are: environmental effectiveness, economic efficiency achieved by an optimal allocation of resources and implying that the economic cost of complying with environmental requirements is minimized; equity in regard to the distributive consequences; administrative feasibility and cost, including the ease and cost of monitoring given the existing legal and institutional arrangement; and acceptability.[783]

a) Taxation[784]

Taxes and charges are the price paid for environmental degradation caused by activities of GR access or utilization. The users have to pay for their implicit claim for environmental services. Charges also may have a revenue–raising impact, intended for collective treatment, and may not be high enough to be a disincentive. Taxes can finance environmental investments and provide incentive to reduce pollution and waste, but the state must monitor and if necessary correct the tax rate in order to ensure the goal is achieved. For the accessed and prospected GR, the tax can be applied like tax for natural resources. This can charge according to the quantity of plant or others harvested. There is user's charge that is payments either at a uniform rate or based on amounts involved for the costs of GR prospected. Administrative are control and authorization fees paid for government services, such as registration of chemicals or for implementation and enforcement of certain regulation.[785]

[783] KISS.A, SHELTON.D, 2000, *Ibid, p.*214
[784] See more MILNE.J, DEKETELAERE.K, KREISER.L, ASHIABOR.H,*Critical issues in environmental taxation, International and comparative perspectives*, Volume I, Richmond,
[785] KISS.A, SHELTON.D, 2000, *Supra,* p. 216

b) Negotiable permit

A system of negotiable permits fix a total amount of GR as raw materials can be exploited to ensure recovery threshold of the plant and animal in one certain areas.[786]

c) Marketable permit:

This measure was suggested to use during the negotiation of the Protocol as a user measure. This is useful and important to ensure the user comply with the PIC and MAT. It is assumed that only the users who satisfy PIC, MAT, obtaining international recognized certificate can get the permit to access and participate market for their products and services.

d) Labelling

This the supplemented measure for marketable permit. That suggest all the products use foreign of GR and TK should label (as form of "disclosure of origin") to notice their customer to aware and make choice of utilization.[787]

5) Monitoring, surveillance and auditing

The implementation, as well as the formulation, of environmental laws and policies must be based on the collection of reliable information and on its continuous assessment. The measures adopted in international and national environmental laws to ensure this are surveillance, reporting and monitoring.

a) Monitoring

Monitoring is the continuous assessment and comparison of information to mandated parameter. Monitoring is a necessary foundation for giving effect to all environmental obligations. Generally, the monitoring organ can intervene based on report and other surveillance means that make it possible to assess the effectiveness of legislation or action taken. Monitoring provides constant feedback for decision making, from long term protection to rapid guidance in emergency situations. To ensure progress the effectiveness of surveillance and monitoring must it self be monitored and assessed.

Therefore, Article 17 of the Protocol provides on monitoring the utilization of GR as measures to support compliance. The limits and constraints of this provision are analyzed by Part I that can be addressed at national level application.[788]

b) Surveillance

There is requirement of the acquisition of data through surveillance, mainly scientific activity, on which further action such as monitoring may be based. Surveillance includes taking samples of the effected environments. It can be done by individual

[786] KISS.A, SHELTON.D, 2000, *Ibid,* p. 218
[787] KISS.A, SHELTON.D, 2000, *Ibid,* p. 219
[788] KISS.A, SHELTON.D, 2000, *Ibid,* p. 220

enterprises, by associationor by local or national authorities. One the information is gathered; it must be assembled, organized and analyzed by an appropriate agency or institution to which the information is sent. [789]

c) Auditing

The eco-audit or environmental audit or independent review has come to serve two purposes. First, it is a legislative control mechanism of growing popularity. Second, it is a device of importance to business in sales, acquisitions and other transactions involving assets where the risk of liability for environmental non-compliance can be a crucial element in negotiations and contracts. It differs from environmental monitoring because it is not a continuous process but an overall evaluation at a specific moment.

With increasingly complex technology, company's user structure and environmental regulation it is sometime difficult for management and authorities to remain fully informed on the environmental consequences of company operation. This can result in hidden problems, leading to accidents as well as to violation of environmental laws and regulations, including access and benefit-sharing laws. Eco-auditing is the systematic investigation of the procedures and work methods of a company or institution as it is relevant to its environmental and access and benefit-sharing responsibilities. It is designed to determine to what degree these procedures and methods are consistent with legal regulations and generally accepted practices.

The main elements of the eco-audit are the introduction of systematic approach by companies (users) to setting environmental standards, self assessment by companies of their performance, an independent body to audit companies and companies' right to use a certified statement of their participation in the scheme. The regulation includes criteria for accrediting environment verifier and listing of their functions.

Eco-auditing can be part of the legal administrative procedure for decision making or part of the role of the judiciary. There can be parliamentary commissions of inquiry or studies by NGOs which play an important review role. Often research is undertaken by independent experts in the field. Eco-audits add an element of external quality control to the administrative system.

From their function as a regulatory mechanism, eco-audits form a growing part of business transactions. Purchasers or business may seek to have environmental representations and warranties or a determination of whether they will be assuming liabilities of property and assets, including any disposal site used in the process carried out on the property; examination of documents, including all operating licenses and permissions and physical and scientific analysis of processes. Specific investigation usually is made for any signs of past environmental misconduct that would lead to a claim of

[789] KISS.A, SHELTON.D, 2000, *Ibid,* p. 220-221

liability for environmental damage in the future. The results of the audit can govern the nature and extent of protection built into the contract covering acquisition of the user's company or asset.[790]

In conclusion, there are many various measures are introduced in this section. However, depending on the specific context of each country, some or all of measures are considered application properly during the process of integration and implementation of the Nagoya Protocol in nation law.

§ II – Factors impact on the integration of the Nagoya Protocol into national laws

There are many factors impact on the integration of the Protocol into national law, including: economic, social, cultural, political, historical, technical factors and so on. It is recognized that "Every legal system needs to be understood in its own cultural, economic and political context. Even if black-letter law as expressed in legislation and case-law may turn out to be quite similar (between various countries' legal systems), the political and cultural context of the law,"[791] It should be evident that "conservation laws which are not carefully adapted to the distinctive political, social, economic, cultural, and ecological conditions in each nation are likely to prove useless or worse."[792] Thus**,** "countries have adopted different approaches to regulating access and benefit-sharing, reflecting their national administrative structures, priorities, cultural and social specificities"[793]. Moreover, "each country's legal system and methodology is unique in some way – which raises a more complex problem that can be difficult to respond to, requiring in-depth legal research to determine how the source country interprets and applies its law".[794] Romi.R illustrates that "the problems of effect of the international law are political, ethic and cultural problems in enabling the international norms".[795] However, it is impossible for this thesis to provide a detailed analysis of all factors impact on integration of the Nagoya Protocol into national law. Some justifications of various factors' impact will be expressed by analysis of selected countries in the next Title. This subsection, therefore, considers analysis of typical cultural factors and linguistic factors that are challenges for the process by which the Protocol becomes part of national law.

A. Cultural factors

In general, the impacts of cultural factors on international law, then, on Nagoya Protocol and its integration into national law in particular, can be explained by the fact that dependency of international law consecrated in the domestic sphere that is recognized by

[790] KISS.A, SHELTON.D, 2000, *Ibid,* p. 222-224
[791] BHATTI. S, CARRIZOSA.S, MC GUIRE. P, YOUNG. T, *Supra*, p. 9
[792] http://ecovitality.org/badlaw.htm, last accessed April 23, 2012
[793] MEDAGLIA.C.J, SILVA.L.C, *Supra*, p. 20
[794] TVEDT. M. W, YOUNG. T, 2007, *Supra,* p. 38
[795] Edited by PRIEUR.M, DOUBE-BILLE.S, 1994, *Supra,* pp.62-63

Article.38.1.c of the Statute of ICJ with its reference to the general principles of law recognized by civilized nation.

This is clear that, the determinative feature of the international law is sovereignty equality of States, the cultural tendencies form any region or group of civilization also are opened. In legal term, there can be no monopoly of law making by leading nations, notwithstanding the simple truth that in fact the traditional legal system which have evolved over centuries have but an indelible hallmark on international law as it stand today. The pragmatism and the realism of the American in international legal culture, as well as the formalism and the positivism of French in international legal culture are as the dominant model.[796] "They are the twin pillars of the immediate iteration of this global legal culture: the civil law and the common law systems. At present, the civil law model has spread throughout the world and now covers over half of the world's population."[797] The common law model, along with systems mixed with it; include 28.24% of the jurisdictions, 14.68% of the world's population. [798] In addition, some much more cautious attempts are made to identify aspects of other legal cultures, e.g., Islamic or Asian, that might have impact on the current development of the global legal culture.[799] Although, this sub-section recognizes importance and influence of those traditional law systems, it is not paid attention to analyse them in details. It only indicates some cultural factors impact directly to national access and benefit-sharing law, so, they should be considered during the integration of the Nagoya Protocol into national laws.

If "access and benefit-sharing " is, by definition, the fusion of two concepts which are politically and (to a very limited extent) legally or contractually linked,"[800] "it will be most important to remember that contracts are one of the key areas in which the law interfaces with cultural factors in determining how commercial and regulatory systems actually function. "This statement is equally true between countries within the same region or sharing a common type of legal system (i.e., between two common law countries or between two civil law countries, for example) as between those with completely divergent systems. In fact, countries with the most in common, legally, will often be so different, in cultural and geographic terms, that their practical needs and implementation of access and benefit-sharing will be entirely different in some ways." [801]

As culture is different from country to country, its impacts are various in each country during the integration of the Nagoya Protocol. These impacts may be positive or negative in different countries with different culture. In the same words, they can become

[796] Societe Francaise pour le droit international, *Droit international et diversité des cultures juridiques*, International law and diversity of legal cultures, Editions A. Pedone, Paris, 2008, p. 52, 54, 72
[797] KOCH.H.C, *Envisioning a global legal culture*, Michigan Journal of International law, vol.25:1.fall 2003, p 19
[798] KOCH.H.C, *Ibid*, p. 3
[799] KOCH.H.C, *Ibid*, p. 6
[800] TVEDT. M. W, YOUNG. T, *Supra*, p. 2
[801] BHATTI. S, CARRIZOSA.S, MC GUIRE. P, YOUNG. T, *Supra*, p. 24

facilitiation or challenge for the Nagoya Protocol. In fact, it seems to be that there are more challenges than facilitiations.

Regarding culture is facilitation for integration of the Nagoya Protocol into national law; I wish to analyze the 'Guidelines on Access to GR for Users in Japan' and the culture of Japanese as a good example. The implementation of the guidelines in recent time can be seen as a positive signal in the recent context of rare user measures to support compliance with access and benefit sharing law. Although, being a completely voluntary instrument, the guidelines are formally supported and used by the Ministry of Economy Trade and Investment, which pays particular attention to the relationships between Japanese companies and other countries. Where any access and benefit-sharing claim or allegation is leveled against a Japanese company, the Guidelines serve as a basis for discussions between the ministry and that company. As a result of cultural factors in Japan, a company that is singled out for such discussion is intensively motivated to come into compliance with the Guidelines, and other companies have a similar interest in avoiding being singled out at all. Consequently, the use of voluntary guidelines has a high level of effectiveness in Japan. Currently, however, "the practical value of those guidelines in reducing disputes and claims of biopiracy has been limited by the lack of clear international standards regarding access and benefit-sharing and GR issues."[802]

In contrary, there are also the others examples on challenges of culture. It is recognized that "under customary regimes, where rules governing access to biological resources (in the broadest sense), and cultural taboos are often far better understood and implemented than statutory measures".[803] In this case, legislation with reenactments to integrate the Nagoya protocol into national law may meet challenges. Especially, the Protocol provide obligations of the Parties to take into consideration Indigenous and local communities' customary laws, community protocols and procedures, as applicable, with respect to TK associated with GR, [804] and not restrict the customary use and exchange of GR and TK within and amongst Indigenous and local communities.[805]

In addition, determination of GR ownership regime also impacted by cultural factors. GR ownership is an extremely important condition for the development of access and benefit-sharing laws and the Nagoya Protocol does not provide on this issue but leaves each nation defines GR under its sovereignty. In this respect, "Oral cultures and practices" seem to be a challenge. "They are the primary medium for communication, and approaches to property are likely to be very different from western norms, and more firmly embedded in a community collective than in a monopolistic, individualistic and privatized system". Some experts point out that one of the difficulties which countries have had in developing

[802] BHATTI. S, CARRIZOSA.S, MC GUIRE. P, YOUNG. T, *Supra*, p. 24
[803] YOUNG.T, *Supra*, p. 49
[804] Article 12.1 of the Nagoya Protocol
[805] Article 12.4 of the Nagoya Protocol

a workable legal framework is to clarify ownership of GR. Because a definition of GR is ambiguous, it has been hard to legislatively determine who has rights to dispose of, give access to, or receive benefits from such resources. "Where customary laws apply at the community level, the situation is even more fraught. Access and benefit-sharing legislation clearly needs to take into account the impact of different systems of land ownership on the way in which resources can be accessed and used."[806]

The other states that due to legal cultural traditions, countries exhibit a mixture of ownership arrangements that range from traditional common tenure to state-enforced private rights to land and resources, including the broad diversity of biological material. "In Common Law Systems: natural resources are frequently viewed as primarily 'private property,' however the legal fact is that the state retains powers to regulate them or to control, limit or even prevent their use. In Roman-Napoleonic systems include concepts of private property, but usually recognize natural resources as property of the State, or patrimony. A number of these countries have directly regulated GR, providing that they are public property and/or in the domain of the State. In other legal systems, there are basically three other categories of legal system - religious law, customary law, and central-plan-based law. Under these three, private property concepts may not exist, or may involve a much stronger level of primary oversight and control. While most countries believe themselves within one of these categories, the practical reality is that a mixed approach applies in virtually all countries."[807]

B – Linguistic factors

Linguistic diversity is defined the need but also the burden of public international law. In view of the considerable disadvantages it entails the call for a multilingual public international law, however should not be accepted all too readily.

The problem connects with divergent authentic treaty version and the risk of language shopping, the problems of translation, is the non existence of certain notions. "While numerous legal notions associated with distinct legal concept rooted in the national legal order are well known. Therefore, tiny linguistic sensitivities may cause a big point on the diplomatic parquet. Apart from diplomatic sensitive, linguistic diversity in public international law may entail grave practical problem. Beside, these shortcomings and enormous costs, linguistic diversity may produce more fundamental adverse effects. Instead of integrating, it could also become further feature of the "fragmentation of international law" namely fragmentation of legal doctrine".[808]

[806] YOUNG.T, *Supra*, p. 49
[807] BHATTI. S, CARRIZOSA.S, MC GUIRE. P, YOUNG. T, *Supra*, p. 43
[808] Societe Francaise pour le droit international, 2008, *Supra*, p. 172

In general rule, the interpretation of a treaty, in accordance with regulation of the Vienna Convention, always take the difficulties in practice in the foreign language through in interest. This is the reason why the judges and administrative authority in reality, take application in their own national language (in authentic text or a translation). They have recourse to authentic texts to any difference between the different language versions. In this context, it may be noted that countries whose language is neither English nor French complained, without reason in the often not sufficient quality translations. In fact, this can make an application's obstacle to correct and uniform international treaty. [809]

All of these problems should be considered during integration of the Protocol into national law. In addition, it should address question: "what weight is given to the translated text of a treaty into national language when the only authentic versions are in other languages?"[810] In some countries, the judge would use an authentic text in UN language and must be translated into national language, such as Netherland, [811] but not all the others countries.

There are also the problems of linguistic diversity, transparency and equal representation. The Protocol defines "The original of this Protocol, of which the Arabic, Chinese, English, French, Russian and Spanish texts are equally authentic".[812] The question may arise on the equality of representation of other languages. In fact, between five UN languages, there may also problems of their differences each other. The Nagoya Protocol has experienced with many corrections of French versions.[813]

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[809] EISEMANN.P.M, *Supra*, p.24 stated "Ils ne recourent aux texts authentiques qu'en cas de divergence entre les différentes versions linguistiques. Dans ce contexte, on peut signaler que les pays dont la langue n'est ni l'anglais ni le francaise se sont plaints, non sans raison de la qualité souvent in suffisante des traductions. De fait, ceci peut faire obtacles à une application correct et uniforme du traité internationale. "

[810] EISEMANN.P.M, *Ibid*, p. 451

[811] EISEMANN.P.M, *Ibid*, p. 451

[812] Article 36 of the Nagoya Protocol

[813] ***C.N.115.2011***.TREATIES-7 du 18 mars 2011 (Proposition de corrections du texte original (version française) et des exemplaires certifiés conformes) et ***C.N.356.2011***.TREATIES-26 du 17 juin 2011(Corrections du texte original du Protocole (version française) et des exemplaires certifiés conformes);***C.N.711.2011***.TREATIES-70 du 1er novembre 2011 (Proposition de corrections du texte original du Protocole (version française) et des exemplaires certifés conformes) et ***C.N.53.2012***.TREATIES-88 du 31 janvier 2012 (Corrections du texte original du Protocole (version française) et des exemplaires certifiés conformes); ***C.N.825.2011***.TREATIES-78 du 18 janvier 2012 (Proposition de corrections du texte original du Protocole (version chinoise) et des exemplaires certifés conformes) et ***C.N.200.2012***.TREATIES-XXVII.8.b du 18 Avril 2012 (Corrections du texte original du Protocole (version chinoise) et des exemplaires certifiés conformes).
See more at website of UN *http://treaties.un.org/pages/ViewDetails.aspx?src=TREATY&mtdsg_no=XXVII-8-b&chapter=27&lang=fr* **,** last accessed May 20, 2012

Conclusion of Chapter 2

There are many principles of international law, but in this chapter, the author only focuses on some basic principles that directly impacts to the Nagoya Protocol. At first, this Chapter analyzes the foundation principles such as principle of sovereignty which repeated in the CBD and the Protocol, principle of cooperation, the principle of common concern of human kind and shows the articles recognized those principles. Then, it considers the common legal principles of international environmental law in both aspects: substances and processes. The substantive principles include principles prevention, polluters pay, precautionary and new principle of non-regression. In consideration of natural resources, the author analyzes principles of conservation and sustainable use of natural resources, reasonable use and abuse of rights. In aspect of equity, this chapter analyzes principle of intergenerational equity, equitable utilization, and principle of common but differentiated responsibilities. The principles of process includes: duty to know, duty to inform and consult and public participation. In my point of view, all these principles should be considered during the process of integration of the Nagoya Protocol and application of the protocol into national law for implementation. Those principles have interacted and linked to each other. The implementation of one principle or group of principles will impact to each other and guide the country follow –up in right way with the others international instruments that recognize those principles.

This chapter also analyzes three main methods of integration of the international law into national law for the case of the Nagoya protocol, including: re-enactment, incoporative norm and intepretation. The author suggests using several of measures for integration of the Protocol into national law: regulatory measures, administrative and judicial measures, technical measures, economic measures, monitoring, surveillance and auditing. Depending on the specific situations and conditions of each country, those measures should be considered application appropriately.

This chapter also analyzes key factors impact on the integration of the Protocol, including cultural factors and linguistic factors. Those factors may facilitate the process of integration of the Protocol but also may challenge to the integration. Therefore, they should be taken into account when integrating the Protocol into national laws on access and benefit-sharing.

Conclusion for Title 1

This Title presents an overall picture analyzing matters of integrating the Nagoya Protocol into national law. They include: the weakness of international law, non-self-executing treaty, monist and dualist doctrines. Those are also traditional matters of most international law discussions. The Chapter 1 of This title analyzes key points impacts on the process by which a treaty like the Nagoya Protocol becomes part of national law. The Chapter 2 finds principles, methods, measures and ways for integration of the Protocol into national laws. The chapter focuses on three main methods relevant to the Nagoya Protocol by descriptive analysis and finding problems. There are also many measures and factors that should be considered in specific context of each country. There are also many principles should be considered to apply to the process of integration. These are general principles of international law and principles for environmental protection management, natural resources conservation and for access and benefit-sharing issue. Even though, someone can pose a question: "Do the principles really represent a significant advance for environmental law, or is it purely cosmetic with no real legal effect?"[814] I suppose that these are necessary to consider all of them for an effective integration of the Nagoya protocol that keeps up its objective and approach. The next Title of this Part 2 analyzes cases studies in selected countries that will make a justification of the foresaid statement.

[814] SADELEER.N, *Supra*, p. 2

TITLE 2 – ACCESS TO GENETIC RESOURCES AND BENEFIT-SHARING IN NATIONAL LAWS AND THE CASE OF VIETNAM

It is uncontroversial for the role of national laws in realization of international treaty law. Analysis of national laws for justification and clarification of international law always draws attention of many researches. This is happening truly with the access and benefit-sharing issue and the Nagoya Protocol. During process of international negotiation for development of the Protocol on access and benefit-sharing, efforts at national level to develop legislative, administrative and policy measures for its implementation have been increased significantly. However, challenges in designing the needed access and benefit-sharing measures arises in many jurisdictions.

It is clear that there are various approaches adopted by different countries regarding access and benefit-sharing. As a result, "it is difficult to draw general conclusions from the analysis of these measures because countries have adopted different approaches in terms of the types of measures adopted".[815]

In this title, the author makes efforts to analyze the situation of development and implementation of access and benefit-sharing law at national level in general and in selected countries in particular. This analysis will justify the findings and analysis of the Protocol in Part 1 and the factors impact on the the Protocol becomes part of national law in Title 1 of the Part 2. This Title will address questions: what are happening at national level? Whether existing national laws are sufficient for the Protocol's implementation or not? What would improve its access and benefit-sharing regime for joining to the Nagoya Protocol if there has no substantial guidance for the country needs to do?

This title includes two Chapters: Chapter 1 analyzes access and benefit-sharing in national laws of selected countries and problems of the integration. Chapter 2 focuses more details in the case of access and benefit-sharing legislation of Vietnam.

[815] UNEP/CBD/WG-ABS/5/5, *Supra*, p. 3

CHAPTER 1 – Access to genetic resources and benefit-sharing in national laws of selected countries and challenges for integration of the Nagoya Protocol

The process for access and benefit-sharing issue of the CBD and the Nagoya Protocol becomes part in national laws always is long and difficult that depends on politics will, socio-economic conditions, current legal system and historical and tradition of legal views. Some of these factors are mentioned above that are different from country to country, but there are still some common problems of access and benefit-sharing that can be synthesized. This chapter provides not only an analysis of general situations of national laws on access and benefit-sharing but also a deeper look on each selected countries to have findings on integration of the Nagoya Protocol in to national law of each country.

Section 1 - General situation of national laws on access to genetic resources and benefit-sharing

§ I – Insufficiencies of national laws on access to genetic resources and benefit-sharing for implementing the Protocol

A – Some common insufficiencies of national laws on access to genetic resources and benefit-sharing

Even though the CBD had come into force for many years before the Nagoya Protocol was negotiated and approved; development of national legislation on access and benefit-sharing is still limited. This sub-section analyzes some common insufficiencies basing on synthesis official report, research and published information, documents of the UNEP and the CBD that mainly 39 countries which have measures, are included in the database of the CBD, such as Afghanistan, Australian, Bhutan, Bolivia, Brazil, Costa Rica, Ethiopia, India, Kenya, Malawi, Panama, Peru, South Africa, Philippines, Vanuatu, Venezuela, Uganda, Austria, Canada, China, Finland, Germany, Japan, Norway, Spain, Switzerland, Canada, the Czech Republic, and the European Communities…[816]. That reflects current situation and needs of national laws on access and benefit-sharing.

1) Gaps and lacks of national legislation on access and benefit-sharing issues

a) Not many adopted regimes or not relevant adopted access and benefit-sharing national legislation

A majority of Parties have still not adopted national access and benefit-sharing regimes. According to official sources, "at least 58 countries are in the process of developing or have adopted access and benefit-sharing measures."[817]"Out of these 58 countries, measures from 56 countries are included in the database of the CBD".[818] "Some have adopted measures referring to access and benefit-sharing without providing detailed

[816] See more document UNEP/CBD/WG-ABS/5/4, UNEP/CBD/WG-ABS/5/3 and UNEP/CBD/WG-ABS/5/5
[817] UNEP/CBD/WG-ABS/5/3, p. 4
[818] http://www.cbd.int/abs/measures/groups.shtml, last accessed May 6, 2012

procedures for access and benefit-sharing."[819] Therefore, in comparison with total of States member of the CBD, this is very limited.

The adopted national legislations on access and benefit-sharing are insufficient, for instance, the difference in terms/definitions between countries and in the application of the access and benefit-sharing law within a country regarding key concepts such as "access to GR", "users", "owners" that leads to an uncertain situation by a very broad range of interpretations. This raises a need of harmonization the definitions of the Protocol in national laws. "The rules concerning PIC are also not uniform. This concerns the competent national authorities, procedure as well as the question, whose consent has to be obtained. Not all countries require the PIC of indigenous and local communities. Sometimes it is sufficient to inform them. Sometimes, they are not mentioned at all." "In regard to benefit-sharing, a wide range of regulations exists. Major differences can be seen with regard to who is participating in the benefit-sharing, whether local communities are involved and if funds have been allocated or not. Only few regulations stipulate obligatory monetary benefits". "In order for it to be effective, a national access and benefit-sharing legislation needs a broad acceptance among the country's population. This acceptance can be gained with the participation of a broad variety of stakeholders in the drafting process, and ongoing consultation on the local and regional levels."[820]

"The limited number of countries that have established access and benefit-sharing regimes may be considered an obstacle to creating an enabling environment for the generation of scientific, commercial and social benefits from GR, limiting the ability for equitable benefit-sharing"; "the lack of uniform standards for benefit-sharing". In fact, "existing national access and benefit-sharing measures do not always link benefit-sharing to biodiversity conservation and sustainable use".[821]

There is "the absence of measures adopted by Parties with users under their jurisdiction to support the sharing of benefits between users and providers of GR under measures to support compliance with PIC and MAT".[822]

"On the basis of available information on access and benefit-sharing measures, one of the main conclusions to be drawn is the absence of a harmonized approach due to the multiplicity of approaches Parties and countries have taken based on their existing legislation, needs and constitutional structures. In addition, a number of countries are still in the process of developing their national regimes and therefore the package is often incomplete."[823] "It would appear that few legally binding measures have been adopted by Parties", with users of GR under their jurisdiction, to support compliance with access and

[819] UNEP/CBD/WG-ABS/5/3, p. 4
[820] DROSS.M, WOLFF.F, Supra, p. 45
[821] UNEP/CBD/WG-ABS/5/3, p. 7
[822] UNEP/CBD/WG-ABS/5/3, p. 7
[823] UNEP/CBD/WG-ABS/5/3, p. 4

benefit-sharing requirements. "The consequence of this lack of implementation of the access and benefit-sharing provisions has been the lack of predictability and legal certainty for both providers and users of GR. On the one hand, providers are concerned about the potential misappropriation of GR and the absence of legal certainty, in particular once GR have left their country. On the other hand, users of GR are concerned about the lack of predictability and legal certainty due to absence of clear procedures for access and benefit-sharing in many countries, the absence of easily identifiable competent national authorities, or existing access and benefit-sharing procedures which are sometimes considered too cumbersome, time consuming and involve high transaction costs."[824]

In sum, I suppose that the above situation may challenge for integration of the Protocol into national law, because there are limited bases for national law to be incorporated or transformed by the Protocol. There are not many good lessons learned. However, in positive points, it may be easier to develop a totally new access and benefit-sharing legislation, in case of there is no national access and benefit-sharing legislation that can apply methods of legislation or incorporation to develop new access and benefit-sharing legislation in accordance with the Protocol**.**

b) No traceability and absence of specific access and benefit-sharing remedies

"Monitoring and compliance measures are weak in a majority of access and benefit-sharing measures in provider countries. As indicated above, a number of Parties are still at the stage of raising awareness of their user communities at the national level. No user country measures have yet been adopted by countries to request compliance with PIC and MAT by users under their jurisdiction. In the absence of national measures to address the illegal access of GR from a foreign country, enforcement may be a difficult if not impossible task."[825]

"It could be argued that there is therefore currently a lack of incentives for users to comply with access and benefit-sharing measures and a lack of efficient compliance and enforcement mechanisms in the countries where GR are being used."[826]

"The difficulty in tracing or monitoring GR once they have left the provider country has also been a source of concern for developing countries in relation to the misappropriation of their GR."[827]

"At the same time, the existing provisions are enforced poorly. While it is difficult to obtain an access permit or to enter into access and benefit-sharing agreements, once this has happened, no one is monitoring whether genetic resources leave the country".[828] "The

[824] UNEP/CBD/WG-ABS/5/3, *Supra*, p.32
[825] UNEP/CBD/WG-ABS/5/3, p. 23
[826] UNEP/CBD/WG-ABS/5/3, p. 23
[827] UNEP/CBD/WG-ABS/5/3, *Supra*, p. 32
[828] DROSS.M, WOLFF.F, *Supra*, p. 44

absence of specific access and benefit-sharing remedies at national and international levels may be an obstacle to obtaining access to remedies and access to justice in situations of breach of compliance with access and benefit-sharing requirements of provider countries or in cases of breach of compliance with access and benefit-sharing contracts." [829]

Even though it remains constraints as analysed above, an internationally recognized certificate of compliance under Article 17 of the Protocol may be one possible instrument being considered to address this gap.

c) Unclear definition of rights and ownership on Genetic resources

Following the CBD and the Protocol, the issue of ownership and property rights is to be addressed by national law. "In the absence of clearly defined ownership over GR in national law, difficulties may arise in the negotiation of benefit-sharing agreements." [830] "Countries have had difficulties in developing workable legal frameworks for access and benefit-sharing that clarifies ownership of GR…Their definition of 'genetic resources' is sometimes ambiguous, it has been hard to legislatively determine who has rights to dispose of, give access to, or receive benefits from such resources. As a result, many countries apparently rely on the physical entity (i.e., organism, its parts or land where it is found) to define the legal status of their GR". [831]

The limitation can be explained in both two basic type of existing ownership regimes. "The Anglo - American legal system have a highly individualistic conception of property. In consist of view that almost any thing can be owned. Absolutist view is the right of destruction, formally called the *jus abutendi* or right of abuse, essentially the notion that one can do as he wishes with his own property, even wasting or destroying it however much a loss that might be the society at large. The harmful implication of this highly individualized conception of property for the environment in general" and GR, biodiversity in particular has not been sufficiently emphasized. Thus, "to take a more contemporary example absent some specific law prohibiting such action the owner of land that contains the sole habitat of some species – is entirely to extirpate it. It is notable inadequacy that the basic concept of ownership rights in the law takes no note of contemporary appreciation of the fundamental importance of biodiversity conservation."

"The remaining legal systems have public ownership to natural resources. It is recognized that a more limited and nuanced view of ownership exists. The limited point is explained that the system rests on a fundamental market – driven assumption that ultimately what is good for the owner is good for the public as public demand will generate private supply of that demand and not of what is not wanted or needed."[832] Some

[829] UNEP/CBD/WG-ABS/5/3, *Supra*, p. 32
[830] UNEP/CBD/WG-ABS/5/3, *Supra*, p. 32
[831] *Ibid*, p.5
[832] JEFFERY. I. M, QC, FIRESTONE. J, BUBNA. L. K, *Supra*, p.12 – p. 13

properties may not be suitable for development public interest and ownership, rights to the public is contrary to the right of the private property owner. No one has a property right to destroy the benefits of a natural system. The ownership of GR and TK with responsibility of the State as owner to protect GR, therefore, should be considered.

"The clarification of the legal status of GR is crucial to the implementation of Article 15 of the Convention, it being essential in defining access requirements, procedures, rules and rights over these resources. However, it is evident that countries have diverse ways of defining ownership over biological and/or GR. A distinction between ownership over GR and ownership over biological resources is not always clearly articulated in national legal systems."[833] This conclusion will be justified by the specific case of the selected country in the next section.

2) Obstacles for legislation's implementation

a) Asymmetries between users and providers

Although, the Protocol does not clearly discriminate users and providers, in fact, "asymmetries between users and providers in terms of access to information, knowledge, negotiating skills and capacity" [834] are existed. There is a need to address this problem to promote the fair and equitable sharing of benefits arising out of the utilization of genetic resources.

b) Knowledge gap

"Little is known with respect to the chain of innovation of GR accessed. The analytical studies on access and benefit-sharing arrangements in different sectors will attempt to shed some light on different practices in various sectors, highlighting commonalities and divergences." "It lacks information on the value of GR."[835] This has created distrust, resulting in the adoption of restrictive national regulations and obstacles to access.

In order to improve this situation, it is essential that "trust must be established and that providing countries experience how research can give rise to mutual benefits for both the providers and users of GR."[836]

B – Responding to the insufficiencies

1) General suggestion

Once ratifying or accede the Nagoya Protocol, each country is required to take appropriate measures and develop and improve national legislation on access and benefit-sharing to fill the gaps at national existing legislation to comply with the Protocol.

[833] UNEP/CBD/WG-ABS/5/5, *Supra*, p. 24
[834] UNEP/CBD/WG-ABS/5/3, p. 33
[835] UNEP/CBD/WG-ABS/5/3, p. 33
[836] KLEMM.S.B, MARTINEZ.S, *Supra*, p.17

However, "there are not many legal methods, comprehensive approach, measures; most of suggestions are direct to develop political awareness, institutional strategies, procedures and capacity to enhance implementation access and benefit-sharing legislation."[837]

There is no ideal model for all countries because each country has its own context and position. The access and benefit-sharing national legislation therefore should reflect their economic, environmental, technological development, as well as their legal, institutional, economic and cultural situation.

Generally, the countries are suggested to carry out effective and efficient activities to develop national legislation. These includes: defining and determining certain principles, objectives, priorities and goals in the relation to access and benefit-sharing; imposing certain obligation upon the authorities and citizens of the country in relation to the provisions of the Protocol; preventing possible conflicts between the regulations in force and the provisions of the Protocol if necessary, and create a mechanism to solve such legal conflicts; establishing an institutional structure to fulfil the previously determined objectives and goals, unless an existing structure is already sufficient.[838]

In addition, there are some suggestions for improvement of the national law implementation process. These include: increasing awareness of access and benefit-sharing; initiating a strategic planning process to define the national strategic goals on access and benefit-sharing; accessing the role of legislation in the context of strategic goals and examining the feasibility of a framework legislation to ensure a nationally consistent approach to access and benefit-sharing; evaluating the legal protection of local and indigenous knowledge and livelihoods; building and developing the required institutional capacity to address access and benefit-sharing issue; developing model agreements in consultation with relevant experts and build capacity in business and negotiating skills; considering appropriate funds or funding sources.[839]

2) Suggestion for provider or users countries

Some researchers make recommendations available for provider countries or user countries. "The provider countries could respond to the current state of no access and benefit-sharing legislation or lack of uniformity, uncertainty to implement the Protocol by developing a regulatory framework enables access to GR, a process for the formal recognition and approval of requests for access; a legal framework effectively governs the negotiation and implementation of contracts, including dispute resolution."[840] More detailed suggestions to develop the system include: definitions; scope of application; designation of national focal point and competent national authority, procedures for

[837] CARRIZOSA.S, BRUSH.S.B, WRIGHT.D.B, MC GUIRE.E.P, *Supra*, p. 229
[838] CARRIZOSA.S, BRUSH.S.B, WRIGHT.D.B, MC GUIRE.E.P, *Ibid*
[839] *Ibid*, p.267
[840] IISD, *ABS – Management Tool, Best practice Standard, 2007*, at 6, http://www.iisd.org

obtaining PIC; procedures for negotiating the MAT, using contracts for benefit-sharing; mechanisms for monitoring and control; and sanctions for non-compliance such as penal, civil and administrative measures.[841] The recommendations above may also be good criteria for examining a national legislation in compliance with the Protocol.

For user countries, as the Protocol's provisions on monitoring and compliance are flexible and limited in specific user measures as analyzed in Part 1, I agree that "national legislation should create of user measures that would enable and encourage each user to engage in contractual negotiations and it would require compliance with MAT". Therefore, it should provide "a basis of rationality, legality and equity on which to define and limit the application of foreign law and to control domestic users". This can be considered some practical ways: *First*, "these same process provisions can provide the legal basis of enforceability, by which the courts and agencies can determine whether and how to apply source-country law or to interpret an access and benefit-sharing contract." *Second*, "the user government can provide a basis of rational and transparent valuation in access and benefit-sharing contracts, indirectly, through its regulation of users who have not obtained access and benefit-sharing contracts from the source country. In essence, by stating how access and benefit-sharing requirements will be calculated and applied to this group of users, the law can provide a "baseline" that can serve as guidance to users in negotiating benefit-sharing contracts". *Third*, "these provisions can clarify the key difference between users who have obtained access and benefit-sharing contracts and those that have not. For the latter group, the government will decide what benefit-sharing measures are required. This may be a very important incentive for users to comply with access and benefit-sharing requirements and negotiate access and benefit-sharing contracts at an early stage in their activities." *Fourth*, "overall user-side measures demonstrate how the laws from source countries and contracts negotiated under those laws will be applied in user countries." *Fifth*, "over time, the cumulative force of all national user-side measures could help define the common international bases that can be used in access and benefit-sharing processes (PIC and MAT) and their application worldwide. Where the users are governmental (government-sponsored research institutes, projects and other activities), they can adopt these principles directly in procurement and other policies required of all persons negotiating with a source country on behalf of the user government."[842]

Some researchers suggest that to achieve the desired results, however, "user-side measures must be integrated into a coherent, internally consistent framework of legal requirements, administrative agencies and regulatory systems, motivational provisions, and enforcement standards". In more specific, despite the challenge arises, accepting the need for user measures, the country must adopt several elements: (i) Scoping provisions; (ii)

[841] MEDAGLIA.C.J, SILVA.L.C, *Supra*, p. 8
[842] TVEDT. M. W, YOUNG. T, *Supra*, p. 108

Direct benefit-sharing obligations; (iii) Implementation and oversight structure; (iv) Enforcement; (v) Incentive measures/voluntary measures.[843] All of these seem to be essential to the overall functioning of the access and benefit-sharing regime, although "for many countries, only the first two will be needed immediately, accompanied by a commitment to future legislative development for its implementation, and many countries may choose to delay the adoption of incentive measures while experience with the basic system develops."

Other researchers suppose that to a functional Nagoya Protocol, "a legal framework in the user country is necessary in order to enable the provider country to assert its sovereign rights over GR in the place in which those rights are infringed. To make legal regime related to access and benefit-sharing to be complete and effective, some remedies that could to be needed in access and benefit-sharing claims, might take into account with various types of remedies through judgment, contractual remedies, orders of limit, permission, Punitive or exemplary damages, rescission, cancellation, reformation, revision."[844] Moreover, the method of legislation is suggested to use as the only way to enable the use of remedies in access and benefit-sharing. "The most important legislative needs to make remedies effective are to adopt "user-side" measures by all countries. Those measures ensure that users who do not comply with access and benefit-sharing requirements of the provider country are subject to remedial claims in courts, agencies and other forums in user countries; and/or to clarify the country's rules and procedures regarding enforcement of foreign judgments apply to access and benefit-sharing claims."[845]

Those are some very general suggestion that can apply for many countries in the common situation of access and benefit-sharing legislation. Those may be useful in certain level in process of integration of the Nagoya Protocol into national law. However, they should be considered in the specific conditions of each country. The next sections and chapters will consider in specific case of each selected country.

§ II – Bases for selected countries for studies

A – Explanation of reasonableness of bases

Representative factors for selection of national legislation for this study include: 1- continentences; 2- provider countries or user countries; 3- developed countries or developing countries; 3- legal views in relation between national law and international law 'dualist' or 'monist' for integration of the Protocol into national law; Common Law system or Roman - Napoleonic Civil Law system, 4- long and much experience of biodiversity law and access and benefit-sharing law development. Namely, selected countries more or less

[843] See UNEP/CBD/WG-ABS/7/3, *Supra* p. 16
[844] TVEDT.M.W, YOUNG.T, *Supra*, p. 108
[845] YOUNG.T, UNEP/CBD/WG-ABS/5/INF/3, *Supra,*

have access and benefit-sharing legal instruments within list of countries following the database of the CBD.[846]

B – Selected countries for studies

Following above explanation, the selected countries includes:

Vietnam is a country in Asia; it is a developing country, potentially presumed as a provider country, with the access and benefit-sharing legislation has been started to develop.

Brazil is a country in America and has more experiences in development of biodiversity law and some lesson learned in access and benefit-sharing issue. Brazil has also typically been considered a provider country, but actively developing domestic industries and companies based on the utilization of domestic genetic and biological resources. Its access and benefit-sharing legislation is very comprehensive, addressing a broad range of activities, applicable to domestic users of Brazilian biological diversity. We have examined Brazil's Provisional Act implementing the CBD.[847]

South Africa is a typical country in Africa that is provider country and developed biodiversity law and access and benefit-sharing provision. The legislation on access and benefit-sharing of South Africa will be analyzed in extension of African Model Law of African Union.

France is a developed country in Europe that also has strong industry with long tradition of using GR such as pharmacy, chemical cosmetics and agriculture. It also is a provider country in consideration its overseas departments and territories which are very rich on biodiversity. The case of national legislation relates to access and benefit-sharing of France will be considered in context of the European Union.

Section 2 – Access to genetic resources and benefit-sharing in selected countries

This section provides analysis of main factors of national laws on access and benefit-sharing and related legal issues that facilitate or challenge the Protocol integrate into national law of Brazil, South Africa, France and extends consideration regional instruments African Model Law and relevant legal instruments in EU. The analysis is referred to the results of above parts, chapters and sections. This section will examine the issue of legal status of GR and its ownership in national law that is not provided by the Nagoya Protocol as the matter of sovereignty right of State member. It also analyzes the main elements of access and benefit-sharing in national laws and possibility of conformity with the Protocol and vice versa. The main principles, methods and measures for integration also are justified by the specific case of each country's legislation. From that,

[846] http://www.cbd.int/abs/measures/groups.shtml, last accessed May 6, 2012

[847] TVEDT. M. W, YOUNG. T, *Supra,* p. 26

findings can be found and concluded as lessons learned and best practices for the Nagoya Protocol's implementation.

§ I – Brazil

The dimension of the country's territory with the different climatic zones and geological diversity confers to Brazil the mega diverse conditions; the biggest country of the Latin America is also huge to maintain and control its natural heritage, and also to conserve biological resources in it.[848] Brazil is the most biologically diverse nation in the world with six terrestrial biomes and three large marine ecosystems and at least 103,870 animal species and 43,020 plant species are currently known in Brazil. There are two biodiversity hotpots currently acknowledged in Brazil – the Atlantic Forest and the Cerrado and 6 biosphere reserves are globally recognized by UNESCO in the country.[849]

A – General overview

1) Development of national law on biodiversity and access to genetic resources and benefit-sharing

Brazil was the first nation to sign the CBD. With the passage of Legislative Decree No. 2 in 1994, Brazil ratified the CBD.[850] The CDB was promulgated by the Decree nº 2.519, 16/03/1998.[851]

Prior to the Convention, the access to GR and TK was unregulated for Brazilian nationals except for the export of material. The work of foreign researchers in this field was regulated by Decree 98.830 of 15 January 1990. One limitation of the decree is the absence of protection for TK of indigenous people.

Apart from that, Article 225 of the Constitution of 1988 contains a number of environmental provisions. It deals exclusively with environmental protection, including specific references to the preservation of diversity and the integrity of genetic patrimony.

After Brazil ratified the Convention, several acts concerning GR and TK were presented and discussed in Congress. Subsequently, three federal bills regulating access to GR and their derived products, the protection of the TK and the sharing benefits were proposed, [852] but not approved yet. In June 2000, the Provisional Rule 2052 was published and later transformed into Provisional Rule 2186-16/2001 after several re-editions, is still main Brazilian legal instrument regulating access and shipment of genetic heritage and TK. Since its publication, the Provisional Rule had some of its articles regulated through

[848] FEIT.U, DRIESCH.M.V.D, LOBIN.W, *Access and Benefit-Sharing of Genetic Resources, Ways and means for facilitating biodiversity research and conservation while safeguarding ABS provisions*, Bonn, Germany, 2005, p. 55
[849] Ministry of the Environment of Brazil, Office of the National Program for Biodiversity conservation, *Forth national report to the Convention on Biological Diversity, COP 10 Special Edition*, 2010, p.16
[850] DROSS.M, WOLFF.F, 2005, *Supra*, p. 27
[851] http://www.lexml.gov.br/urn/urn:lex:br:federal:decreto:1998-03-16;2519, last accessed 16 August 2012
[852] DROSS.M, WOLFF.F, *Ibid*, p. 27

decrees. Decree 3945 of September 2001 regulated Articles 10, 11, 12, 14, 15, 16, 18, 19; Decree 5949 of June 7, 2005 regulated Article 30 which establishes and regulates infringements to the Provisional measure and remedies to illegal activities involving to the GR and TK,[853] and Decree 6915 of July 2009 regulates Article 33.

However, "the Provisional Executive Order is only a provisional measure of by the President, but is not adopted by the Congress (which has legislative power). It is clear that a proprer Act wasn't approved. The reason is the lack of consensus between the stakeholders".[854] The regulation of the remaining articles is still being discussed. Debates and public consultations to define a final text for legislation on this theme initiated with the Provisional Rule are still ongoing. [855]

The Brazilian's Competent National Authority - Genetic Heritage Management Council (hereafter called as Council) associated to the Ministry of Environment was created to control and to legislate the use of the genetic and cultural heritage related to biodiversity. It has been operative and several authorizations for access to GR and TK were granted in accordance with PIC requirements. The Council has also clarified some terms in order to facilitate the adequate understanding of the process by the Contracting Parties.[856] In the very beginning of the Council works generated many conflicts, because, it had a Government composition and many social organizations was unhappy about it; besides, the academy was not sufficient represented and the letter of the Provisional Rule did not make any difference between terms which denotes pure science and bioprospecting. Notwithstanding, this Council only began its activities in April 2002, which produced a state of uncertainty as to the possibility to carry out research in the country and difficulties concerning the exchange of biological matter for scientific purposes.[857] Currently, the Council has a wider and heterogeneous representation in governmental sectors (ministries, autarchies, justice, and defense), scientific sectors (institutes and scientific societies), industrial sectors (federations) and NGOs associated to the TK or to indigenous populations. This extremely wide composition, if, on the one hand, it makes decision quitrent quite plural, on the other hand, decreases the representation weight of the scientific community.[858] This institutional arrangement would be a base to meet firstly requirement of Article 13 of the Protocol on national focal point and competent national authority(s) when Brazil ratified the Protocol.

However, Brazilian policy makers have not yet been able to establish regulations on access to GR. This is actually a problem for the adoption of a legal framework on access

[853] Ministry of the Environment of Brazil, *Supra*, p.52
[854] Following comments of Dr. Ana Rachel Teixeira-Mazaudoux
[855] Ministry of the Environment of Brazil, p. 201-210
[856] UNEP/CBD/WG-ABS/3/5, p. 7
[857] FEIT.U, DRIESCH.M.V.D, LOBIN.W, *Supra*, p. 55
[858] FEIT.U, DRIESCH.M.V.D, LOBIN.W, *Ibid*, p. 94

and the reason is the lack of consensus between the different stakeholders[859] with opposing interests among them. "Many conflicts of interest among stakeholders could come to an end, once a Brazilian law for access to GR enters into force". [860]

2) Background factors for integration of the Nagoya Protocol

The development of the legal instruments that comprise the Brazilian legislation is initiated both by the governmental legislative body and the executive body, and evolves according to the most pressing social, economic, cultural or environmental demands. Legal instruments from different hierarchies are constantly added to the national legal frameworks, among which: laws, provisional, rules, decrees, normative rules, administrative rules and resolutions, which gradually format each sector's legislation, including the set of instruments comprising the Brazilian environmental legislation. International instruments such as treaties, agreements, conventions, protocols, among various other instruments that characterize an international commitment, integrate into the national legal framework after being subscribed by Brazil. [861] The process of integration of a treaty could be: "firstly the congress gives accord to ratify a treaty, after the President can ratify the treaty with the accord, then the treaty is promulgated by a Decree integrating at this time into the national legal system"[862]. This feature reflects that Brazil is a 'monist' country as above analysis.

Brazil also operates a federal system of government. There is challenge to define the competence of the Union (federal level) and of the Member States to regulate specific issues. Concerning to some issues, there are a concurrent competence, it means that both are competent, but in a different way. The general rules come from the Union and the specific ones from the States. In case of lacking federal legislation, the States can adopt their own laws. However, in case of the federal law is approved after the State's law, it will revoke the conflictual provisions from the State's laws, because, federal law takes precedence in Brazil in accordance with the Constitution.[863] This situation is complex and makes difficulty of analyzing and implementing the Brazilian legal system.[864]

By becoming party to the CBD, Brazil engaged in the adjustment of its national legal framework to harmonize it with CBD's principles and rules.[865] However, with federal system of government; access and benefit-sharing law development depends basically on the rest of the legal system of Brazil at the both federal and State level. Since Brazil's ratification of the Convention, there have been several initiatives to regulate access to Brazilian's GR, but no

[859] Discussion with and comments of Dr. Ana Rachel Teixeira-Mazaudoux
[860] FEIT.U, DRIESCH.M.V.D, LOBIN.W, *Supra*, p. 94
[861] Ministry of the Environment of Brazil, 2010, p. 234
[862] Discussion with and comments of Dr. Ana Rachel Teixeira-Mazaudoux
[863] UNEP/CBD/WG-ABS/5/5, *Supra*, p. 24
[864] Comments of Dr. Ana Rachel Teixeira-Mazaudoux
[865] Ministry of the Environment of Brazil, 2010, p. 234

federal law has yet been enacted as mentioned above.[866] However, the States of Amapa and Acre have passed their own laws regulating access to genetic resources.[867]

In addition, the country's infrastructure and capacity to execute legislation and enforce compliance requires significant will and financial investment to keep pace with the policy advancement. Considering the policitical and economic scenario that influenced Brazil environmental policy, there are four primary challenges for its implementation. The first is to deal with heterogeneity of actors involved in the national environmental policy. The second is defining the ways and means to incorporate this diversity of actors in the processes of policy development and implementation. The third is to ensure the incorporation of the environmental policy in all sectoral policies. Finally is to maintain coherence at the various levels of environmental policy development and implementation: local, state, regional, national, continental and global. [868]

B – Legislation on access to genetic resources and benefit-sharing

1) Legal status and ownership of Genetic Resources

Article 225 of the Federal Constitution of Brazil affirms that the right to an environment constitutes a "common asset of the people essential for the healthy quality of life inherent in every collectivity and should be protected and preserved for present and future generations".[869] By virtue of the provisions of Article 225 of the Federal Constitution and the special nature of the resources, GRs have been described as the heritage and patrimony of the Federal Government.[870] There is no provision of Constitution or any other federal legislation provides directly and clearly on legal status of GR. Some commentators consider that "GR are public goods of special use subject to special procedures in order to allow their utilization".[871] There is also a proposal for constitutional alteration to include genetic patrimony as a Union good.[872] It is stated that, "there are no specific regulations over property, but the state has the right to control or authorize the use of GR."[873] Therefore, in case of the States of Amapa and Acre with their own laws regulating access to GR, "GR are considered the patrimony of the state and are distinguished from biological resources, which contain them and may be owned privately

[866] GARFORTH.K *et al*., *Overview of the National and Regional Implementation of Measures on Access to Genetic Resources and Benefit- Sharing,* CISDL report for Environment Canada, December 2005 Available online: http://www.cisdl.org/pdf/ABS_ImpStudy_sm.pdf
[867] UNEP/CBD/WG-ABS/5/5, *Supra*, p.12
[868] Ministry of the Environment of Brazil, 2010, p. 55
[869] Article 225 of the Constitution of Brazil
[870] LIMA.A, *Ownership of Genetic rights: from whom? For whom?* Online: http://www.socioambiental.org/pib/english/rights/patrgeni.shtm.
[871] MEDAGLIA.C.J., *A Comparative Analysis of Legislation and Practices on Access to Genetic Resources and Benefit-Sharing (ABS) Critical Aspects for Implementation and Interpretation IUCN, Bonn. Available online:* http://www.iucn.org/themes/law/absdocuments/eng_critical_aspects.pdf , p. 214
[872] DROSS.M, WOLFF.F, p 30
[873] MEDAGLIA.C.J, SILVA.L.C, *Supra*, p. 42

or communally." [874] "It appears that the states may regulate access, at least until the passage of federal legislation." [875]

In contrary, Cabrera Medaglia supposes that "it is possible to deduce that the States do not have the genetic patrimony ownership, because the States are not usually part of the access and benefit-sharing Contracts" (Provisional Rule, Article 24 and 27).[876] He further notes that "there is a proposal for constitutional alteration to include the genetic patrimony as a Union good, which was considered a common good of the Federal in accordance with Article 225 of the Federal Constitution, but so far this remains a proposal".[877] There is an attempt in the draft Bills on Access to GR, to highlight the difference between biological and GR and to distinguish the ownership and control. In that case, "GR will be a public good residing in the Union (or Federal Government), while the biological resources containing them may be owned or controlled by any other entity, whether private or public".[878]

One of the practical challenges that may arise if GR is defined as State owned is that it precludes a landowner can enter into private transactions with a bioprospector through private contracts or transactions. Individuals can deal with their property, but if the use of biological material fall into the category of defined GR, state-stipulated procedures will be applied and have to be observed.[879]

2) Elements of access and benefit-sharing regime as provider country

Brazil provides that mutually agreed terms for access and benefit-sharing must be written or set of documents that may include permits, contracts, and material transfer agreements. [880]

a) Access

Brazil has adopted different requirements for access depending on the type of applicant. Accordingly, foreign legal entities shall be "authorized only when it is joined by a Brazilian public institution, the latter having mandatory coordination of activities" for access of GR and TK (Article 16.6 of the Provisional Rule). [881]

There is a differentiation between commercial and basic access and benefit-sharing research. The Council dispenses with some requirements and fast tracking. Scientific research is defined as using GR with no economic purpose. Access for non-commercial purposes is considered to "contribute to the advance of knowledge of biodiversity of the country and not present previously identified potential for economic use as with the

[874] MEDAGLIA.C.J., p. 214
[875] DROSS.M, WOLFF.F, p. 30
[876] MEDAGLIA.C.J., p. 65
[877] UNEP/CBD/WG-ABS/5/5, *Supra*, p. 11
[878] UNEP/CBD/WG-ABS/5/5, *Ibid*, p. 12
[879] UNEP/CBD/WG-ABS/5/5, *Ibid*, p. 24
[880] UNEP/CBD/WG-ABS/5/3, *Ibid*, p. 5
[881] UNEP/CBD/WG-ABS/5/3, *Ibid*, p. 9

activities of bioprospecting or technological development".[882] The Technical Guidelines help to implement the Provisional Rule fairly with access to GR for science and bioprospection for commercial interests. However, access to TK or GR, it requires a specific authorization to access TK and/or components of genetic heritage for scientific research, bioprospecting and technological development purposes. Individuals, institutionally unaffiliated researchers (including foreign institutions), are not allowed to request such authorization, unless they become associated with national research and development institutions in order to participate in research, involving to access.[883] Therefore, "access and benefit-sharing contract also is required to regulate both domestic and foreign users of their GR."[884] "The procedures for cases in which there was participation of foreigners working on national territory were still pending, as the Ministry of Science and Technology, also intervened in the control of collecting, done by foreigners, regarding data and Brazilian scientific materials."[885] All these provisions are background to incorporate Article 8 of the Protocol, however, these "create conditions to promote and encourage research through simplified measures on access for non-commercial research purposes" may be a question.

In fact, the Provisional Rule was criticized by the international scientific community. All projects involving access to GR have to be submitted to the Council's authorization and judgment process, even those only involving basic research in morphology or systematic, "the reception of the scientific community was the worst as possible, once the feeling was of restricting activities by an authoritarian control motivation". [886] They suppose that there is an error of focus. Because, the focus of the legislation is aimed at research institutions with predominantly basic research motivation, while it should be focused at private companies with the bioprospection. The public research institutions and competent researchers have fixed addresses and ask for permission that are easy target for legislation restrictions, while the others do not ask for permission work without being disturbed. The result is the worst that many competent researchers work beyond the law without permission. Research projects are delayed or being devoid of their main characteristics due to collect restrictions. Researchers choose for researching groups of plants or animals of lesser interest in order to avoid materials from conservation units or associated to the TK. Finally, "the true pirates still work unpunished and ignoring any type of inspection and punishment."[887]

In access and benefit-sharing contract negotiations, indigenous and local communities and private individuals may be direct 'providers' of GR, and are encouraged

[882] MEDAGLIA.C.J, SILVA.L.C, *Supra*, p. 48
[883] FEIT.U, DRIESCH.M.V.D, LOBIN.W, *Supra*, p. 55
[884] BHATTI. S, CARRIZOSA.S, MC GUIRE. P, YOUNG. T, *Supra*, p. 75
[885] FEIT.U, DRIESCH.M.V.D, LOBIN.W, *Supra*, p. 55
[886] FEIT.U, DRIESCH.M.V.D, LOBIN.W, *Ibid*, p. 94
[887] FEIT.U, DRIESCH.M.V.D, LOBIN.W, *Ibid*, p. 95

to negotiate access and benefit-sharing contracts directly.[888] This is relevant to incorporate Article 6.2, Article 7 and Article 12 of the Protocol to ensure involvement of the indigenous and local communities in PIC.

A closer look to the two specific laws in two states of Brazil may be necessary here. In case of Acre, the legislation was passed responding to a particular case of "bio-piracy" involving an NGO that was cataloguing the native use of medicinal plants.[889] Acre State Law No 1235/97 defines access to GR including the TK of indigenous and local communities. The Acre Law provides to require the PIC of the indigenous and local peoples in three cases: access to GR in areas that they occupy; their domesticated agricultural crops; and the TK that they hold. However, the decision to grant access to GR is made by the State Council on the Environment, Science and Technology and by a commission. The commission consists of representatives from the state government, municipal governments, state research entities, the scientific community, and entities representing the indigenous and local populations. The law protects the rights of local communities to benefit collectively and to receive compensation for the use of their rights. It also includes a provision for the local communities to deny permission to collect GR and to deny access to TK if they can justify "these activities threaten the integrity of their natural or cultural patrimony".[890]

The Amapá legislation was one of results of a sustainable development program. Amapá Law No 388/97 was passed at the end of 1998. To implement the law, in June, 1999, Decree No 1624 was issued for further regulations in detail. The Amapá law is more concise than the Acre Law counterpart. It contains 49 terms related to access to GR. Article 1 of the law establishes the participation of indigenous and local peoples in decisions relating to the access to GR in the areas where they live, as well as their participation in sharing benefits arising out from the access to GR. In accordance with the law, the State's Secretary of the Environment, Science and Technology has authority to plan, coordinate, supervise, control, license, authorize and evaluate the development of activities of access to GR, as well as to guarantee and facilitate the participation of indigenous and local peoples in decisions on access to GR. A permit of access to GR will be granted by an Access to Biodiversity Resources Commission. The Commission composed of representatives from: Secretary of the Environment, Science and Technology Attorney General's Office, the Legislative Assembly, the Federal University of Amapá, the municipality involved, the Secretary of Health, the Secretary of Justice, Land Commission, and indigenous and local communities, NGOs, social organizations like the workers' union, the forest engineers, the fishers, the organization of cooperatives. [891]

[888] BHATTI. S, CARRIZOSA.S, MC GUIRE. P, YOUNG. T, *Supra*, p. 61
[889] DROSS.M, WOLFF.F, *Supra*, p. 29
[890] DROSS.M, WOLFF.F, p. 29
[891] DROSS.M, WOLFF.F, p. 30

However, following report of Ministry of Environment in 2010, "two foresaid legal instruments have not yet been regulated and are not in force".[892]

For requirement of certainty, clarity and transparency of access and benefit-sharing legislation following Article 6.1.a of the Protocol, it may be difficult when the Brazil Provisional Rule states an unequivocal prohibition on 'practices that are harmful to the environment and human health and for the development of biological or chemical weapons' (Article 5). There remains within this provision, "some room for debate over what specific practices would violate it."[893] The certainty is provided where the law specifies objective criteria and specifications, in this case, objective decision criteria is difficult. Additionally, in access and benefit-sharing context, many subjective factors (scientific, social and other impacts, policies and concerns) must be considered. It is supposed that in such cases, "the applicant may have little basis for assessing the chances that his application will be approved".[894] There are also additional requests and in-process stakeholder participation, following Article 12 of the Provisional Rule.[895]

The uncertainty is also reflected in the national legislation which does not use the term 'genetic resources' in their legislation, but have identified another term 'genetic heritage.[896] The Provisional Rule of Brazil defines Genetic Heritage as "information of genetic origin contained in the samples of all or part of plant, fungal, microbial or animal species, in the form of molecules and substances originating in the metabolism of these living beings or from extracts obtained from in-situ or ex-situ conditions…"[897]. In normal circumstances, it is reasonable for a country to use a term different from the international term and to define that term clearly for national implementation. However, when another country's court considers a case involving that term, the court can make an analysis by comparing the term to the international requirements (for example, terminology definition of the CBD whether is the term stricter or more inclusive or less). If concept of GR is unclear, it would be difficult to know which of these laws includes fully all GR, which is broader or less. "This kind of uncertainty would make it difficult for most courts to apply principles or national laws based on the GR concept. In many countries, where a law or contract is too ambiguous for a court to understand and apply, it is deemed to be unenforceable. In that case, no matter what remedy exists and applies to access and benefit-sharing issues, that remedy would be unavailable through the courts and arbitration."[898] To response with this problem, there is a need to apply method of interpretation to conformity with the CBD and the Protocol.

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[892] Ministry of the Environment of Brazil, *Supra*, p. 210 - 21
[893] YOUNG.T, *Supra*, p. 85
[894] YOUNG.T, *Ibid*, p.85
[895] YOUNG.T, *Ibid*, p. 86
[896] YOUNG.T, *Supra*, p. 176
[897] MEDAGLIA.C.J, SILVA.L.C, *Supra*, p.30
[898] YOUNG.T, *Supra*, p.177

b) Benefit-sharing

Indications regarding the types of benefits to be shared vary depending on the measures. Following the Article 5.4 of the Protocol, benefits may include monetary and non-monetary benefit. Section 25 of Brazilian Provisional Rule provides for both monetary and non-monetary benefits. Those include: capacity-building, access and transfer of technology, the involvement of local citizens or institutions in the research, collection, the technological development of the products derived from GR and royalties. It is also interesting to note that the Provisional Rule of Brazil in Section 16.7 mentions that research on GR should preferably be carried out in Brazilian territory.[899]

Section 9 of the Provisional Rule provides many national measures for owners/holders of TK shall get a share of benefits arising from the use of their TK. Section 33 of the Provisional Rule provides for the establishment of funds, in which the benefits received by the State or not allocated to stakeholders, shall be kept.[900]

However, following the Ministry of the Environment of Brazil, the rules for complying with the legislation are complex and difficult to implement, benefit-sharing is still incipient. Since 2002, when the Council became operational, 25 contracts for benefit-sharing were agreed and signed. In 2007, the Council agreed to four benefit-sharing contracts, these contracts related to bioprospection projects involving access to GR from public land, which were signed between federal government and four universities. However, these are bioprospection projects without immediate commercial use. These contracts indicate that benefit-sharing will only occur when the economic potential is identified. The Council also negotiated with the Federal University a contract to implement the system to disseminate the legislation, manage the access and benefit-sharing activities, as well as, to assist in identification of non-authorised access. The system recorded over 250 projects and products potentially involving access activities for bioprospection or technological purposes. In 2008, the Council evaluated and agreed to two benefit-sharing contract, both referring to bioprospection projects involing access to GR in private property and TK from indigenous and local communities, was signed by the Federal University of Amazonas. Some benefit-sharing contracts is being implemented, such as contracts of the Natura cosmestic company. However, the paid benefit values are still considered information at the company's request. In 2009, Natura used 31 certified active ingredients from organic or sustainable agriculture or forest management. All research projects for new active ingredients from biodiversity submitted by Natura to the Council are currently pending evaluation and approval. [901]

[899] UNEP/CBD/WG-ABS/5/3, p. 5
[900] UNEP/CBD/WG-ABS/5/3, p. 6
[901] Ministry of the Environment of Brazil, *Supra*, p 210-21

There was a diagnosis for the definition of benefit-sharing procedures in production chains involving Brazilian biodiversity as well as payment level for benefits, in 2009, by Brazilian Association of Technological Research Institutions. It describes seven production chains of the seven species as the basis for defining the levels of benefit-sharing, given the economic importance of their products and possible industrial uses. For at least 5-7 species, the report also includes a list of priority criteria for calculating the value of each production chain. A methodology was proposed to calculate benefit-sharing based on actual data from existing production and commercialization chains. [902]

This fact shows the diversity of benefit-sharing in practice, and flexible provisions of the Article 5 of the Protocol can be integrated in to the national laws in various methods of incorporation . The provisions of benefit-sharing also are reflected clearly almost the foresaid principles.

c) Traditional knowledge

Brazil is quite developed in conservation and promotion of TK and indigenous and local communities following the report of the Ministry of Environment to the CBD 2010. This includes recognition of the rights of traditional lands in the Constitution, institutional arrangement by creation of inter-ministerial National Commission for the Sustainable Development of Traditional Communities. The Commission provides an interlocution channel between federal government and communities. This commission developed and approved the National Policy for the Sustainable Development of Traditional communities (Decree 6040 of February 7, 2007) in addition to the National Policy to promote the socio-biodiversity production chains with objective of strengthening the production chains of traditional communities while conserving biodiversity and ensuring social and market inclusion.

Despite of the legal instruments are already in place, various challenges remain before satisfactorily achieving the conservation and protection of TK. Those include: published information used by third parties; systematized and disseminated TK for its broader use while not misused by third parties; and clear identification of the community from which specific knowledge originated; associated TK that exist out of the traditional context that is already widely disseminated. Ministry of the Environment has implemented, since 2006, a capacity building and awareness raising program for indigenous and other traditional communities on the existing access legislation.[903]

Significant progress was obtained in the demarcation of indigenous land providing official protection of these areas and to a certain extent, protection of indigenous culture, biodiversity, agrobiodiversity and practices. Indigenous and traditional culture is legally protected by numerous relevant legal instruments. However, it is necessary to develop

[902] Ministry of the Environment of Brazil, *Ibid*, p 210-21
[903] Ministry of the Environment of Brazil, *Ibid*, p. 52

specific legislation, innovations and practices to take into account their peculiarities, such as means of transmission, collective and dynamic characteristics. Such instruments are still in the early stages of discussion with indigenous and local peoples. Several publications derived from projects and activities involving the access to TK with identification of original information required by the Provisional Rule. However, the Provisional Rule lacks of regulation for the access to TK through secondary sources (books, publication, databases is disincentive to complying the rules. The total number of publication issued before 2011 when the legislation was put into force, is large, which increases the difficulty to collect data to define the degree of target achievement. It also has question of the efficacy of practice recording TK of indigenous and local communities as a means of protection in case their TK might be used without their consent.[904]

In 2007, the Council issued a resolution determining that the patent requests should necessarily include information on the origin of the GR being used and proof of authorized access. This resolution resulted in the development of a second resolution by National Institute of Industrial Property to ensure compliance with Council resolution. New resolution determined that the patent requests involving access to GR where this access occurred at the time or after publication of the Provisional Rule are also required to present information on resources origin and authorized access. Because of a serious deficit in staff number, there is delay of several years in the analysis of patent requests deposits with the institute. As the information provided at the time of request presentation is only verified when the request is analyzed, information to access is not available.[905]

c) Compliance

Section 9 of the Provisional Rule requires the disclosure of origin of GR or TK referred to publications or other uses and disseminations. This is the requirement is higher than the requirements of the Protocol, because, in all the Protocol, there is no disclosure requirement. The granting of intellectual property right obtained through the use of components of the genetic heritage is contingent on the observance of the access and benefit-sharing legislation. The applicant is obliged to specify the origin of the genetic material and the TK.[906]

Regarding to taking appropriate, effective and proportionate measures in Article 15 of the Protocol, in Brazil, under Section 30 par. 1(I) of the Provisional Rule, the sanctions range from a written warning to a fine (in some cases, a scale of fines is included). Following, Section 30 par. 1 (II) et par. 2, a ban on undertaking prospecting of biological and GR.[907] In case of any violation of 'relevant legal provisions,' the penalties include

[904] Ministry of the Environment of Brazil, *Ibid*, p. 210-221
[905] Ministry of the Environment of Brazil, *Ibid*, p. 210-21
[906] Art. 31 Provisional Measure No. 2.186-16, Brazil.
[907] UNEP/CBD/WG-ABS/5/3, p 20

suspension or cancellation of the access and benefit-sharing rights, as well as seizures, embargos on sales and other activities, and even the loss of the right to contract with any public agency for up to five years. "Since the Provisional Rule does not set a formal application process and procedure, and since in many cases, the access and benefit sharing rights appear to be granted by private landholders and others, it would appear that the individual access and benefit-sharing contracts, licenses, etc., may be considered 'other relevant legal provisions' for these purposes." [908]

The different studies on the implementation of national access and benefit-sharing laws confirm the difficulties that are faced by provider countries in seeking to obtain or verify adequate compliance with the current legislation. "In practice, the level of enforcement of these laws is relatively low. In Brazil, the number of permits has grown steadily in the last few years, mostly having to do with non-commercial applications; for example, in 2005 there were almost 100 access applications for basic research and 20 for bioprospecting and technological development." [909]

3) Legislation provisions as user country:

There are some measures of user country that can be found in the Provisional Rule of Brazil. This can be considered initial base for integration of Article 15, 16 of the Protocol.

Title IX, Article. 34, provides that "the person who uses or makes economic use of GR and TK should make their activities compatible with the provisions of this Act."[910]

At first, there is requirement of obligation of disclosure of origin. In Brazil, obtaining the intellectual property right through the use of components of the genetic heritage depends on the observance of the access and benefit-sharing legislation. The applicant is obliged to specify the origin of the genetic material and the TK following Article 31.[911]

The critical question is whether the user-country law enables remedies, or only imposes penalties. "Penalty" describes any action intended to punish the offender and/or to prevent future offences. Some kinds of penalties can be enhanced by the creation of a permanent public record of the offence. For example, the revocation of a government permit or license may be enhanced by the creation of a list of offenders. Being named on such a list may affect the chance that the violator will ever be able to obtain a similar permit in future. Title VIII, Art. 30, par. 1.XIII of the Provisional Rule of Brazil allows

[908] YOUNG.T, *Supra*, p. 92
[909] MEDAGLIA.C.J, SILVA.L.C, *Supra*, p. 24
[910] TVEDT. M. W, YOUNG. T, *Supra*, p. 32
[911] DROSS.M, WOLFF.F, p 90

administrative violations to be punished by *inter alia*, "prohibition of entering into contracts with the public administration for up to five years." [912]

'Remedies' are measures "designed to compensate the injured party in a lawsuit. Remedies may include a variety of forms of compensation, ordered by a judge or agency." [913] They include: payment of funds (either the funds due under contract, or the liquidated value of the damage suffered by the injured party); fulfillment of contractual requirements (including a judge's interpretation of the specific actions required); mandate or prohibition (orders to take action or to refrain from action); or rescission or cancellation of a contract or other document.[914] In contrary, actions for remedies are initiated by the injured party; and the amounts awarded are paid to the injured party. "In most countries' organic law, the government is not allowed to bring private actions on behalf of individuals – it must focus on penalties rather than remedies. Typically, the only civil actions a government may bring will be those alleging a violation of a contract with the government or a tort against the government." [915] Similarly, Title VII, Article 28.8 of the Provisional Rule provides that "When the Federal government is a party to the contract; the access and benefit-sharing contract shall be ruled by public law."

In fact, a country's implementation of its user measures is normally focused on penalty, rather than on ensuring or assisting the provider country to obtain compliance with its access and benefit-sharing requirements. National courts usually interpret their rights narrowly. If the user country's law does not specifically authorize its courts to issue an order requiring compliance, the chance of this result will be very low. "On questions of legal redress, however, it is also interesting to consider the measures and legislation adopted by countries which regulate domestic users of domestic GR. It may be argued that the same rights that the country provides for itself in dealing with users of its own GR may also apply where users in that country are utilizing another country's GR". [916] Title V, Article. 16. 10 of the Provisional Rule presumes that private rights under the access and benefit-sharing contract are resolved in civil actions, but gives an additional, specific statutory right to the provider (country, community or individual) to receive compensation, if the user has caused any harm or damage in the course of his removal of specimens. Title VIII, Article. 30. 1 of the Provisional Rule also empowers the government to impose administrative penalties such as suspending permits and invalidating other administrative approvals. It notes that these penalties will be "without prejudice to applicable civil or criminal sanctions." It is possible that Brazil might take the same administrative actions, where it gets notice from another country, about utilization of GR in violation of Brazil's

[912] TVEDT. M. W, YOUNG. T, *Supra,* p. 41
[913] TVEDT. M. W, YOUNG. T, *Ibid,* p. 41
[914] TVEDT. M. W, YOUNG. T, *Ibid,* p. 41
[915] TVEDT. M. W, YOUNG. T, *Ibid,* p. 42
[916] *Ibid*

access and benefit-sharing laws. Brazilian law also specifically empowers and requires competent federal bodies to supervise, intercept and seize samples that have been "accessed in a manner contrary to this Act." It further provides that those powers and duties may be disseminated to other bodies following Title IX, Article 32 of the Provisional Rule.[917]

It can be seen that some provisions on user measures provided by the Provisional Rule of Brazil are not as much specific as the provisions on provider measures. The user measures described by the Provisional Rule are for both domestic users and foreign users. Although, the Provisional Rule is not approved by the Congress of the Brazil, it is still considered improvement as one of legal instruments of a few countries mentioned user measures.

In sum, Brazil has already developed legal instruments on access and benefit-sharing such as Provisional Ruling legal instrument regulating access and shipment of genetic heritage, as well as the access of TK resulting from access. However, it still has not defined a final text for legislation. There are some lacks and gaps of the legal instruments and some challenges for compliance. There are only two states of Brazil that promulgate legislation on ABS, it includes Acres and Amapá, but two foresaid legal instruments have not yet been regulated and are not in force, they need to be put in to practice and make it come into effect. There may also have need to other states of Brazil to develop their own legislation on ABS.

In fact, Brazil already signed the Nagoya Protocol in February 2nd 2011. I suppose that the Brazil chooses an approach of signing to the Protocol first and then deciding ratification and development of its national law later. In this case, it needs to incorporate the provisions of the Protocol into national law on access and benefit-sharing. The existing law uses the term 'genetic heritage' which is different with the term 'genetic resources' of the Protocol, so, it needs to apply method of interpretation to conformity with the Protocol. Brazil also needs to improve law to have a clear legal status of GR, such as adopting draft Bills on Access to GR by the Congress. It needs also improvement of law to meet requirements of certainty, clarity and transparency of access and benefit-sharing legislation in accordance with the Protocol, especially to promote compliance.

§ II. **The African Model Law**

An interesting point is that the South African Constitution 1996 uses the term "international agreement"[918] instead of the more commonly used term 'treaty'. There is strong support for the view that the term 'international agreement' is wide enough to include both legally binding agreement (treaties) and non-legally binding, unenforceable

[917] *Ibid*
[918] Section 231(4) of the South African Constitution 1996

informal agreements.[919] Despite of an argument of uncertainty over the meaning of Section 231 of the Constitution[920], the 2001 African Model Law for the Protection of the Rights of the Local Communities, Farmers and Breeders and for the Regulation of Access to Biological Resources (the African Model Law) is one of international agreements that South Africa must comply. The African Model Law is a reference voluntary instrument of the African Union, which the South Africa is a member.

The African Model Law was commenced through a number of initiatives in 1997 and adopted in 1998 by the African Union Heads of States. It sought to fulfil two strategic objectives, that include representative of an African common position on the issues at the WTO, CBD and FAO's treaty and serve also as a framework for African Union member States to craft specific national legislation in compliance with international commitments and consistent with their political orientation, national objectives and level of socio-economic development. The African Model Law consists of eight parts which include: scope; access to biological resources; community rights; farmers' rights; plant breeders' rights; institutional arrangements; and, enabling provisions. The Model Law applies to biological resources in both in-situ and ex-situ conditions; derivatives of the biological resources; community knowledge and technologies; indigenous and local communities and plant breeders (Article 2.1). However, it does not affect to the traditional systems of access, use or exchange of biological resources; and access, use or exchange of knowledge and technologies by and between local communities. The African Model Law applies several core principles. They include: principle of food sovereignty and security; the principle of state sovereignty and inalienable rights and responsibilities; protecting community rights and responsibilities for livelihood security and the value of indigenous knowledge; the full-participation of indigenous and local communities; PIC, fair and equitable sharing benefit arising out from access to GR; specific responses to the TRIPs Agreement's requirements for protection through intellectual property rights and attendant patenting of life forms; gender equality. Africa's view was that an effective *sui generis* system for protection of plants was necessary to respond to Africa's unique agricultural production system.[921]

The Nagoya Protocol clearly requires country Parties to put in place national access and benefit-sharing laws or regulations before it can start working for them. Questions are: "how the African Model Law can be used to inform the national measures that are needed to trigger the workings of the Nagoya Protocol"; "how the African Model Law can be used to bring about a coordinated African approach to access and benefit-sharing

[919] DUGARD.J, *International law, A South African Perspective*, third edition, Juta&Co,Ltd, Capetown, 2005, p. 63
[920] DUGARD.J, *Ibid*, p. 63
[921] MUNYI.P, MAHOP.M.T, PLESSIS.P, EKPERE.J, BAVIKATTE.K, *A gap analysis report on the African model law on the protection of the rights of local communities, farmers and breeders and for the regulation of access to biological resources*, The ABS capacity Development Initiative, commissioned by the Department of Human resources, Science and Technology of the African Union Commission, Feb, 2012, pp. 6 -12

implementation". "To answer these questions, it is necessary to examine and address key gaps and variances between the African Model Law and the Nagoya Protocol." [922]

1) Definitions

Firstly, it is important to note that the African approach has been broader than CBD and the Nagoya Protocol that encompassing biological resources.

Secondly, 'derivatives' is now defined in Article 2 of the Nagoya Protocol would include some of the derivatives mention in the African Model Law, such as oils, resins, gums and proteins (which in most cases would actually contain functional units of heredity), in addition to purified extracts. The other kind of "derivative" is more properly described (as indeed it is in the African Model Law) as a "product developed from" a biological resource; e.g. plant varieties or, synthetic analogues of natural compounds. This class of derivatives is included - at least for purposes of benefit-sharing - under the "subsequent applications and commercialization" language in Article 5.1 of the Nagoya Protocol.[923]

Article 2 of the Protocol defines "utilization of GRs" to mean conducting "research and development on the genetic and/or biochemical composition of GRs, including through the application of biotechnology as defined in Article 2 of the Convention". This definition in turn includes using "derivatives ... to make or modify products or processes for specific uses".

The Nagoya Protocol, therefore, "creates a clear need to reflect on these subtle differences, how they relate to the scope of the African Model Law insofar as access and benefit-sharing is concerned." [924]

2) Access with special considerations

Article 8 of the Nagoya Protocol addresses the need to take into account some special considerations relate to research that contributes to conservation and sustainable use of biological diversity; present or imminent emergencies that damage or threaten human, animal or plant health; and plant GR for food and agriculture and their special role for food security. The Protocol requests Parties to consider simplified and expeditious access measures in these situations.

"The African Model Law mentions access by academic and research institutions, public agencies and intergovernmental institutions, but largely leaves it to national authorities to devise measures tailored to these categories of actors. The African Model Law does not expressly suggest that access procedures for these categories of actors must be 'simplified' in order to promote and encourage research. Furthermore, the African Model Law does not address emergency situations, especially in the context of health, for

[922] *Ibid*, p. 51
[923] *Ibid*, p. 52
[924] *Ibid*, p. 52

which expeditious access measures may be needed. Such situations have in recent years emerged in human and animal health, implying that the African Model Law may need to consider special arrangements as foreseen in Article 8 of the Nagoya Protocol." [925]

3) Benefit-sharing

Article 5.4 of the Protocol provides benefits may include monetary and non-monetary benefit. However, the African Model Law does not elaborate on the non-monetary aspect of the benefit-sharing. It focuses only on the monetary benefit-sharing by Article 12. Community right to benefit is provided by Article 22 of Part IV. In fact, "African counterparts in benefit-sharing agreements are likely to benefit a great deal from non-monetary benefits and this aspect should be added to an African access and benefit-sharing framework. It is undeniable that non-monetary benefits are as important as monetary benefits in benefit-sharing arrangements, particularly in situations where there is uncertainty during early phases of bioprospecting." [926]

It is interesting to note that the African Model Law suggests the establishment of a Community Gene Fund, deriving its funds from the sharing of benefits with local farming communities which would be used to finance projects developed by the farming communities (Article 66, Part VII of the African Model Law).

4) Transboundary cooperation and transboundary genetic resources

Article 10 of the Protocol recognizes access to GRs and TK that occur in transboundary situations. It calls on Parties to consider the need for and modalities of a global multilateral benefit-sharing mechanism for such GR. Article 11 deals with instances where the same GRs are found in-situ within the territory of more than one Party, and where the same TK is shared by one or more indigenous and local communities in several Parties. The article then calls on Parties to cooperate in these situations.

Transboundary co-operation and transboundary TK are important issues in access and benefit-sharing, especially in Africa. "However, the African Model Law does not address issues of transboundary cooperation for the regulation of access to and exploitation of transboundary GR and TK. It is also silent on possible mechanisms for the fair and equitable sharing of benefits derived from the utilization of GR and TK that occur in transboundary situations or for which it is not possible to grant or obtain PIC." [927]

5) Traditional Knowledge

Article 12 of the Nagoya Protocol on TK also improves on the African Model Law. The Nagoya Protocol proposes the development of community protocols and calls on

[925] *Ibid,* p. 54
[926] *Ibid,* p. 54
[927] *Ibid,* p 53

parties to endeavor to support their development by indigenous and local communities. However, the African Model Law is silent about the actual mechanisms through which local communities can ensure that collectors of TK will respect the rights and customary rules of communities, although, it is being heavily community-centered. "There is a need to incorporate this aspect in guidance to African countries about the implementation of national access and benefit-sharing measures".[928]

In sum, the model legislation also clearly contains prominent gaps when seen in the context of the Nagoya Protocol. It is noted that "one of the objectives of the African Model Law was to give effect to the third objective of the CBD. The adoption of the Nagoya Protocol, an instrument that reflects some if not most of the aspirations contained in the African Model Law". Therefore, it has become necessary "to find a way to use and improve the positive characteristics of the African Model Law to help African countries meet their international obligations, including implementation of the Nagoya Protocol". There are two potential approaches are suggested. The first is "a revision leading to a new text document for adoption by the African Union Heads of States, but it may not be the most effective way to boost African countries' desire to domesticate the Model Law and implement the Nagoya Protocol as the African Model Law was never intended to have the status of a Convention or Treaty in Africa". The second is "a complementary guideline document to be used alongside the African Model Law. This option is probably more practical for immediate purposes, as it would not only highlight recent developments and the positions that the African Group subscribes to on each of the issues contained in the African Model Law, but would also offer an opportunity for model forms and checklists to be formulated that would aid African countries in the fulfilment of their obligations under the Nagoya protocol".[929]

It is noted that the Model Law was adopted in 1998 before the Protocol negotiations, before Bonn Guidelines 2002 and was a model law for implementation only of the CBD. It may be assessed that the Model Law has played a certain role in a certain period of time in implementation of the CBD, but the questions arises why not now should there have a model law specific for the Nagoya Protocol that is the same for the CBD? And the model law would be not only for Africa? The answer could be found by reminding the role and objectives of the Bonn Guidelines. The analysis of the Bonn Guidelines and recommendations in Part 1 of the thesis would suggest that it would be better to have only guidelines from the COP and the Bonn Guidelines may be updated and amended to support the Nagoya Protocol as decision of adoption the Protocol of COP 10. In my personal point of view, making too many international legal texts are not as important as focusing on capacity building for effective implementation and compliance while there are enough

[928] *Ibid,* p. 53
[929] *Ibid,* p.6 and p. 56

instruments. As the African Model Law already has been there, the approach for solutions are mentioned above to be consistent with all instruments, but it is not necessary to have a Model Law in universal scope. May be, in specific context of each region, there would have regional instruments such as draft ASEAN agreement, draft Central American agreement, Andean Pact decision 391.[930]

§ III - South Africa

A – Generalities

South Africa's diversity of topography, climate, geology and people provides it with a wide variety of natural and cultural resources. It is considered one of the most biologically diverse countries in the world due to its species diversity and endemism as well as its diversity of ecosystems. South Africa is home to 10% of the world's plant species and 7% of the reptile, bird and mammal species. Its oceans are home to about 10 000 species, representing about 15% of the world's marine species with more than 25% of these species endemic to South Africa. In terms of the number of endemic species of mammals, birds, reptiles and amphibians, South Africa ranks as the fifth richest country in Africa and the 24th in the world.[931]

1) Development of national law on biodiversity and access and benefit-sharing

South Africa had the advent of the democratic government in 1994. It has embarked on an extensive process to introduce new policies in line with its democratic constitution. "The policies have sought to dismantle the discriminatory laws of the past and create a society based on the principles of equity, non-racialism and non-sexism. The ultimate goal of the changes is to improve the quality of life of all South Africa's people by addressing the poverty and inequality that still prevails in the society. South Africa became a party to the CBD in 1995 and this afforded it the opportunity to incorporate its commitments under the CBD into its policy framework." [932]

South Africa has a well developed policy framework for biodiversity management with the basis laid by the White Paper on the Conservation and Sustainable Use of South Africa's Biological Diversity, published in 1997, was the first national policy to chart South Africa's policy on access and benefit-sharing and emerged following a two year period of public consultation.[933] This and other relevant policies take effects through various legislations. The biodiversity legislation is harmonized under the overarching framework of the National Environmental Management Act, 107 of 1998 which establishes

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[930] See more information of regional instruments in document UNEP/CBD/WG-ABS/5/3,

[931] South African National Biodiversity Institute - Department of Environmental affairs and tourism, Republic of South Africa, *Forth National Report to the Convention on Biological Diversity*, 2009, p. ii

[932] South African National Biodiversity Institute, *Ibid*, p. 36

[933] LEWIS-LETTINGTON.R, MWANYIKI.S, *Case Studies on Access and benefit –sharing*, The International Plant Genetic Resources Institute (IPGRI), 2006, p 134, available at http://www.bioversityinternational.org/fileadmin/bioversityDocs/Policy/Access_and_Benefit_Sharing/ABS_CaseStudies_IPGRI_06_58.pdf, last accessed 19th May, 2012

principles for environmental legislation. Biodiversity Act, No 10, 2004 and Protected Areas Act, No 57, 2003 are key legislation. [934]

The Biodiversity Act, which was promulgated in 2004, is of particular importance in respect of South Africa's commitments under the CBD.[935] This act sought to resolve the fragmented nature of biodiversity related legislation at national and provincial levels by consolidating different laws and giving effect to the principle of cooperative governance. The Biodiversity Act provides for the management and conservation of biodiversity in South Africa and the components of such biodiversity; the use of indigenous biological resources in a sustainable manner and the fair and equitable sharing amongst stakeholders of the benefits arising from bioprospecting involving indigenous biodiversity. While the initial focus was on getting the policies and legislation in place, South Africa has also developed strategies and plans that support the policies and legislation for biodiversity management such as the National Spatial Biodiversity Assessment 2004, the National Biodiversity Strategy and Action Plan, 2005, the National Biodiversity Framework 2008 to 2013. [936]

The Biodiversity Act established the South African National Biodiversity Institute as a public entity falling under Department of Environmental Affairs and Tourism, with the mandate to play a leading role in South Africa's national commitment to biodiversity management. In partnership with the Department and the biodiversity sector, the National Biodiversity Institute is tasked to lead the biodiversity research agenda, provide knowledge and information, give policy support and advice, manage botanical gardens, education and engage in ecosystem restoration and rehabilitation programs.[937]

2) Background factors for integration of the Nagoya Protocol

South African law may generally be described as a system, originally based on Roman-Dutch law, influenced substantially by English law and given a character of its own through numerous statutes, passed by legislation at central, provincial and local government level.[938] Therefore, South Africa has dualist system with monist elements. Section 231(4) of the South African Constitution provides that "any international agreement becomes law in the Republic when it is enacted into law by national legislation". It also provides that "a self executing provision of an agreement that has been approved by Parliament is law in the Republic unless it is inconsistent with the Constitution or an Act of Parliament".[939] Therefore, "the Constitution of the Republic of

[934] South African National Biodiversity Institute, *Ibid*, p. 16
[935] LEWIS-LETTINGTON.R, MWANYIKI.S, p.134 - 135
[936] South African National Biodiversity Institute, *Supra*, pp.16-17
[937] South African National Biodiversity Institute, *Ibid*, p. 17
[938] RABIE.A.M, *South Africa*, BOES.M, (ed.) *International enclopaedia of laws, Volume 1 – Environmental law*, Kluwer Law and Taxation Publishers Deventer, Boston, June, 1991, p 23
[939] LAYTON.R, When and how can domestic judges and lawyers use international law in dualist systems, available at http://training.itcilo.org/ils/cd_use_int_law_web/additional/Library/Doctrine/Dualist%20Systems_Layton.pdf, last accessed May 10, 2012, p. 4

South Africa, 1996 specifically provides for the incorporation of international law into their constitutions and also specifies whether such international law has supremacy over domestic law that is a hierarchy of laws." [940]

However, one researcher states that the provision of Section 231 (4) is bound to create problems as it introduces the concept of self-executing treaties into South African law. The provisions of a treaty approved by Parliament, but not incorporated into national law by Act of Parliament that are 'self-executing' become part of national law unless inconsistent with the Constitution or an Act of Parliament. South African courts are required to decide whether a treaty is self-executing that existing law is adequate to enable the South Africa to carry out its international obligation without legislative incorporation, or whether is non-self-executing that requires further legislation. However, there is no general guideline for this matter. Each case, the courts decide that a treaty is self-executing due regard to the nature of treaty, the precision on its language and the existing South African law on that subject.[941] When interpreting any legislation, in terms of Section 233 of the Constitution, South African courts are obliged to prefer any reasonable interpretation of the legislation that is consistent with international law over any alternative interpretation.

Regarding access and benefit-sharing legislation, in June 2004, South Africa issued Biodiversity Act with Chapter 6 deals with bioprospecting and access and benefit-sharing. According to Section 80 and Section 1, 'indigenous biological resources' are resources consisting of organisms of indigenous species, including any derivative and genetic material of such organism. The scope of regulation of the Biodiversity Act is extended to specified exotic animal, but it excludes human genetic material. Section 81 requires a permit for bioprospecting and exporting indigenous biological material. According to Section 82, in addition to the permit, the PIC of the stakeholders must be obtained when their interests are affected. A stakeholder is the person who provides the access to the indigenous biological resources and the indigenous community whose TK is relevant for the proposed activity. Furthermore, as conditions for the permit, the stakeholder and the applicant have to make arrangements which are to be approved by the Minister, concerning material transfer and benefit-sharing. The contents of these arrangements are described generally by Section 83 and 84. These include the type of biological material to be collected, the area of collection, the use, quantity as well as traditional and present potential use. The permit itself is regulated by Sections 87. The issuing authority has to assure that the permit is consistent with national and international law following Section 88. When a specimen of an alien species or of a listed invasive species is involved, the permit shall only be issued after extensive examination of the potential impacts and the

[940] LAYTON.R, *Ibid*, p. 4
[941] DUGARD.J, *International law, A South African Perspective*, Third edition, Juta&Co,Ltd, Capetown, 2005, p. 62

potential benefits associated with the activity following Section 91. Chapter 9 deals with offences and penalties. Section 102 stipulates that a person convicted of an offence pursuant to section 101 (e. g. performing an access activity without a permit) is liable to be fined or imprisoned for a period not exceeding five years.[942]

To give effect to Chapter 6 of the Biodiversity Act, the Regulations on Bio-prospecting, access and benefit-sharing was promulgated, came into force on 1st April 2008. "These regulations have been workshopped with the provinces as this is a co-operative governance function between national and provincial government, but many of the provinces have not yet had the responsibility delegated to them by their respective provincial cabinet ministers, so the regulations are not yet operational in all provinces."[943]

There are many challenges for access and benefit-sharing legislation implementation in South Africa that are also factors impact to the integration of the Protocol into access and benefit-sharing legislation of the South Africa. *Firstly*, the implementation is constrained by resources and human capacity. *Secondly*, land use planning decisions do not always take biodiversity into consideration or lack of uniform approach to land reform process. There is limited fine scale biodiversity data available for incorporation into tools that inform land use planning and decision-making and inadequate intergovernmental co-operation in regulating land and resource use. It has conflict within the community property associations regarding restituted land and sharing of benefits. *Thirdly*, there are concerns about the lack of coordination and cooperative governance between the different organs of state involved in biodiversity management or insufficient coordination between institutions implementing the legislation. *Fourthly*, funds available for biodiversity management in South Africa are limited. *Fifthly*, there are also information gaps in certain areas that need to be filled. The research that is produced in South Africa is generally distributed through publications, websites and participation in international forums. Monitoring is an important aspect of biodiversity management. Although monitoring does take place at various levels the National Biodiversity Monitoring and Reporting Framework is still under development. *Finally*, there is limited incorporation of TK into biodiversity management.[944]

B – Legislation on access to genetic resources and benefit-sharing

1) Legal status and ownership of Genetic Resources

South Africa's Constitution 1996 provides a central framework for status of GR in South Africa. Although the Constitution does not consider explicitly GR and their ownership it provises particular importance to respective powers of national, provincial

[942] DROSS.M, WOLFF.F, p. 42 - 43
[943] South African National Biodiversity Institute, p. 40
[944] *Ibid*, pp.30 - 41

and local spheres of government. Through the Constitution, national government and the nine provinces are accorded concurrent legislative competence to biodiversity conservation. The Constitution also demarcates relevant areas under national competence, such as national parks, botanical gardens, and marine resources. Relevant areas are under exclusive provincial jurisdiction, such as provincial planning. The Constitution provides for the administration of certain functions at the local government level, such as beaches and municipal parks.[945]

Section 24 of the Constitution provides that everyone has the right (a) to an environment that is not harmful to their health or well-being; and (b) to have the environment protected, for the benefit of present and future generations, through reasonable legislative and other measures that (i) prevent pollution and ecological degradation; (ii) promote conservation; and (iii) secure ecologically sustainable development and use of natural resources while promoting justifiable economic and social development.

Much of South Africa's biodiversity falls within private ownership. This is a feature of Common Law legal system. Section 25.1 provides that "no one may be deprived of property unless this is in terms of a law of general application, and is not arbitrary. Property may be expropriated only for a public purpose, or in the public interest, and is subject to compensation. Under South African common law, a landowner owns everything beneath and above the land. This includes plants but excludes wild animals which are considered *res nullius* (owned by nobody)."[946]

There are several categories of land ownership exist in South Africa, characterized by a broad division between freehold or Western notions of ownership, and customary approaches to land ownership. Most state land and commercial agricultural land is held under freehold, while land under customary tenure falls within the so-called ex-homelands. Statutory laws apply in both circumstances. In communal areas, customary law also applies. This is frequently the system best understood and implemented by communities living in the area. Although certain resources are accorded different levels of protection, there is no distinction between GR and other natural resources.[947]

Section 1 of Biodiversity Act 2004, defines "genetic resources" as including, any genetic material or the genetic potential or characteristics of any species. This definition is

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[945] LEWIS-LETTINGTON.R, MWANYIKI.S, *Case Studies on Access and benefit –sharing,* The International Plant Genetic Resources Institute (IPGRI), 2006, p 129, downloaded at *http://www.bioversityinternational.org/fileadmin/bioversityDocs/Policy/Access_and_Benefit_Sharing/ABS_CaseStudies_IPGRI_06_58.pdf*, 19 May 2012

[946] UNEP/CBD/WG-ABS/5/5, *Supra*, p. 22

[947] WYNBERG.R, Bio-prospecting, *Access and benefit-sharing in South Africa: towards a strategic assessment,* Southern African Biodiversity Support programme and National Biodiversity Strategy and Action plan, stocktaking Report, 2004. Available at *http://www.environment.gov.za/ProjProg/ProjProg/2004Jun10/stocktaking/NBSAP%20stocktaking_Access%20and%20Benefit%20Sharing_%20May%2004.doc*, last accessed May 11, 2012

further articulated is in Section 3 of the Act dealing with the state's trusteeship of biological diversity, which states: In fulfilling the rights contained in Section 24 of the Constitution, the state through its organs that implement legislation applicable to biodiversity, must: a) manage, conserve, sustain South Africa's biodiversity and its components - GR and b) implement this Act to achieve the progressive realization of these rights.

Chapter 6 of the Biodiversity Act on 'Bioprospecting, access and benefit-sharing' provides the framework for the regulation of access and benefit-sharing in South Africa and provides greater guidance of the legislation. Following Section 80, the purposes of the chapter 6 are to: regulate bioprospecting involving indigenous biological resources; regulate the export from the country of indigenous biological resources for the purposes of bioprospecting or any other kind of research; and provide for a fair and equitable sharing by stakeholders in benefits arising from bioprospecting involving indigenous biological resources.[948]

For indigenous biological resources, a Material Transfer Agreement is required between the applicant and 'stakeholder',[949] as well as a benefit-sharing agreement, PIC to permit issuance. Section 82.4(b) and 82.4(c) of the Biodiversity Act also requires a ministerial approval of all benefit-sharing or material transfer agreements. The Minister may require to ensure of the arrangement is fair and equitable. Negotiations between the applicant and 'stakeholder' must be facilitiated to ensure equality for issuing permit.[950]

The Biodiversity Act also recognizes private ownership of GR. For instance, they are found or located in private property or land. Section 82 (1) provides that certain interests to be protected before permits are issued. Accordingly, negotiations should be carried out and agreement should be reached between a "stakeholder" and an applicant" before the Ministry issues necessary permit. The State only intervenes at the permit level and to ensure the equitable benefit-sharing arrangements have been made. [951] This is a feature different with the situation of Brazil when the Council control more strictly, with requirement of reporting regimes to this authority.

Section 3 of the South African Patents Amendment Act, 2005 requires the Registrar of Patents "call upon the applicant to furnish proof in the prescribed manner as to his or her title or authority to make use of the indigenous biological resource, GR, or of the TK or use if an applicant lodges a statement that acknowledges that the invention for which protection is claimed is based on or derived from an indigenous biological resource, GR, or TK or use."[952]

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[948] UNEP/CBD/WG-ABS/5/5, *Supra*, note 54, p. 23
[949] ''stakeholder'' means a person, an organ of state or a community contemplated in section 82.1.*a*; or an indigenous community contemplated in section 82.1.*b* of the Biodiversity Act
[950] UNEP/CBD/WG-ABS/5/5, *Supra*, p. 23
[951] UNEP/CBD/WG-ABS/5/5, *Supra*, p. 23
[952] UNEP/CBD/WG-ABS/5/5, *Supra*, p. 23

2) Elements of access and benefit-sharing regime as provider country

a) Access

Access to GR for bioprospecting is regulated by Chapter 6 of the Biodiversity Act. Following that, a permit is required for access to GR in South Africa. Section 82 of Biodiversity Act requires that the applicant and the stakeholder have entered into a material transfer agreement and a benefit-sharing agreement before the issuance of permit of access provided by the competent national authority. In addition, different requirements are adopted for access depending on the type of applicant. [953] Section 82.3 provides that the contract is to be negotiated between indigenous and local communities or any relevant stakeholder and the applicant. In this respect, it requires to obtain the PIC from the owners/holders of the TK. This provision is relevant to incorporate Article 6.2, Article 7 of the Protocol to ensure involvement of the indigenous and local communities in PIC. It also requires that standard clauses be incorporated in the contract. Such clauses include the geographical area where the GR are to be accessed, the quantity to be accessed, the purpose of the access, and the duration of the contract.[954] Measures for the consultation of relevant stakeholders by the competent national authority before entering into an agreement are provided by Sections 82 (2), 82 (3), 83 (2) and 84 (2) of the Biodiversity Act.

The licensing processes and governmental responsibilities on special access and benefit-sharing procedures and milestones vary from general rules following the Chapter 7 of Biodiversity Act, Sections 87 to 96 (using general procedures applicable to all environmental permits), and Section 81 on special additional disclosure and local right-holder protection provisions for access and benefit-sharing permits.[955]

For requirement of certainty, clarity and transparency of access and benefit-sharing legislation following Article 6.1.a of the Protocol in South Africa, it is difficult to meet this requirement because the regulatory framework is perceived to be unclear and where relationships with the relevant authorities and stakeholders have not yet been established.[956] There are also additional requests and in process stakeholder participation that the primary factor affecting both the cost and timing of the access and benefit-sharing application process relates to additional requests. “It is not generally possible to eliminate all possibility of additional requirements from national law, particularly in the access and benefit-sharing context where informational requirements depend on a constantly shifting frontier of new scientific development and discovery. However, legal certainty is enhanced where the laws specifies ‘reasonable controls’ on such requests, giving the applicant some level of predictability” [957]. However, in South Africa, following Section 82.(3) of the

[953] UNEP/CBD/WG-ABS/5/3, p. 9
[954] FEIT.U, DRIESCH.M.V.D, LOBIN.W, *Supra*, p. 15
[955] YOUNG.T, *Supra*, p. 85
[956] LAIRD. S, WYNBERG. R, *Supra*, p. 25
[957] YOUNG.T, *Supra*, p. 85

Biodiversity Act the issuing authority has power to request 'all information concerning the proposed bioprospecting and the …resources to be used that is relevant' at any time without limit.

In addition, "although the specific identified bases for the competent national authority's decision may not affect legal certainty, the manner in which the law specifies them can have a significant impact on certainty. Where the decision criteria are very subjective, they provide much less certainty for the user/applicant. [958] Article 89.3 of the South Africa Biodiversity Act requires consistency with various national enactments.

Moreover, claims of non-compliance may impact to requirement of certainty. A user, who fails to comply with the terms and conditions of his access and benefit-sharing rights, will face with loss or cancellation of those rights. User certainty in such cases is increased where legal measures clarify some situations. For example, what kinds of violations can result in revocation of the access and benefit-sharing rights; whether and when the overseeing agency must first give notice and an opportunity to correct the fault; whether the process of addressing non-compliance is administrative only (or may involve the courts); whether there is an appeal against such decisions, and other information?[959]

b) Benefit-sharing

Following the Article 5.4 of the Protocol, benefits may include monetary and non-monetary benefit. And more national legislations provide for both monetary and non-monetary benefits. However, it is interesting to note that, South Africa only focuses on monetary benefit.[960] The Biodiversity Act also provides for the establishment of trust funds, in which the benefits received by the State or not allocated to stakeholders will be kept.[961] For example, in San and Hoodia case, currently all the Hoodia money will be paid into the San Hoodia Benefit-sharing Trust, which is subject to the Trust Laws of South Africa. These laws are very restrictive, and the Trustees as well as the San Councils will require assistance in order to properly receive, allocate, and account for money, in a manner that is perceived by the San communities to be effective and fair.[962]

There are also some measures also establish conditions with respect to the transfer of GR to third parties or provide that these conditions shall be set out in the agreement.[963]

In fact, even though South Africa only focuses on monetary benefit, it should still consider requirement of Article 16 of the CBD of which the provider country of GR should

[958] YOUNG.T, *Ibid*, p. 86
[959] YOUNG.T, *Supra*, p. 91
[960] Section 85 of the South Africa Biodiversity Act
[961] Section 85 of the South African Biodiversity Act
[962] GenBenefit, *Benefit-sharing - Lessons Learned, A Summary and cross-comparison of the Case Studies for GenBenefit*, 2008, p.9, available at http://www.uclan.ac.uk/schools/school_of_health/research_projects/files/health_genbenefit_lessons.pdf, last accessed May 19, 2012
[963] Section 84 (1) (vii) of South African Biodiversity Act,

receive transfer of technology. This also is spirit of Article 23 of the Protocol on technology transfer, collaboration and cooperation. In some cases, technology transfer has made a vital difference to the provider institution whilst in others. To a large extent technology transfer is case specific, but it also varies significantly across sectors and companies. For example, "in the Hoodia case study the CSIR benefited from the construction of a US FDA approved medicinal plant extraction facility for the manufacture of material for clinical trials, and there are plans for the extraction facility for Hoodia to be located in South Africa." Moreover, economic and competitive interests typically underpin the extent to which technology transfer occurs. In the Ball- South African National Biodiversity Institute case study, technology transfer entailed knowledge transfer through technical training rather than representing direct technology investments and product development within South Africa. However, this case causes various arguments, such as criticism of "the agreement was lambasted for not optimizing local economic opportunities" but in opposition to that "people have unreasonable expectations of what we can do. It doesn't make economic sense to set up a Ball equivalent in South Africa: why would we set up a competitor?"[964]

c) Traditional knowledge

Chapter 6 of the Biodiversity Act has provisions to protect the interest of the indigenous and local communities and the use of TK. Section 82.1 provides that the issuing authority considering the application for the permit must protect any interest of an Indigenous and local community in the proposed bioprospecting project. An indigenous and local community is whose traditional uses of the indigenous biological resources to which the application relates have initiated or will contribute to or form part of the proposed bioprospecting or whose knowledge of or discoveries about the indigenous biological resources to which the application relates are to be used for the proposed bioprospecting. Section 83.1 provides that a benefit-sharing agreement must specify any traditional uses of the indigenous biological resources by an indigenous community. Thus, owners/holders of TK shall get a share of benefits arising from the use of their TK.

In addition to the Chapter 6 of the Biodiversity Act, there is also other legislation and policies in place to provide for indigenous and local communities and TK, such as the Indigenous Knowledge Systems Policy. The Policy provides fair and adequate compensation of the indigenous and local communities for their contribution to the protection and conservation of biodiversity, research and outcomes involving their TK. The Patent Amendment Act, No. 20 of 2005 allows for the disclosure of origin of GR and associated TK when application is made for a patent and the Registrar can also request proof that PIC was obtained to access the GR and/or TK.[965]

[964] LAIRD. S, WYNBERG. R, *Supra*, p. 32
[965] South African National Biodiversity Institute, p. 55

Those are relevant bases to incorporate Article 2 of the Protocol to respect TK and take fair and equitable sharing of benefit arising from the utilization of such knowledge. However, in fact, little attention has been paid to the need to obtain PIC from holders of TK. This is best illustrated through the case of the San, who only recently learned about the patenting of their knowledge about Hoodia by the CSIR, for use in an anti-obesity drug. The San tribe has now retrospectively been included in a benefit-sharing agreement with the Council for Scientific and Industrial Research of South Africa to share a percentage of benefits accruing from the sale of an anti-obesity drug that was developed by the Hoodia from a substance used traditionally as an appetite suppressant by the San tribes in the region. However, many questions remain unresolved: who qualifies as the rightful community or group from whom consent should be obtained? Can knowledge be attributed to a single group or individual? Is the privatization of TK through intellectual property rights not contrary to the belief of many communities that such knowledge is collectively held, for the benefit of the broader community? What happens – as in the case of the San – when consent is only obtained after the fact? Communities clearly require legal and strategic assistance in dealing with these issues, combined with active and ongoing vigilance of patent applications for 'prior art', or knowledge already recorded. A supportive legislative environment is also critical, especially given the difficulties and inappropriateness of using existing intellectual property right systems to protect indigenous and local communities' rights.[966]

There is also a popular situation of commercialization of product developed by modifying TK use, especially, research products that were developed from TK and later commercialized. They also serve to highlight what kind of challenges are faced in the light of inadequate policy measures to ensure that benefits are shared with the TK holders for their contributions, the Hoodia and San community case above was an example. [967]

In sum, a number of crucial legal gaps remain. First, "despite longstanding initiatives to develop legislation to protect and promote indigenous knowledge, these have not come to fruition and there is currently no legal protection for holders of TK". Second, "farmers' rights remain unrecognized, and there is little consensus as to how this matter should be legally resolved". Third, "South Africa has well-developed patent laws but they require review to ensure consideration of access and benefit-sharing and TK issues". Moreover, "a number of issues relating to the interface between TRIPS and the CBD have not yet been resolved at national level". In addition to TK protection, these include the disclosure of origin for patent applications; and approaches towards the patenting of life.

[966] LEWIS-LETTINGTON.R, MWANYIKI.S, p.161
[967] SUNEETHA.M.S, PISUPATI.B, *Supra*, note 412, p. 8

"Aligning procedures and definitions between different authorities and laws provides an enormous challenge to authorities and legislators."[968]

d) Compliance

"The measures generally indicate that any infraction to the provisions of the legislation, regulation or guidelines and any unauthorized access to genetic or biological resources will be subject to sanctions. Moreover, many measures indicate that the non-respect of the clauses of an agreement related to access and benefit-sharing will also be subject to sanctions."[969]

Section 101(1) of the Biodiversity Act provides that 'a person is guilty of an offence' if that person contravenes or fails to comply with a provision of Section 81. (1), which states "No person may, without a permit issued in terms of Chapter 7- 10: engage in bioprospecting involving any indigenous biological resources; or export from the Republic any indigenous biological resources or the purpose of bioprospecting or any other kind of research."

Following Section 102, penalties can be applied to person who convicted of an offence in terms of section 101above that include a fine, imprisonment for a period not exceeding five years, or to both fine and such imprisonment. A fine may not exceed an amount prescribed in terms of the Adjustment of Fines Act, 1991 (Act No.101 of 1991). And if a person is convicted of an offence involving a specimen of a listed threatened or protected species, an amount determined in terms of paragraph or which is equal to three times the commercial value of the specimen in respect of which the offence was committed, whichever is the greater. In addition, Section 93(a) of the South Africa Biodiversity Act provides for sanctions of cancellation of permits in the case where a person gives false or misleading documents or information in an application for a collection permit.

In conclusion, like Brazil, South Africa has also developed legislation on access and benefit-sharing, namely Biodiversity Act, which was promulgated in 2004 with Chapter 6 deals with bioprospecting and access and benefit-sharing. The provisions of the Biodiversity Act also have facilitated for benefit-sharing, protecting traditional knowledge and compliance. However, there are some lacks and gaps of the legal instruments and some challenges for compliance with the Protocol as indicated. South Africa already signed the Nagoya Protocol in May 11th 2011. It is the same with the case of Brazil; South Africa chooses an approach of signing to the Protocol first and then deciding to ratification and development of its national law. In this case, it needs to incorporate the provisions of the Protocol into the national law on access and benefit-sharing. Therefore, it needs an improvement of law to meet requirements of certainty, clarity and transparency of access and

[968] LEWIS-LETTINGTON.R, MWANYIKI.S, p.150
[969] UNEP/CBD/WG-ABS/3/5, p 9

benefit-sharing legislation in accordance with the Protocol. In addition, African Model Law and a potential complementary guideline document may help South Africa to meet its obligations to implementation of the Nagoya Protocol in case of its ratification to the Protocol.

§ IV. France and European Union

By virtue of its geographic position in Europe and overseas, France possesses a very rich natural and cultural heritage. It is a "megadiverse" country. French overseas territories encompass a variety of latitudes: the Muscarene islands, the Guyana plateau, the Caribbean, the South Pacific, Austral and Antarctic islands and the North American boreal environment. In mainland Europe, France lies at the crossroads of influences of Atlantic, Alpine, continental and Mediterranean. This variety of territories and biogeoclimatic influences is reflected in a variety of ecosystems and landscapes, such as the mangrove swamps, coral reefs, aquatic habitats, wetlands and certain agro-pastoral or cave environments. Within these ecosystems, France has a very rich and diverse flora and fauna.[970] Metropolitan France comprises 40% of Europe's flora, which is characterized by a high rate of endemism of 4,700 species and 486 of them are considered endangered or vulnerable. [971] The national register of natural heritage currently lists nearly 11,934 plant species, 43,727 animal species and 14,183 types of fungi in mainland France. In overseas territories, despite often very patchy knowledge, registers show a far wider specific diversity than in mainland France with more than 50 times as many endemic plant species. French Guyana, with a vast track of untouched primary Amazonian forest, has over 5,350 species of vascular plants, and 183 terrestrial mammals. New Caledonia has a flora which is 85% endemic, with several families and genus found no where else in the world. [972] The genetic heritage of species found in France is little known, except livestock breeds and varieties which are cultivated or planted.[973]

A – Generalities

1) Development of national law on biodiversity and access and benefit-sharing

France has ratified a range of international conventions related to biodiversity conservation, such as Bern Convention 1979 on the Conservation of European Wildlife and Natural Habitats, Bonn Convention 1979 on the Conservation of Migratory Species of Wild Animals, The Ramsar Convention on Wetlands of International Importance, especially as Waterfowl Habitat, 1971. It ratified the CBD in 1994. In addition, France also applies the directives and regulations of the European Community related to protection of the wildlife, such as Directive 79/409 dated 2/4/1979 on conservation of wild bird and

[970] Premier Ministre, République Francaise, *Stratégie nationale pour la biodiversité 2011-2020,* available at http://www.cbd.int/doc/world/fr/fr-nbsap-v2-fr.pdf, last accessed May 12, 2012, pp. 11-13
[971] http://www.cbd.int/countries/profile.shtml?country=fr#status
[972] http://www.cbd.int/countries/profile.shtml?country=fr#status
[973] Premier Ministre, République Francaise, *2011-2020, Supra,* pp. 11-13

Directive 92/43/CEE dated 21/5/1992 on the conservation of natural habitats and wild fauna and flora. It also applies the regulation CEE No 3626/82 dated 3/12/1982 on the application of the Convention CITES within space of community.

To realize the politic objectives of biodiversity protection, the France also has adopted its legislation and regulatory. It has been supplemented, amended in improvement and updated time to time. First of all, the law of 1st July 1957 added Article 8 bis to the law of 2nd May 1930 in directly way to create natural reserve, then, Law of 22nd July 1960 related to creation of national parks. It needs to wait until the law of 10th July 1976 related to the protection of nature. This law established new principles to give the nature an equivalent space in the hierarchy of value and economic needs. It also gave series of special measures to protect endangered species. It modernized inadaptable and dispersed texts. Article 1 of the law of 10th July 1976 was modified by the Law of 2nd February 1995 that listed elements of the nature to implement protection. The preservation of biological heritage also is imposed by the Article R.214 of the Rural Code 1989. All these texts were codified by the Code of Environment that was published in September 2000.[974] Title 1 "protection of fauna and flora" of Book IV "Fauna and Flora" comprises of 5 chapters: Preservation and supervision of biological heritage, activity to authorization, establishments of keeping non-domestically animals, conservation of natural habitat and wild fauna and flora and penalty disposition.[975] The biodiversity and natural balance also is mentioned by the preamble of the constitutional Charter of Environment 2004, founds one part of environmental balance that has been known by Article 1 of the Charter as a basic right.[976]

If those legal instruments are fundamental supports to the international environmental law, they can not only allow stopping the disappearance of species of wildlife but should accompany with follow-up actions. France has set up an action program for the conservation that describes political implementation objectives: monitoring preservation and restoration of the most endangered species, protecting and managing biological diversity, including establishment of protected areas system; integrating biodiversity protection into other policies. It also describes legal, administrative or financial principles, the main proceedings, by which these programs are implemented. It also details key species or groups of fauna and flora species presented in France (where they are subject to a public action) their situation and the nature of threats which they are exposed and described by the action programs.[977] The National Biodiversity Strategy adopted in 2004, was the answer of France to request to States Parties to the CBD to

[974] PRIEUR. M, *Droit de l'environnement*, Dalloz, 6e Edition, 2011, pp. 342 - 348
[975] PRIEUR.M, *La mise en oeuvre national du droit international de l'environnement dans les pays Francophones*, Pulim, CRIDEAU, 2001, pp. 287 - 290
[976] PRIEUR.M, 2011, *Supra*, p. 343
[977] PRIEUR.M, 2001, *Supra*, pp. 290-291

implement national strategies on their territories. The French strategy covers the main objectives of the CBD. It is implemented through the application plans sectoral action for biodiversity. These action plans proposed concrete targets and practical help to integrate the management and maintaining biodiversity in different fields of activity in a sustainable manner. The national strategy came in the wake of the commitment of halting by 2010 biodiversity erosion, as part of the National Strategy for Sustainable Development.[978]

2) Background legal factors for integration of the Nagoya Protocol

As mentioned above, France is a typical example for Roman – Napoleonic legal system and for a monist country. This also is characterized by application of EU's rules as member of the EU.[979] In addition, it also creates matter of implementation of international law of French overseas regions. Those are main factors affect to integration of the Nagoya Protocol into French national law.

a) Constitutional, institutional, judicial provisions

The integration of international law into French law presents some difficulties like its insertion of legal framework integrated into EU. This integration is impacted by constitutional, institutional, judicial provisions that determine the conditions of application of international environmental law directly or indirectly.[980]

Firstly, in constitutional point of view, the international environmental law integrated in French law following the classic procedures that they are themselves subject to a differentiated approach with the integration of France into judicial space of EU's specific rules.[981] As principle, in French law, the international norms are integrated following the procedures under Article 53, 54, 55 of the Constitution. Following Article 53 "Peace Treaties, Trade agreements, treaties or agreements relating to international organization, those committing the finances of the State, those modifying provisions which are the preserve of statute law, those relating to the status of persons, and those involving the ceding, exchanging or acquiring of territory, may be ratified or approved only by an Act of Parliament. They shall not take effect until such ratification or approval has been secured. No ceding, exchanging or acquiring of territory shall be valid without the consent of the population concerned." The certain disposition of international law may rise in this article. International law imposes to refer to institution and operation of international organization, others may commit the finances of State (international operation, aids to development) and commerce related to the species or resources.

[978] Ministère de l'Écologié, de l'Énergié, du Développement durable et de la Mer, *Quatrième Rapport national de la France à la Convention sur la diversité biologique*, 2009, p. 5
[979] PRIEUR. M, *Droit de l'environnement*, Dalloz, 6e Edition, 2011, p.1045
[980] PRIEUR.M, 2001, *Supra*, p. 266
[981] *Ibid*, p. 267

Following Article 55 of the Constitution, "Treaties or agreements duly ratified or approved shall, upon publication, prevail over Acts of Parliament, subject, with respect to each agreement or treaty, to its application by the other party." The insertion of international norms into national law and its application can be subordinated its validity regarding of fundamental norm is the Constitution. In this point of view, two texts of the French constitution permit to assure this control. *Firstly*, it allows verifying an international norm to conform to the Constitution. Article 54 of the Constitution provides that "If the Constitutional Council, on a referral from the President of the Republic, from the Prime Minister, from the President of one or the other Houses, or from sixty Members of the National Assembly or sixty Senators, has held that an international undertaking contains a clause contrary to the Constitution, authorization to ratify or approve the international undertaking involved may be given only after amending the Constitution." It is then to verify that a text (including treaty and agreement regularly ratified or approved), which is taken into domestic law, complies with the constitution and has superior standards. In fact, the '*Conseil constitutionnel*' (Constitutional Council), before engagement, defines procedures to control the conformity of the treaty to the constitution.[982] Article 61 of the Constitution states that "Institutional Acts, before their promulgation, Private Members' Bills before they are submitted to referendum, and the rules of procedure of the Houses of Parliament shall, before coming into force, be referred to the Constitutional Council, which shall rule on their conformity with the Constitution. To the same end, Acts of Parliament may be referred to the Constitutional Council, before their promulgation, by the President of the Republic, the Prime Minister, and the President of the National Assembly, the President of the Senate, sixty Members of the National Assembly or sixty Senators. In the cases provided for in the two foregoing paragraphs, the Constitutional Council must deliver its ruling within one month. However, at the request of the Government, in cases of urgency, this period shall be reduced to eight days. In these same cases, referral to the Constitutional Council shall suspend the time allotted for promulgation".

This control is also exercised in a wider context of EU law that is subject to specific development of the French constitution in its integration results from an adapted procedure in Constitutional reform in 1992. A title XIV named "the European Union", by Article 88.4 precises "The government shall lay before the National Assembly and the Senate drafts of European legislative acts as well as other drafts of or proposals for acts of the EU as soon as they have been transmitted to the council of the EU. In the manner laid down by the rules of procedure of each House, European resolutions may be passed, even if Parliament is not in session, on the drafts or proposals referred to in the preceding paragraph, as well

[982] EISEMANN.M.N, *Supra*, p.245

as on any document issuing from a EU's Institution. A committee in charge of European affairs shall be set up in each parliamentary assembly." [983]

However, in spite of successive modification and unlike many countries in the EU, neither provision of the Constitution, nor the 'constitutional block' makes reference to the environment law. The result is that the '*Conseil constitutionnel*' did not decide on the integration of international law under the provisions of the French Constitution. Nevertheless, Drobenko.B states that "the absence of a formal acknowledgement of environmental law in French does not constitute of an obstacle preventing the integration of international environmental law into national law, the modality of realization allows this appropriately".[984]

Therefore, in case of ratification of international law like Nagoya Protocol, the France has been obliged to adopt its positive laws ("the treaty is not higher than Constitution and can not be contrary to the Constitution but it is higher than the law or regulatory act or administrative"[985]). It is noted that implementation of the international environmental law by domestic law, the '*Conseil constitutionnel*' does not appreciate the conformity of the laws to the treaties, except direct violation of the Article 55 of the Constitution and under reservation of modality of implementing the Community's provisions.

Secondly, in institutional point of view, the application of international law into national law appears requirement of capacity of a state to apply the provisions adopted. The institutional approach can be distinguished by the result of implementation in framework of the convention itself and modality of domestic institution.

The application of international law into national law put on place the administrative and politic capacity to transpose the text and implement the means of the execution. When an international law was ratified or approved through a legislative process or it had been implemented by the normative process, there were politic administrative authorities being in charge to consider conventions which have been taken place. If the transposition of the international law reposes voluntary to the State, the regulation of the application of the Community's law shall generare the real obligation more precisely following the Article 250 of the Reception of Treaty of the EU: "the regulation has a general range, it is obligatory in all elements and it is direct applicable in all State member" in which " the direct binding to all member States destines to result affecting to all national competences in all forms and ways".

The evolution of environmental law lead to creation of institution of Commission of Sustainable Development in France under Prime Minister which is in charge of define policy of sustainable development to meet objectives of Rio Conference.

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[983] PRIEUR.M, 2001, *Supra*, p. 268
[984] PRIEUR.M, 2001, *Ibid*, p. 269
[985] EISEMANN.M.N, *Supra*, p.262 (personal translation from French)

The major difficulty of French institutional process is the capacity of integration of international environmental law through actors themselves. As not being identified clearly, the international environmental law in general and biodiversity in particular, has not been really aware by the public as the way of the Community and national institution. The determination to exercise international norm does not appear that the texts ratified should be public on the official newspaper. This does not exist in an 'institutional culture' of international environmental law.[986] In addition, there is a number of administrative or special institutions (in fact, they are public establishments) participate in application of international law in France, but, the new Code of Environment does not translate well the institutional way. Especially, the Title 3 named by 'Institution' does not treat institutional issues. Other institutional difficulty of the application of the international law in national law is the coordination between the institutions in concerns of information is too little developed.[987]

Thirdly, in judicial point of view, the role of judge is fundamental in application of the international law in national law. This is new for awareness of degree of integration of 'external' norm. In point of modality of application, the effectiveness depends on the precision of the treaties because not all the treaties are self-executing. Moreover, the application also resulted and more exercised externality that lead to further integration via EU jurisdiction (precisely EU and European Commission). Therefore, capacity of internal jurisdiction to implement international law is significant. The weakness of juridical disposition can make difficulties.

In fact, the judge identifies the formality following Article 53 – Article 55 of the Constitution[988] to verify the integration that does not constitute a constitutional control themselves. It is necessary for the control of intervention of the text application is subject to publication. It is underlined that administration omits to public a number of considerable international accord or convention. Thus, the '*Conseil d'etate*' supports this application following Article 55 of the Constitution in respect of regulation of reciprocity raised by Ministry of Foreign Affair. The sanction a *posteriori* does not exist.[989]

It is the other part of integration of international law is hierarchy of national law in the conformity to the international law that must be appreciated with control frame of internal jurisdiction, notably the '*Conseil d'etate*' who has jurisdictional function to consultation and refers to the conditions of integration of international law. One juridical difficulty relates to application of international law into national law is the possibility of direct application of treaty into national law. In this point, '*Conseil d'etate*' considers that direct effect is admitted if the concerned provisions are clear and precise or in contrary, it

[986] PRIEUR.M, 2001, *Supra*, p. 272
[987] PRIEUR.M, 2001, *Ibid*, p. 273
[988] Article 53 on the intervention of the Parliament and Article 55 on the publication, EISEMANN.P.M, *Supra*, note 478, pp.250-257
[989] EISEMANN.P.M, *Supra*, note 478, p.249

is not possible to apply.[990] However, the '*Conseil d'etate*' states to refuse to control regulatory to ratification on approval of international agreements that formality constitute acts of government (that means act of legal control) in application; control the material reality of ratification or approval.[991] Even though, French Conseil d'Etat, Assemblée 11 avril 2012 n° 322326, gave a new definition of "direct effect" more in favour of direct application of international treaties.[992]

In addition, in France, the role of the judge is determined by the social and cultural context. The judges are not the only actors in development of environmental law, there are multitude actors appear.[993]

Finally, it is the question of the means for integration, including human and material, financial and technical resources for implementation of application of international law in national law. In France, the State must take financial engagement with direct 0.7% of GDP for environmental protection.[994]

b) No national legal framework on access and benefit-sharing regime

France has not transcribed Article 15 of the CBD on access and benefit-sharing except some certain overseas territories have the local mechanisms and their own legislation on access and benefit-sharing (Southern Province New Caledonia) or being defined (Guyana Amazonian Park). There is no national legal framework on access and benefit-sharing covering the whole French territory. This legal loophole is particularly sensitive in overseas, where biodiversity gives rise to many research activities and developing. The result is a lack of predictability and legal certainty that are harmful to trust activities and relationships among stakeholders.[995] Users meet difficulties of access to resources, while local authorities are trying to implement, at their level, the principles of the access and benefit-sharing[996]. In general, there is a strong request to clarify for the actors about their rights and obligations in this field. In this context, within the National Biodiversity Strategy and Action Plan Overseas 2006-2010, and in view of the adoption of the Nagoya Protocol, there is an inter-ministrial preparing draft of the French access and benefit-sharing law. Inter-ministry is composed by national co-focal point on access and

[990] PRIEUR.M, 2001, *Supra*, p. 277
[991] EISEMANN.P.M, *Supra*, p.249
[992] see comments of Denys Simon, Europe, Lexis Nexis, Mai 2002, p. 1 and conclusions Dumortier and note of Gautier in Revue Française de Droit Administrative, N° 3, 2012, p.547
[993] PRIEUR.M, 2001, *Supra*, p. 286
[994] PRIEUR.M, 2001, *Ibid*, p. 286
[995] Ministère de l'écologie, du développement durable, des transports et du logement en partenariat (MEDDTL) avec Fondation pour la Recherche sur la Biodiversité, *Études & documents Pertinence et faisabilité de dispositifs d'accès et de partage des avantages en Outre-mer sur les ressources génétiques et les connaissances traditionnelles associées*, Sept, 2011, p 13, *available at* http://www.fondationbiodiversite.fr/images/stories/telechargement/ed_48_ABS_outre_mer.pdf last accessed May 11 2012
[996] *Ibid*, p 27

benefit-sharing: the Ministry of Ecology, Sustainable development, Transport and Housing (MEDDTL), the Ministry of Foreign and European Affairs, leaded by the MEDDTL. [997]

In Guyana Amazonian Park, the access and benefit-sharing provisions are codified in Article L331-15-6 of the Environmental Code of 14 April 2006. The regional council of Guyana is the competent authority to allow access. Outside Guyana Amazonian Park, there is no regulation on access and benefit-sharing in Guyana. In the Southern Province of New Caledonia, Deliberation 06-2009 of 18 February 2009 on the harvesting and exploitation of genetic and biochemical resources, codified in Sections 311-1 of the Environment Code of the Southern Province. In French Polynesia, the process of negotiation on access and benefit-sharing (Bill of countries 2006) has not resulted in adoption of a law. However, practices exist to guide access and benefit-sharing by case. To conduct research in French Polynesia, foreign researchers must obtain a protocol of the host local authorities. This control of entry and staying of foreign researchers can have information on research projects locally and provide some follow-up. It is, however, access and benefit-sharing provisions do not address all key elements, such as benefit-sharing or PIC.[998]

Despite diversity of statutes conferring a degree of variable autonomy vis-à-vis the metropolitan law, all French overseas are concerned by the implementation of international commitments. Because, under the principle of classical public international law, only the French Republic - which has the international status of State - is empowered to conclude treaties with other states, even if, their purpose is strictly limited to a specific part of its territory. (...) Treaties to which the Republic of France is a Party, shall apply throughout the territory of the Republic, including all overseas departments regions, communities and its metropolitan territory, unless expressly stated otherwise.[999] Consultation procedures can be organized, when treaties and conventions involved in the field of competence of the overseas territories before their entry into force (like French Polynesia). Once those treaties are ratified, such as CBD, they apply to entire French territory including all overseas. Consequently, all overseas are concerned with the implementation of the CBD and its Protocol.[1000]

The overseas territories have experienced a constant institutional evolution. St.Barthélemy and Saint Martin detached from Guadeloupe in 2007 to become communities overseas, while Mayotte has officially become the fifth overseas department in March 2011. New Caledonia, meanwhile, continues the process initiated by Noumea agreements with self-determination referendum in 2014. The French overseas departments, regions and communities have a special status. The overseas consists of departments and overseas regions (DOM). Five departments are: Guadeloupe, Guyana, Martinique, Reunion, Mayotte, in which overseas departments and regions of France governed by

[997] http://enqueteur.cgdd.developpementdurable.gouv.fr/index.php?sid=89381&lang=fr
[998] MEDDTL, Fondation pour la Recherche sur la Biodiversité, *Supra,* p16
[999] *Ibid*, p.121
[1000] *Ibid*, p.122

Article 73 of the Constitution, except Mayotte, is also the outermost region of the EU. Mayotte, becomes the 101st French department in March 2011, is currently an overseas territory. The question of eligibility status of outermost regions of France arises if it will be accepted by all Member States of the EU.

Five overseas communities (COM) are: French Polynesia, St. Barthelemy, St. Martin, Saint Pierre and Miquelon, Wallis and Futuna. The COM is governed by the Articles 73 and 74 of the Constitution. French Polynesia, Saint Pierre and Miquelon and Wallis and Futuna are overseas countries and territories (PTOM) of the EU. The status of COM at French level does not automatically lead to the PTOM or outermost regions of France at European level. Also, St. Martin and St. Barthelemy, recently detached from the Guadeloupe, are outside the European categories. A *sui generis* community: New Caledonia, specifically governed by title XIII of the Constitution (Article. 76 and 77), is also a PTOM of the EU. The French Southern and Antarctic Lands (TAAF) is governed by Article 72-3 of the Constitution and has its administration based in Reunion. It is composed by five districts: three sub-Antarctic districts (Kerguelen Crozet Islands and St. Paul and Amsterdam), a district is located in the channel Mozambique (Scattered Islands: Glorioso, Juan de Nova, Europa and Bassas da India Tromelin), the last one is located on a portion of Antarctica (Adelie Land). The TAAF does not count permanent population and constitute a PTOM at the EU level. Clipperton is mentioned by Article 72-3 of the Constitution, due to the dominical property of the State. Clipperton does not count permanent population.[1001]

Furthermore, an overseas regime on access and benefit-sharing is likely to be articulated with the measures taken at the EU level. The EU law enforcement depends on the classification of overseas territories of outermost regions of France or PTOM: Four French outermost regions of France (Martinique, Guadeloupe, Guyana, Reunion) are an integral part of the EU and are applying the EU law in full, with exceptions possible depending on the characteristics and constraints of these regions (Article 299 (2) EC Treaty). Six French overseas PTOM (Mayotte, New Caledonia, Polynesia French, Saint Pierre and Miquelon, TAAF, Wallis and Futuna), are linked to a Member State (by France), and contrary to the outermost regions of France they are not part of the EU. At this point, the EU law does not apply to them, with the exception of the regime association based on Part IV of the EC Treaty: "association of overseas countries and territories" (Section 182.).[1002]

Under the principle of sovereignty over the natural resources, states are responsible for implementation of the CBD and must develop measures laws, regulations or policy to establish a system access and benefit-sharing. Currently, the Protocol Nagoya is not ratified by France, so it does not yet take effects in the national legal order. However, in

[1001] *Ibid,* p.34-35
[1002] *Ibid,* p.40

case of ratification, it is obligatory under the Nagoya Protocol to provide explanatory and operational capability. If the CBD and the Nagoya Protocol is applied throughout the overseas, responsibility for implementation rests on institutional division of powers with French State. The situation of overseas departments and regions can be distinguished from that. The division of powers between overseas departments and regions and the State has direct consequences on access and benefitsharing. It shows whether a single regime is applicable to all overseas, and if not, to determine which authorities would be competent to adopt and implement such regime. For departments and regions overseas of France, such as Guyana, Article 73 of the Constitution provides that "in overseas departments and regions, the laws and regulations are fully applicable. They may be adaptations related to the characteristics and constraints of those communities."[1003] This is the principle of legislative identity applies for adaptations and exemptions provided by the Government and Parliament. There is a right to waive a trial basis with laws and regulations in the case of "Adaptations related to the characteristics and constraints of those communities". Adaptations and exemptions are provided for a French overseas department and region "in matters where they are competent" and when "there have been empowered by law". Paragraph 3 of Article 73 of the Constitution allows the Regional Council and the General Parliament Council to seek clearance to adapt general rules of each French overseas department and region (except for the Meeting) in a number of governance's areas. The principle of empowerment provides a real transfer of legislative powers to benefit communities. Therefore, regard to implementation of the CBD, a French overseas department and region has priority to adopt its own law or regulation. The principle of adaptations and exemptions has a lower use. For COM, their status reflects their own interests with the Republic (Article 74 of the French Constitution). An organic law determines the status and fixes the competences of the communities. Therefore, depending upon their recent competences, they may adopt rules for access and benefit-sharing matters. This is the case of New Caledonia where an access and benefit-sharing regime was adopted in Southern province, and of French Polynesia where a draft scheme was developed by local authorities. [1004]

B – Legislation on access and benefit-sharing

1) Legal status and ownership of genetic resources

a) Legal status of genetic resources

The national legislation of the France has no provision defines directly legal status and ownership of GR. However, based on provisions of the Code of Environment, GR can be defined as common heritage of the nation by virtue of Article L.110-1 of the Code of

[1003] *Ibid,* p.39
[1004] *Ibid,* p.123

Environment: "Spaces, resources and natural habitats, sites and landscapes, air quality, species animal and plant diversity and biological balance which they participate are part of common heritage of the nation."[1005] Their protection, enhancement, restoration, reparation and management are general interest and contribution to the objective of sustainable development which aims to meet the needs of development and health of present generations without compromising the needs and ability of future generations.[1006] They draw under the laws that define the scope, the following principles: the precautionary principle, the preventive principle, the polluter pays principle, the principle of participation.[1007]

However, the legal status of 'common heritage' has problem in the property law. Article 714 of Civil Code of France listed '*les choses communes*' that are "things not belongs to anyone, so, are common for use to all people"[1008] or become '*des choses sans maître'*.[1009] Some modern appearances of 'heritage' are equivalent to *rescommunis.* The wildlife is *res nullius* but the soil, the forest and the flora are *res propriae*. Nevertheless, these classic qualifications can not apply to things that those are non-identified property,[1010] for example, the ecological processes and landscapes are not property.[1011] Thus, Professor.Prieur.M posed a question "are…genetic resources common property or common heritage"?[1012] The common heritage also faces with personal law. The question raises: Who will be right's holder of the heritage on multi-facet that transcends space and time? In classical legal persons: State, nation, associations, people, who will manage the heritage? Who will take standing status before the courts to defend for common heritage? It would be unclear to address these questions. "There is not unique legal status for common heritage, neither national law nor international law".[1013] At present, the France is under process of development of access and benefit-sharing law[1014], so, the questions of legal status and owner of GR become more serious in the context of property law and personal law, with certain characteristics of GR which include tangible and intangible values in a rapid

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[1005] The 'common heritage' is a complex, variable geometry, which transcends the distinction between subject and object, and the allocations between public and private law and between international and domestic law. Behind the word 'heritage', there are two aspects: first, the classic notion taken from civil law on property that heritage is assembly of property and obligations of person that is cross-cutting between property law and personal law. Second, it expresses a collective value attached to the property or things independently to their legal status, the common heritage present a collective interest to the preservation of natural and cultural richness. PRIEUR.M, *Reflexions introductives sur la notion de patrimoine commune prive*, La revue Juridique d'Auvergne, Les themiales de Riom 1998, Les presses Universitaires de la faculte de droit Universite d'Auvergne, pp. 21-22

[1006] Article L.110-2 of the Code of Environment

[1007] PRIEUR.M, 2011, pp. 61 - 186

[1008] PRIEUR.M, *Reflexions introductives sur la notion de patrimoine commune prive,* La revue Juridique d'Auvergne, Les themiales de Riom 1998, Les presses Universitaires de la faculte de droit Universite d'Auvergne, p. 23

[1009] BRISSET. V. I, *Properiété publique et environnement*, LGDJ, Librairie générale de droit et de jurisprudence, 1994, p. 19

[1010] PRIEUR.M, *Reflexions introductives sur la notion de patrimoine commune prive, Supra,* p. 23

[1011] BRISSET. V. I, *Supra*, p. 19

[1012] PRIEUR.M, *Reflexions introductives sur la notion de patrimoine commune prive, Supra,* p. 23

[1013] *Ibid*

[1014] Following dicussion with Dr.Ana Rachel Teixeira-Mazaudoux, in 4th June 2012

development of science and technology. How the access and benefit-sharing law will be designed to meet requirement of clarity is being studied and considered.

One of challenges relate to access to in-situ GR and common property law is the case of current owners are forced to grant access to their property to collect resources and participate in the access and benefit-sharing process as providers. That raise question of ensuring respect for human rights, including property rights of private persons, while putting in place a system of access and benefit-sharing available. Identification of consent of indigenous and local communities and individual owners is a challenge in developing regime of access and benefit-sharing.[1015]

For ex-situ GR collections, France has no regime that determines specific rules applicable to GR. In legal aspects, they may be considered "property" like everything subject to law, particularly property), include material or associated intangibles elements. Actually, the ex-situ GR therefore are under property law and also the regime of common property. Under French law, the rules governing the operations for these resources depend on the quality of its holder (public or private person eg.). For private owners, there seems no restriction to exercise this property right, except requirements on environmental protection and species, the solution may be different for public organization.[1016] Consequently, there is no general rule is applicable to all ex-situ GR, regardless of the quality of their holders, in other words, they have no status or special legal regime. The definition of such a regime is out of responsibility of competent authorities in this area, state or specific overseas. Furthermore, it is important to note that a large number of ex-situ collections are present in French overseas territories. [1017]

Ex-situ GRs are not covered by the FAO's treaty, are included in the access and benefit-sharing regime of the Nagoya Protocol following its Article 4.4, because France is member of the FAO's treaty.

b) Provider of genetic resources

Following the Nagoya protocol, actors concerns in an access and benefit-sharing are defined as 'provider countries' and 'user countries', therefore, the State parties need to clarify persons who are considered 'provider' or 'user' in their national law. If the CBD and the Nagoya Protocol provides elements of the users by definition of 'utilization' and indigenous and local communities explicitly as provider, it needs to determine who becomes 'provider'.

Firstly, regarding to attribution of competence in the environment, public owner person is considered providers of GR.

[1015] MEDDTL, Fondation pour la Recherche sur la Biodiversité, *Supra*, p.20
[1016] *Ibid*, p.49
[1017] *Ibid*, p.47

Secondly, if GRs constitute 'property' in the legal sense, they do not have a particular status regime, in other words, they are subject to common property governed by law. Therefore, when these GRs in their natural state are incorporated in biological resources (such as plants), they fall under the regime applicable to biological resources, which generally follows regime of land property on which they are located. For example, owner of land on which biological resources are located, will be owner of GR. Therefore, it should also take into account that the rights holders as providers under the CBD and the Protocol. Summary in view of administrative law and property law in France, the terminology 'providers' includes:

i) Competent authorities issue for access to GR (license or equivalent). These may be the authorities in charge of the environment (natural resources). According to request for access, other services may be involved (culture, research, agriculture, etc…). The competent authority is considered a beneficiary to benefit-sharing.

ii) Individual persons or collectivity, founded by law who provide their prior consent. These include individual persons who are land's owners where the GR are found (following property rights) and indigenous and local communities who have rights on TK or interest that recognized by the national legislation on land where resources are located. These entire indigenous and local communities are considered beneficiaries of benefit-sharing.[1018]

2) Elements of access and benefit-sharing regime as provider country

a) General limitations

As mentioned above, access and benefit-sharing regime in France exists only in its overseas territories. There are three examples reflect development of access and benefit-sharing regime, they include: access and benefit-sharing system for the only Southern province of New Caledonia, process of definition of access and benefit-sharing regime in Guyana Amazonian park[1019], the process of access and benefit-sharing negotiation in French Polynesia. The limitations of existing access and benefit-sharing regime can be found:

Firstly, the existing access and benefit-sharing regimes have different scope of applications that can be analyzed by territorial scope or their purpose. Concerning the territorial scope, only the access and benefit-sharing regime of French Polynesia applies virtually the whole of the community. The others do not apply to the entire territory. In New Caledonia, the access and benefit-sharing regime only applies for the Southern province, which has adopted a system under provincial authority for environmental matters. The access and benefit-sharing regime of Guyana concerns only the territory of

[1018] *Ibid* p.68
[1019] The park's charter is expected to adoption in 2012, according to MEDDTL, Fondation pour la Recherche sur la Biodiversité, p.68

Guyana Amazonian Park. These limits represent a geographical gap in terms of regulating access and benefit-sharing.

Moreover, there is delimitation of scope of application in terms of resources and purposes of their uses. The Southern province of New Caledonia makes its system applicable to any collection of biological materials, retaining only few exceptions. The code of conduct on access and benefit-sharing, projects on access to GR within broad meaning of their use and value, may cover any scientific or commercial purpose without clarity about the terms of use and resources. The interpretation of the scope has emerged as a major challenge for all stakeholders: whether such activity should be included or not, what is the trigger of the regime (the collection or use of GR). The code of conduct only includes a requirement for obtaining PIC in case of using TK and/or collection of materials that takes place in living areas of indigenous and local communities. Other provisions do not take into account this dimension. However, the inclusion of TK in access and benefit-sharing regime appears necessarily for compliance with the CBD and the Protocol as providing the TK holders conditions for PIC and MAT. In French Polynesia, access and benefit-sharing has no legal basis thus it applies on a case-by-case. A French Polynesia's protocol does not constitute an instrument that applies generally to all GR users. Furthermore, only foreign researchers are required to obtain a protocol, which enable them to enter and stay in French Polynesia. The French and other users (such as private operators) are excluded from the system. [1020]

Secondly, identification of competent authorities responsible to issue a permit of access can be problem for users. In some cases, several authorities have a jurisdiction over natural resources that gives them a power of authorization to access. For example, in Guyana, it is sometimes difficult for applicants to identify adequate entry point to handle their requests because there is only general principle and the regime has not fully defined yet. In Guyana Amazonian Park, practice shows that the Management Authority of Guyana Amazonian Park is the first contact for users but Regional Council is competent authority to issue a permit of access according to the 2006 Act. In French Polynesia, the contracting procedure is carried out by delegation of French Polynesia, the environmental services does not involve in the procedure.

Moreover, the lack of regime for whole territory of New Caledonia and Guyana causes multiplicity of authorities in case of access to GR located outside the Southern province of New Caledonia and the Guyana Amazonian Park. For example, in Guyana, the regional environment and the national Forestry Board are responsible and competent to authorize withdrawals and uses for collection sites in protected areas or forests outside Guyana Amazonian Park. This multiplicity authorities and rules of the territory are quite complex. [1021]

[1020] *Ibid*, p.126
[1021] *Ibid*, p.126

There are different actors concerned about access to GR and TK, such as land owners and indigenous and local communities. In New Caledonia, the regime of the Southern province provides land owners have rights to enter into the agreement on access to resources on their land. Thus, to collect any resources located on private land, it requires a contract or a customary act in case the land is in customary status. However, they are not always recognized the rights claimed by the communities. For example, public sea is considered extension of the land, even if it happens, local actors claim and require as informal opportunity to access the space. In addition, community participation is not always easy, because, the customary rules on access are not codified. In Guyana, 96% of the territory belongs to the State and the rest is private land. Nevertheless, the State grants use rights, concessions and divestitures for indigenous and local people whose traditional livelihoods depend on forest. However, contents of these rights in terms of controlling access to resources are not always clearly stated. Furthermore, in accordance with the code of conduct, the Guyana Amazonian Park is obliged to obtain written PIC from communities in case of using TK and collecting biological material in areas under the indigenous and local communities' usage rights or/and in their collective living areas. Therefore, in practice, researchers have difficulty to identify which are affected by their research projects and to determine the licensing process (eg. existence of a representative to grant access, or need of a consultation of the whole community) for their application to a permit of access. In French Polynesia, existing provisions do not take into account the agreement of owners and do not provide their consultation to users. Nevertheless, it seems to be difficult to have consent of private landowners in case GR located on their land. Conditions of PIC and MAT of the owners are not framed. [1022]

Generally, there is a strong demand for a legal framework by stakeholders and overseas suppliers and users. The administrative and political authorities of overseas territories (Guyana, New Caledonia, French Polynesia) expect to have a legal basis for granting access to GR, to monitor and control uses of GR. There are many practical difficulties such as length and cumbersome procedures of certain existing access and benefit-sharing regulations that threat their activities, delays in procedures may limit research's investment, creation of new knowledge in territories. In turn, private sector expresses a need for legal certainty to continue to develop innovative projects and continue their activities. Overseas contractors sometimes require their metropolitan partners a guarantee of obtaining GR's use. Thus, they are requested to prove that access to the GR is under compliance with current regulations. However, such guarantee is impossible to obtain in the absence of any rules. Finally, indigenous and local communities would consider an access and benefit-sharing regime like a first step towards to recognize and respect to their TK, which would ensure effective benefit-sharing. A provision on access

[1022] *Ibid*, p.127

and benefit-sharing would restore trust relationships between actors and ensure legal certainty.[1023]

b) Access to genetic resources

i) Permit to access from Competent National Authority

Following Article 13 of the Nagoya Protocol, designating a National Focal Point and one or more Competent National Authority is a mandatory obligation of the Member States. The tasks of the Competent National Authority and the National Focal Point may be performed by a single entity. The Competent National Authority is responsible for granting access and advising on applicable procedures and requirements for obtaining PIC and entering MAT. The Competent National Authority would be in default as an administrative department in charge management of natural resources in coordination with other concerned departments and with support of a scientific body.

In France, there is a question of the determination of Competent National Authority (s) for overseas and its entire territorial level, because of its specific institutional and administrative organization as outlined above. In case the State ratifies the Nagoya Protocol, the implementation will depend on overseas authorities.

Currently, each mentioned COM adopts their access and benefit-sharing regime; they are likely to design its own Competent National Authority. The State, in view of its jurisdiction over natural resource management, is able to provide a regime for five departments and regions overseas of France and St. Martin, St. Pierre and Miquelon, Clipperton and the TAAF. Therefore, there may have two possibilities: a central Competent National Authority for all these territories or each local Competent National Authority for each territory or defined area, for example, the Regional Council for Guyana Amazonian Park and an inter-department desk or ad-hoc body for the TAAF. For any possibility, it requires the highest relevant and feasibble access and benefit-sharing regime to ensure greater harmonization of procedures for user's side (eg.standard procedures) or provider's side (technical, financial, human) and taking into account participation of indigenous and local communities. Therefore, the study of MEDDTL and Fondation pour la Recherche sur la Biodiversité suggested for a access and benefit-sharing focal wide network of the French overseas, which could be organized to promote exchanges and interactions between different overseas departments and communities, while it can operate closely with the access and benefit-sharing national focal point in mainland.[1024]

ii) PIC from providers who are private rights' holders

Although, participation of private rights holder is not considered explicitly by the Nagoya Protocol, they are providers of GR under ownership rights of land where these

[1023] *Ibid,* p.127
[1024] *Ibid,* p.71

resources are found as analyzed above. Access and sampling requires acceptance of the land's owner (or his beneficiary). The question is: how do the private rights' holders participate to the access and benefit-sharing process?

There are some options and arguments. In one option, private rights holders should be limited in requiring their PIC for access to GR in their land, thus, it is advantage for users as there is no major constraint. Accordingly, this procedure does not require monitoring or obtaining a new PIC in case of changing conditions of use. Therefore, it limits the participation of rights' holders to grant necessary authorization to enter their private property to collect GR or to verify the authorization to access to GR materials has been informed. This will lead to a frustration for private rights' holders because of being excluded from parts of the regime and their potential benefits. This is contrary to the CBD's provisions that providers are encouraged to conserve biodiversity from the benefits they can get.

However, in other opinions, it is unnecessary to ensure full participation of the right's holders for their PIC by informing them all responsibilities and scientific subjects that they may not know or not have enough capacity to understand. There will be burdensome for the users to inform for the right's holder, concurrently, they still have to negociate with the Competent National Authority to obtain a permit of access, because, the PIC from providers does not replace the permit issued by the Competent National Authority. Or, it is cumulative for responsibilities of the users. It should be one of responsibilities of the authority to take into account in his directives and ensure the proper progress. [1025] Therefore, it needs some exceptional measures to allow access without PIC from private rights' holder. A land right entitles the holder exorbitant powers, likely to be barriers to research. An example from the fact, in New Caledonia, where the only specimens of an endemic plant species is located on a land, the consent of the land owner to access and use of GR affects negatively to a permit of access to the species. The access and benefit-sharing regime should explicitly provide exceptional measures to require the land rights holder to allow access and use of this GR for public interest, but, justifying an overriding public interest in the property right would be legal burden and have difficulties in practices.[1026]

iii) PIC from indigenous and local communities

Following Article 7 of the Protocol, access to TK is subject to PIC or approval and involvement of indigenous and local communities who are holders. The question is how the right of indigenous and local communities on their TK is addressed within the scope of an access and benefit-sharing regime. According to Article 6.2 of the Nagoya Protocol, the indigenous and local communities can also give their PIC to access to GR, where they

[1025] *Ibid*, p.79
[1026] *Ibid*, p.80

established right to grant access. Participation of indigenous and local communities in an access and benefit-sharing regime thus depends on the existence of rights to land where GR are located (eg. land rights). The manner of indigenous and local communities' participation is related to their representation.

In French overseas territories, indigenous and local communities already benefit from recognized land rights on the land where GRs are located. In some cases, members or groups of indigenous and local communities such as Kanak and Private Law Groups in New Caledonia have customary land. These lands are governed by custom law and are inalienable, non-transferable and incommutable. This is the simplest case insofar as the right's holders are already identified, which also facilitates the issue of their representation.

However, there are some cases indigenous and local communities do not enjoy recognized rights to GR. Indigenous and local communities can access to biodiversity for their use, but they have no rights to allow legally control to access. For example, certain communities in New Caledonia occupy and access to the public marine areas and the shore to reefs; the native American communities in Guyana benefit from collective use rights in certain forest areas to exploit forest resources for their livelihood, but they don't have property rights and do not allow them to control access to resources located in that territory.

Therefore, it should to recognize rights of indigenous and local communities to allow them to grant or withhold their consent for access to GR. This could be broader land rights or a specific consent under the access and benefit-sharing regime without causing other effects. It facilitates the acceptability of the access and benefit-sharing regime under their views. In addition, it is necessary to organize their consultation through internal protocols. However, it will be difficult for them to benefit from this right, if their own organization does not clearly identify a legitimate representative on their behalf of.[1027]

The representative of indigenous and local communities is necessary for their effective participation in an access and benefit-sharing regime. Actually, their representative is ensured either informally or through designation of 'administrative heads' under non-specific customs. There are some examples of representative structures of TK's holders. In New Caledonia, which offers the most successful example of the recognition customary law, there are customary areas with Councils, tribes and clans' holders of TK. The representative of TK's holders could be based on clans and Councils of area. In French Polynesia, the representative could be based on extended families holders in land ownership. In other areas, an association existing under French law has been already used, for example, in Guyana, La Reunion and Antilles. However, this legal form is not preferred by the indigenous and local communities because they mistrust to an unknown system. A specific legal form - 'local customary community' also is created, which would be

[1027] *Ibid*, p.81

sufficiently flexible and could be the solution for all overseas. In any case, solutions developed for each area should be specific and implemented by the indigenous and local communities or in consultation with them. The choice of representative should be defined by their conditions.[1028]

c) Benefit-sharing

The questions of sharing benefit always arise with whom, what, how to share, especially providers are indigenous and local communities. The users sometimes have difficulty to identify them, to know the procedures to obtain MAT, or to adapt to the situation. In addition, the users and the providers do not always share the same definition of benefits or sharing.[1029]

In French oversea territories, there is a lack of consensus among stakeholders on the concept of benefits. These different concepts sometimes cause tensions and unsatisfied feeling of being looted of local authorities or communities. None of existing access and benefit-sharing regime specifies the nature of benefits arising from the use of GR and TK should be shared. [1030] Therefore, the definition of benefits based on understanding of the stakeholders is essential and should take any form of monetary or non-montary benefits.

In fact, benefit-sharing is a condition treated differently. Only the Southern province of New Caledonia provides precisely benefit-sharing arrangements, including commercial benefits that are subject to supervision (level and distribution between the land-owner and the province). Similarly, it is expected that application of the sums perceived by the Southern province is intended to conserve biodiversity. Guyana and French Polynesia, there are no such rules. In Guyana, terms of benefits share are indicated by users in his application for access to the park. There is no more specific guidance provided. In French Polynesia, both the host protocol and the convention signed between the users and the President of French Polynesia, do not have supervision sharing arrangements. However, standard clauses in the agreement, oblige users to submit a report in a specific form to the authorities at the end of harvest. They also provide the community consultation before any deposit in the field of intellectual property.[1031]

d) Indigenous and local communities and traditional knowledge

i) Legal matters on indigenous and local communities in French law

The French overseas is partly the legacy of French colonization. Most of overseas departments and territories were already occupied by experienced successive populations before the French arrival. The indigenous and local communities made conservation with

[1028] *Ibid*, p.84
[1029] *Ibid*, p 87 - 92
[1030] *Ibid*, p.128
[1031] *Ibid*, p.128

their traditional lifestyles, persistence of customary law of their own, retaining close ties with respective environments, result of links between TK and biodiversity. The access and benefit-sharing provisions represent an interest in recognition of their TK and ensuring fair and equitable sharing of benefits.[1032]

Local sustainable development approaches have been developed in France since the 1960s, with strong cultural, social, and countryside conservation elements, notably through Regional Natural Parks. Local communities are consulted during the process that leads to creation of natural reserves and national parks.[1033]

The Law on National Parks of April 14, 2006, recognizes the linkages and interactions between indigenous and local communities and ecosystems. The law confirms the influence of indigenous and local communities in shaping natural, cultural and landscape. Accordingly, it is legitimate to open, in each national park the possibility to benefit adapted regulations on certain activities, if these particular regulations are compatible with a high level of protection. Specific provisions have been adopted for the Guyana Amazonian Park to determine a special policy for local American Indian and Maroon-black populations. The first time in French law, a Board of Directors of the Park including five representatives from customary authorities, was recognized to enable them to directly participatory decisions. In addition, an advisory board of American Indian was established by Decree of June 2008. This board consults any proposed resolution of General Council of Guyana in environmental or cultural activities of the American Indian. Communities of New Caledonia also divided into eight customary areas; each area establishes a customary council. These councils have representatives at New Caledonia customary senate to consult any matter of identity or structures of Kanak.[1034]

However, regarding to legal status of indigenous and local communities, their rights do not correspond to a true recognition of rules and customary structures by state law. In general, French law does not recognize the concept of 'ethnic minorities, religious or linguistic minorities' to preserve the principle of equality. There is no reference under 'indigenous and local communities' with the exception of the framework Law on Overseas in 2000 which Article 33 literally adopts Article 8.j of the CBD. The French Constitution, in Article 72-3, recognizes 'the overseas populations' within the French people without defining them. Nevertheless, the peculiarities of overseas population (eg, Custom languages), are taken into account, including statutory and organic laws establishing the organization of the COM. In certain territories, native populations cohabit with alien. This

[1032] *Ibid*, p.121
[1033] http://www.cbd.int/countries/profile.shtml?country=fr#status
[1034] Ministère de l'Écologié, de l'Énergié, du Développement durable et de la Mer, *Supra*, p 64

is the case of New Caledonia, Guyana and French Polynesia. Each case presents particular features in terms recognition of rights and status. [1035]

In New Caledonia, right of communities is best provided by state law. Since the Noumea Accords 1999 that recognizes existence of Kanak people and precedence over the territory. The Kanak are similarly recognized as a personal particularity with existence of customary land and customary institutions. Also for access to GR, the state law includes to a large extent the principles of customary law. Access to GR on these lands is subject to custom rules on customary land (Article 18 of Accords 1999). Compliance with these rules is then formalized in a customary public act.[1036] However, there is no equivalence in Guyana and French Polynesia.

In Guyana, the black brown American Indians do not have a special status that allows them to have recognition of their customary rules. Nevertheless, the indigenous communities, which have traditional livelihood depending on the forest, can be granted rights to use of the forest. In French Polynesia, despite their majority share in the population of the indigenous communities, they are not recognizes a personal particularity and do not have specific territorial rights. However, in cases of joint ownership within 80% of the territory, Polynesian communities retain the use of customary law in informal land rights. These situations have different consequences on the ability of communities to control access GR and TK, as well as to be shared fairly and equitably benefit. Nevertheless, the ability to contract or to exercise a remedy in cases of abuse of the communities is a question. [1037]

ii) Legal matters of Traditional Knowledge (TK) in French law

France ratified the Convention for the Safeguarding of Intangible Cultural Heritage, which entered into force in 2006.[1038] However, finally, in all the overseas, TK is not recognized by the law. Their protection may be offered by the intellectual property rights standard, eventhough, it is not adapted to the characteristics of TK.

The question of utilization of TK already releases two consequences: first, the disappearance of direct relationship between user communities, which may increase distrust and difficulties to follow the evolution and use of this TK; second, it deprives indigenous and local communities of any right or claim of knowledge already disseminated. [1039]

In fact, a lot of information from TK has already been published by the scientific literature, works of great missions of ethnography, ancient accounts of travelers and other

[1035] MEDDTL, Fondation pour la Recherche sur la Biodiversité, *Supra,* p.36
[1036] *Ibid,* p.124
[1037] *Ibid,* p.124
[1038] Ministère de l'Écologié, de l'Énergié, du Développement durable et de la Mer, *Supra,* p. 64
[1039] *Ibid,* p.60

memories abound, descriptions of practices various uses of natural substances (herbs, foods, dyes physical, magical-religious, psychotropic, toners, poisons for hunting or fishing, agents crop protection, veterinary products, etc..). This information can draw attention on activity of a plant or a species, family, genus and direct research in another region of the world than where they were collected. However, what is already published can not be patented and can not be 'reclaimed' or controlled by indigenous and local communities. These can oppose the use of already published knowledge or claim authority over the use which might be made.[1040] Implementation of the Protocol of Nagoya is also not retroactive, this knowledge already released are outside the scope of an access and benefit-sharing regime. This situation in French overseas territories is similar to what happened in South Africa and Brazil.

TK has no specific protection by intellectual property rights, the feasibility of proposed solutions depends on the local contexts with very different situations of overseas territories, depends on the degree of organization of indigenous and local communities and particularly considered TK. It may face with challenges as risk of exploitation rights granted to indigenous and local communities beyond the objectives of the CBD or incompatibility between intellectual property right and cultural of indigenous and local communities.

There is an opinion supposes to protect indirectly TK by intellectual property right, on the patent regime as any other intellectual property rights. Concerning relationship between any intellectual property rights holders and rights of indigenous and local communities on their TK, these rights currently exist in the French legal system. In this sense, the changes in existing intellectual property rights allow inclusion of TK in a merger between indigenous and local communities and researchers from public and private sectors. However, anything devotes a *sui generis* that would be directly binding. The measure would be enforceable against any intellectual property rights' holder (patent, trademark, plant variety, etc…). It would fit also as part of a joint desirable intellectual property. [1041]

Other opinion suggests creating a *sui generic* to provide legal solutions for relationship between indigenous and local communities and TK in law. It looks to the links in customary law of indigenous and local communities or 'community's protocols and procedures'. In other words, it should take into account characteristics of TK understood by indigenous and local communities to bring compatible legal terms to French legal system. It does not create an entirely new category of unknown law to the French law but appeals to concepts, skills that allow existing legal accountability for specific culture of indigenous and local communities. The term of *sui generis* therefore includes these rights distinguished above from all intellectual property right. The current works of WIPO is tracking in that way. It is currently being discussed within WIPO, in conjunction with the

[1040] *Ibid,* p.60
[1041] *Ibid,* p.67

discussion on the right of patents, the possibility of a *sui generis* protection of TK applies to biological and GR.[1042]

If international treaty to which France is or becomes party, stipulates protecting to TK, the choice of a *sui generic* regime in connection with customary law (when it exists) is an option, in terms of Article 12.1 of the Nagoya Protocol that appears as more consistent with the spirit of the Protocol. *Sui generis* protection should be consistent with the commitments made by France at international, particularly in the context of the TRIPs. A *sui generis* system of protection for TK should be accompanied where appropriate by accommodations of intellectual property right to allow suitable protection, avoiding conflicts between intellectual property right's holders and a *sui generis* TK holder. It also should address question of required level of development: French, EU or international.[1043]

However, there are some challenges for legislative reform for TK protection. The need of such legislative reform depends on the French overseas departments and regions. It may be legally feasible in New Caledonia or French Polynesia French but may not be in Guyana or elsewhere. It also requires designation of a corporation, existing or not, owner/custodian rights. The establishment of a system of perpetual protection leaves little room for the public domain. The recognition of a *sui generis* protection for TK is even limited to TK associated with GR as a matter of policy.[1044]

e) Compliance

i) Measures to support compliance

For compliance, different measures of monitoring and control are suggested to provide, such as disclosure enable tracking of projects and establishment of check-points.

The competent authority may to monitor compliance with access conditions at the issuance of permits for access and use or require a continuous disclosure to consider the potential development and modification of R&D activity and changes of uses and users. The disclosure requirement when requesting access can be a prior control. It should not be a too heavy burden for users to provide all required elements, or for providers to understand and process this data. This will reduce requirement of user at the beginning and facilitate access to resources. The information is requested to any user, whether a French national, or citizen of the EU or not.

Further information is submitted when the access request. There are two types of obligations on information. First is a simple disclosure requirement of the transmission of reports on the activities of R&D. The periodicity of these reports may vary to types of

[1042] *Ibid,* p.67
[1043] *Ibid,* p.67
[1044] *Ibid,* p.67

research and timing of expected results. The competent authority shall acknowledge receipt of these reports, then tracking the progress of the project, monitoring compliance with the permit was granted. Second is an obligation to notify in case of substantial change of R&D. This may be limited because of available information when the access permit was issued, such as new partner, transfer of resources not provided to third, new use, unintended benefits, etc... In this case, the competent authority may conduct a review of new conditions to determine whether or not to renew the access permit. If substantial changes relate to individuals, then they may have to give a new consent.

The content of the disclosure requirement should be clear enough and harmonized to level of overseas territories (according responsibilities for access and benefit-sharing).

Checkpoints to monitor the use of GR is provided by Article 17 the Nagoya Protocol, thereof, each Party shall designate one or more checkpoints to monitor the use of GR during the process of R&D, innovation, pre-marketing or marketing. Checkpoints are responsible to collect or receive information about obtaining PIC, establishment of MAT and/or utilization of GR. This information indicates that GR was obtained in accordance with the laws of provider country. In terms of monitoring and control, traceability of GR and TK and control of their use seems to be difficult. In fact, how to control starting point (collection) to its end point (scientific research or commerce)? GR can pass from hand to hand, from territory to territory; GR can take many different forms: purified extracts, synthesized molecules etc… thus, it can be difficult to be recognized. The end point may be a potential starting point for research or for another other commercial use.

Several checkpoints can be seen in French overseas territories for different stages of R&D under the Protocol and subject to their technical, financial capacity. Public and private organizations conducting R&D control during mission requests and more general awareness programs/training for their members. Research funding organizations, in the financing application files, control the form of applying principles of access and benefit-sharing and procedures in the access and benefit-sharing have been met such as permit or certificate of compliance when it is available. Intellectual property rights organizations, such as Patent Offices, provide proof of compliance with access and benefit-sharing procedures. The disclosure of the source of GR or TK on intellectual property rights allows a usage tracking. Requirement of the introduction of export/import certificates such as phytosanitary certificate, veterinary certificate, etc are likely to weigh down the regime.

Article 14 of the Nagoya Protocol provides for the establishment of an access and benefit-sharing Clearing-House and each Party shall provide certain information. Thus, French overseas departments and regions record information which could be centralized at the national level and freely accessible by overseas correspondents and any designated Competent National Authority (in the territories where the state is competent to develop an

access and benefit-sharing regime), subject to the confidentiality of certain information. An overseas access and benefit-sharing network for the exchange of information with COM should also be organized. The establishment of network will require material investment, mobilizing agents, while the human and material capacities of the overseas authorities are limited, thus it needs material, financial assistance from the State.

In overseas territories, some kinds of monitoring and control are generally provided such as delivering harvest reports, publications, obligation to consult the authority on selling resources of an actor in public research to a commercial enterprise in New Caledonia. In French Polynesia, monitoring and control are part of the relationship between the applicant and French Polynesia (through agreement) or between the applicant and host organization (through protocol host). These procedures involve local authorities or require the user to conduct his research as partner of a host Polynesian institution, constitute a framework to guarantee compliance with access and benefit-sharing conditions. In all cases, control of field activities is hampered by low numbers of services provided. These difficulties are compounded by the geographical extent, the number of research to monitor and track, and inadequate access to information resources (networks distribution of publications, for example).[1045]

ii) Remedies available in user countries

In view of administrative law and property law in France, the terminology 'users' includes: researchers from private and public sectors and economic actors working overseas. Users are also French, EU and non EU nationals.[1046]

For remedies, there are existing administrative and judicial procedures applicable in France, including to foreigners, in situations of conflict arising, enabling or facilitating foreign claimants seeking redress in French courts. Some national remedial measures can be considered. The Civil Code of Procedure governs international arbitration in its articles 1492 to 1507; and judicial cooperation at the different procedural stages, (listing three international instruments relating to the procedural ability of foreign parties to bring legal actions in courts of another country) is completed by a regime of judicial assistance defined by Law No 91-1266, 18 December 1991.

In case of disputes, France is a party to a number of private international law multilateral agreements addressing disputes related to economic issues, which may be applicable to access and benefit-sharing agreements. They include "the European Community Convention on the Law Applicable to Contractual Obligations (Rome, 1980), Convention on the Law Applicable to Agency (The Hague, 1978); UNGA resolution 57/18 (which seeks to promote the use of international conciliation mechanisms in public

[1045] *Ibid,* p.128
[1046] *Ibid,* p.69

international law disputes); the Convention on the Taking Evidence Abroad in Civil or Commercial Matters (The Hague, 1970); the Convention on the Service Abroad of Judicial and Extrajudicial Documents in Civil or Commercial Matters (The Hague, 1965); and the UN Convention on the Recognition and Enforcement of Foreign Arbitral Awards (New York, 1965). Some of these documents have regional application, but many are global in scope. There use in the context of access and benefit-sharing contracts will be enhanced if (i) such contracts are drawn in the expectation of being interpreted under a consistent international system such as those represented in this list, and (ii) the courts in the country of the user apply such a system. This is complemented by a regime of judicial assistance defined by law no 91-1266, 18 December 1991. Legislative and administrative provisions therefore exist in France for the different aspects of the settlement of economic disputes concerning private entities."[1047]

Conditions under the remedy can be asserted. As noted above, "civil procedure, arbitration and related international instruments do not provide or constitute remedies, but rather facilitate access to remedies by the foreign claimants in the courts of the legislating country. Without this facilitation, remedies could not be made available to anyone. This provides a good overview of the possible sources of such procedural assistance in bringing an action seeking remedy."

Some special issues relevant to access and benefit-sharing compliance, can be noted that "Legislative and administrative provisions therefore exist in France for the different aspects of the settlement of economic disputes concerning private entities." This clearly demonstrates that access and benefit-sharing remedies in France are expected to be those remedies that can be asserted using the country's general commercial law.[1048]

In conclusion, France has no national legal framework on access and benefit-sharing covering the whole French territory. In its overseas, there are some provisions and practices of access and benefit-sharing. The national legislation of the France also has no provision defines directly legal status and ownership of GR. Identification of competent authorities responsible to issue access permissions is a challenge. The result is a lack of predictability and legal certainty. There is a strong demand for a legal framework on access and benefit-sharing by stakeholders, suppliers, users in overseas.

France signed the Nagoya Protocol in 2011. It is clear that it chooses an approach of signing to the Protocol first and then decides to ratification and development domestic law on access and benefit-sharing. Therefore, the provisions of the Protocol need to be incorporated into the national law.

[1047] UNEP/CBD/WG-ABS/3/5, p. 11
[1048] UNEP/CBD/WG-ABS/5/INF/3, p. 37

France is under process of development of national legislation on access and benefit-sharing. There are a range of questions to incorporate the Protocol properly into national law such as determination of legal status and ownership of GR, rights holder, compliance, designation of Competent National Authority(s), National Focal Point, consensus among stakeholders on the concept of benefits, legal matters on indigenous and local communities, TK in French law.

3) European Union (EU) as user of genetic resources

a) Generalities

Europe is an important user of GR from around the world, as well as a potential provider. "The EU possesses significant ex-situ collections, and commercial demand for access to GR spans a wide range of sectors including pharmaceuticals, biotechnology, botanical medicines and cosmetics."[1049] "The level of demand within the EU across each of these sectors is hard to estimate and shifts with time in line with technological innovations. Nevertheless, the EU possesses substantial commercial R&D capacity. Excluding traditional pharmaceutical and biochemical companies, European entrepreneurial life sciences industry generated revenues of EUR 8679 million in 2001 alone."[1050]

The EU has become party to the CBD since 21 December 1993 and signed the Nagoya Protocol on 23 June 2011 but not ratified yet.[1051]

"On the politic plan, the EU did not approach the question of GR".[1052] "A small number of EC legislative and policy measures directly address the CBD's provisions on access and benefit-sharing. Considering the provider-side issues within the EU (access to European GR); it focuses on assisting developing countries to develop access and benefit-sharing frameworks. Its "user-side" discussion focuses primarily on disclosure of origin in patent applications."[1053] "Community policy links between intellectual property right and benefit-sharing."[1054]

However, some major policies of the European Commission (EC) express rationally access and benefit-sharing legislation from the perspective of the user country and commercial and market interests. These are effected by a point of view that the issue of access and benefit-sharing is potentially a win-win situation for trade and environment, benefits arising from the commercial use of GR can be used to foster the protection of

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[1049] EUROPEAN COMISSION, Second report of the European community to the Convention on Biological diversity, Thematic Report on Access and Benefit-sharing, October 2002, p. 1
[1050] EUROPEAN COMISSION, 2002, p. 4
[1051] http://www.cbd.int/convention/parties/list/, http://www.cbd.int/abs/nagoya-protocol/signatories/, last accessed August 3, 2012
[1052] SADELEER.N., BORN.H.C, *Supra*, note 138, p. 570, p. 571, p. 572
[1053] EU Directive on Patents in Biotechnology (EC/98/44); "Communication from the Commission to the European Parliament and the Council, the implementation by the EC of the "Bonn Guidelines" COM (2003) 821 final, Brussels, 23.12.2003; and EC Regulation No 761/2001 allowing voluntary participation by organizations in a Community eco-management and audit scheme
[1054] EUROPEAN COMISSION, Second report, 2002, *Supra*, p. 4

biodiversity. “The adoption of user-side measures would be a win-win situation for users of GR”. “User-side measures can provide a balance in access and benefit-sharing which is currently heavily weighted in addressing only the interests of provider countries”.[1055] For instance, the 1998 European Community Biodiversity Strategy (COM(98)042) notes the need of the EU to “promote appropriate multilateral frameworks for access and benefit-sharing”, “to encourage the development of voluntary guidelines for access and benefit-sharing” and “to support countries of origin of GR in developing national strategies on bioprospecting”. The 2002 EC Biodiversity Action Plan for Economic and Development Cooperation refers to “the need to support capacity-building in developing countries, so as to enable them to share the benefits from utilization of GR”. The parallel EC Biodiversity Action Plan for Agriculture highlights “access to enhanced material by the original providers of GR”. [1056]

The EC has also suggested the possible applicability of a certification system in access and benefit-sharing. Although, “no legislation has addressed the matters, they have been prominently discussed in the EC’s primary report on access and benefit-sharing EC, 2003, at 9 and 22.”[1057]

Directive 98/44/EC dated 6th July 1998 on the legal protection of biotechnological innovations is the only “EC legal instrument that specifically takes into consideration the CBD’s provisions on access and benefit-sharing, encourages recognition of the geographical origin of biological material used in biotechnological inventions on patent applications”. “The Directive harmonizes and clarifies existing national legislation that introduced to improve patent protection for biotechnological innovations in an attempt to enhance the competitiveness of EU’s biotechnology industry.”[1058] Recital 27 to the Directive states that “Whereas if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known; whereas this is without prejudice to the processing of patent applications of the validity of rights arising from granted patents.”[1059] Recital 55 of the Directive “requires Member States to give weight to CBD Article 8.j when introducing law, regulations and administrative procedures to implement the Directive. Recital 56 takes note to call for further work on the links between intellectual property rights, the TRIPs Agreement and relevant CBD provisions relating to technology transfer; the conservation and sustainable use of biodiversity and the equitable sharing of benefits arising out from GR’s use.”[1060] “Disclosure of origin is, meanwhile, a binding criterion in the legal arrangements of some developing countries and

[1055] TVEDT. M. W, YOUNG. T, *Supra,* p. 132
[1056] EUROPEAN COMISSION, Second report, 2002, *Supra* p 7
[1057] TVEDT. M. W, YOUNG. T, *Supra,* p. 27
[1058] EUROPEAN COMISSION, Second report, 2002, *Supra* p.9
[1059] http://www.cbd.int/doc/measures/abs/msr-abs-eu-en.pdf last accessed May 15, 2012
[1060] EUROPEAN COMISSION, Second report, 2002, *Supra* p.10

is also recommended to applicants in the EU's Directive on the legal protection of biotechnological inventions. Under certain circumstances, the EU Commission, too, seems willing to support origin disclosure in the context of a multilateral approach. This provision seeks to support compliance with national legislation in the source country of biological material and with any contractual arrangements governing the acquisition and use of that material."[1061] "In this respect, the European Commission/Member States are prepared to engage in a positive manner in an attempt to agree, within the appropriate fora, on a multilateral system for disclosing and sharing information about the origin of biological material relied on in patent applications. Such discussions could also address the issue of a self-standing obligation for patent applicants to disclose the origin of biological material relied on in patent applications. If such a system could be agreed, it would be a logical step to include it as a mandatory minimum standard in a future TRIPs agreement." According to the EU Directive on the Legal Protection of Biotechnological Inventions, "further utilization of protected germplasm, for instance, in the context of commercial follow-up breeding programs, will be regulated by a system of cross-licensing."[1062]

A number of other EU legislative and policy measures could contribute to the implementation of the CBD's provisions on benefit-sharing. These include regulations and directives on geographical indications and community plant variety rights, as well as on the conservation and characterization of plant GR for food and agricultural. Measures in support of research and technology transfer may also be relevant. Although access and benefit-sharing is not mentioned, the EU's documents and strategies on technology transfer[1063] have been identified as potential mechanisms for benefit-sharing. In addition, there are a number of legislations that may consider indirectly support to access and benefit-sharing. For example, Directive 96/9/EC of the European Parliament and of the Council (11 March 1996) on the legal protection of databases may help to secure compliance with requirements for PIC and MATs for access though makes no reference to the CBD. Protocol No 3 on the Sami people[1064] of the Act of Accession of Austria, Finland and Sweden to the EU (1994) is potential relevance to implementation of the CBD's provisions on Article 8(j), though makes no specific reference to the CBD or to traditional knowledge. Council Regulation No 2100/94 (27 July 1994) on Community Plant Variety Rights might facilitate benefit-sharing. Council Regulation No 2081/92 (14 July 1992) on geographic indications enables groups and natural or legal persons to register designations of origin and geographical indications for agricultural products and foodstuffs. Council Regulation No 2982/92 of 14 July 1992 on certificates of specific character for agricultural

[1061] *Ibid*, p. 2
[1062] SEILER.A, DUTFIELD. G, *Supra*, p.38
[1063] These include the "Innovation and SME (small and medium enterprise) program," the "Partnership Agreement between Members of the African, Caribbean and Pacific (ACP) States and the European Community (Cotonou Agreement), and its Compendium on Cooperation Strategies," mentioned in EC, 2002. None of these documents specifically mentions ABS or is, in its current form, applicable to ABS.
[1064] Indigenous peoples of Northern Norway, Sweden and Finland

products and foodstuffs, Directive 98/95/EC on conservation varieties (14 December 1998), Council Regulation on the conservation, characterisation, collection, utilisation of GR in agriculture and amending Regulation (EC) 1258/1999…may support to implement access and benefit-sharing.[1065]

The EC also supports the implementation of institutional policies and codes of conduct on access and benefit-sharing by stakeholder groups, including for ex-situ collections. Specifically, the EC supported "the development of the Micro-organisms Sustainable Use and Access Regulation International Code of Conduct by the Belgian Coordinated Collections of Micro-organisms, together with 16 other organizations from around the world". In addition, the EC has supported "a small amount of policy research on access and benefit-sharing, including the commercial demand for access to GR".

"The EC's existing array of measures should be considered alongside other stakeholder initiatives to develop policies and codes of conduct, complementary of both the CBD and national access and benefit-sharing legislation. Such 'user' measures have been pioneered by botanic gardens, culture collections, as well as pharmaceutical and biotechnology companies."[1066]

b) Challenges for integration of user measures obligations of the Protocol

"EU member countries have hitherto mostly regarded themselves as user countries"[1067]. Adopting user measures always may face with political difficulty, because "user measures appear to require industrial and research communities of the country to pay money to other countries in viewed independently in each country. This political difficulty to "sell" to legislators within any country may constitute a major disincentive preventing legislators from adopting real user measures."[1068] This may be a main reason of slow progress and delay in development of legislative and policy measures directly address the CBD's provisions on access and benefit-sharing, even though the rationale of win-win solution mentioned above. In addition, there are many challenges for integration of user measures obligations of the Protocol in the EU. They include:

Firstly, "most of the challenges are relating to the requirements of the provisions of the Protocol to domestic legislation and other measures on the domestic level, since ratification of the Protocol, thus presuppose for most countries, legislation on and administrative regulation of an area, which has hitherto mostly been unregulated." [1069] Moreover, a number of countries are still at the preliminary stages of awareness raising of

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[1065] EUROPEAN COMISSION, Second report, 2002, *Supra,* pp.11-14
[1066] EUROPEAN COMISSION, Second report, 2002, p 3
[1067] KOESTER. V, The Nagoya Protocol on ABS: ratification by the EU and its Member States and implementation challenges, Studies N°03/12, IDDRI, Paris, France, 2012, 32 p., available at: *http://www.iddri.org/Publications/Collections/Analyses/The-Nagoya-Protocol-on-ABS-ratification-by-the-EU-and-its-Member-States-and-implementation-challenges*, last accessed 22 June 2012
[1068] TVEDT. M. W, YOUNG. T, *Supra,* p. 132
[1069] KOESTER. V, *Supra*, Studies N°03/12, IDDRI, Paris, France, 2012, p.30

potential users of GR. Following available information of the Secretariat, "administrative and judicial remedies available in countries with users under their jurisdiction regarding non-compliance with PIC and MAT, have been limited to those which apply in cases of non-compliance with disclosure requirements in patent applications."[1070] In addition, access and benefit-sharing is "a legally complex area with many actors and diverse, sometimes conflicting, interests. The fact that the Protocol also indirectly regulates issues under private law, including international private law, only accentuates this challenge. 'In addition to this is the EU perspective which is, of course, only relevant to industrialized countries being Member States of the EU." [1071] "The EC also argued that the Protocol is likely to require new EU policies or new EU legislation. EU legislation would be affected by ratification of the Protocol, and unilateral ratification would be in conflict with the EU Treaty. It is obvious that Member States would have to consider carefully the views of the Commission."[1072]

Secondly, Directive 98/44/EC, which is the only EC legal instrument that specifically takes into consideration the CBD's provisions on access and benefit-sharing, is weak for enforcement. "As elements of the Directive's preamble, both Recitals 27 and 56 are non-binding, intended only to assist interpretation of the Directive's binding articles. Recital 27 is in line with CBD Decision VI/24C on the role of intellectual property rights in the implementation of access and benefit-sharing arrangements that only invites Parties and Governments to encourage the disclosure of the country of origin of GR". Moreover, "Directive 98/44/EC is implemented within the framework of the 1973 European Patent Convention that is not an EC institution."[1073]

Thirdly, entry into EU has complicated the situation for EU members States. Members States must now implement and apply the legal norms issued by EU institutions and also the international commitments undertaken at the regional level. Some member states leave it to the courts to find a solution. In the contrast, constitutional amendments have been enacted in some states to ensure that the provisions of treaties governing the EU and the rules issued by its institutions apply directly in national law, as provided EU law. Beyond the legislative parameters of the EU, the Jurisprudence of European court of Justice (as well as that of the European court of human rights) has added a new dimension to the interaction of domestic and international law within Europe.

Moreover, "a directive is binding, as to the result to be achieved, upon each Member State to which it is addressed, but leaves to the national authorities the choice of form and methods for implementing the Directive in question in domestic law". In accordance with settled case-law, "the transposition of a directive into domestic law does not necessarily

[1070] UNEP/CBD/WG-ABS/3/5, p. 10
[1071] KOESTER. V, *Supra*, Studies N°03/12, IDDRI, Paris, France, 2012, p.30
[1072] KOESTER. V, *Supra*, Studies N°03/12, IDDRI, Paris, France, 2012, p.29
[1073] EUROPEAN COMISSION, Second report, 2002, p.10

require the content of the Directive be incorporated formally and verbatim in express of specific legislation. Depending on its content, a general legal context may be adequate for the purpose of incorporation that does indeed guarantee the full application of the Directive in a sufficiently clear and precise manner. In that regard, it is important in each individual case to determine the nature of the provision, laid down in a directive, to which the action for infringement relates, in order to gauge the extent of the obligation to transpose imposed on the Member States". "The provisions of Directives must be implemented with unquestionable binding force, and the specificity, precision and clarity necessary to satisfy the requirements of legal certainty". "The principle of legal certainty requires appropriate publicity for the national measures adopted pursuant to Community rules in such a way as to enable the persons concerned by such measures to ascertain the scope of their rights and obligations in the particular area governed by Community law. It would be contrary to the principle of legal safety if a Member State could rely on the regional authorities' power to issue regulations in order to justify national legislation which does not comply with the prohibitions laid down in a directive. Member States are, in the context of the Directive, under a particular duty to ensure that their legislation intended to transpose that Directive is clear and precise".[1074]

In sum, EU also has no legal instrument that guide specifically on access and benefit-sharing but there are some legislative and policy measures could contribute to the implementation of the protocol. There are also challenges for integration of user measures obligations of the Protocol such as limited awareness on access and benefit-sharing issue, weak compliance and complicated situation of the member countries.

It is clear that the EU chooses an approach of signing to the Protocol first and then considers ratification and development domestic law on access and benefit-sharing. Because, Member States might ratify provided they are capable of implementing the Protocol from its entry into force. "Ratification by Member States would not prevent the introduction, at a later stage, of EU legislation, as appropriate and in light of experience gained. In any event, it would be regrettable if ratification by Member States would have to wait until late 2014 as indicated by the Commission, or maybe even longer than that". As Koester notes that "for most industrialized countries, the approach vis-à-vis becoming parties to an international treaty is normally different. They do not ratify before they are in a position to implement the treaty. Thus, if the first COP-MOP of the Protocol takes place in 2012, there is not much time if the EU and its Member States would wish to participate in the meeting in a capacity of being parties. On the other hand, according to the statement of the Commission this is not relevant, because the EU and the Member States would be in

[1074] EUROPEAN COMISSION, *Nature and biodiversity cases, ruling of the European court of justice*, Office for official Publications of European communities, Luxembourg, 2006, p.14, available at http://ec.europa.eu/environment/nature/info/pubs/docs/others/ecj_rulings_en.pdf, last accessed May 16, 2012

a position to ratify only late 2014."[1075] In case of ratifying the Protocol, a specialized legal instrument on the issues of access and benefit-sharing may be necessary for the EU. This may be under type of directive or a model law or guidelines for the member countries to implement.

Conclusion of Chapter 1

Access and benefit-sharing legislation differs from each other in selected countries. This difference depends on characteristics of approach of legal system, development of law, situation of genetic resources, traditional knowledge, as well as, socio-economic, politic factors of each country and even continence, regions. Despite having same target towards to third objective of the CBD, national provisions differs from the legal status of GR, the way to provides PIC and MAT, types and means of benefit-sharing, measures supports to compliance and protection of TK and legal status of indigenous and local communities. "Many countries are aware national interest of access and benefit-sharing issues, their sovereignty on GRs, and then develop their national law, join to international treaty to protect their national right and property. Many of them are signatories of the Nagoya Protocol."[1076] The law analysis indicates that most of national laws are basically conformed to principles of sovereignty over GR and applying PIC and MAT in access and benefit-sharing process. However, development of law and implementation is facing up with many difficulties and challenges. The selected countries also have been found some limitations in access and benefit-sharing legislation and in integration of the Nagoya Protocol.

As Professor Prieur.M states "The most important legal obstacles to implementation of international law at national level are from national law but not international law that is the question of the direct effect of treaties, the jurisprudence still remains to be limited in this respect of the environment field."[1077] The analysis of this chapter also proves difficulties from national law. Thus, the access and benefit-sharing national legislation is decisive to realize the objective and provisions of the Nagoya Protocol. Most of countries have planned to improve national legal framework on access and benefit-sharing before ratifying or acceding to the Protocol.[1078] This is necessary preparation for integration of the Nagoya Protocol.

[1075] KOESTER. V, *Supra*, Studies N°03/12, IDDRI, 2012, p.30
[1076] http://www.cbd.int/abs/nagoya-protocol/signatories/
[1077] PRIEUR. M, *Droit de l'environnement*, Dalloz, 6e Edition, 2011, p. 19
[1078] For example, France is preparing develop national legal system on ABS and at EU level, they are also preparing their European legal system on ABS. The ABS french system should have been put to negotiation with the stakesholders http://enqueteur.cgdd.developpement-durable.gouv.fr/index.php?sid=89381&lang=fr

CHAPTER 2 - Access and benefit-sharing legislation of Vietnam and integration of the Nagoya protocol

Engels.F was concerned "Nature is the proof of dialectics". Dialectics stated Engels "is nothing more than the science of the general laws of motion and development of nature, human society and thought." Everything is moving, changing, either rising and developing or declining and dying away. Any equilibrium is only relative, and only has meaning in relation to other forms of motion.[1079] That would be appropriate philosophy approach of research of this Chapter.[1080] The chapter will analyze the practical and legal bases for development of access and benefit-sharing legislation, current situation of national access and benefit-sharing legislation and consideration of opportunities and challenges to accession of the Nagoya Protocol and integration of the Protocol into national law of Vietnam. All these basic issues have been viewed in the context of Vietnam which has rich biodiversity but its biodiversity is being degraded and need effective conservation and sustainable use. The access and benefit-sharing legislation of Vietnam is still being developed. It still remains many gaps, overlappings and weakness. In practice, there are some good practices that require the law changes its regulation for reasonableness and effectiveness or some cases has been changed from bad conditions to better situations when awareness has been approved.[1081] Therefore, both access and benefit-sharing legislation development and implementation should be improved to meet requirements of the Nagoya Protocol for its effective integration into national law.

Section 1 – Practical and legal bases for development of access and benefit-sharing legislation and acceding the Nagoya Protocol of Vietnam

§ I - Overview of situation of genetic resources and access and benefitsharing of Vietnam

A – Situation of genetic resources of Vietnam

1) Richness of genetic diversity, traditional knowledge and their role

Vietnam is classified as part of one of the world's biodiversity hotspots.[1082] The country is one of 12 centers of plant variety diversity in the world, with 16 groups of

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[1079] Cited by Sewell.R at *http://www.marxist.com/what-is-dialectical-materialism.htm*

[1080] See more FELT.B, GOUJON.PH, HERIARD6DUBREUIL.B, LAVELLE.S, LESCH.W, Ethique, technique et démocratie, Academia Bruylant, 2007, p.57, "La dialectique de l'acte de connaissance se conçoit plus précisément du fait des limites problématiques de la séquence commençcant avec l'intention de connaissance, se poursuivant avec l'execution de l'acte de connaissance"

[1081] « Quand connaître, c'est agir », FELT.B, GOUJON.PH, HERIARD6DUBREUIL.B, LAVELLE.S, LESCH.W, Ethique, technique et démocratie, Academia Bruylant, 2007, pp.56-81

[1082] Conservation International. Biodiversity Hotspots http://www.biodiversityhotspots.org/xp/hotspots/hotspots_by_region/Pages/default.aspx. Accessed May 20, 2012

Vietnam Ecology and Nature protection handbook, International Business Publications, USA, Washington DC, USA-Vietnam, 2008, p. 43

varieties.[1083] There are 13,766 recognized species of flora. Vietnam's national gene bank conserves 12,207 varieties of 115 species.

The role and importance of GR has been significant in the socio-economic development of Vietnam in recent years, notably in the fields of agriculture, forestry and fisheries which account for a significant percentage of the national economy.[1084] Moreover, the rapid development of biotechnology, pharmaceuticals, cosmetics and trade can bring out more great benefit for the country. Therefore, the GR is one of renewable resources which can be considered key factor of sustainable development in Vietnam to replace the current exploitation of un-renewable resources such as coal, oil, gas and minerals.

Vietnam is rich in varieties of rice and fruit trees. The rice GR of Vietnam is one of the most abundant sources of specific varieties in the world. The Hanoi National Plant Gene Bank currently preserves 6,000 varieties of local rice. For example, fragrant rice is the precious materials to help countries in temperate zone to plant these rice varieties. In the Mekong Delta, there are strains of export-quality rice that can float and others that can be grown in deep water. The Mekong Delta Rice Institute maintains 1,800 samples of traditional rice from Southern Vietnam and 160 land races of wild rice.

Fruit trees also are a plentiful source of genetic resources. The Institute of Fruit Trees Research recognizes more than 130 species of 39 families with hundreds of fruit tree varieties. Due to the extent of their distribution in the country, fruit trees are very important for nutrition, the environment and the economic development of local people.[1085]

The genetic resources of traditional domestic animals also have significant economic value in Vietnam. These animals include various endemic chickens (such as Dong Tao or Mong), ducks (such as Bau Quy or Muong Kuong or Meo or Soc or Quy Chau), pigs (such as Van Pa or Ba Xuyen), H'mong bulls, Phan Rang sheep, black and grey rabbits.[1086] For example, endemic Mong chickens brought breeding benefits to each village 3 million VND, each village's household 4 billion VND on average.[1087] For example, endemic Mong chicken brought breeding benefits to each village 3 million VND, each village's household 4 billion VND on average.[1088] Vietnam also is a center of primate

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[1083] Lê Xuân Cảnh, Hồ Thanh Hải, *Report of State of Biodiversity of Vietnam*, at National Workshop on Biodiversity, Vietnam National Conference on Environment, Institute of Ecology and Biological Resources, Hanoi, . Available online: http://vea.gov.vn/vn/truyenthong/sukien-ngayle/hoinghimttq/khoahocchuyende/Pages/H%E1%BB%99ingh%E1%BB%8BKhoah%E1%BB%8Dcv%E1%BB%81%C4%90ad%E1%BA%A1ngsinhh%E1%BB%8DcHi%E1%BB%87ntr%E1%BA%A1ngv%C3%A0suytho%C3%A1i%C4%91ad%E1%BA%A1ngsinhh%E1%BB%8Dc%E1%BB%9FVi%E1%BB%87tNam.aspx. Accessed 18 May 2012.

[1084] Trần Thị Hương Trang, 2006. *Legislation on genetic resources conservation in Vietnam* , p.13, Thesis for Master of Law, Hanoi Law University, Hanoi.

[1085] Vietnam Association for Conservation of Nature and Environment *(*VACNE*), Vietnam –Environment and Life*, The National Political Publisher, Hanoi, 2004, p. 176

[1086] Unnamed author posted by *Agriculture Newspaper*. No 202. 8 October 2004.

[1087] Unnamed author posted by *Agriculture Newspaper*. No 202. 8 October 2004.

[1088] Võ Văn Sự, http://www.vcn.vnn.vn/PrintPreview.aspx?ID=2625 Accessed 6 March 2012.

genetic diversity. Primates in Vietnam comprise 25 species belonging to three families, of which several are endemic species with high economic value, including: Tonkin snub-nosed monkey, golden-headed langur (Cat Ba langur), black langur, stripe-headed black langur (Hatinh langur), Delacour's langur, and the white-rumped black langur, all of which are listed in the Red Book of Vietnam as threatened with extinction.[1089]

There are 7,500 known species of microorganisms, of which 700 species are useful and 1,500 species are pathogens for humans and animals.[1090]

In the health care field, traditional knowledge used widely in association with medicinal plants contributes significantly to the variety of treatment options available. Vietnam is home to an estimated 12.000 species of higher-level plants, of which 10,500 have been identified. Approximately 3,830, or 36 % of those, have medicinal properties. Vietnamese medicinal plant species account for approximately 11 % of the 35.000 species of medicinal plants known worldwide.[1091] This figure is artificially low because there are many medicinal plants species whose properties are not yet generally known that are used by ethnic minority groups. More than 800 species of medicinal plants are currently used officially; many of these have been domesticated and planted on a large scale, yielding productive harvests. Traditional medicines are used not only to cure common ailments, but are also used in combination with modern medicines to treat other diseases. Vietnam is abundant in TK. The TK constitutes a significant cultural heritage of indigenous and local communities[1092]. Protection of the culture of all ethnic minority groups contributes to maintaining the cultural richness of Vietnam and is one important factor for sustainable development. With the richness and diversity of GR and TK in Vietnam, access and benefit-sharing may become one way to improve sustainable economic growth.

2) Degradation of genetic resources in Vietnam

Extinction and degradation of the genetic resource base continues without effective solutions. These processes are aggravated by many factors including: the increase of the human population brings about the increase in consumption of animal and plant products; the impacts of large-scale commercial agriculture, forestry, and aquaculture; economic planning policies that have not estimated all values of the environment and natural resources; inequity in land and resource ownership and benefit-sharing; lack of knowledge and lack of information on how to use the legal system and institutions to facilitate sustainable use; unscientific basis for land use changes; infrastructure development without

[1089] VACNE, *Supra,* pp. 181, 182.
[1090] Lê and Hồ, *Supra*
[1091] Trần Công Khánh. 2004. *Traditional medicinal plants, indigenous knowledge and fair and equitable ABS.* National Workshop of ABS. Hanoi, Vietnam.
[1092] BEURIER.J-P, *Supra*, p. 424

sustainable planning; overexploitation of biological resources; invasion of alien species; illegal hunting and wildlife trade; environmental pollution and climate change.[1093]

At present, 350 plant species and more than 300 species of animals are at risk, according to the Vietnam Red Book. Currently, 28 per cent of total animal species, 10 per cent of birds, and 21 per cent of reptiles and amphibians are at risk of extinction.[1094]

In addition to 3948 medicinal plants that are recorded, there are a lot of plants that used by 53 ethnic minority people (of. 14% of population), called ethno-medicin plants. Demand on medicinal plants is increasing rapidly. With the thought that medicinal plants are common resources belonging to everybody, or a "gift from God", hundreds thousand tonnes of raw med. materials are exploited from wild plants. This causes to a rapid exhaustion of plant resources and many precious species facing to the risk of extinction.[1095]

Traditional knowledge associated with medicinal plants is not recognized by Vietnam's intellectual property rights system. The long-term interests of the indigenous and local communities that have created the knowledge[1096] have not been taken into account when traditional knowledge associated with Vietnam's genetic resources has been used to create new products. That is one reason why traditional knowledge and customs that underpin local people's sustainable use of genetic resources are declining.

In Vietnam, providers and users of GR and TK are generally unaware of the CBD's, and the Nagoya Protocol's requirements for ABS. Intentionally and unintentionally, users of GRs and associated TK have not taken responsibility for sharing benefits with providers, whose rights have been ignored. Indigenous and local communities, who provide the TK, are even more unaware of its value, and their legal rights to it, so, do not know how to demand compensation. The collection of GR for research, development and commercialization attracts foreign as well as national organizations and individuals. The extent of the loss of GR to unauthorized collection is unknown, as is the scale of the benefits the country may have enjoyed had it been aware and able to claim them. This situation is complicated by Vietnam's becoming a member of the WTO and its obligations for opening to access natural resources, including GRs.[1097]

[1093] Vietnam Environment Administration, *Report of biodiversity conservation management in period of 2005-2010 and orientation of 2011-2015.* Vietnam National Conference of Environment, Hanoi, 2010, Available online: *http://vea.gov.vn/vn/truyenthong/sukien-ngayle/hoinghimttg/khoahocchuyende/Pages/H%E1%BB%99ingh%E1%BB%8BKhoah%E1%BB%8Dcv%E1%BB%81%C4%90ad%E1%BA%A1ngsinhh%E1%BB%8DcB%C3%A1oc%C3%A1oc%C3%B4ngt%C3%A1cb%E1%BA%A3ot%E1%BB%93n%C4%91ad%C3%A1ngsinhh%E1%BB%8Dcqiai%C4%91o%E1%BA%A1n2005-2010v%C3%A0ph%C6%B0%C6%A1ngh%C6%B0%E1%BB%9Bnqqiai%C4%91o%E1%BA%A1n2011-2015.aspx*

[1094] VACNE, *supra*, p. 141.

[1095] TRAN.C.K, Access to medicine plant resources and benefit-sharing in Vietnam, ABS workshop, Manila , 2011, p. 3

[1096] CORREA.M.C, *Supra*, p.8

[1097] Ministry of Natural Resources and Environment. 2008. *Report of Overview of Biodiversity of Vietnam: Synthesis of expert input for project of elaboration of Biodiversity Law*, p. 4. Hanoi. (Unpublished)

In summary, Vietnam is a biodiversity hotspot with many of its species and their genetic resources at risk of extinction. Endemic animals and plants used for food and traditional medicine provide significant economic benefits, but the declining conservation of traditional knowledge indicates that many potential benefits may never be realized. Vietnam must act effectively to regulate ABS and at the same time must ensure the conservation of GR and TK

B - The need for Vietnam to accede to the Protocol

Vietnam became member of the CBD since 1995, but it is not a member of the FAO's treaty. As the CBD's scope of regulation covers all kinds of GR and the Nagoya Protocol is instrument for implementation of the access and benefit-sharing of the CBD that also covers all kind of GR except the cases of Article 4.4 the Protocol. Therefore, GR for food and agriculture in Vietnam also will be regulated by the CBD and the Nagoya Protocol, in case, Vietnam accedes to the Protocol. However, the Biodiversity Law 2008 seems not regulate GR for food and agriculture in its access and benefit-sharing regime.[1098]

Acceding to the Protocol will contribute to implementing Vietnam's responsibilities as a Party to the CBD. Although the Protocol has been criticized as "weak", a positive perspective is that the Protocol is an international incentive and opportunity for countries to develop and improve their own domestic policy and legislation as well as their participation in international cooperation.

One of three main objectives of the CBD is the "the fair and equitable sharing of the benefits arising out of the utilization of GR, including by appropriate access to GR and by appropriate transfer of relevant technologies…"(Article 1). To implement this objective, the Article 15 of the CBS provides obligations on each Contracting Party to create conditions to facilitate access to GR for environmentally sound uses, and to take legislative, administrative or policy measures, as appropriate, with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of GR.

Becoming a Party to the Protocol will create an additional obligation on Vietnam to facilitate access to GR and to ensure the fair and equitable sharing of benefits arising from the use of GR and TK. Acceding to the Protocol will also create an incentive for Vietnam to develop markets for products derived from GR, to improve socio-economic activities related to access and benefit-sharing, and to promote understanding of the values of GR.[1099]

Acceding to the Protocol also may bring opportunities for Vietnam to access international resources for national capacity building to implement the Protocol. Developed

[1098] THOMAS.F, *Supra*, p. 48
[1099] UNEP/CBD/WG-ABS/8/INF/3, *Supra*, p. 28.

countries have begun to contribute funds, which developing countries may be able to access for building their capacity to implement the Protocol.[1100]

In addition, acceding to the Protocol would provide an opportunity to raise awareness among Government officials, communities, the private sector and the public in general of the values and potential benefits of GR and TK, as well as the importance of biodiversity conservation.[1101] Doing so would improve implementation of the existing access and benefit-sharing regulatory regime and contribute to biodiversity conservation, poverty reduction and improving the livelihoods of local communities.

II – National legal system and development of law on biodiversity and access and benefit-sharing

A – Generalities on national legal system

1) National law in relationship with international law

Vietnam's law is affected by socialist legal system.[1102] In common situation of "social legal systems occurred in countries of the civil law tradition", "Vietnam used French law from late nineteenth century".[1103] Currently, Vietnam's law is characterized by a modification model of monism country. Legal norms of international law cannot be applied directly into national law and still requires transformation of the international law into the national law, but, in some cases, the act of ratifying the international law incorporates the law into national law to directly apply. Clause 3, Article 6, Law on Conclusion and implementation of international agreement, 2005, of Vietnam provides that "based on requirements, contents and natures of international agreements, when deciding approval binding of the international agreements, the National Assembly, President, Government shall concurrently decide to apply directly one part or whole international agreements for agencies, individuals when provisions of the international agreements are clear, concrete to implement, decide or propose to amend, supplement, revoke or promulgate legal normative documents to implement those international agreements". Moreover, almost enacted laws provide a similar regulation of application law, like "In case the provisions of international treaties to which the Socialist Republic of Viet Nam is a Contracting Party, contradict the provisions of this Law, the international treaties shall

[1100] CBD, ICNP, Measures to Assist in the Capacity-Building, Capacity Development and Strengthening of Human Resources and Institutional Capacities in Developing Countries and Parties with Economies in Transition. UNEP/CBD/ICNP/1/4, 5 May 2011, para. 6,7. Available online: http://www.cbd.int/absicnp1/documents/. Accessed 4 March 2012.
[1101] *Ibid.*, n. 75, para. 44.
ICNP/1/4, supra
[1102] Hanoi Law University, *Textbook on State and Law*, Hanoi Police Publishing house, 2004,
[1103] QUICGLEY.J, *Socialist law and the civil law tradition*, The American Jounal of Comparative law, vol.37, No4, Autumn,1989, pp 781-808, available at *http://www.jstor.org/stable/840224*, last accessed May 20, 2012

prevail"[1104]. Accordingly, depending on requirements, contents and natures as well as clarity, concreteness for implementation, the international agreements, which ratified by the competent agencies of Vietnam, will take effect directly and immediately or will be integrated into national law through activities of "amend, supplement, revoke or promulgate legal normative documents to implement those international agreements". In author's view, this modification seems to take advantage and avoid problems of both monist and dualist view and current situation of international law making. It may avoid negligence, delay or unwillingness to transform international law, or misinterpretation of international law into national law. It also avoids the problem of "*lex posterior derogat legi priori*" that means original international law has been transform through method of legislation into national law, but then, this national law can then be overridden by another national law as the later law replaces the earlier one. Another problem that international law describes what countries must do, but usually says nothing about regulated persons or entities. Treaties call on countries to "adopt legislative, administrative and policy measures," that cannot be imposed on an individual, thus, until the national law is adopted, the international instrument is binding within the country**.**

2) Some explanation of legal texts system of Vietnam

Types and functions of legal normative texts of Vietnam include:

Constitution, Laws and Resolutions of the National Assembly provide for the fundamental and important matters pertaining political, economic, social regimes, basic rights and responsibilities of the citizens, the organization and operation of State apparatus, on social relations and the activities of citizens, financial and monetary policies, nation, religion, defense and security tasks, to external and internal relations.

Ordinances, Resolutions of Standing Committee of the National Assembly provide for the matters assigned by the National Assembly, explanation constitution and law, supervising the implementation of constitution and law.

Orders and Decisions of State President promulgated to implement the responsibilities and jurisdiction of the State President following the Constitution and Law provided.

Decrees of the Government provide in details to implement above legal documents, provide responsibilities, jurisdiction and machine organization of the Government, concrete methods to implement responsibilities and powers of the Government.

[1104] Article 2, Law on Environmental Protection 2005, Article 3 of Land law 2003, article 2 of Law on Forest Protection and Development 2004, of the Socialist Republic of Viet Nam

Decisions of the Prime Minister promulgated to decide the policy, method of leading, directing and managing operation of the Government, the coordination between the Government's members.

Resolutions of the Judges' Council of the Supreme People's Court and Circulars of Chief Judge of the Supreme People's Court provide to guide the Courts to apply laws in a uniform way and to sum up trial experiences. Circulars of Chairman of the Supreme People's Prosecuracy are issued to define the measures to ensure the implementation of the tasks and powers of the People's Procuracies at all level

Circulars of Ministers provide measures of organization and operation of the establishments directly attached to them, measures to direct, urge, coordinate and supervise their activities, guide to implement the above mentioned legal documents in the scope of management (if it is related to more than one Ministry, ore ministerial agencies, it should be promulgated Joint Circulars and Joint Resolutions)

Resolutions of the People's Council regulate local important social relations, implement the central legal documents. Decisions of the People Committee at levels are issued to implement the resolutions of the People's Council and regulation of the central State agencies, direct the operation of lower State agencies.[1105]

Effect and priority of application order of legal texts are stipulated following the principles: priority of application for the higher valid documents, priority of application for the latest promulgated documents; priority of application for the specialized legal document in comparison with the generic legal documents, non-retroactivity (excluding exceptions).

It is noted that, some texts promulgated by the same competent person but the legal validity is different because of jurisdiction of representation, for example, both Decree and Decision are signed of the Prime Minister but Decree of the Government has higher validity; both Law on Ordinance are signed by the Chairman of National Assembly, but law has higher legal validity. Some legal texts are in different name but have the same validity, such as Law and Code (but scope, size and contents of regulation are different, at present, Vietnam has only 6 codes: criminal code, civil code, labor code, civil procedures code, criminal procedures code, maritime code.)[1106]

B – Development of law on biodiversity and access and benefit-sharing

[1105] Summary from the Law 17/2008/QH12 on the issuance of legal texts dated *03th June 2008 of the Socialist Republic of Vietnam*
[1106] *Ibid*

1) Access and benefit-sharing legislation before the Biodiversity Law

Before the Biodiversity Law[1107] was enacted in 2008, Vietnam had no clear and comprehensive legal provisions on access and benefit-sharing,[1108] much less a comprehensive access and benefit-sharing regime. There were only some general provisions, which governed one or more aspects of access and benefit-sharing, such as protection and commercialization of plant varieties and livestock breeds, exploitation of aquatic resources, patents for plant varieties, and export of GR.

The Ordinance on Plant Varieties and Ordinance on Livestock Breeds 2004 guarantee equality and affirm the crucial principle that organizations and individuals who engage in activities related to the development of plant varieties and livestock breeds have the right to control their innovations, and lawfully benefit from them. These ordinances stipulate conditions for producing and commercializing plant varieties and livestock breeds including quality standards and labeling requirements.

For aquatic GR, the Fisheries Law, 2003 enables the exploitation and sustainable use of aquatic resources by organizations and individuals, promotes aquaculture on seas, lakes, reservoirs, lagoons, ponds and other natural water sources, and establishes obligations to regenerate aquatic resources. The law also stipulates conditions for fisheries, requiring fishing licenses and providing for the issuance of certificates that specify rights to exploit aquatic resources when statutory conditions have been met. The rights set out in such exploitation certificates are protected by the State.

The Law on Forest Protection and Development, 2004, stipulates that organizations and individuals have rights to exploit and enjoy the benefits of forest products in accordance with their obligations as set out in regulations governing each category of forest.

Export of GR is regulated in the same way that other types of exports have been regulated, by listing exports that are permitted and those that are not. Existing lists, however, do not cover all GR under Vietnamese sovereignty that have actual or potential value. This is partly due to the fact that many species have not yet been scientifically identified and that GR of known species may have value that will only be recognized in the future.

The legal instruments that currently regulate export of GR have been issued by the Ministry of Agriculture and Rural Development (MARD), which is also responsible for fisheries, and include: Decree 32/2006/ND-CP of dated 30 March 2006 on the management of endangered forest fauna and flora; and Decree 82/2006/ND-CP of 10 August 2006 on the management of the import, export, re-export, introduction from the sea, transit,

[1107] Law No. 20/2008/QH12 of 28 November 2008, *of the Socialist Republic of Vietnam* can be downloaded from http://www.theredddesk.org/countries/vietnam/info/law/law_on_biodiversity_vietnam, accessed 6 March 2012

[1108] Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ) and IUCN-Vietnam Country Office. 2004. *Capacity-Building for Access and Benefit-Sharing in Vietnam*. Available online: http://www.gtz.de/de/dokumente/en-biodiv-vietnam-capacitybuilding-2004.pdf. Accessed 3 March 2012.

breeding, rearing and artificial propagation of endangered species of wild fauna and flora. GR not included in the lists in these Decrees can be legally exported after completing quarantine requirements.

There are documented cases of foreign organizations and individuals having commercially exploited GR from Vietnam that were collected and exported ostensibly for scientific research. In other cases, foreign individuals and organizations, who work in cooperation with domestic stakeholders to access GR, but shared benefits, were disproportionately small in comparison with those enjoyed by the foreign partners. Some Vietnamese scientists who have had to send samples to laboratories abroad due to domestic lack of equipment and technology, have not entered into prior agreements to establish conditions for use of the samples and the results of analyses and to specify the rights and benefits that should accrue to Vietnam. Consequently, some new species found in Vietnam have been identified by non-nationals and the standard samples used for taxonomic identification are held outside the country.[1109]

Patenting of plant varieties and livestock breeds raises issues related to access and benefit-sharing. Effective patent protection of plant varieties and livestock breeds would ensure fair and equitable sharing of benefits as well as promote the creation of useful plant varieties and livestock breeds and the conservation and enhancement of genetic diversity. Patents on plant varieties are regulated by the Law on Intellectual Property, Decree 104/2006/ND-CP dated 22 September 2006 on guiding implementation of the Law on intellectual property right to plant varieties which provides for granting a certificate that recognizes and protects intellectual property rights in new plant varieties. There is no corresponding legal recognition of rights in new livestock breeds, although the existing regulatory regime covers research leading to the creation of new breeds and naming them. Similarly, there is no protection for local communities' rights in traditional livestock breeds, including, for instance, Mong fowl and Dong Tao fowl, nor is there any legal protection for the knowledge associated with traditional medicines.[1110] Legal protection for new livestock breeds is essential to encourage scientific research for agricultural development and control, establish the responsibilities of livestock breeders and provide for accountability, and to promote awareness of and prevent potential adverse effects of new livestock breeds.

Notwithstanding the legal instruments discussed above, most issues arising in the context of access to GR are not regulated in Vietnam, in particular the fair and equitable sharing of benefits arising from their use. The Biodiversity Law contains framework

[1109] Vietnam Environmental Protection Agency. 2004. *Report on ABS and challenges in implementation of CBD in Vietnam*, presented during National Workshop on ABS, Hanoi.
[1110] Võ Văn Sự, *http://www.vcn.vnn.vn/PrintPreview.aspx?ID=2625*
Accessed 6 March 2012

provisions for regulating access and benefit-sharing that have been partially regulated, but which still require additional regulations for their implementation.

2) Access and benefit-sharing under the Biodiversity Law and its regulations

Access and benefit-sharing is regulated by Section 1 (Articles 55-61) and some related Articles of Section 2 of Chapter V of the Biodiversity Law and by Decree 65/2010/ND-CP of 11 June 2010 guiding implementation of the Biodiversity Law, which are the basis of Vietnam's national access and benefit-sharing regime. Their provisions are in accordance with the basic principles of the CBD.

Exercising the principle of sovereign rights over biological resources, including genetic resources, as expressed in Article 3 of the CBD, and the country's responsibilities to maintain, conserve, and sustainably use genetic resources in national territory, Article 55.1 of the Law on Biodiversity provides that, "The State uniformly manages all genetic resources in Vietnamese territory". This confirms that the State, on behalf of the people of Vietnam, is the sole owner of genetic resources in national territory, in accordance with Article 17 of the Constitution of 1992.

Organizations and individuals assigned to manage GR have certain rights and responsibilities set out in Article 56 of the Biodiversity Law. Rights to share benefits are specified in Article 58 and Article 61.

PIC and MAT are governed by the Biodiversity Law and specifically regulated by Decree 65/2010/ND-CP.

The Biodiversity Law sets out procedures for access to GR (Article 57), requires a contract for access and benefit-sharing (Article 58), and a permit for access to genetic resources (Article 59), and specifies minimum requirements for both the contract and the permit. The Law also establishes conditions for ensuring biosafety and protecting ecosystems during access.

Procedures for access and for applying for an access permit are provided by Article 18.2 and 18.3 of Decree 65/2010/ND-CP, which provides that the permitting authority must act within 45 days of receipt of a complete application for access to GR. If a permit is not granted, a written justification must be provided to the applicant.

Article 18.3 of Decree 65/2010/ND-CP designates the Ministry of Natural Resources and Environment (MONRE) as the permitting authority for access to the GR of endangered species. Authority to grant access permits is delegated to the Biodiversity Conservation Agency under Article 6.2 of the Biodiversity Law, Article 2.8.a of Decree 25/2008/ND-CP of 4 March 2008 on the functions, responsibilities, powers and structure of MONRE, and Article 2.6 of Decision 132/2008/QD-TTg of 30 September 2008 of the Vietnam Environment Administration which is part of MONRE.

Provincial People's Committees (PPC) are designated as the permitting authorities for access to GR of non-protected species.

For the purposes of Article 13 of the Protocol, MONRE and the PPC could be competent national authority (s) and the responsibilities of those bodies are prescribed clearly. A national focal point is not explicitly identified, but as Article 69.3 of the Biodiversity Law specifies that MONRE is the national focal point for the CBD, there is a presumption that MONRE would become the national focal point of the Protocol and that its responsibilities would be carried out by the Biodiversity Conservation Agency.

Section 2 – National access and benefit-sharing legislation of Vietnam and integration of the Nagoya protocol

§ I - Vietnam's access and benefit-sharing legislation in question of conformity with the Protocol and applicability

The provisions of Vietnam's Biodiversity Law and Decree 65/2010/ND-CP, both adopted prior to the adoption of the Protocol, conform substantially to the Protocol. The Protocol provides generally that "Each Party shall take appropriate, effective and proportionate legislative, administrative or policy measures…" to ensure compliance. The Protocol does not, however, provide criteria to define such measures. In general terms, therefore, Vietnam's national ABS regulatory regime is in conformity with the Protocol.

A - Legal status and ownership of genetic resources

The first job of law must give the GR a status that permits it to become a part of legal system. If the GR is considered a subject of law, its protection will be maximizing. If it is considered an object of law, it can not be defended. Accordingly, one judicial status is privileged to its quality of the GR. It is important to underline a question that whether the parties are able to develop a legally consistent understanding regarding the nature of GR and of the rights to own and use them or not. Clarity on these subjects will not only facilitate but also is a prerequisite for the successful consideration of the international regime.

The CBD and the Protocol only affirm the principle of sovereign rights over natural resources but not provide on property right. States enjoys the sovereign right and have jurisdiction to regulate property right of GR. "There is a difference between sovereign rights and property rights. The property rights grant their holder the right to use, to enjoy and to own the thing or idea over which s/he has such rights. The sovereign rights are those rights that are exercised by the State in two different ways: first, in regulating the behaviour of its own inhabitants by promulaging and enforcing national laws; and second, by being recognized internationally as an independent state by other States. Thus, the

soveverign rights of the States over their GR do not automatically give them the right to use, enjoy or own such GR"[1111].

In case of Vietnam, the Biodiversity Law provides that "The State uniformly manages all GR in Vietnamese territory" (Article 55.1). This confirms State ownership of all GRs in national territory on behalf of the people of Vietnam. This ownership regime is consistent with Article 17 of the Constitution of the Socialist Republic of Vietnam, 1992, as amended in 2001 that provides:

"The land, forests, rivers and lakes, water sources, underground natural resources, resources in the territorial waters, on the continental shelf and in the air space, capital funds and properties invested by the State in enterprises and projects in the various branches and fields of the economy, culture, social life, science and technology, foreign affairs and national security and defense and other property defined by law as belonging to the State fall under the ownership of the entire people."

Exercising its property right, the State assigns organizations and individuals to manage GR with specific rights and responsibilities under different types of property rights stipulated in Article 56 of the Biodiversity Law and Article 18 of Decree 65/2010/ND-CP. In theory, "the property rights differentiate between four types of property rights: the right to use the resource, the right to retain the profits of the resource, the right to modify the form or appearance of the resource, the right to transfer the entire resource or portions of it to others and to retain the gains."[1112] The organizations and individuals manage GR are: i) Management Board of protected areas or organizations are assigned to manage GR of Protected Areas; ii) Heads of biodiversity conservation facilities, scientific research and technological development institutions, and GR storage and preservation establishments shall manage their own GR; iii) Organizations, households and individuals assigned to manage or use land, forests or water surface shall manage GR assigned to them for management or use; iv) Commune-level People's Committees shall manage GR in their localities (Clause 2, Article 55 of Biodiversity Law). Those organizations and individuals have property rights and also responsibilities to manage GR. The right to benefit-sharing is provided by Articles 58 and 61 of the Biodiversity Law, and elaborated by Article 19 of Decree 65/2010/ND-CP.

In legal doctrine, "a general classification of property as tangible, corporal, or intangible has been established. In case of GR, there may be a basis for distinction between the rights over the physical entity (physical property) and over the genetic information that the resources contain (intangible property)"[1113]. This last represents the real value of the

[1111] STOIANOFF. P. N, *Supra*, p. 229
[1112] TAUBER.S, MULLER.H.K, JACOB.T, FEIT.U, *Supra*, p.186

[1113] VOGEL.J.H et al., *'The Economics of Information, Studiously Ignored in the Nagoya Protocol on Access to Genetic Resources and Benefit-sharing'*,7/1 *Law, Environment and Development Journal* (2011), p. 55, states that

resources, and where the judicial problems are particularly complex. "The material and geographic aspects of GR pose an extraordinary challenge because most living organisms reproduce and disperse naturally, irrespective of restrictive measures that policy makers wish to lay on them, carrying out into the world the very qualities that bioprospectors and users are seeking rights and provider countries are seeking to control. This biological fact is compounded by the elusive nature of information as valued added: information, even when derived from biological resources, is intangible and therefore requires a special property regime."[1114] However, in common understanding of ownership, no distinction has been made between ownership of tangible and intangible element of GR. A complicated problem may arise following the Biodiversity Law for the case of access GR included TK associated with that GR. While GR is physical property right that belongs to the State on behalf of entire – people ownership, TK is intangible property that may belong to certain individual person, communities or undetermined owner such as folk knowledge, public TK.

B – Elements of access and benefit-sharing

1) Access

Procedures for access to GR are set out in Article 57 of the Biodiversity Law, which stipulates three key procedural requirements: to register access to GR; to enter into written contracts on access to GR and benefit-sharing with organizations or individuals assigned to manage GR under Articles 58 and 61 of the Law; and to apply for licenses for access to GR under Article 59 of the Law. Decree 65/2010/ND-CP provides more detail on the procedural steps required for access. These include a written register, signing an agreement on access to GR and benefit-sharing, submitting an application dossier to the competent national authority, and obtaining the permit. However, these provisions do not provide deadlines, guidelines or the forms required. The provisions of Decree 65/2010/ND-CP are too general to be applied in practice and therefore do not meet the requirements of the Protocol for legal certainty, clarity and transparency of domestic access and benefit-sharing legislation and for fair and non-arbitrary rules and procedures for accessing GR in a cost-effective manner and within a reasonable period of time.

The Decree 65/2010/ND-CP provides some basic steps, they include: Step 1: written registration at PPC where the GR located. After approved by the PPC (Article 18.2.a), applicant goes to Step 2: to sign written agreement on access and benefit-sharing with organizations and individuals who are assigned to manage GR, the commune People Committee certifies for the agreement (Article 18.2.b) but duration is not provided. Step 3, the applicant send dossiers to the competent national authority to grant the access permission. The authority is defined that the MONRE grant permit of access to GR of

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"Biological resources exhibit both tangible and intangible aspects the latter conceptualised as a set of natural information where value currently added in a patent is access to a subset not previously accessed."

[1114] MEDAGLIA.C.J, SILVA.L.C, *Supra*, p. 40

species with special priority of protection and the remaining species belongs to authority of PPC, the term is 45 days since the date of receipt of sufficient dossiers. The competent national authority can refuse to grant permit and send written notice of refusal to the applicant but there is no provisions on reasons of the refusal (Article 18.3.b). Step 4 is to notify the granted access permit to the Commune People Committee, agreed organization and individual who are assigned to manage GR.

Problem here is demarcation of jurisdiction of granting permit for access GR of protected species between MARD and MONRE when there is serious conflict and overlapping in State management between them following the Biodiversity Law 2008, the Law on Forest Protection and Development 2004 and the Law on Fishery 2003.[1115] Following the Biodiversity Law, MONRE is assigned as Competent national authority for granting the permit for access GR, however, in practice, the MARD is managing most of the country's protected area and protected species and holds most of the national databases and information on biological resources following the Law on Forest Protection and Development 2004 and the Law on Fishery 2003. MONRE, therefore, will meet with difficulties in trying to grant licencse to access GR of protected species, for example. Similar difficulties will arise in granting access licenses at provincial level. If MONRE is authorized to grant licenses to access the GR of protected species, provincial Departments of Natural Resources and Environment (DONRE) will also be authorized to grant access licenses for that purpose. DONRE have no information and databases on species, and the capacity of DONRE with respect to biodiversity in general and access and benefit-sharing is particular is very limited. Some DONRE have no officer specialized in managing biodiversity, their understanding of biodiversity and the Biodiversity Law is limited, and there are no provincial action plans on biodiversity conservation. [1116]

In addition, access to GR always attaches to TK associated with GR, but this is under management of the National Intellectual Property Agency of the Ministry of Science and Technology (MOST). Therefore, if there has no cooperation mechanism, the MONRE will be very difficult to implement its authority of granting permit for access. Moreover, both the Biodiversity Law 2008 and Decree 65/2010/ND-CP do not stipulate access to GR attaches with TK associated with that GR. Moreover, with such regulations on the access GR can not be deployed in practice if no access and benefit-sharing agreement stipulated by Article 58 of the Biodiversity Law 2008. It requires at least following matters: i) The purpose of access to GR; ii) Types of GR and collected volume; iii) Location of access to GR; iv) Plan of access to GR; v) The transfer to third party if any; vi) R&D activities and production of commercial products from GR; vii) The parties of R&D and production of

[1115] Law and Policy of Sustainable Development Research Center (LPSD), *Report on legal issues of responsibilities of Ministries and line ministries of State management on biodiversity*, MONRE – JICA, 2010

[1116] Report of the Biodiversity Conservation Agency 2010, Report of social survey on implementation situation of the Biodiversity Law 2008 (un-published report).

commercial products from GRs; viii) Location of R&D activities and production of commercial products from GR; ix) Sharing benefits to the State and other stakeholders, including both the distribution of intellectual property right of results of innovative based on access to GR and TK

However, there is no more detailed guidance, even the Decree 65/2010/ND-CP, it will be very difficult to local people and local officials to implement the provisions on access and benefit-sharing agreement. In fact, with current awareness and capability of the local people and officials, it is impossible for them to negociate and enter to the access and benefit-sharing agreement with the users to protect their rights and benefit. The Nagoya Protocol also has Article 19 on model contractual clauses for development, update and use of sectoral and cross sectoral model contract clauses for MAT. Therefore, development of model contractual clauses is necessary for implementing practice of Vietnam and realize the Protocol's provisions.

In addition, the Biodiversity Law and Decree 65/2010/ND-CP do not provide on enforcement of law. There is only a statement that "disputes and complaints related to access and benefit-sharing shall be resolved in accordance with Vietnamese law and international treaties that Socialist Republic of Vietnam is a member" (Article 58.5 of the Biodiversity Law). While, the Protocol encourages providers and users must take into account the specific dispute resolution when developing MAT such as: jurisdiction of dispute resolution, applicable law and the alternative dispute resolution such as mediation and arbitration, this statement of the Article 58.5 of the Biodiversity Law can not meet the requirements of providers and users of GR and TK.

Applying for a license is a mandatory step in the procedures of access to GR. The access permit is specified by Article 59, the Biodiversity Law 2008. This access permit and access and benefit-sharing agreement is base to ensure compliance with access and benefit-sharing law following PIC and MAT.

There is no differentiation between domestic users and foreign users to GR. The law also has no provision for commercial intermediators between GR providers and users. However, feasibility of State management for domestic users is low in case of commercialization, R&D and production of GR and TK.

2) Benefit-sharing

The Biodiversity Law and Decree 65/2010/ND-CP have created a basic legal framework with minimum regulation for benefit-sharing under MAT as set out in an access and benefit-sharing contract. Vietnam's regulatory regime conforms to the Protocol, which specifies only that "Each Party shall take legislative, administrative or policy measures, as appropriate…" (Article 5.2) and requires only that Parties "establish clear rules and procedures for requiring and establishing mutually agreed terms" (Article 6.3.g) without

setting out concrete requirements. In spite of its conformity with the Protocol, it is difficult to ensure fair and equitable benefit-sharing under Vietnam's current access and benefit-sharing regulatory regime. There are many serious loop-holes for fair and equitable benefit-sharing.

Under the Article Article 61 of the Biodiversity Law, benefit arising from access to GR must be shared to three parties: 1- The State; 2- Organizations, households and individuals who are assigned to manage GR; 3- Organizations and individuals licensed for access to GR and related parties as prescribed in the licenses. The base to share benefit arising from access to GR is the access and benefit-sharing agreement following the law. Obviously, this article does not include the indigenous and local communities who provide TK associated with GR. The indigenous and local communities also are not one of related parties as prescribed in the licenses of access to GR following Article 59.3 of the Biodiversity law, although, Article 60.2.c provides "To share benefits with related parties, including the distribution of intellectual property rights over invention results based on their access to GR and copyrights of TK associated with GR".

The same problem to share benefit to local communities resident in buffer zones of the protected areas, while the local communities should be the priorities targets groups to share benefit to encourage them to join conservation activities following approach of community based conservation. Because, Article 55.2 of the Biodiversity Law only mentions the Management board of the protected areas and organization assigned to manage GR in the protected areas, who shall be shared benefit arising from GR of protected areas under the Article 61.2 of the Biodiversity Law. The local communities reside in and near around the protected area that are not assigned to manage GR of the protected areas, shall not be shared those benefit. Moreover, following existing law, area of buffer zones is not accounted for the area of protected areas[1117], thus, it is much more difficult to find legal bases to share benefit arising from GR of protected areas to the local communities residing in and near the protected areas.

Decree 65/2010/ND-CP provides a list of benefit that includes monetary benefit and non-monetary (Article 19.1). They include: (a) Sharing results of R&D, produce commercial products and profits earned from commercialization of products of GR; (b) Cooperative R&D, information science, engineering related to GR; (c) Transfer of technology development for providers; (d) Training, strengthening the capacity of R&D of GR; (e) Contributions to local economic development, development of public works, support poverty alleviation; (f) Direct benefit share in cash or in kind; (g) other kinds of benefit according to written agreements and regulations in licenses for access to GR; h) intellectual property rights for creative results on the basis of access to GR in accordance

[1117] Clause 4, Article 24, Regulation on forest management issued by Decision 186/2006/QĐ-TTg dated 14/8/2006

with the Law on Intellectual Property. The above kinds of benefits cover broadly, in addition in case of necessity; involved parties may refer to Appendix 1 of the Nagoya Protocol on kind of monetary benefits or non-monetary or in Bonn Guidelines on access to genetic resources and benefit-sharing.

One progressive point of Decree 65/2010/ND-CP is to qualify ratio of total benefit arising out from access to GR that is to share to related parties following license and agreement but not less than 30% of benefits shall be converted into cash (Paragraph 2, Article 19). However, this provision seems to be infeasible and difficult to apply when it does not specify how to determine the total benefits, the time of benefit arises out to be shared, the time of termination of sharing benefit from chains of benefit arising from R&D, transfer and business benefits arising in the case of secondary use onwards.

There is also one big gap of regulating benefits arise from utilization of GR which has been accessed without access license or access and benefit-sharing agreement or did not meet the PIC and MAT. The Biodiversity Law 2008 and Decree 65/2010/ND-CP do not mention to share this kind of benefit, they mostly refers to benefits derived from access to GR based on license and agreement (Article 61.2, the Biodiversity Law 2008) and (Article 19.2, Decree 65/2010/ND-CP). In fact, many GRs of Vietnam had been accessed and taken out of the country before the CBD or the Biodiversity Law 2008. The right to be shared benefit is still arisen for continuous utilization of those GR. These benefits may be considered as national property and contributed to national trust fund for biodiversity conservation. Although, the CBD and the Protocol does not clarify this case of sharing benefit arising out from GR accessed without PIC and MAT, the guidelines on access and benefit-sharing for user of Japanese government clarifies that "in the case where in the laws and administrative measures of the providing country regarding pre-CBD matters provide otherwise, it is necessary to comply with them."[1118]

Decree 65/2010/ND-CP MONRE provides that MONRE, MARD and Ministry of Finance cooperate to issue a joint-circular guiding the management and use of shared benefits from access to GR. This may be a place to over the gap of GR accessed before the CBD and the Biodiversity Law, but it limit to GR managed by the State, the other GR and benefit is still open that should require amendment of the Decree.

3) Traditional knowledge

The Biodiversity Law defines "TK associated with GR means knowledge, experience and initiatives of indigenous and local people on the conservation and use of GR" (Article 3.28). It also provides some general statement that "Encouraging organizations and individuals to invest in and apply scientific and technological advances

[1118]Ministry of Economy, Trade and Industry of Japan and Japan Bio-industry Association *Guidelines on Access to Genetic Resources for users in Japan,* 2006, p.13

and TK to the biodiversity conservation and sustainable development, and guaranteeing their lawful rights and interests" (Article 5.3).

However, as analyzed above, provisions on access and benefit-sharing agreements and subjects to be benefited do not include TK provider. While the Article 60.2.c only stipulates to share benefits with related parties, including the distribution of intellectual property rights over invention results based on their access TK's copyrights. That means benefits only are shared when the TK have copyrights. Furthermore, the current regime does not provide IPR for TK. Now, there is only a general provision of Article 64 on TK copyright on GR "The State protects TK copyrights on GR and encourages and supports organizations and individuals to register TK copyrights on GR". And it is assigned to MOST "shall assume the prime responsibility for, and coordinate with concerned ministries and ministerial-level agencies in, guiding procedures for registration of TK copyrights on GR." Until now, the MOST has not issued yet any guiding procedures for registration of TK copyrights on GR. In addition, there is no provision clarify right and benefits of indigenous and local communities, it is still a gap. While from practical experiences, Westra.L states that "in such cases, the role of government ministries and agencies should be to protect not only the valuable biodiversity, but also the indigenous peoples who are its *de facto* custodians."[1119]

Vietnam is member of WIPO and WTO. Vietnam also is member of the 1995 ASEAN Framework Agreement on intellectual property cooperation. In Vietnam, intellectual property rights are regulated by one chapter of Civil Code 2005, the Law on Intellectual Property 2005, Decree 104/2006/ND-CP dated 22nd September 2006, on providing in detail and guiding implementation of the Law on Intellectual Property to plant varieties.

In fact, some kinds of TK was protected under intellectual property rights such as Geographical Indications, Indication of Origin such as "Phu Quoc" for fish souse, "Moc Chau" for green tea, traditional medicines for Vietnamese Ginseng Ngoc Linh, and other granted patents for snake bike medicines, medical oils....[1120]

Question of public available TK may arise that: who will become the owner of such TK? Because there was no identifiable holder of the TK, but such TK was not freely accessible and the PIC and MAT requirements should also apply. Therefore, it requires registering to apply copyright for protecting national benefit to public TK of Vietnamese. This issue was raised by India and China, during negotiation of the Nagoya Protocol[1121],

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1119 WESTRA.L, 2008, *Supra,* p.36

1120 *https://docs.google.com/viewer?a=v&q=cache:5MV1fDB_StkJ:www.apaaonline.org/pdf/committee_reports/emerging_ipr/Vietnam.doc+Vietnam+%2B+genetic+resources+%2B+benefit+sharing&hl=fr&gl=fr&pid=bl&srcid=ADGEESqESG-2TklDpLzU_8otYXeW6SQwzArjsK0YrET8iLHmVqBEX6N3zg-LkWc_eM12gdxZt-vXGqwC4m7xOv3oJWdR1bNylFdd7pMO_f_XekQvajg_iWTZ7KzNBEWrBXOs3GkAsqnb&sig=AHIEtbR_6LRUYzgl_hFvLNvpKb1ssAeztw*

1121 NIJAR.G.S, *Supra*, p. 28

logically, it is presumed that the Government will be representative for public available TK, but which State management agency will be authorized to provide that has no answer.

4) Compliance

Compliance, enforcement is important to ensure the objectives of the Protocol, the CBD on access and benefit-sharing fair and reasonable are realized. The Protocol requires "each Party shall take measures, as appropriate" (Article 17) some measures are provided by the Protocol, including internationally recognized certificate of compliance (the certificate) that is constitute by a permit or its equivalent issued in Article 6.3.e of the Protocol and made available to the access and benefit-sharing Clearing House (Article. 17.2).

In Vietnam, the permit for access to GR, which is presumed to become the certificate if Vietnam accede to the Protocol and meet requirements of Article 17.2 above, is provided by Article 59 of the Biodiversity Law. Accordingly, the Law provide conditions to applicants to obtain the permit for access to GR that include: (a) Registering with a competent state management agency; (b) Having signed access and benefit-sharing agreement with the organization, household or individual assigned to manage GR; (c) Access to GR does not fall into the cases of access to GR of species are on the list of endangered species prioritized for protection, except cases licensed by competent state agencies and the use of GR threatens to harm humans, the environment, security, defense or national interests.

The permit for access to GR shall contain the following information: (a) Purpose of GR's utilization; (b) GR to be accessed and the volume of GR to be collected; (c) Location of access to GR; (d) Activities related to GR; (e) Periodical reporting on the results of R&D or production of commercial products related to GR to be accessed. (Article 59.3 of the Biodiversity Law)

In comparison with Article 17.4 of the Protocol requires the minimum information required for the certificate when it is not confidential that is different with the Article 59.3 of the Biodiversity Law. The Article 17.4 requires the certificate shall contain the following minimum information "(a) Issuing authority, (b) Date of issuance, (c) The provider, (d) Unique identifier of the certificate, (e) The person or entity to whom PIC was granted, (f) Subject-matter or GR covered by the Certificate, (g) Confirmation that MAT were established, (h) Confirmation that PIC was obtained and (i) Commercial and/or non-commercial use". Therefore, in case of Vietnam accede to the Protocol, it is necessary to incorporate or interpret the information of Article 17.4 of the Protocol in to the permit for access to GR that to meet the requirements of the Protocol to make the permit become the certificate.

In accordance with the contents of the permit under Article 59 and 60 of the Biodiversity Law, the applicants have following rights and obligations: "(a) To investigate and collect GR and carry out other activities as indicated in their licenses for access to GR;

(b) To take out of the Vietnamese territory GR not on the list of those banned from export under law; (c) To trade in products made from GR they are permited to access; (d) To have other rights as specified in their permit for access to GR and access and benefit-sharing agreements". The applicants have following obligations: "(a) To adhere to the provisions of their permit for access to GR; (b) To submit reports to competent agencies to grant permit for access to GR on the results of R&D or production of commercial products according to the time prescribed in the permit; (c) To share benefits with related parties, including the distribution of intellectual property rights over invention results based on their access to GR and TK's copyrights on GR; (d) To have other obligations as specified in their permit for access to GR and access and benefit-sharing agreement." Those are an open clause with wording "other rights, obligations as specified by the permit for access to GR, access and benefit-sharing agreement". Therefore, when entering to access and benefit-sharing agreement, parties take into accounts the terms and conditions on access and fair and equitable benefit-sharing.

The question is that if above mentioned obligations are broken, which will enforcement regulations be applied? Decree on handling administrative violations in the field of biodiversity is still not issued. The provisions on handling of administrative violations in the field of environment, in fisheries of forest protection and development have not included the access and benefit-sharing issues.

The breach of contractual obligations on access to GR and sharing benefits following access and benefit-sharing agreement that can apply the general provisions of the Civil Code 2005, but will not be effective when there is no general guidelines in consideration of characteristics of the access and benefit-sharing issue. Especially, a common concern of most provider countries is that violation happened outside their territory when the accessed GR is taken out from their country after the access and benefit-sharing agreement and permit for access is granted, while the Nagoya Protocol provides flexibility on this matter and has no specific measures for user country. Therefore, national legislation of each country would be better to be elaborate and precise in order to support as much as better for the enforcement, notably, the introduction, reference to foreign law, mutual support mechanisms, bilateral judicial cooperation, measures of reciprocity.

Institutional mechanisms to ensure implementation, compliance and enforcement of Vietnam with access and benefit-sharing issues have not been assigned in specific responsibilities. Meanwhile, the Nagoya Protocol requires a series of national institutions for monitoring and enforcement such as checkpoints established under Article 17.1 establishment of one or more National Competent Authorities under Article 13.1, the National Focal Points under Article 13.3. Therefore, if it accedes to the Nagoya Protocol, Vietnam needs to improve specific institutional access and benefit-sharing clearly to ensure the new national interest perspective, especially in aspect of provider country of GR. In

addition, to protect national rights and benefit and to contribute to the CBD's implementation, Vietnam needs to develop stronger regulations for compliance with and enforcement of the access and benefit-sharing regime.

§ II – Access and benefit-sharing in practice and integration of the Nagoya Protocol into national law

A – Access and benefit-sharing in practice in Vietnam

As the above analysis on the current access and benefit-sharing legal framework of Vietnam indicates, most of its provisions are general statements, inapplicable without more elaborated guidance.[1122] Therefore, there is no official assessment from State agencies on practice in the implementation of access and benefit-sharing law. However, even prior to the adoption existence of national access and benefit-sharing legislation, access and benefit-sharing activities have been happened. This section provides an analysis of some typical access and benefit-sharing's cases in Vietnam that may justify the analysis of national legislation above, reflecting provisions of the Protocol and supporting Vietnam's consideration of the needs to accede to the Nagoya Protocol.

It is noted that information on the following cases was collected mostly from the foreign reports and studies and from the research institution. Most of these cases happened before the Law on Biodiversity, 2008. The CBD's National Focal Point of Vietnam and other Vietnamese providers have not collected information on access and benefit-sharing or have no concept of access and benefit-sharing.[1123] This indicates that awareness of the access and benefit-sharing issue in Vietnam is limited and capacity is very weak; these will be challenges to integrating the Nagoya Protocol in to national law of Vietnam. The following cases show the diversity of users and providers involved. The types of GR involved were plant varieties for food and agriculture, plants for medicine and for cosmetics, microorganism and enzymes. Some of the GR came from protected species; TK was associated with some of the GR and not with others.

[1122] The Biodiversity Law 2008, is the law that governs access and benefit-sharing in Vietnam. It came into forces on 1th July 2009, Decree 65/2010/NĐ-CP on guiding the Biodiversity law, was issued on 11 June 2010 and took effects on 30 July 2010

[1123] The author was consultant to the Biodiversity Conservation Agency of MONRE to prepare the report for consideration of acceding to the Nagoya Protocol and examined all related information.

1) Nature's Way with Panax vietnamensis[1124]

The user was Nature's Way – a dietary supplement manufacturing and marketing company based in the USA. The main categories of products produced are herbs or botanicals, vitamins, minerals and amino acids. For a number of years, Nature's way worked with contacts in Vietnam to develop a direct research and sourcing relationship for a recently-discovered species of ginseng Panax vietnamensis. This species had not previously been marketed in the USA and showed great promise. It was subsequently discovered to be endemic to a region of Vietnam where it is used traditionally and where cultivation for local markets was underway.

Nature's Way spent nearly 18 months in its attempts to track down researchers and companies in Vietnam – a very laborious process, then hired an intermediary Rem Ventures to help identify collaborators and sources of materials in Vietnam, Rem Ventures to help identify collaborators and sources of materials in Vietnam. The intermediary was Rem Ventures – a small private concern located in Tukwila, Washington, with nearly a decade of business in Vietnam which conducted intermediary research and provided brokering assistance for the relationship.

While Rem Ventures was successful in securing samples of locally produced tablet, it was difficult to further identify who actually had control over the plant resources and to whom the company should speak directly about sourcing partnerships. The providers were finally determined to be the PPC of Kon Tum province, represented in local Sedang communities in the Central Highlands where the plant is found, and the Government of Vietnam, MARD in the Central Highlands, university researchers – conducting ongoing work of Panax Vietnamenis.

At the beginning of the negotiation, the Nature's Way planted to invest in Vietnam to cultivate the Panax vietnamensis. The Nature's Way launched a 5-30 year investment program to cultivate the plant in the area in order to provide income to poor local communities (350 members of the Sedang ethnic group) while helping to protect the plant from over-harvesting in the wild, but it had limited local capacity to manage implementation of such a strategy over time and to the standards required. The benefit-sharing agreement was that 70 % of the total produced would go to Natrure's Way, and 30 % to the Government. Nature's Way would reimburse the Government for the cost of labor, material and other expenses, and 25 % of the budget would be used to reestablish the

[1124] Panax vietnamenis is an herbaceous plant, it was discovered by scientist during a botanical expedition in the montane forest of Ngoc Linh region, Kon Tum Province. It's one kind of Gingseng that has long been used by the Sedang Ethnic group living in Truong Son range. It is used locally as a secret life – saving medicine for the treatment of a range of diseases and to enhance physical strengthen. It was only in 1985 that the plant was designated as a new species. Local named as Sam Ngoc Linh, Panax Vietnamenis is included in the Redbook of Vietnam which list 250 rare, threatened and endangered medicinal botanicals. The description of this case is adapted from TEN KATE. K. and LAIRD.S. A, *The commercial use of biodiversity. Access to genetic resources and benefit-sharing, Earthscan*, London, 1999, p.113

plant in its natural habitat. “Researchers at the university had contributed a great deal over the years of cultivation and medical research on the species and Nature’s way considered it important to support their efforts as well.” The benefits suggested for this group included equipmet, training and support for graduation, research exchanges with US universities, sponsorships for scientific meetings, among other things. However, cultural, commercial and political factors made it difficult for the company to commit to a longterm investment despite a significant desire to do so. Those include the limited value placed on benefits for local communities and conservation of the species by some government officials, the lack of understanding within government of the value of the species to the country and a sense that the terms of the commercial relationship would keep shifting. It was found that it was easier to get phytosanitary permits to export bulk raw materials from Vietnam than it is to get a permit to ship out herbarium species. There need to be controls on the export of seeds and seedlings, especially for rare, threatened and endangered plants.

Finally, Nature’s Way decided to continue work on this project through a non-profit organization or foundation experienced in this type of project development. The company collaborated to develop a symposium in Hanoi involving scientist, local communities, government officials and others with an interest in the species. Nature’s Way role would be smaller than previously envisioned.

Among the lessons learned from this case are that, at the time, there was little awareness within the government about sharing benefits with local communities for the commercial use of their TK and to benefit conservation. “Bureaucracy is a major threat to any regulatory system for natural products. Capacity building at the local community and university level are important elements of commercial partnerships.” The differences between the way the botanical medicine companies and pharmaceutical industry pay royalities must be clear prior to drafting access and benefit-sharing legislation. [1125]

After a long period of limited awareness and capacity to conserve Panax vietnamensis, now, it is protected and developed as a national product under an official strategy for development and conservation. An association of the Panax vietnamensis developers and conservasors also is established. Vietnam is in the process of developing a case for establishing a protected geographical indication for Panax vietnamensis.[1126] The appearance of foreign actors is not mentioned in current activities, which raises the significance of the collaboration between the Government, researchers, and local communities in the access and benefit-sharing relationship. The question of fair and

[1125] DROSS.M, WOLFF.F, p. 174, Kate and Laird, 1999, p.112 seq
[1126] See more information at *http://www.samngoclinhkt-qn.org/index.php?option=com_content&view=frontpage&Itemid=1*, last accessed May 22, 2012

equitable benefit-sharing may not be addressed clearly in the end, but there has clearly good news that endangered, nearly distinctive species like Panax vietnamensis is saved.[1127]

2) United States National Cancer Institute (NCI)

The United States National Cancer Institute (NCI), a research organizations, "… aware of the potential of natural products as source of treatments for cancer, has continuously and consistently commissioned botanical gardens and universities to collect biological samples of plants and terrestrial and marine microorganisms, from over 35 countries for the last 40 years. About four years before the CBD was drafted the NCI pioneered the use of Letters of Collection (LOC) that proposed benefit-sharing terms in the event of the licensing and development of a promising drug candidate. So far 14 countries have signed LOCs."[1128] Vietnam Institute of Ecology and Biological Resources, National Center for Natural Science and Technology signed LOCs in 1997.

Nevertheless, "the NCI is committed to the terms of the LOC irrespective of whether or not an official agreement has been signed. Biological samples collected by the NCI are stored in its Natural Products Repository in Frederick, MD (USA). Pharmaceutical companies such as Aphios Corporation have signed Material Transfer Agreements with the NCI in 2004 in order to access its natural products repository and they are required by the NCI to comply with the terms of LOCs if products are developed and marketed from the samples covered by these agreements."[1129]

There is no information of benefit-sharing, except one Vietnamese expert visited the USA for short-term (1 to 2 weeks) as visitors and sponsored by the University of Illinois under the NCI-LOC program.[1130] In comparison with the list of benefit-sharing in Annex of the Nagoya Protocol, the visit of Vietnamese expert could be understood as one kind of non-monetary benefit, namely: expert exchange.

This case shows the complexity of the partnership in one access and benefit-sharing relationship. It is not easy to determine whether requirements for PIC and MAT have been satisfied, consistently with objectives of the CBD. The case also shows the difficulty and unfeasibility of applying the current access and benefit-sharing provisions under Biodiversity Law 2008 and its implementing.

3) The University of Illinois-Chicago and Collaborative Research in the Pharmaceutical Sciences

An effort of the NCI called the International Cooperative Biodiversity Groups (ICBGs) that support experimentation in implementation of the CBD through development

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[1127] Ibid
[1128] BHATTI. S, CARRIZOSA.S, MC GUIRE. P, YOUNG. T, *Supra*, note 208, p. 184
[1129] BHATTI. S, CARRIZOSA.S, MC GUIRE. P, YOUNG. T, *Supra*, note 208, p. 184, p. 185
[1130] BHATTI. S, CARRIZOSA.S, MC GUIRE. P, YOUNG. T, *Ibid*, p. 184, p. 185, p.255

and execution of international agreements for bioprospecting. Since 1993, the ICBGs have facilitated the participation of 14 major biotech and pharmaceutical companies, institutions in bioprospecting projects. These projects have delivered mixed results and accomplishments.[1131]

One such ICBG program was carried out between the University of Illinois at Chicago and institutions in Vietnam and Laos. "The USA ICBG Project of Vietnam has been carrying out bioprospecting activities since 1998 and its funding was renewed in late 2003."[1132] The project is coordinated by the Program for Collaborative Research in the Pharmaceutical Sciences, University of Illinois at Chicago College of Pharmacy. The Vietnamese actors has been defined are the National Center for Science and Technology of Vietnam and Cuc Phuong National Park .[1133]

The University of Illinois-Chicago had tried to make a single umbrella agreement with Laos and Vietnam to cover the entire consortium. "Most end up developing 3-7 different agreements that function in interlocking ways. Often they result in a sort of web, but sometimes more a hub and spoke format… While people generally start with some model that they are familiar with or has been recommended to them, they are almost always greatly modified to fit the particular needs of the parties. They are diverse in format and structure and types of agreements. Therefore, in the end, the model agreements are only a starting point."[1134]

The core elements contained in the single, five-way Memorandum of Agreement are the arrangements for intellectual property rights, treatment of PIC, and plans for benefit-sharing (including the sharing of short- and long-term royalty benefits, capacity building, and community reciprocity). Program participants were able to develop a practical and flexible agreement that satisfies the wishes of all institutions that are parties to it.[1135]

The lesson learned in this case is about transboundary cooperation between Laos and Vietnam in the same program and with the same partner from the USA. The difficulty was a diversity of formats and structures and types of agreements. If model agreements are only a starting point, the question remains how to define an access and benefit-sharing agreement that is a basis for MAT, PIC and prerequisites for granting a permit for access. It also raises a a question of applying the Protocol's provisions on access and benefit-sharing in the national laws of diffirent countries.

[1131] BHATTI. S, CARRIZOSA.S, MC GUIRE. P, YOUNG. T, *Supra*, note 208, p. 184, p. 185, p.227
[1132] CARRIZOSA.S, BRUSH.S.B, WRIGHT.D.B, MC GUIRE.E.P, *Supra*, p. 78
[1133] http://cat.inist.fr/?aModele=afficheN&cpsidt=15526981
[1134] , Technical No 38, Acces and Benefit-sharing in Practice: trends in partnerships Across Sectors, p. 28
[1135] http://cat.inist.fr/?aModele=afficheN&cpsidt=15526981

4) New EnglandBio-labs(NEB) and enzymes

New England Biolabs Inc. is incorporated in Massachusetts, USA. Laboratory in Vietnam is one of Partners laboratories with the NEB conducting research to find enzymes (the others partners of NEB are China, Portuga, Cameroon, Uganda, and Nicaragua). The NEB pays to partner laboratories 5 % of the royalties on sales of enzymes found by them. The New England Biolabs Foundation (NEBF) established in 1982, "fosters community-based conservation of landscapes and seascapes and the bio-cultural diversity found in these places" that is supporting scientific research for environmental projects in developing countries.[1136]

In this case, a small monetary benefit in the form of royalties was shared with the Partner, as well as non-monetary benefits including support in scientific research. This case did not mention about the access and benefit-sharing agreements or procedures of PIC.

5) Japanese National Institute of Technology and Evaluation (NITE) and microorganisms

The Japanese National Institute of Technology and Evaluation (NITE) researches to prospect microbial diversity in the search for new commercial products. NITE is collecting in Vietnam (and at the same time in Indonesia, Myanmar) to find heat-resistant microorganisms in these tropical areas. [1137]

NITE Biological Resource Center (NITE-BRC) was established in 2002 by the Japanese government within the NITE, based on the awareness that "microbiological resource centers are fundamental to preserving and harnessing microbial biodiversity and genetic resources. The availability of precisely identified and validated microbial resources is essential for scientific research and industrial and other applications." The importance of microorganisms to both pharmaceutical and biotechnology R&D programs cannot be underestimated. Microbes are the most abundant, diverse, and least understood organisms on the planet. "In many cases, microbial resources are centers of excellence for preserving microbial biodiversity and training microbial taxonomists. In recent decades, academia in Japan has experienced a decline of taxonomic experts trained to discover, identify, describe and classify microbial biodiversity."[1138]

"The concept of international collaboration that has been leading NITE-BRC is described in the 'Tsukuba Statement' issued by the Global Taxonomy Initiative (GTI) Program of Work in Microbiology that took place in Tsukuba, Japan in October, 2003. Key points from the Tsukuba Statement include: strategic inventory of microbial diversity should be developed in each country; taxonomists themselves should recognize the

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1136 DROSS.M, WOLFF.F, p 179, Kate and Laird, 1999, p. 257 seq

1137 , Technical No 38, Acces and Benefit-sharing in Practice: trends in partnerships Across Sectors, p. 14

1138 United Nations University Institute of Advanced Studies (UNU-IAS) and Japan Bioindustry Association (JBA), *ABS Case Studies, 2008*, p.11. http://www.jba.or.jp/english/pdf/080918_IAS-JBA_case_studies.pdf, last accessed May 20, 2012

importance of their role for solving biodiversity problems; national governments should establish laboratories and institutes for applied microbial taxonomy; developed countries are requested to draw up and implement a plan for the advancement of microbiology in collaboration with developing countries; providers and users of microbial resources must respect and follow the CBD and the Bonn Guidelines; national governments should pay attention so that the CBD does not hinder development of strategic inventorying of microbial diversity." [1139]

"The data from the inventory work in each country should be managed within database systems which support global networking."[1140] NITE-BRC signed memorandums of understanding with governmental organizations of Indonesia, Mongolia and Vietnam for collaborative research for the conservation and sustainable use of microbial resources. The framework and content of the joint projects varied on a case-by-case basis. [1141]

A business corporation gathers plants and microorganisms with use of the scheme established by NITE. If the research result has led to a granted patent or product commercialization, the donor country receives part of the profits. Such access and benefit-sharing complies with the CBD and the Bonn Guidelines, and various partners take advantage of it. If a lot more schemes are established, such as above, under which a provider of GR and a user thereof can reach an agreement on the terms of use and on benefit-sharing, and smooth utilization of GR can be promoted, GR are expected to be utilized in business operations in proper and aggressive manners.[1142]

A typical example of benefit-sharing includes sharing of research results, installation of equipment for capacity building, collaboration in sampling, isolation and taxonomical characterization, on-site workshops for technology transfer, hosting of researchers at NITE-BRC facilities for joint research and/or technology transfer. [1143]

This case is indicative of certain trends in user and provider perceptions on the access and benefit-sharing process for GR. It is apparent that users, whether in scientific research or commercial R&D, are conscious of the principles of the CBD, and have developed their practices, in cooperation with their partners, that are in line with CBD obligations and equity considerations. This study highlights that commitments of countries to the principles of the access and benefit-sharing and equity of CBD, can be translated into industry best practices if guidelines are effectively communicated and implemented. This case also indicates that users enter into benefit-sharing arrangements based on a case-by-case approach in terms of needs of the collaborators. NITE being a government organization has been transferring technology for institutional capacity building in partner

[1139] UNU-IAS and JBA, *ABS Case Studies, 2008, Supra*, p.12.
[1140] *Ibid*, p.12
[1141] *Ibid*, p.11 – p.19
[1142] http://www.harakenzo.com/en/column/article/20080130.html, last accessed May 20, 2012
[1143] http://www.harakenzo.com/en/column/article/20080130.html, last accessed May 20, 2012

countries, and the benefits shared were non-monetary." This case presents lack of clarity on national regulatory procedure on access and benefit-sharing in provider countries. This trend is worrisome to the use of biodiversity for development purposes or access and benefit-sharing mechanism. It indicates "that access and benefit-sharing partnerships between users and providers through bilateral arrangements could provide instances of access and benefit-sharing best practices. These could feed into multilateral negotiations to culminate in a meaningful access and benefit-sharing regime. It is noteworthy that while examples of partnerships have their merits, they cannot ensure general applicability in implementation across different regions. It is therefore important to ensure multilateral consensus- building that guarantees all parties agree to adhere to a set of principles."[1144]

6) International Rice Research Institute and the national Center for Plant Genetic resources of Japan and breeding new varieties of rice

The Vietnam Agricultural Genetics Institute cooperated with International Rice Research Institute and the National Center for Plant Genetic Resources of Japan to breed rice using varieties from Vietnam.. The foreign partners collect rice varieties in Vietnam to map the genes. When the genome is published, it becomes a common product of the parties. The Vietnam Agricultural Genetics Institute was provided $15 millionby two foreign partners for equipment and research. The parties have also agreed to share profits from new rice varieties that are based on Vietnam's rice varieties.[1145]

In this case, benefit-sharing included monetary and non-monetary benefits, including technology and equipment transfer. Intellectual property was shared when the result of R&D was a genome that became the common products of both parties.

7) Netherlands Centre for Genetic Resources (CGN)

The Netherlands Centre for Genetic Resources (CGN) CGN was a "…party to agreements concluded with SEARICE (the Philippines) and Can Tho University (Vietnam). These agreements specify the conditions under which CGN acquired material and, in the case of SEARICE, includes PIC from the communities concerned for rice varieties." [1146]

The access and benefit-sharing agreement is legally binding, signed by appropriate government agencies as well as project partners. The Agreement includes specific terms on benefit-sharing including bilateral research, training and capacity-building. The agreements differ from Memorandums of Understanding that are non-legally binding agreements,

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[1144] UNU-IAS and JBA, *ABS Case Studies, 2008, Supra*, pp.11 - 19

[1145] Insitute of Strategy and Policy on Natural Resources and Environment, Scientific Report of theory and practical studies on mechanism for ABS management in Vietnam, Hanoi, 2010, p.30

[1146] EUROPEAN COMISSION, Second report of the European community to the Convention on Biological diversity, Thematic Report on Access and Benefit-sharing, October 2002, p.41, available at *www.cbd.int/doc/world/eur/eur-nr-abs-en.doc* last accessed February 4, 2011

setting out the general terms of conditions of collaboration. Memorandums of Understanding are generally used for taxonomic research involving Herbarium specimens and not for living material. Both the access and benefit-sharing agreements and Memorandums of Understanding complement the Principles on access and benefit-sharing for participating institutions. [1147]

This case could indicate a lesson learned on identifying the types of agreement that satisfy the requirements for PIC and MAT stipulated by the Protocol and the Biodiversity Law.

8) SAPA Essential Company and Medicinal Plants Association

The SAPA Medicinal Plants Association is a local cooperative comprised of largely ethnic minority farmers who organically propagate, cultivate and semi-process local medicinal plants. SAPA Essential Company is a local private company that supports local farmers in their activities and subsequently purchases the products developed by the SAPA Medicinal Plants Association. SAPA Essential Company uses these semi-processed products to further develop entirely novel natural products, some of which contain novel essential oils. After extraction of these essential oils through a simple steam distillation process, they are then used in special formulations to develop 100% pure natural products, including handmade massage balms, soaps, and pure essential oils, among other things. These products are marketed using the TK 'story' of the different local ethnic minorities. Through this marketing strategy, royalties are paid back to the SAPA Medicinal Plants Association on each product sold with money placed into a community social and conservation fund that is managed by the SAPA Medicinal Plants Association for the benefit of the local community. All intellectual property rights associated with the traditional uses behind these products are maintained by the SAPA Medicinal Plants Association.

The SAPA Medicinal Plants Association, officially established in 2005, comprises local farmers from the H'mong, Dao, Giay and Kinh ethnic groups in Sapa district, Lao Cai Province of Vietnam. The management board of the association comprises four persons from each of the ethnic groups (two men and two women). Decisions are made collectively and operations conducted on a fair and equitable basis.

Both SAPA Essential Company and SAPA Medicinal Plants Association, and their activities, were established through the Medicinal Plants Innovation project funded by the New Zealand Agency for International Development's Asian Development Assistance Facility from 2003 to 2006. The Medicinal Plants Innovation project operated through a New Zealand natural products company, Forest Herbs Research Ltd; product formulations were provided by Carol Priest Natural Cosmetics NZ Ltd. [1148]

[1147] EUROPEAN COMISSION, 2002, *Ibid*, p.41

[1148] http://www.twnside.org.sg/title/hidden.htm last accessed May 20, 2012

Before the Medicinal Plants Innovation, one conservation research tour program to Vietnam in 1993 organized by the UK-based non-profit organization Society for Environmental Exploration operating under the name Frontier was criticized as 'biopiracy initiative'. The program "...volunteers collected a wide range of plant and insect samples in the forests of Tam Dao Nature Reserve and Ba Be National Park, without appropriate permission from park officials, and took them out of the country." [1149]

The access and benefit-sharing model of SAPA Medicinal Plants Association, SAPA Essential Company, Forest Herbs Research Ltd, and Carol Priest Natural Cosmetics Ltd, New Zealand raises the question of the legal relationship between them. This model was established before the Biodiversity Law and it is still existing and operating. If the provisions of the Biodiversity Law requiring a permit for access and benefit-sharing were applied, this arrangement would become more complicated and there would be obstacles for its implementation. The Biodiversity Law does not provide for sharing benefits with indigenous and local communities; it stipulates only that a minimum of 30% of the total benefit arising from GR utilization benefits is to be shared with the State. The State is not a party to the access and benefit-sharing arrangement with the SAPA Medicinal Plants Association and the SAPA Essential Company and the roles and interests of ethnic local communities have been promoted and guaranteed.

9) WHO and samples of H5N1 viruses

Under the present WHO-organised scheme, the developing countries are obliged to donate their avian influenza viruses to WHO.[1150] Vietnam is one of the countries that has been asked and obliged to donate samples of viruses from new human cases of avian influenza. This raises the issue of global inequities in the supply of avian influenza vaccines. Rich countries have already paid hundreds of millions of dollars to place advance orders for vaccines that the poor countries cannot afford. Vietnam, like other poor provider countries would face shortages of scarce and expensive vaccines in the event of a pandemic outbreak.

Vietnam has been asked and obliged to donate samples of viruses so that scientific work can be done to characterize the viruses and track the development of the influenza.[1151] The country has sovereign rights to its GR and may require PIC for providing the viruses and MAT for benefit-sharing, according to the CBD. According to WHO's 2005 Guidance on sharing flu viruses, the country of origin of the virus has the right to determine access to the virus, and also to specify conditions for access including benefit sharing arrangements. WHO reference labs will seek permission from the originating country/lab to co-author and/or publish results obtained from the analyses of viruses. There

[1149] http://www.twnside.org.sg/title/hidden.htm *last accessed May 20, 2012*

1150 *http://www.docstoc.com/docs/25072687/SHARING-OF-AVIAN-INFLUENZA-VIRUSES*, p.5-6, last accessed May 20, 2012

[1151] *http://www.twnside.org.sg/title2/avian.flu/news.stories/afns.004.htm*, last accessed May 22, 2012

will be no further distribution of viruses/specimens outside the network of WHO reference labs without permission from the originating country/lab. The CBD and WHO's own guidelines assure that results of the scientific analysis of donated viruses will not be misused for commercial profit.[1152] However, evidence is emerging that the viruses contributed by countries are already being extensively used for commercial activities. The centres and laboratories have been passing on the viruses or the information contained in the viruses to other institutions, including companies, even if this is not in line with the CBD or the WHO Guidance. Many commercial activities linked to the viruses are already taking place. Lucrative contracts for supplying large quantities of vaccines have already been signed between drug companies and many developed countries.[1153] For example, Sanofi Pasteur (the vaccines business of the Sanofi-Aventis Group) signed a $117.9 million contract with the US Department of Health and Human Services (HHS) for the production of bulk concentrate of a new type of H5N1 pre-pandemic vaccines. It also was awarded a contract by the French Ministry of Health to produce a 1.4 million dose stockpile of the H5N1 vaccine. It also entered into agreements with Italy and Australia to supply vaccines in the event of a pandemic influenza outbreak.[1154] Another company, GlaxoSmithKline (GSK) entered into a supply contract with the Swiss Federal Office of Public Health for 8 million doses of GSK's H5N1 antigen influenza vaccine and its proprietary adjuvant for pre-pandemic use.[1155] In May 2006, GSK received an HHS contract worth $274 million to develop cell-culture technology to speed the development of new cell culture-based seasonal and pandemic influenza vaccines and to scale-up its cell culture manufacturing capability.[1156] In November 2006, GSK received a $40 million initial order for bulk H5N1 antigen from HHS while in January 2007 GSK received from the HHS a $63.3 million contract to develop antigen-sparing H5N1 pandemic influenza vaccines.[1157] Another company Novavax Inc., has received positive study results from a live virus challenge to ferrets inoculated with its pandemic influenza vaccine, paving the way for clinical trials. According to the study, ferrets that received Novavax's H5N1 vaccine were protected not only against the Indonesian strain of avian flu but also were cross-protected against a separate strain originating in Vietnam.[1158] One agency reported that the global vaccine market was expected to top $10 billion in 2007 and $23.8 billion by 2012, with flu vaccines sales forecasted to grow to $14 billion by 2012.[1159]

Factors which relates to commercial activities linked to the donated viruses is applications for patents, research aimed at vaccine production, and sale of vaccines and other medical products. However, patent applications and vaccine sales have been taking

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[1152] http://www.who.int/influenza/human_animal_interface/guidelines/Guidance_sharing_viruses_specimens/en/, last accessed May 23, 2012
[1153] http://www.twnside.org.sg/title2/avian.flu/news.stories/afns.004.htm, last accessed May 22, 2012
[1154] **http://www.sanofipasteur.com/sanofi-pasteur4/ImageServlet?imageCode=23017&siteCode=SP_CORP**, last accessed May 23, 2012
[1155] **http://articles.marketwatch.com/2006-10-18/news/30862302_1_vaccine-doses-pandemic-glaxosmithkline**, last accessed May 23, 2012
[1156] **http://www.gsk.com/media/pressreleases/2007/2007_01_17_GSK957.htm**, last accessed May 23, 2012
[1157] **http://www.gsk.com/media/pressreleases/2007/2007_01_17_GSK957.htm**, last accessed May 23, 2012
[1158] **http://www.novavax.com/download/File/H5N1._Oct_08pdf.pdf** last accessed May 23, 2012
[1159] **http://www.terradaily.com/reports/Global_Vaccine_Market_To_Top_23_Billion_Dollars_999.html**, last accessed May 23, 2012

place following the issuance of the WHO March 2005 Guidance.[1160] Applications for patents could include patents for the gene sequence (or part of it) of the virus. Patents are being applied for pandemic flu vaccines, which make use of parts of the gene sequences from viruses sent by countries with an outbreak to the WHO centres. One patent application in the US was even filed by a WHO collaborating centre, to patent modified influenza virus that includes genes from a Vietnam influenza virus. An example of a patent application relevant to H5N1 influenza vaccines that makes use of parts of the avian flu viruses is "an application for a US patent by St. Jude's Children's Hospital (USA), which is a WHO Collaborating Centre..., for a Modified Influenza Virus for Monitoring and Improving Vaccine Efficiency. This application, published in February 2007, makes claims on small changes to influenza HA genes, intended to strengthen the immune system reaction to the genetically engineered virus. It makes patent claims on any influenza HA gene modified in a certain way and also specifically claims the modified HA gene from an influenza virus isolated in Vietnam in 2004 (A/Vietnam/1203/04)." Another example is "an application for a US Patent by the University of Pittsburgh (USA), for vaccines for the rapid response to pandemic avian influenza. This application, published in January 2007, claims new human and animal influenza vaccines based on (theoretically) replication-deficient adenoviruses. These genetically engineered vaccines incorporate genetic sequences from H5N1 viruses. This application claims pieces of any influenza HA gene used in the adenovirus-based vaccine. It specifically makes claims on the HA gene from the same influenza virus isolated in Vietnam in 2004 (A/Vietnam/1203/04)." A third example is "an application for a patent in the US, EU, Australia, and Canada, by Medimmune Vaccines Inc. (USA) and the US government for influenza hemagglutinin and neuraminidase variants. This patent application claims any influenza HA and NA gene modified and used in specific ways. The patent application specifically uses H5N1 types isolated in Vietnam and China as examples (A/Vietnam/1203/2004, A/Hong Kong/491/97, and A/Hong Kong/213/2003)". Patent applications in the above cases were also filed with the Patent Cooperation Treaty (which is linked to the WIPO), which helps facilitate applications in many countries that are a party to the treaty.[1161]

Analysis indicates that the drug companies are making commercial use of the viruses as they wish. "Meanwhile, the provider countries have so far not benefited from this scheme. They face potential astronomical bills, should they wish to purchase vaccines in sufficient quantities to protect their populations." With inadequate financial resources to purchase vaccines, they would suffer the most in the event of a pandemic outbreak. As it is,

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[1160] This guidance 2005 is replaced by Guidance 2009, see more, *Pandemic influenza preparedness and response, A guidance document,* Global influenza programme, World Health Organization, 2009, available at http://www.who.int/influenza/resources/documents/pandemic_guidance_04_2009/en/, last accessed May 23, 2012
http://www.cidrap.umn.edu/cidrap/content/influenza/panflu/news/apr1811sharing-br.html last accessed May 23, 2012

[1161] http://www.docstoc.com/docs/25072687/SHARING-OF-AVIAN-INFLUENZA-VIRUSES, last accessed May 23, 2012, p. 8

they already suffer immense economic losses from having to cull poultry in areas of avian flu outbreaks. If a pandemic of the human version of avian flu emerges, the cost to life, economy and society in these countries could be of unimaginable proportions.[1162]

The issue of donated virus was also discussed during negotiation of the Nagoya Protocol as access and benefit-sharing regime for pathogens.[1163] However, the adopted Nagoya Protocol only implies a reference to WHO's 'relevant ongoing work or practices' in Article 4.3. In comparison with access and benefit-sharing national legislation of Vietnam, it does not obviously stipulate on this issue. It is still a gap in Vietnam.

B – Integration of the Nagoya protocol in to national law

This last sub-section uses the analysis of all of the above sections to clarify opportunities and challenges for integration of the Nagoya Protocol into the national law of Vietnam and for implementation in the event the country accedes to the Protocol.

1) Opportunities

Acceding to the Protocol will contribute to implementing Vietnam's responsibilities as a Party to the CBD. Although the Protocol has been criticized as "weak", a positive perspective is that the Protocol is an international incentive and opportunity for countries to develop and improve their own domestic policy and legislation as well as their participation in international cooperation.

From the socio-economic perspective, the benefits from GR, TK and importance of access and benefit-sharing are clear and undeniable.[1164]In Vietnam, some enterprises and research institutes have begun undertaking activities related to access and benefit-sharing, including cooperation with foreign partners in researching rice and other plant varieties and animal breeds, and research and development for medicine and cosmetics.[1165] Accession to the Protocol will receive strong support from those enterprises and institutes

From the legal perspective, as explained above, a basic policy and legal framework has begun to be elaborated in Vietnam. The Biodiversity Law and Decree 65/2010/ND-CP have established basic principles that are in harmony with the general principles of the CBD and the Protocol and provide a solid foundation for more comprehensive implementation. Supplementing the Biodiversity Law and Decree 65/2010/ND-CP are the Law on Forest Protection and Development, the Fisheries Law, the Ordinance on Plant Varieties, the Ordinance on Livestock Breeds, and the Law on Intellectual Property, and their implementing decrees and other guiding documents. These legal instruments together

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[1162] *http://www.twnside.org.sg/title2/avian.flu/news.stories/afns.004.htm*, last accessed May 22, 2012
[1163] NIJAR.G.S, *Supra*, p. 24
[1164] CBD, ABS, theme: access and benefit-sharing, , *Supra*, p. 2
[1165] http://dantri.com.vn/c20/s20-205468/mot-du-an-kinh-doanh-vn-duoc-de-cu-giai-the-world-challenge-dai-bbc.htm, http://www.clrri.org/, *http://www.ibt.ac.vn/*,

contribute to a comprehensive regulatory regime for implementing the Protocol, as long as overlaps and conflicts are resolved.

From the perspective of governmental management, establishment of the Biodiversity Conservation Agency under the Vietnam Environmental Agency, which in turn is part of the MONRE, facilitates ABS management in Vietnam. Before the Biodiversity Conservation Agency was established, responsibilities for biodiversity conservation management were shared by different ministries and line agencies, with no national focal point and without clear allocation of responsibilities. MONRE would likely assign the Biodiversity Conservation Agency to become the national focal point for the purposes of the Protocol, in the event that Vietnam accedes to it; the Agency also would likely carry out other responsibilities assumed by the Vietnamese Government as a Party to the Protocol.

Specific issues related to ABS that are assigned to different Ministries and line agencies include intellectual property rights, which are the responsibilities of the Ministry of Science and Technology (MoST), and genetic resources for food, agriculture and livestock, which are the responsibility of MARD. These ministries are appropriate authorities for access and benefit-sharing management if there is good collaboration and close, responsible cooperation.

Acceding to the Protocol would provide an opportunity to raise awareness among Government officials, communities, the private sector and the public in general of the values and potential benefits of genetic resources and traditional knowledge, as well as the importance of biodiversity conservation. Doing so would improve implementation of the existing ABS regulatory regime and contribute to biodiversity conservation, poverty reduction and improving the livelihoods of local communities.

In addition, access and benefit-sharing in Vietnam has received project support from bilateral and international organizations to improve capacity and raise awareness. Those projects have produced results and been sustainable up to now. Their results include a primary database of GR of plants, livestock and domestic fowl, medicines, and microorganisms, two websites on genetic resources created by MoST, and many publications.[1166]

There is increasing interest and attention from the international community in ABS and its role in promoting green economic growth. In Vietnam, many projects have been implemented with bilateral partners and international organizations. Total investment capital for such projects under the National Action Plan for 1996-2005, was US$13

[1166] Ministry of Natural Resources and Environment, Institute of Strategy and Policy of Natural Resources and Environment. 2010. *Report of research project of background for recommendation of management mechanism for ABS in Vietnam*, p. 94.

million.[1167]. Those projects concentrated on protecting plant varieties, livestock breeds and medicinal plants. Becoming a Party to the Protocol will create an additional obligation on Vietnam to facilitate access to genetic resources and to ensure the fair and equitable sharing of benefits arising from the use of genetic resources and associated traditional knowledge. Acceding to the Protocol will also create an incentive for Vietnam to develop markets for products derived from genetic resources, to improve socio-economic activities related to ABS, and to promote understanding of the values of genetic resources[1168].

2) Challenges

There are persuasive arguments in favor of Vietnam acceding to the Protocol, but there are also practical drawbacks to consider.

While its purpose is to implement the ABS provisions of the CBD, the Protocol itself seems to be a framework agreement with many intentional ambiguities and gaps, especially regarding benefit-sharing and compliance, and it is weak compliance that is at the root of misappropriations of genetic resources. It may be, therefore, that it will be difficult for the Protocol to obtain the 50 ratifications required for it to enter into force.

Awareness of the potential of genetic resources and of fairly and equitably sharing the benefits arising from them, and of the need to create market access for communities, enterprises and institutes, is still limited. Supporting policies are also limited, as are sources of capital, tax incentives, and human resources. Without research and development, commercialization, and access to markets to demonstrate the values and benefits of genetic resources and traditional knowledge, and how those who benefit can provide support back to conservation, the potential value of genetic resources and traditional knowledge for the country will be degraded and lost. [1169]

Conservative local customs still perceive genetic resources as a free gift of nature for humankind. Differentiating and communicating the values of genetic resources as public goods as well as common heritage, and allocating the responsibilities and benefits of related stakeholders are very complicated. To make the regime effective will require the coordinated efforts of all stakeholders.

Vietnam had established the foundations of its ABS regime prior to the adoption of the Protocol. Recognizing the weaknesses in its domestic regulatory regime, Vietnam looks to the Protocol to provide substantive guidance. The Protocol, however, provides that it is the responsibility of its Parties to issue measures regulating and facilitating access which create legal certainty, clarity and transparency, and does not provide criteria to define these requirements. The Protocol's provisions on sharing benefit are also too general

[1167] *Ibid.*, p. 27.
[1168] Paul Oldham, *The Role of Commons/Open Source Licenses in the International Regime on Access to Genetic Resources and Benefit Sharing*, UNEP/CBD/WG-ABS/8/INF/3, July, 2009, p. 28.
[1169] STOIANOFF. P. N, *Supra*, p. 9 and p.193

to provide additional guidance for Vietnam's ABS regulatory regime. There is little guidance in the Protocol for national development of effective compliance mechanisms[1170]. Because the value of intangible traditional knowledge is such a significant issue with access to genetic resources, resolving issues of ownership and possession is another challenge. Existing legal provisions pay more attention to managing genetic resources as tangible materials and less to the intangible values. Current resource management, which is organized according to geographic location and administrative jurisdiction, struggles to deal with intangible values in practice.

Procedures for access to genetic resources are still not regulated in detail. There is no application form for applicants and the officials of competent national authorities to use. Stakeholder accountability is not stipulated. There are no guidelines for the contents of ABS licenses or model contract clauses to implement Article 58 of the Biodiversity Law. The qualifications of local government officials to administer ABS are weak and the individuals, households and communities that are providers of traditional knowledge have little capacity to negotiate, develop or sign a contract to ensure fair and equitable benefit-sharing. Article 19 of the Protocol calls on Parties to develop, update and use model contract clauses to ensure implementation of MAT..

There are also no detailed regulatory provisions or implementation guidelines on how to resolve claims, complaints and disputes that may arise in implementing the national ABS regulatory regime. Greater regulatory specificity is needed concerning jurisdictions, procedures, applicable laws, and the availability of alternative dispute resolution mechanisms. The Biodiversity Law has only one provision (Article 58.5) which stipulates that: "Disputes over or complaints about access to genetic resources and benefit-sharing shall be settled under Vietnamese law and treaties to which the Socialist Republic of Vietnam is a contracting party". This provision is too general to apply to new and complicated situations arising from ABS in various sectors within and outside the jurisdiction of Vietnam.

The existing regime does not address situations in which commercial intermediaries provide genetic resources to users abroad. There needs to be consideration of whether the ABS regulatory regime should differentiate between domestic and foreign providers and users.

Benefit-sharing provisions in the current regulatory regime do not take into account local communities which are not assigned to manage a specific genetic resource in a particular geographic or administrative area, but which are holders of traditional

[1170] Convention on Biological Diversity, Open-Ended Ad Hoc Intergovernmental Committee for the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization. 2011. *Cooperative procedures and institutional mechanisms to promote compliance with the Protocol and to address cases of non-compliance*. UNEP/CBD/ICNP/1/6/Rev.1, 9 June 2011, para. 4. Available online: http://www.cbd.int/doc/?meeting=icnp-01. Accessed 4 March 2012.

knowledge associated with that resource, or are residents of the buffer zone of a protected area which conserves the biological resource from which the genetic resource is derived. Although such communities do not have rights of possession in the genetic resource, they play an important role in its conservation and should arguably be eligible to share in any benefits that arise from its use.

The existing regime does not regulate a situation of which a genetic resource has been accessed in Vietnam but used outside Vietnam and is therefore not subject to national regulation. In addition, there is a gap of regulation of sharing benefits arising from genetic resources accessed before the Biodiversity Law came into force. There also no provisions establishing time limits for sharing benefits and for concluding obligations to share benefits.

Provisions on compliance, enforcement and implementation of PIC and MAT are also lacking in the national ABS regime. There need to be guidelines for the contents of access licenses that ensure that they are suitable for use as the internally recognized certificate of compliance. Measures and remedies to support compliance also need to be developed in more detail and should take into account the operation of foreign laws and the possibility of bilateral judicial cooperation and mutual support mechanisms. Even with improved national regulation, it will still be difficult to reach foreign users outside Vietnamese territory because few countries have provisions for reciprocal recognition of access and benefit-sharing regulation.

The Biodiversity Law, the highest legal text on access and benefit-sharing is criticized as the law protects biodiversity badly in Vietnam against a number of biopiracy of local varieties. This is the biggest weakness of the law in its current form"[1171]

One of the greatest obstacles for Vietnam at this time is conflicts and overlapping jurisdiction between MARD and MONRE, which arise from provisions in the Biodiversity Law, the Law on Forest Protection and Development, and the Fisheries Law.[1172] In practice, MARD is managing most of the country's protected areas and protected species and holds most of the national databases and information on biological resources. MONRE, therefore, will meet with difficulties in trying to grant licenses to access genetic resources of protected species, for example. Similar difficulties will arise in granting access licenses at provincial level. If MONRE is authorized to grant licenses to access the genetic resources of protected species, provincial Departments of Natural Resources and Environment (DONRE) will also be authorized to grant access licenses for that purpose. DONRE have no information and databases on species, and the capacity of DONRE with respect to biodiversity in general and ABS is particular is very limited. Some DONRE have

[1171] THOMAS.F, *Supra*, p. 49 – p. 50

[1172] The Law and Policy of Sustainable Development Research Center. 2010. *Report of overview and findings of legal issues of responsibilities of Ministries and line ministries in biodiversity state management*. Hanoi.

no officer specialized in managing biodiversity, their understanding of biodiversity and the Biodiversity Law is limited, and there are no provincial action plans on biodiversity conservation.[1173]

Following the Protocol, each Party shall designate a national focal point on access and benefit-sharing and it presumes that the MONRE will become the national focal point of the Protocol in case Vietnam accedes to the Protocol. However, many thought that government ministries dealing with trade and industry, or scientific research, should be the home for national focal point, rather than ministries of environment and natural resources. Some feel that the role of those with relevant scientific expertise in provider countries has diminished over the last ten years, and that the access and benefit-sharing policy process is now dominated by groups with little scientific or commercial experience.[1174]

In sum, to integrate the Nagoya Protocol into national law, in case of acceding to the Protocol, it is necessary for Vietnam to overcome all challenges and to promote opportunities to make the Protocol's implementation effective. Some lessons learned from access and benefit-sharing cases in practice are necessary to consider amendment, development legislation. Some good access and benefit-sharing model could be duplicated for local communities' development.

[1173] Biodiversity Conservation Agency. 2010. *Report on survey and investigation of situation of implementing the Biodiversity Law.*
[1174] CBD, Technical No 38, Acces and Benefit-sharing in Practice: trends in partnerships Across Sectors, p 125

Conclusion of Chapter 2

There are persuasive arguments in favor of Vietnam acceding to the Protocol, but there are also practical drawbacks to consider.

Vietnam had established the foundations of its access and benefit-sharing regime prior to the adoption of the Protocol. Recognizing the weaknesses in its domestic regulatory regime, Vietnam looks to the Protocol to provide substantive guidance. The Protocol, however, provides that it is the responsibility of its Parties to issue measures regulating and facilitating access which create legal certainty, clarity and transparency, and does not provide criteria to define these requirements. The Protocol's provisions on sharing benefits are also too general to provide additional guidance for Vietnam's access and benefit-sharing regulatory regime. There is little guidance in the Protocol for national development of effective compliance mechanisms.[1175] These are among the issues that the country is grappling with in considering whether to ratify the Protocol.

Whether it accedes to the Protocol or not, as a Party to the CBD, Vietnam needs to improve the access and benefit-sharing regulation implementing its national Biodiversity Law. The author agrees that a proposal to develop a Government decree on access and benefit-sharing and an implementing circular jointly issued by the related ministries with jurisdiction for issues involved in access and benefit-sharing should be considered. The decree should regulate in detail the provisions of the Biodiversity Law to fill the gaps and overcome the conflicts and overlapping jurisdictions created by current laws and decrees. Such a decree, issued by the Government at the highest possible level of the national legal hierarchy, would express the strong interest and determination of the Government of Vietnam in implementing its international commitments under the CBD.

A Government decree on access and benefit-sharing should complement other decrees under the Biodiversity Law which are currently being developed, including a decree on natural ecosystem management and a decree on species management. Adhering to an approach regulating biodiversity conservation which recognizes the diversity of ecosystems, of species, and of genetic resources, with one decree regulating each issue, will be easy for national lawmakers to understand.

The proposed Government decree would have to clearly define the respective jurisdictions of MARD, MONRE and MoST. A decree issued by the Government as the highest State administrative body, would have the authority to assign clearly the responsibilities of each ministry and the cooperation mechanism that would resolve the current problem of jurisdictional conflict.

In addition to resolving existing jurisdictional overlaps, the proposed decree should regulate substantive issues of implementing access and benefit-sharing development. In

[1175] UNEP/CBD/ICNP/1/6/Rev.1, *Supra,*

particular, the decree should specify how violations should be dealt with in the emerging biodiversity sector. An inter-ministerial circular should be issued jointly by MONRE and MoST to guide implementation of access to traditional knowledge associated with genetic resources. An inter-ministerial circular should be issued jointly by MONRE and MARD to provide the basis for cooperation in managing access to the genetic resources of plant varieties and livestock breeds.

A roadmap to develop the proposed access and benefit-sharing decree should be based on the Program of Implementation of the Biodiversity Law for the period 2009-2014, issued by the Biodiversity Conservation Agency.

A final question that arises for Vietnam as a potential provider of GR in considering whether or not to accede to the Protocol is its capacity to handle the legislative and administrative burden that accompanies becoming a Party to a binding international agreement. While it considers whether to ratify the Protocol, Vietnam should improve its existing domestic access and benefit-sharing regulatory regime. In addition, in order to increase international cooperation, the country should also consider ways to facilitate judicial measures for enforcing national access and benefit-sharing legislation abroad. If it becomes a Party to the Protocol, Vietnam should strengthen its voice at the COP/MOP, together with other developing countries, to propose clear and effective measures for benefit-sharing and compliance to overcome the weaknesses of the Protocol.

Conclusion of Title 2

"Global thinking – local action" is becoming a common slogan related to international policies which apply to all areas of environmental protection. It seems to be necessary to apply it in the case of the Nagoya Protocol, from international law to national law or from international lawmaking to national and local implementation of law. The law in each country is different and the conditions and contexts for integrating international law, in this case, the Protocol, are different as demonstrated by case studies of selected countries: Brazil, South Africa, France and Vietnam. Each country has its own opportunities and challenges for access and benefit-sharing law development and implementation, among them: legal status and ownership of genetic resources; regulating being both a potential provider country or user country; regulating access and benefit-sharing; regulating access to and use of traditional knowledge, and establishing mechanism for compliance and enforcement. All those elements are arranged and analyzed in the same logic of each country to clarify the comparative factors. The case studies from France and South Africa also analyze each country's obligations with respect to access and benefit-sharing law in the EU or African Union.

Within the scope of this thesis, it is not possible to provide a detailed analysis of the entire legal systems of the selected countries with respect to integration of the Nagoya Protocol into national law, nor is it possible to draw the same conclusions, lessons learned and recommendations for all countries. This title focuses on the basic factors that directly affect integration of the Protocol into national law and analyzes the trends that support integration. The selected issues are a basis for analysis and are useful as practical experiences for other countries in developing and applying an access and benefit-sharing regime.

Conclusion of Part 2

"How is international law being integrated into domestic legal system as yet none too well-known? To gain a clear overview to this grey area requires more than knowing about the various constitutional rules…administrative practices and attitudes of the national courts…transcending the classical position based on the theories of monism and dualism"[1176] This observation on integration of international law into national law illustrates why Part 2 of this thesis focuses on an analysis, from monist and dualist perspectives, principles, methods and measures for integration. The author expects that the analysis will contribute to clarifying the 'grey area', especially in the case of the new Nagoya Protocol. This thesis makes efforts to analyze other factors, such as cultural and linguistic factors, that affect the process of how the Protocol is integrated into national law.

The second Part of this thesis also considers case studies of four selected countries and how they [may approach] [are approaching] integration of the Nagoya Protocol into national law. The elements of constitutional rule, administrative practices, and the attitudes of the national courts are analyzed in the context of each country and in consideration of its assess and benefit-sharing law and policy. The procedures and formalities of integrating the Protocol into national law are different from country to country, depending on each country's constitutional regime, the control of constitutionality, and the roles of parliament and other elected bodies. This second Part also has some conclusions and recommendations from the case studies that can contribute to improving national law on access and benefit-sharing during the process of integration.

[1176] EISEMANN.P.M, *Supra,* note 478, p. vii

GENERAL CONCLUSION

"…Foundational laws, such as the property regime that essentially drive behavior by creating a deep structure of incentives and disincentives and that fundamentally describe the directions the society is going." Therefore, Sax.J.L suggested that we learn more how people are actually going to behave by looking at the incentive structure of these laws than by looking at expressions of environmental goals or at most environmental regulatory regimes. This basic point is illustrated in every field of law. In fact, the property law has not changed much at all to create incentives to preserve and restore those natural services that we have learned to value.[1177] The Nagoya Protocol seems to go towards the change by including provisions for privatization, commercialization, and marketization that facilitate creation of incentives to preserve nature. It is also consistent with the concept of "selling nature to save it".

However, transforming this idea into law and putting it into practice is a long and difficult process that is influenced by many different factors. While its purpose is to implement the access and benefit-sharing provisions of the CBD, the Protocol itself seems to be a framework agreement with many intentional ambiguities and gaps, especially flexibility in benefit-sharing and compliance with non-mandatory responsibilities that make the Protocol 'weak,' 'imperfect' and 'incomplete'. Therefore, each country that becomes a Party to the Protocol will need to develop national legislation to meet its obligations under the Protocol, filling in gaps with national legislation in accordance with its particular situation. This thesis indicates that the integration of the Protocol into national law is important in both respects – the lawmaking process and the bridge of putting the legal provisions of the Protocol into practice. There are many problems with the Protocol in the international context, including relations with other relevant international treaties and intrinsic problems of the Protocol in legal, technical, and scientific aspects' As well, there are legal problems of integrating the Protocol into national law including the weakness of many of its provisions, the competing perspectives of dualism and monism, and the fact that the Protocol is non-self-executing, among other factors.

The weakness of the Protocol and the many challenges of integrating it into national practice are reasons why many States are reluctant to ratify. It seems be difficult to for the Protocol to obtain the 50 ratifications required for it to enter into force. As of 4 March 2012, one month after the period for signing the Protocol had closed, 92 countries had signed the Protocol; only four countries had ratified or accepted it by August, 2012.[1178]

There are different scenarios for the future of the Protocol. In the first scenario, it has 92 signatures but does not get 50 ratifications and thus does not enter into force. In this

1177 JEFFERY. I. M, QC, FIRESTONE. J, BUBNA. L. K, *Supra*, pp.9-11

[1178] The CBD, Nagoya Protocol. *Status of Signature, and ratification, acceptance, approval or accession*. Available online: http://www.cbd.int/abs/nagoya-protocol/signatories/. Accessed 24 May 2012.

case, there would be problems of indirect legal obligations. The other scenario is that the Protocol would enter into force with the minimum number of ratifications, but not from all the signatory States. In this scenario as well, its legal effect would also be limited.

The COP/MOP of the Protocol should propose clear and effective measures, including measures to support benefit-sharing and compliance to overcome the weaknesses of the Protocol. It should consider establishing institution for compliance in accordance with Article 30. The COP/MOP also is expected to develop guidance on compliance and implementation for general statement provisions of the Protocol.

Preparing for entry into force, application and implementation, two meetings of Open-ended Ad Hoc Intergovernmental Committee of the Nagoya Protocol (Montreal, 5-10 June 2011 and New Delhi, 2-6 July 2012) also were held following Decision X-1 of the COP 10 of the CBD. The two meetings included in their provisional agenda the necessary issues for implementation and application of the Protocol. They include: modalities of operation of the Access and Benefit-sharing Clearing-House, measures to assist in capacity-building, capacity development and strengthening of human capacities and institutional capacities in developing countries; measures to raise awareness of the importance of genetic resources and associated traditional knowledge; cooperative procedures and institutional mechanisms to promote compliance with the Protocol and to address cases of non-compliance, a programme budget for the biennium following the entry into force of the Protocol; elaboration of guidance for the financial mechanism; elaboration of guidance for resource mobilization for the implementation of the Protocol; and rules of procedure for the Conference of the Parties serving as the meeting of the Parties to the Protocol.[1179]

The Resolution A/RES/66/288 of the General Assembly of the United Nations (Draft A/66/L.56 dated 24 july 2012), "The future we want" at para 199 recognizes the importance of the Nagoya Protocol and calls for ratification: "We note the adoption of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity, and we invite parties to the Convention on Biological Diversity to ratify or accede to the Protocol, so as to ensure its entry into force at the earliest possible opportunity. We acknowledge the role of access and benefit-sharing arising from the utilization of genetic resources in contributing to the conservation and sustainable use of biological diversity, poverty eradication and environmental sustainability".[1180]

There are two strategies for States to choose for adopting the Protocol. A State may first develop national legislation in accordance with the Protocol, and then considers that it

[1179] See more UNEP/CBD/ICNP/1/1, UNEP/CBD/ICNP/2/1/Rev.1, UNEP/CBD/ICNP/1/6/Rev.1, UNEP/CBD/ICNP/2/12

[1180] Outcome of Rio +20 "The future we want" http://www.uncsd2012.org/thefuturewewant.html last accessed August 1, 2012

is ready to ratify or accede. Or, a State ratifies or accedes and then takes the implementing national legal measures.

Of the four countries for which this thesis provides case studies, three –Brazil, South Africa and France – signed the Protocol; Vietnam did not sign. Vietnam has chosen the first strategy – to improve its existing domestic access and benefit-sharing legislation before acceding to the Protocol. It is a good way for a Party to the CBD to make best use of its time and resources – during the time the State considers whether to ratify or accede to the Protocol, it improves its existing domestic access and benefit-sharing regulatory regime, which is an obligation under the CBD.

Consequently, the role of national access and benefit-sharing legislation should be emphasized. On one hand, we would also have to realize that "industrialized countries cannot comply with their user obligations, since national legislation and other implementation measures by provider countries in accordance with the Protocol is a precondition for the obligations of industrialized countries in their capacity as user countries".[1181] On the other hand, the significance of legislation in user countries with provisions for user measures could derive from the view of 'win-win' solution that all stakeholders should compromise to 'win' to get benefit equitably that serves for sustainable development in its broadened meaning. "…while the Protocol and the CBD itself are binding upon states, whereas benefits are created by private entities, like companies, universities etc. Thus, for the Protocol to have any effects on the private users of genetic resources, its obligations need to be implemented in the home jurisdiction of the user". "If one user of GR shall be expected to enter into MAT and share a fair and equitable the benefits arising out of utilization of GR, there must be incentives or obligations for that user to do so. The private company must be obliged under the laws in its home jurisdiction to share benefits or to have an agreement describing how benefits are to be shared."[1182] In addition, various check-points in user countries should be established. Even though the Nagoya Protocol does not mandate strictly this responsibility, the studies in selected countries indicated that it would be more effective for checkpoint through research funding, patent offices; capital institutions or market access control.[1183]

[1181] KOESTER.V, Supra, Studies N°03/12, IDDRI, Paris, France, 2012, p.31
[1182] TVEDT. M. W, RUKUNDO. O, *Supra*, p.2
[1183] MEDDTL, Fondation pour la Recherche sur la Biodiversité, *Supra,* p.128

THE FRENCH SUMMARY/
LA RÉRUMÉ DE LA THESE EN FRANÇAIS

Introduction générale

Contrairement aux idées traditionnelles de «protection absolue» de la biodiversité, le Protocole de Nagoya sur l'accès aux ressources génétiques et le partage juste et équitable des avantages découlant de leur utilisation implique la privatisation, la commercialisation et la marchandisation de la biodiversité pour maximiser les avantages découlant de la bioprospection et de son utilisation. Dans le cadre économique et des marchés, les questions fondamentales sont les suivantes: le contrat, les parties du contrat - les vendeurs et les acheteurs ou les fournisseurs et les utilisateurs et les objets du contrat - les ressources génétiques (RG) et leur utilisation, et/ou des connaissances traditionnelles associées aux ressources génétiques (savoirs traditionnels). Toutefois, le Protocole de Nagoya soulève non seulement des questions de valeur économique et de marché, mais aussi les questions de responsabilités morales des utilisateurs RG, les droits des populations locales et autochtones et des communautés, la justice et l'équité et le développement durable avec des droits intergénérationnels et intra-générationnels. Par une vue introspective du Protocole de Nagoya, les ressources génétiques - qui sont comparées en tant que «or vert» - ne sont pas seulement prévues comme des ressources pour le développement, mais aussi pour la conservation naturelle et la protection de l'environnement. En approchant RG en vertu de ces deux aspects, il dispose déjà d'un point de vue : "Vendre la nature pour la sauver".

Par conséquent, le Protocole de Nagoya serait nécessaire pour atteindre un équilibre entre les droits et les responsabilités, les fournisseurs et les utilisateurs et autres parties prenantes, les pays développés et en développement, l'intérêt économique et la morale commune. Chaque composante de l'accès et le régime de partage des avantages en vertu du Protocole élabore des droits et des responsabilités différents pour les parties. Chacun d'eux a des intérêts et des positions différentes sur le pouvoir de contrôler le processus de mise en place ainsi que le fonctionnement du régime international sur l'accès et le partage des avantages.

Ainsi, l'équilibre présente de nombreuses difficultés principalement causées plus par la perspective de «vendre la nature» pour un intérêt maximum, que par la volonté de l'intérêt de «sauver la nature». Il y a aussi de nombreux défis et problèmes de contenus et de procédures, d'obligations juridiques et le respect du Protocole est difficile pour atteindre cet objectif idéal : «vendre la nature pour la sauver».

Dans la relation entre le droit international et droit national il est nécessaire que le droit international intègre le droit national pour sa mise en œuvre, ceci est indéniable et indispensable. En dépit de la question de la ratification ou d'adhésion au Protocole et pour lequel le Protocole doit obtenir le cinquantième instrument de ratification ou d'adhésion pour son entrée en vigueur, la recherche de l'intégration du protocole de Nagoya dans le droit national est importante et constitue un pont pour mettre les dispositions légales du Protocole dans la pratique.

La première partie de cette thèse analyse les problèmes du protocole de Nagoya dans le contexte international, les relations avec les autres traités internationaux pertinents et des problèmes intrinsèques du Protocole de Nagoya à la fois juridiques et techniques, ainsi que les

aspects scientifiques. La partie 2 de la thèse clarifie les problèmes juridiques de l'intégration tels que la faiblesse du droit international, les points de vue juridiques : le dualisme et le monisme, les problèmes des traités non-auto-exécutoires, les principes, méthodes et mesures pour l'intégration. Ensuite, il fournit des études de cas des droits nationaux du Brésil, l'Afrique du Sud, la France et un regard plus particulier sur la pratique de la législation nationale du Vietnam.

PARTIE 1 - Le Protocole de Nagoya et les questions juridiques pertinentes

Titre 1 - Le Protocole de Nagoya - processus de développement d'un régime international sur l'accès aux ressources génétiques et le partage des avantages

CHAPITRE 1 - Les besoins juridiques de l'accès aux ressources génétiques et le partage des avantages

La nécessité d'un accès et partage des avantages du régime international est originaire I - du fait de la dégradation et de la perte de la biodiversité dans les ressources générales et génétiques en particulier, et de la sensibilisation des responsabilités à la conservation naturelle en terme de justice internationale ou pour faire face à des préoccupations mondiales pour le développement durable; II – Des exigences relatives aux traités pertinents, tels que la CDB, traité de la FAO et Lignes directrices de Bonn qui constituent un régime international pour l'accès aux ressources génétiques et le partage des avantages.

La dégradation et la perte de la biodiversité peut être prouvée par la croissance de l'utilisation et la dégradation des ressources biologiques. Le secteur de la biotechnologie couvre un large éventail d'activités, y compris la biotechnologie des processus pharmaceutiques, agricoles et industriels. L'industrie dans son ensemble a augmenté de plus de 14% en 2006, avec des revenus de sociétés publiques de plus de 70 milliards de dollars. La biotechnologie est l'une des plus forte intensité de recherche des industries dans le monde, et en 2006 la recherche et développement (R & D) d'investissement a augmenté de 33% par rapport à 2005. Cependant, l'extinction et la dégradation de GR, qui est due à diverses raisons, qui existent encore sans solution efficace de prévention. Les résultats révèlent que 21% de tous les mammifères connus, 30% de tous les amphibiens connus, 12% de tous les oiseaux connus, et les reptiles de 28%, 37% des poissons d'eau douce, 70% des plantes, 35% des invertébrés étudiés jusqu'à présent sont menacés .

L'extinction et la dégradation des RG ont de nombreuses causes: changement climatique, l'augmentation de la population humaine, les impacts de l'agriculture, la sylviculture, l'aquaculture commerciale, la planification des politiques économiques, l'injustice dans la propriété et le partage des avantages, le manque de connaissances et la restriction de l'accès à la connaissance des aides, la méconnaisance des systèmes juridiques et des institutions n'ont pas été facilités. Ainsi, il ya une grande urgence pour protéger la biodiversité restante par des moyens légaux. La dégradation et la perte de la diversité de RG exhorte la communauté internationale à se doter d'outils juridiques efficaces pour conserver la biodiversité en général et RG en particulier. L'insuffisance et l'inefficacité de la CITES pour protéger les ressources génétiques est démontrée par les chiffres ci-avant.

La prise de conscience éthique de la conservation de la nature de la responsabilité de la conservation de la nature est également nécessaire pour développer le protocole. Celà comprend : «l'intérêt commun» et «la dette écologique» et aussi de l'équité pour les communautés autochtones afin de protéger les ressources génétiques et les savoirs traditionnels. La justice internationale vise à l'intérêt commun, mais l'intérêt n'est pas individuel. Pour la biodiversité, ses avantages doivent servir l'intérêt commun de toutes les personnes et les générations au sens large. En ce qui concerne l'équité entre les générations, il est un argument conséquent de l'exploitation biologique dans la «dette écologique» passée des pays industrialisés afin de compenser la «dette écologique»; les pays industrialisés fournissent un financement suffisant et d'autres soutiens pour permettre aux pays en développement de préserver durablement de leur biodiversité. «Eco-justice» à base morale et scientifique, il est convenu que les pays riches doivent s'acquitter de leurs fonctions intergénérationnelles d'une manière directe, mais aussi par l'accomplissement de leurs obligations intragénérationnelles envers les pays en développement et des populations pauvres.

Le droit international actuel exige également la création d'un régime juridique international. Parce que, la CDB et d'autres instruments internationaux existants ne remplissent pas cette tâche; ils ont besoin d'un nouveau traité sur l'accès aux ressources génétiques et le partage des avantages que la CDB met en place en arrière-plan juridique pour le développement. La CDB est un traité-cadre qui n'a exprimé que des objectifs généraux et politiques, plutôt que des obligations fortes et précises. En outre, il faut une approche globale plutôt qu'une approche sectorielle de la conservation de la biodiversité et l'utilisation durable. Ainsi, pour mettre en œuvre les articles 15 et 8.j et atteindre le troisième objectif de la CDB, il est besoin d'un protocole spécialisé pour réglementer l'accès aux ressources génétiques et le partage des avantages. Il y avait deux documents juridiques liés à l'accès aux ressources génétiques et le partage des avantages, qui sont le traité de la FAO et les Lignes directrices de Bonn. Le traité de la FAO est considéré comme «un instrument international sur d'accès spécialisé et de partage des avantages des ressources phytogénétiques pour l'alimentation et l'agriculture. Les Lignes directrices de Bonn devraient être appliquées d'une manière qui soit cohérente et solidaire de la mise en œuvre des accords internationaux pertinents et des institutions. Par conséquent, ils ont besoin d'être soutenus par un traité qui couvre l'accès toutes sortes de ressources génétiques et du partage des avantages pour le régime de conformité de la CDB.

Le processus de développement du Protocole de Nagoya avait été adopté en vertu d'une longue négociation. Il a fallu près de douze ans afin de déterminer la nature d'un régime international sur l'accès éventuel aux ressources génétiques et partage des avantages et la négociation du Protocole. Et huit années de négociations internationales, avec un investissement considérable de temps et de ressources, ils ont atteint l'objectif fixé par le Sommet mondial sur le développement durable de 2002 et pour l'Année internationale de la conservation de la biodiversité en 2010.

Toutefois, l'adoption du Protocole de Nagoya laisse encore des questions non résolues. Ces questions sont examinées dans des contextes théoriques et des impacts politiques. Tout d'abord, la néolibéralisation de la nature qui est marquée notamment par la privatisation et la marchandisation. Deuxièmement, la notion (subalterne) de «légalité cosmopolite», qui pose la loi

comme un lieu de lutte et implique un mouvement populaire qui «cherche à élargir la conception juridique au-delà des droits individuels et met l'accent sur l'importance de la mobilisation politique en faveur de la réussite des droits de stratégies centrée sur «Le protocole est le résultat d'une lutte permanente comme un mouvement de «contre-pouvoir». Le Protocole de Nagoya pourrait certainement être considéré comme une expansion de la «légalité cosmopolite» qui conduit à ce qui pourrait mieux être appelé de nouvelles formes de «jurisprudence bio-culturelle».

Malgré la tension des négociations, la finalité du Protocole de Nagoya a été difficile à atteindre. Il ya de nombreux défis aux concepts de la privatisation et la marchandisation, les conditions de la légalité cosmopolite qui n'ont pas été résolus après négociation. Les négociations de l'accès aux ressources génétiques et du partage des avantages ont ressemblé à des discussions entre «les crocodiles et les anacondas». Les courants politiques ont fait ressortir de grandes divergences entre pays industrialisés et en développement. Il y avait quelques grandes divergences lors de la négociation et même après l'adoption du Protocole.

Il y a aussi quelques problèmes pratiques: La critique et la suspicion ont accentué les différences entre pays en développement et développés. Les pays en développement ont souligné l'importance d'assurer le partage des avantages et des mesures de conformité efficaces, tandis que les pays développés ont insisté sur les normes d'accès. Enfin, dans le protocole adopté, il ya des règles assez spécifiques et donnent des précisions sur l'accès, en revanche, les mesures de conformité sont vagues, creuses et manquent de précision. La suspicion et la méfiance entre les pays pendant et après la négociation peut affecter négativement le processus d'intégration du Protocole de Nagoya dans le droit national pour la mise en œuvre ultérieure. Parce que, quelques questions abordées ne sont pas réglées. Les problèmes ci-avant évoqués du protocole sont également des caractéristiques communes de droit international qui peuvent se produire pour d'autres traités multilatéraux. Cela s'explique par "Le plus petit dénominateur commun", approche qui implique compromis et accords multiples, d'ou la difficulté qu'ont les États à trouver un projet de texte autre que sous forme de résumés à la formulation vague.

CHAPITRE 2- Accès aux ressources génétiques et le partage des avantages en vertu des traités pertinents

En théorie et en règle générale, il n'y a pas de hiérarchie entre les traités, à l'exception des normes *jus cogens* et le principe de *lex superior*. La nature judiciaire obligatoire des traités repose directement sur la volonté des Etats souverains d'être légalement responsable.

Il semble impossible de concevoir des degrés dans la volonté d'être légalement responsable. L'article 4.1 du Protocole a également reconnu : «Les dispositions du présent Protocole ne portent pas atteinte aux droits et obligations des Parties découlant de tout accord international existant, sauf si l'exercice de ces droits et obligations causerait un dommage grave ou une menace à la diversité biologique. Ce paragraphe ne vise pas à créer une hiérarchie entre le présent Protocole et d'autres instruments internationaux ». Ce paragraphe peut être compris comme une «clause de sauvegarde" du Protocole. La «clause de sauvegarde», affirme la relation entre l'instrument et d'autres instruments connexes. Quand une telle clause figure dans le texte du

dispositif d'un traité, il peut indiquer de quel traité - le traité existant ou le nouveau traité - les parties destinées à faire prévaloir dans le cas d'un conflit.

Cependant, en fait, il existe une hiérarchie « soft » entre les traités. Ce n'est pas formel, mais basé plus sur des raisons de priorité que sur des préoccupations communes. Par exemple, la sécurité alimentaire est généralement considérée comme ayant une priorité supérieure à la conservation, de sorte, le traité de la FAO semble être plus élevé dans la hiérarchie que des conventions sur la conservation des zones humides telles que la biodiversité, y compris le Protocole de Nagoya. Cette hiérarchie souple du droit des traités sera le défi pour l'intégration du protocole de Nagoya dans le droit national s'il y a un conflit entre eux.

En vertu de la CDB, des problèmes peuvent être soulevés : le premier est l'accès aux ressources génétiques. L'article 15 de la CDB prévoit que l'accès aux ressources génétiques devrait être soumis à la procédure du consentement préalable donné en connaissance de cause de la partie fournissant les ressources génétiques, sauf décision contraire de cette Partie. En ce qui concerne la souveraineté, le GR situé dans le territoire d'un État est réputé soumis à la souveraineté de cet Etat. En vertu de ce droit, chaque État est libre de réglementer l'accès aux ressources génétiques. Toutefois, cette liberté est contrebalancée par l'exigence de base qu'elle ne soit exercée de façon à faciliter l'accès aux ressources génétiques pour le développement durable et l'utilisation écologiquement rationnelle. Mais «écologiquement rationnelle» n'est pas définie ou interprété.

Pour GR à l'état sauvage, la CDB vise la conservation domestique à la fois *in situ* ou *ex situ*. Toutefois, la définition de la CDB ne correspond pas à l'usage habituel scientifique qui serait normalement de restreindre le terme dans le pays où ils ont été élaborés. Pour l'application dans le temps, la réglementation de l'accès n'est pas appliquée à la suite de l'article 15.3 pour la collecte des ressources génétiques avant l'entrée en vigueur de la CDB le 29 Décembre 1993. Beaucoup de GR ont été utilisées en dehors du pays d'origine, ces RG sont toujours utilisées sans partage des avantages et sans contrôle de ces dernières. En outre, en dépit de son entrée en vigueur, la CDB présente une ambiguïté en termes de temps ou de signification juridique parce qu'elle ne définit pas quand un RG a été «fourni» par un pays d'origine ou lorsque cela est jugé «acquis» par un utilisateur.

Le second est un problème de partage des avantages. La CDB prévoit de manière générale que chaque partie doit prendre les mesures législatives, réglementaires et administratives conformément à l'article 15.7. Toutefois, les dispositions de la CDB sont difficiles à mettre en œuvre. Il manque un régime d'accès international efficace et une organisation internationale pour surveiller et faire respecter les accords de bioprospection le partage juste et équitable devient une fiction plutôt qu'une réalité.

La troisième est la protection inadéquate des savoirs traditionnels, la CDB échoue dans sa tentative d'assurer le partage juste et équitable des avantages découlant de l'utilisation des connaissances traditionnelles associées aux RG. La valeur de la RG intégre deux éléments différents : l'élément tangible, tel qu'en lui-même et le RG éléments incorporels ou de connaissances y relatives. La CDB n'établit pas les conditions efficaces pour reconnaître le droit des communautés locales. L'objectif de la CDB de conserver la biodiversité devient alors difficile

à réaliser lorsque les dispositions sur la conservation de communautés autochtones ne sont pas suffisantes pour protéger leur diversité culturelle.

En relation avec les Lignes directrices de Bonn, la question est de savoir si les Lignes directrices de Bonn sont efficaces et assez concrêtes pour la mise en œuvre de la CDB, si les États doivent d'être liés par le Protocole de Nagoya ou non? Surtout, le protocole n'apporte pas de nouveaux progrès par rapport au texte des Lignes directrices de Bonn. À mon avis, le Protocole de Nagoya constitue un développement progressif à partir d'un instrument volontaire de Lignes directrices de Bonn vers un traité juridiquement contraignant.

Même si certains contenus et des articles sur les mesures de renforcement des capacités, la sensibilisation au Protocole ne constitue pas beaucoup de progrès ou relève de la déclaration encore plus générale que les lignes directrices, un mécanisme d'application est important. Par ailleurs, après quelques années de développement et de négociations, des idées et des mesures ont été ajoutées au Protocole tels que : certificat de conformité reconnu à l'échelle internationale, et les points de contrôle. En regardant en arrière dans le processus international et élaboration d'un régime de l'accès et au partage des avantages, on peut dire que les Lignes directrices de Bonn étaient une étape importante pour mener au Protocole de Nagoya. Chaque instrument joue son rôle et tient sa place. Comme étant un instrument complémentaire, les Lignes directrices de Bonn peuvent être mises à jour, et modifiées afin d'approcher du Protocole de Nagoya.

En relation avec le traité de la FAO, le champ d'application du traité de la FAO traite de l'accès et du partage des avantages pour les ressources génétiques pour l'alimentation et l'agriculture. Pendant ce temps, le Protocole de Nagoya règle l'accès aux ressources génétiques et au partage des avantages des ressources génétiques en restant aux domaines : «chimique, pharmaceutique et / ou d'autres utilisations industrielles non-alimentation ". Il est convenu que tous les membres du traité de la FAO sont également membres de la CDB, alors que toutes les Parties à la CDB sont parties au Traité de la FAO. Comme le protocole de la CDB, le Protocole de Nagoya est ouvert seulement aux membres de la CDB pour signer et ratifier. L'article 4.4 du Protocole prévoit clairement que le Protocole est l'instrument de la mise en œuvre des dispositions de la CDB sur l'accès aux ressources génétiques et le partage des avantages, «le Protocole ne s'applique pas pour les Parties à l'instrument spécialisé en ce qui concerne les ressources génétiques spécifiques couvertes par et pour le but de l'instrument spécialisé ". Par conséquent, le Protocole de Nagoya ne s'appliquerait pas à une partie du traité de la FAO. La situation plus complexe se présenterait avec la possibilité pour les Parties pays adhérents à certains mais pas aux trois instruments.

Dans l'examen de la Convention de l'UPOV, la Convention reconnaît l'importance de l'accès aux ressources génétiques afin d'assurer le développement de variétés de plantes. Grâce à la définition du droit d'obtenteur et les exceptions au droit d'obtenteur, la question se pose à propos de l'impact sur la mise en œuvre du système de protection de nouvelles variétés de plantes selon l'UPOV et sa mise en œuvre nationale. En plus du principe de l'exemption d'impôt pour les cultivateurs et des exceptions pour le droit et les avantages pour les cultivateurs, le partage des avantages peut constituer une autre restriction à l'utilisation et le progrès sur l'accès aux ressources génétiques et le partage des avantages.

En relation avec les ADPIC/(TRIPs), il y a des arguments. D'une part, il est supposé que la CDB se conforme aux ADPIC; d'autre part, il est soutenu que les ADPIC devraient être modifiés pour se conformer à la CDB. Un de la plupart des conflits émergents, vient de ce que la brevetabilité du matériel génétique est illégalement exportée de l'État d'origine, sans le consentement préalable de cet Etat tel que requis par la CDB et le Protocole de Nagoya. Pour faire face au conflit entre la CDB et le GATT, ADPIC de l'OMC/(WTO), selon KISS.A, SHELTON.D, il y a deux méthodes pour trouver des solutions au conflit entre l'Accord multilatéral d'environnement et le GATT, l'OMC; l'une est interprétative et l'autre normative. Toutefois, le Protocole de Nagoya a quitté le droit de propriété intellectuelle des ressources génétiques et des savoirs traditionnels qu'il a ouvert, comme la fourniture d'informations ou des certificats internationalement reconnus lesquels ne mentionnent pas de droit de propriété intellectuelle. Il semble que la question de droit de propriété intellectuelle serait traitée en détail par voie de négociation continue de l'OMC et l'OMPI/(WIPO). L'article 4.2 du Protocole ouvre aux autres accords continuent à traiter de ces questions difficiles. Toutefois, cela signifie qu'aucun progrès n'avait été fait par le Protocole de Nagoya sur cet aspect ou il va créer lacunes au cas ou les autres accords n'ont pas non plus été plus précis. Les dispositions du Protocole de Nagoya semblent être plus du domaine de l'incantatoire et de la déclaration d'intention plutôt que la réglementation applicable.

En conclusion, l'analyse des interrelations entre le Protocole de Nagoya et de la CDB, les lignes directrices de Bonn, traité de la FAO, l'ADPIC en vertu l'OMC, l'UPOV et les accords de l'OMPI montre qu'il y a des limites, des lacunes, des chevauchements ou des conflits potentiels. Pour surmonter ces chevauchements ou ces conflits entre le Protocole de Nagoya et des traités connexes, dans ce chapitre, l'auteur suggère d'appliquer des méthodes d'interprétation normative. Pour les lacunes et les conflits potentiels, "travaux pertinents en cours ou les pratiques en vertu des instruments internationaux et des organisations internationales compétentes" devraient prendre en compte les limites ci-dessus analysées du Protocole ainsi que les autres traités pertinents pour améliorer leur efficacité.

Titre 2 – Le développement du contenu du Protocole de Nagoya

Comme un protocole de la CDB, le Protocole de Nagoya devrait "clarifier les termes, ajouter du texte supplémentaire sous forme d'amendements, et d'établir de nouvelles obligations. Malgré certaines réalisations, le Protocole de Nagoya est également critiqué pour sa «faiblesse», sa généralité, et son imprécision. Cette partie analyse les aspects scientifiques et techniques, ainsi que les aspects juridiques du Protocole.

CHAPITRE 1 – Analyse sous des aspects scientifiques et techniques

Ce chapitre justifie que la bioprospection et l'utilisation des ressources génétiques vont toujours de pair avec la technologie et le développement de la science.

Tout d'abord, la science et la technologie sont les bases des relations entre fournisseurs et utilisateurs aux fins de partage équitable des bénéfices. Toute utilisation de GR n'est pas séparée de la science, la technologie et induit un profit potentiel qui est la relation entre les utilisateurs et les fournisseurs au partage des bénéfices. En fait, la plupart des ressources génétiques se trouvent

dans le Sud, en particulier dans les pays de la diversité méga, tandis que la connaissance, les capitaux, le marché et les organisations de recherche, les entreprises de l'industrie se trouvent dans le Nord. Il peut être entendu que les pays utilisateurs, qui détiennent la technologie, les connaissances scientifiques et des capitaux pour tirer avantage des GR, ont besoin de coopérer avec le pays fournisseur qui possède la RG, pour accéder à ces ressources. Cependant, il est également convenu du rôle décisif de la technologie et de la science dans le processus et la nécessité d'équilibrer les avantages entre les fournisseurs et les utilisateurs pour atteindre l'objectif du partage des avantages juste et équitable.

La CDB suggère de promouvoir le développement d'un marché en reconnaissant le droit de la propriété intellectuelle des produits de la biotechnologie d'une part et d'encourager les différents acteurs dans le Sud pour développer et protéger leurs ressources et les connaissances des communautés autochtones et locales pour le développement durable et un environnement sûr, et faciliter l'accès à une ressource cruciale pour l'industrie. En conséquence, la question de la propriété intellectuelle dans le Protocole de Nagoya peuvent être analysés par deux aspects: le droit de la propriété intellectuelle de la technologie et la science développée par l'utilisateur et droit de propriété intellectuelle pour les savoirs traditionnels des communautés autochtones et locales.

Science et technologie impliquent un besoin de suivi et de contrôle d'accès et du partage des avantages. En conséquence, le suivi, la surveillance et de déclaration peut être simplement un système dans lequel les utilisateurs de ressources génétiques n'ont besoin que de conserver la documentation minimale sur les ressources génétiques qu'ils utilisent, en particulier celles qui sont utilisées en relation avec les conditions et permis d'accès aux ressources génétiques, le transfert de cette information à des tiers qui en reçoivent la matière, et fournir cette information à certains check-points. Le protocole met l'accent sur le certificat de conformité internationalement reconnu comme un outil pour aider au suivi qui aide les pays fournisseurs de s'assurer de leurs droits légaux et de leurs intérêts économiques en GR qui sortent des juridictions nationales et s'éloignent de toute possibilité réelle de contrôle soient effectivement protégés. Toutefois, il sa mise en œuvre sera un véritable challenge. Pour mettre le «certificat de conformité internationalement reconnu » en pratique, une question de coûts importants et de capacité institutionnelle, serons les conditions de sa mise en œuvre.

CHAPITRE 2 – L'analyse juridique du protocole de Nagoya

Ce chapitre analyse les aspects juridiques du Protocole de Nagoya pour mesurer l'impact des problèmes liés à l'intégration du Protocole dans le droit national et clarifier les solutions qui incluent des obligations juridiques pour les parties et le respect des obligations légales.

Etudier les principales obligations juridiques en vertu du Protocole, ce chapitre constate que les dispositions relatives à l'accès plus difficile impliquent des obligations pour le pays fournisseur

Le Protocole réaffirme les droits souverains sur les ressources naturelles et prévoit que l'accès aux ressources génétiques pour leur utilisation est soumise à un consentement préalable donné en connaissance de cause de la partie fournissante. Mais, les exigences de l'article 6.3

donnent du poids à un argument selon lequel les droits souverains des Etats sur leurs ressources génétiques, et leur pouvoir d'en déterminer l'accès est limité. L'article 15 de la CDB exige que les Parties s'efforcent de créer des conditions propres à faciliter l'accès aux ressources génétiques pour des utilisations respectueuses de l'environnement, mais n'exige pas que les Parties adoptent une législation d'accès. Certaines Parties peuvent choisir de ne pas mettre en place des mesures sur l'accès, car elles exercent des droits souverains sur leurs ressources et ont le pouvoir de déterminer l'accès à ces ressources génétiques et ce sera soumis à la législation nationale. Nonobstant, le protocole exige que les pays fournisseurs introduisent des obligations d'accès complexes qui ne sont pas requises par la CDB.

Ce point de vue différent des exigences à adopter une législation d'accès, la CDB n'appelle pas directement à des mesures directes gouvernementales, le Protocole exige l'adoption d'une loi spécifique, comme une condition sine qua non d'exiger le consentement préalable donné en connaissance de cause "qui prend en charge de la sécurité juridique.

En vertu de l'article 6.3 (a) du Protocole, les États fournisseurs sont tenus de fournir pour la sécurité juridique, la clarté et la transparence »de leur législation nationale sur l'accès et le partage des avantages. Il existe également des variétés d'obligations pour les États fournisseurs satisfaisant aux exigences de «sécurité juridique». Cependant, il ne fournit pas de critère pour évaluer la sécurité juridique, la clarté et la transparence » ou de fixer tout mécanisme, l'institution de vérifier et de déterminer objectivement si la législation interne l'accès et le partage des avantages répond à ces exigences. Il manque aussi beaucoup d' explications claires pour une sécurité juridique de référence en cas de besoin.

En outre, la certitude de procédure est une question qui relève du Protocole. En particulier pour les pays fournisseurs, qui sont pour la plupart en développement et dont les capacités institutionnelles sont limitées, les exigences procédurales sont susceptibles de présenter un défi, par exemple, de fournir des informations sur la façon de présenter une demanded'un consentement préalable donné en connaissance de cause, d'établir des règles et des procédures claires pour exiger et d'établir les conditions convenues d'un commun accord (Article 6.3). Ces exigences oblige les Parties nécessitant un consentement préalable donné en connaissance de cause pour créer un Point focal national responsable afin de rendre l'information disponible sur les procédures d'obtention d'un consentement préalable donné en connaissance de cause et des conditions convenues d'un commun accord pour les ressources génétiques et des savoirs traditionnels. (Article 13, 14) L'autorité nationale compétente, qui peut également être le Point focal national, est responsable de l'accès, en fournissant la preuve écrite que les conditions d'accès ont été remplies, et de conseiller sur les procédures applicables et les exigences pour l'obtention de d'un consentement préalable donné en connaissance de cause et des conditions convenues d'un commun accord. La création de points focaux nationaux requiert davantage de ressources et de moyens humains. C'est un grand défi pour les pays fournisseurs que de développer les infrastructures institutionnelles et juridiques nécessaires pour la législation d'accès effectif alors qu'il n'est pas certain que le bénéfice partagé serait suffisant, en particulier dans le contexte actuel de forte concurrence et de conformité fragile. Par conséquent, le pays pourrait s'interroger, à savoir si sa capacité à satisfaire aux exigences de

sécurité de procédure pour un consentement préalable donné en connaissance de cause ou non est le point important ou non pour la préparation à l'adhésion au Protocole.

Le protocole laisse au droit national le soin de déterminer la propriété des ressources génétiques et des savoirs traditionnels associés. L'article 6.2 stipule que lorsque les communautés autochtones et locales ont un «droit établi» aux ressources génétiques, « conformément à la législation nationale », leur consentement préalable et éclairé doit être nécessaire avant d'en autoriser l'accès. L'article 7, réinterprète la CDB en faveur des droits des communautés, en précisant que les mesures qu'une Partie prend doit être "en conformité avec la législation nationale» plutôt que «sous réserve de la législation nationale", tel que spécifié à l'article 8 (j) de la CDB. L'article 12 du Protocole prend en charge les dispositions des articles 6 et 7 en rendant obligatoire pour les Parties de prendre le droit coutumier en ce qui concerne les savoirs traditionnels. En outre, le Protocole demande aux Parties de faire participer et soutenir les communautés autochtones et locales, où les savoirs traditionnels et ressources génétiques sont en cause, et non de limiter leurs usages coutumiers. Bien que leProtocole de Nagoya ai des limites quant à l'étendue de la protection des savoirs traditionnels, le texte qui en résulte fournit de nouvelles opportunités pour les communautés autochtones et locales pour faire valoir leurs droits sur les savoirs traditionnels.

Ce chapitre constate que les dispositions sur le partage des avantages sont plus douces pour les pays utilisateurs. Le partage des avantages juste et équitable est déclaré comme étant l'objectif du Protocole. Cependant, un argument est que le Protocole doit avoir pour objet le partage des avantages pour ce qui est des pays fournisseurs intéressés, mais en fait, il consiste à faciliter l'accès, des pays utilisateurs intéressés

L'article 5 oblige chaque Partie à «prendre des mesures législatives, administratives ou de politique, le cas échéant» (article 5.3) à partager les bénéfices d'une manière juste et équitable avec la partie qui fournit la ressource (article 5.1) et avec la communauté autochtone et locale qui possède les savoirs traditionnels (article 5.2). Cependant, les facteurs de base pour s’assurer que les avantages sont partagés de manière équitable sont encore dans des questions sans réponse claire : Quand et comment les avantages sont-ils présentés? Quels sont les avantages qui doivent être partagés? Et avec qui le bénéfice est-il partagé? Le protocole est moins clair sur les normes à utiliser pour déterminer si le partage des avantages est juste et équitable.

Les réponses ne sont pas claires à cette question qui est de savoir quels avantages doivent être partagés. Ils sont ceux découlant de l'utilisation des ressources génétiques, qui comprend des dérivés, et ceux qui découlent des demandes ultérieures et de commercialisation. Le sens du mot «ultérieure» n'est pas tout à fait clair. Le Protocole dit bien que les bénéfices partageables doivent être compris au sens large. L'annexe au Protocole donne des exemples d'avantages monétaires et non monétaires et l'article 5.4 stipule que les prestations ne sont pas limitées à celles énumérées dans l'annexe.

Le Protocole ne prévoit pas d’utilisateurs particuliers, propriétaires ou bénéficiaires parmi lesquels des prestations doivent être partagées. Il prévoit seulement que les prestations doivent être partagées entre ceux qui ont des droits sur les ressources génétiques (article 5.1-5.2) et des

savoirs traditionnels associés (article 5.5). Ces dispositions reconnaissant les droits des communautés autochtones et locales, crée un précédent dans l'interprétation dynamique de la CDB, à la lumière de la Déclaration des Nations Unies sur les droits des peuples autochtones.

La question de la portée temporelle impacte la détermination du Protocole sur la façon dont les avantages sont partagés et avec qui. Selon le principe de la rétroactivité les dispositions d'un accord international ne sont pas contraignantes à l'égard de tout acte ou fait qui a eu lieu avant ou toute situation qui a cessé d'exister à la date d'entrée en vigueur du traité. Par conséquent, l'accès qui préexistait et les avantages qui avaient déjà été acquis avant l'entrée en vigueur du Protocole ne seraient pas couverts par les nouvelles exigences en matière de partage des avantages. Toutefois, la question de l'utilisation nouvelle des ressources génétiques et des dérivés qui se produiraient après la date d'entrée en vigueur de la CDB, y compris ceux acquis avant son entrée en vigueur, n'était pas expressément réglée dans le Protocole. Cela crée une incertitude juridique pour tous les pays fournisseurs et utilisateurs de ressources génétiques qui devra être résolue dans le futur. «Chaque gain dans le protocole n'est pas une fin en soi, mais le bout plat d'un levier à insérer dans les interstices de négociations, d'autres pour soulever les droits des communautés ouvertes en vertu des ADPIC, l'OMPI de la CIG, la FAO et de la CCNUCC".

En ce qui concerne la conformité avec le Protocole, il est prévu que les Parties doivent veiller au respect, la conformité ou à la non-conformité, et coopérer en cas de violation de la législation nationale régissant l'accès aux ressources génétiques (article 15) et l'accès aux connaissances traditionnelles associées aux ressources génétiques (article 16) et selon les modalités mutuellement convenues établies pour le partage des avantages. Les dispositions de mise en conformité sont qualifiées, cependant, la façon de mesurer la conformité n'est pas spécifiée. Les Parties sont tenues de prendre « toutes les mesures législatives appropriées, efficaces et proportionnées, ainsi qu'administratives et politiques », mais le Protocole n'établit pas de critères pour déterminer ce qui constitue de telles mesures. La signification exacte et le contenu réglementaire des obligations des parties prévues à l'article 15.2 à "traiter" les situations de non-conformité n'est pas claire avec, à nouveau, une absence de critères établis pour déterminer la façon dont les mesures peuvent être considérées comme «appropriées, efficaces et proportionnées». L'utilisation de la formulation « dans la mesure du possible» et «le cas échéant» à l'article 15.3 fait obligation de coopérer en cas de violations alléguées plutôt faiblement. Les questions qui sont laissées à la décision des Parties sont : l'organisme de réglementation doit-il également surveiller la conformité; à quel moment dans le processus d'ajout de valeur à la surveillance des ressources génétiques doit-il intervenir ? Ces questions de fond doivent être surveillées, et quels documents peuvent-ils être admis comme preuve de la conformité.

Jusqu'à présent, presque aucun État utilisateur n'a introduit dans sa législation, des mesures administratives ou de politique garantissant le respect des conditions d'accès et le devoir de partager les bénéfices. Les États utilisateurs qui deviennent Parties au Protocole seront tenus d'introduire de telles mesures, mais le Protocole, laisse à la discrétion de chaque Partie de décider ce que ces mesures seront. L'article 15.1 souligne que la mise en œuvre de mesures visant les utilisateurs est largement tributaire de décisions adoptées au moment de l'accès, en particulier la délivrance d'un permis ou son équivalent, qui sert de «certificat de conformité internationalement

reconnu» à la suite de l'article 17. Ainsi, si le pays fournisseur ne dispose pas d'un consentement préalable donné en connaissance de cause et d'un régime réglementaire exigeant et si aucune condition mutuellement convenue n'est indiquée dans le permis d'un pays fournisseur, le pays utilisateur ne peut pas être obligé de partager les avantages.

Il est clair que l'article 15 est rédigé en termes assez généraux et offre aux Parties une souplesse considérable pour mettre en œuvre les obligations de l'utilisateur. Il ne précise pas le type de mesures législatives, administratives et/ou la politique d'utilisation que les pays doivent adopter, tant qu'elles sont appropriées, efficaces et proportionnées. Cette flexibilité est justifiée par la nécessité des Parties d'adopter les mesures qu'elles estiment les mieux adaptées à leurs réalités nationales.

Le Protocole demande aux Parties de fournir des mécanismes de règlement des différends pour résoudre les problèmes de conformité avec des conditions convenues d'un commun accord. L'article 18 ne semble viser que les situations dans lesquelles l'utilisateur a accédé légalement aux ressources génétiques, mais pas les situations qui impliquent des violations de la législation nationale dans le pays fournisseur. Cette disposition précise que «chaque partie à la possibilité de faire recours en vertu de son système juridique, en conformité avec les dispositions juridictionnelles applicables» et que «chaque Partie doit prendre des mesures efficaces, le cas échéant" ce sera difficile à appliquer pour les pays fournisseurs. Les fournisseurs qui cherchent à appliquer des modalités mutuellement convenues et autres conditions d'autorisation, devront faire face à de nombreux défis, y compris l'accès à l'information et la collecte de preuves, la méconnaissance du système juridique du pays d'utilisateur et de ses institutions judiciaires, et, dans la plupart des cas, le manque de fonds, de moyens d'expertise et de capacité à s'engager dans une action judiciaire prolongée dans un autre pays. Le Protocole reconnaît les difficultés inhérentes à assurer la conformité avec des conditions convenues d'un commun accord en stipulant que l'efficacité de l'article 18 seront examinés à la première Réunion des Parties.

En effet, «la définition du partage des avantages relève de la libre contractualisation, avec toutes les difficultés des discussions, les coûts de litiges, et des frais de poursuites (...) constitue une source de déception pour le fournisseur". Même si la validité des contrats dans des conditions mutuellement convenues est améliorée, l'exécution transfrontalière restera très difficile. Les pays fournisseurs devront être aidés pour faire en sorte que l'application de leurs droits soit possible et il est difficile de savoir si c'est ou non le cas en vertu du Protocole. Néanmoins, il aurait été irréaliste d'exiger des pays utilisateurs d'assurer la mise en œuvre de toutes les transactions impliquant l'accès selon des modalités mutuellement convenues.

L'article 17 oblige les Parties à prendre des mesures pour surveiller et à améliorer la transparence concernant l'utilisation des ressources génétiques en établissant des points de contrôle et de délivrance des permis qui seront reconnues comme des certificats internationaux de conformité. Il n'y a aucune obligation d'informer le Secrétariat ou Centre d'échange sur l'accès et le partage des avantages de la désignation du poste de contrôle proposé et il n'y a pas obligation impérative de divulguer des renseignements à ces points de contrôle. Le texte évite délibérément l'utilisation de «divulgation» des mots ou «exigence de divulgation» et suggère plutôt indirectement qu'une exigence de divulgation aux points de contrôle désignés pourraient jouer un

rôle dans la mise en œuvre de l'article 17.1 (a), à la discrétion des Parties. L'article 17.2 du Protocole stipule qu'un permis ou son équivalent à la disposition du Centre d'échange sur l'accès et le partage des avantages, doit être un certificat de conformité internationalement reconnu, mais il n'est pas certain que «si le simple fait de l'enregistrement dans le système de l'accès et le partage des avantages d'échange élève un permis national ou équivalent au statut d'un certificat de conformité internationalement reconnu, ou si l'information enregistrée elle-même constitue ce certificat. L'article 17.3 empêche les Etats de tracer les ressources génétiques et protège l'utilisateur d'une accusation de bio-piraterie, parce que le certificat de conformité est la preuve que les ressources génétiques ont été consultées en toute légalité. L'article 17.4 contient une liste d'informations minimales qui doivent être incluses dans le certificat. En général, l'article 17 du Protocole reflète un compromis politique délicat entre pays en développement et pays développés. L'approche des «points de contrôle", "certificat de conformité" est conservée, mais le protocole introduit une grande souplesse et ne contient aucune référence à "l'exigence de divulgation» ou «bureau des brevets."

Enfin, la question la plus importante sur les procédures et les mécanismes de conformité est, «Qu'est-ce qui se passera lorsque le Protocole entrera en vigueur? L'article 30 se réfère à la responsabilité de la première Réunion des Parties du Protocole visant à "examiner et approuver les procédures de coopération et un mécanisme institutionnel visant à promouvoir le respect des dispositions du présent Protocole et à traiter de la non-conformité».

PARTIE 2 – L'intégration du Protocole de Nagoya en droit national – le cas du Vietnam

Titre 1 – Les question juridiques

CHAPITRE 1 - Points de vue juridiques sur l'intégration du droit international dans le droit national

Ce chapitre analyse la faiblesse du droit international et deux points de vue principaux de l'impact à l'intégration du protocole dans le droit national dans la première section. La faiblesse du droit international peut être trouvée dans les institutions, la compétence, les sujets à questions, le respect et l'application. *Tout d'abord*, le droit international est essentiellement composé et mis en œuvre par les Etats. Il ne peut y avoir aucune hiérarchie à gouverner des Etats souverains, parce que les Etats obéissent seulement à la « loi » quand il est dans leur intérêt de le faire. *Deuxièmement*, en ce qui concerne le droit international comme «loi», les arguments des critiques centrées sur l'absence d'une législation et, plus récemment, sur le thème de sanctions et de mise en conformité. *Troisièmement*, en comparaison, le droit interne s'adresse à un grand nombre d'organismes gouvernementaux et à des particuliers ou des groupes d'individus tandis que le droit international est principalement lié à la réglementation juridique de la communication internationale des Etats qui sont organisés en entités territoriales, sont en nombre limité et ne tiennent compte que d'eux mêmes.

Le droit international pose également problème pour l'application et le respect de ses normes. La conséquence en est un travail moins efficace dans le droit international que dans le droit national.

Les problèmes dans la procédure d'élaboration du droit international sont réels et amènent potentiellement des déficits démocratiques à deux niveaux. Au niveau international, les institutions internationales ne sont pas directement responsables devant les personnes qui sont souvent touchées par les décisions. Le droit international laisse les procédures par lesquelles un traité est négocié à la volonté des États parties. Les Etats sont encore des acteurs principaux dans la conclusion de traités, ce qui est illustré par leur rôle central dans la négociation et la ratification des traités. Il est évident que dans des domaines particuliers du droit international, les pays industrialisés ont plus de pouvoir décisionnel que les pays en développement. Au niveau national, le problème est de savoir qui représente qui et pour quoi. Il manque une obligation légale de consultation de l'approbation parlementaire pour un traité avant sa ratification. La décision de faire un traité relève clairement de la « common law » à la branche exécutive du gouvernement qui représente l'état à l'étranger.

Les deux principaux points de vue dans le droit international sont monistes et dualiste. La vue moniste suppose que les systèmes juridiques nationaux et internationaux forment une unité. Le droit international n'a pas besoin d'être incorporé dans le droit national. Dans sa forme la plus pure, le monisme dicte que la législation nationale qui contredit le droit international est nulle et non avenue. La vision dualiste reconnaît la distinction entre droit national et international. Les normes juridiques du droit international ne peuvent pas être appliquées directement dans le droit national. Pour être applicable dans l'ordre juridique national, le droit international doit être transformé en droit national. Ce n'est que par la transformation, que les normes juridiques du droit international sont appliquées en tant que loi nationale et enfin les individus au sein de l'Etat peuvent en bénéficier ou se fonder sur le droit international. La transformation d'un accord international est la procédure stipulée par la législation nationale avec le but de l'accomplissement d'un accord international dans les pays signataires. La question centrale est alors de savoir si un système est supérieur à l'autre. Pour le dualiste, le droit international ne peut pas prétendre à la suprématie au sein du système juridique interne.

La controverse entre deux points de vue dure depuis longtemps. Mais certaines opinions s’expriment pour dire que cette controverse est infondée et pose problème. Elle ne reflète pas la pratique des États, et ne donne pas une réponse concluante sur la véritable relation entre droit international et droit national. En fait, droit international et droit national ne sont pas comparables puisque les deux ont leur propre sphère d'activité et on ne peut subordonner l’un à l'autre. La suprématie du droit international dans la sphère internationale est incontestée de la même manière que le droit national dans les affaires internes. Ils sont mutuellement indépendants et normalement n’entrent pas en conflit les uns avec les autres .... Le droit international n’a pas pour objet de régir le contenu de la législation nationale dans la sphère nationale. Le droit international se concentre sur les relations entre les Etats, et la législation nationale traite les relations entre les personnes relevant de sa compétence.

Pour analyser les problèmes des traités *non-auto-exécutoires*, juridiquement «contraignant», cette partie débute avec la définition du traité découlant de la convention de Vienne sur le droit des traités. Dans le Protocole de Nagoya, la responsabilité d'un État n'est pas

claire et dépend de la discrétion de l'Etat. Ainsi, il peut y avoir des problèmes pour définir si l'Etat rompt le protocole ou non.

Ce chapitre analyse également les problèmes de l'accord juridiquement contraignant. *Tout d'abord*, des problèmes d'acceptabilité, ils est mis en évidence que dans les traités multilatéraux, le texte ayant été adopté, il n'est pas rare qu'il faille un temps considérable pour acquérir un nombre suffisant de ratifications nécessaires pour son entrée en vigueur. Un problème comparable, mais certainement plus grave, c'est que de nombreux traités multilatéraux de caractère général ne semblent jamais obtenir quoi que ce soit de la part des États-Unis, traitant par exemple des questions touchant les intérêts de tous ou presque tous les États dans le monde. Donc, il faut «plus petit dénominateur commun» - l'approche la plus couramment rencontrée dans les traités multilatéraux et aussi le Protocole de Nagoya. Cette approche montre que rarement au cours des négociations, d'ensemble d'accords, de surmonter les difficultés auxquelles sont confrontés les Etats dans un projet de texte, et par conséquent, cela se traduit généralement par une formulation assez abstraite et/ou vague du texte concerné. Il ya deux raisons à la ratification lente ou à l'échec de ratification des traités multilatéraux par un grand nombre d'États, ce sont l'incapacité technique et le refus politique. C'est ce qui s'est passé avec le cas du Protocole de Nagoya. Il avait connu une longue négociation, et maintenant, on ne sait pas quand il va acquérir la cinquantième ratification pour entrer en vigueur.

Deuxièmement, il s'agit des problèmes d'adaptation et de changement. La rédaction ouverte des traités n'est pas complètement protégée. Si le système juridique national a mis au point différentes techniques pour faire face et, pour le moins à neutraliser les effets négatifs de la rédaction ouverte des droits, elle ne peut être appliquée que dans une mesure très limitée. Le principal obstacle pour lutter efficacement contre les cas de rédaction ouverte est donc constitué par l'une des caractéristiques fondamentales du droit international que par l'absence d'une structure hiérarchique / organisationnelle.

Il ya des solutions aux problèmes d'un traité non-auto-exécutoire. Il n'existe aucune définition officielle d'un traité auto- exécutoire ou d'un traité non-auto-exécutoire en vertu de la Convention de Vienne sur le droit des traités ou d'autres traités multilatéraux. Cependant, certains chercheurs ont décrit la nature et les caractéristiques des traités auto-exécutoires pour définir ce concept et les obligations des États parties aux traités. Un traité auto- exécutoire est automatiquement partie du droit interne et exécutoire par les tribunaux, mais les traités qui exigent de nouvelles dispositions législatives pour les mettre en œuvre ne sont pas non-auto-exécutoires et ne sont donc pas applicables tant que la législation mise en œuvre n'a pas été adoptée. Les tribunaux examinent les intentions des parties et la teneur de l'accord pour rendre une décision. "Un traité non-auto-exécutoire doit avoir un caractère distinctif d'un traité auto- exécutoire pour sa mise en œuvre nationale.

Il est convenu que le terme « non-auto-exécutoire » a été utilisé pour décrire les traités qui ne sont pas exécutoires par les tribunaux, sans mise en œuvre législative préalable pour une multiplicité de raisons distinctes.

Tout d'abord, l'application des règlements internationaux à travers leur adoption dans la

législation nationale est fréquente. Sous réserve des traités auto- exécutoires ou les traités non-auto-exécutoires, les traités peuvent s'appliquer directement à des pays n'ayant pas de besoins de procédures constitutionnelles pour la ratification ou l'approbation et n'ont pas besoin d'avoir des mesures législatives correspondant.

Deuxièmement, on doit distinguer la technique d'incorporation d'un traité dans le droit national. Un traité peut bien être considéré comme auto exécutoire pour les tribunaux d'un État, mais pas pour un autre. D'autre part le concept de «applicabilité directe» a été considéré comme une question de droit international, selon que le traité de droit international ai été voulu par les parties directement applicable en tant que tel dans leur droit national.

Troisièmement, la question de savoir si un traité est directement applicable ou self-executing dans un pays donné ne peut être utilement abordée que lorsque l'on sait comment sont mis en œuvre les traités sur le plan national et quelles sont les hypothèses conceptuelles les rendants contraignants. Tout d'abord, tous les traités pourraient être considérés comme non auto exécutoires dans les États dualistes, où un traité dûment ratifié n'est pas une des sources formelles du droit et requiert toujours une loi d'application. C'est différent avec les États monistes où un traité non-auto-exécutoire a le même effet juridique interne, et il devient le droit interne quand il a été dûment ratifié. Deuxièmement, les traités non-auto-exécutoires jouissent du statut normatif même dans les États monistes. Ils sont la loi ou une source de droit pour une variété de finalités intrenes. Dans les États dualistes, en revanche, où tous les traités exigent la mise en œuvre la législation avant que de devenir le droit interne, le traité n'est pas dans un sens formel, une source de droit.

Dans le détail, un traité non-auto-exécutoire est soumis à la volonté politique; selon le droit interne à des changements de loi, et à l'interprétation de savoir si un traité est auto-exécutoire ou non-auto-exécutoire, selon les argument des doctrines de non-auto-exécution.

Le Protocole de Nagoya est caractérisée par la formulation d'un « traité non-auto-exécutoire". Les difficultés qu'ont les Etats à intégrer le Protocole de Nagoya dans leur droit national ou de le rendre exécutable avec un langage vague du Protocole, dépends de la volonté politique, et de la situation réelle de la législation nationale en vigueur.

CHAPITRE 2 – Les principes, méthodes et moyens de l'intégration du protocole de Nagoya dans le droit national

La loi ne peut pas exister sans le principe qu'il est nécessaire de remarquer une situation essentielle pour identifier les caractéristiques des caractéristiques de qualité de la loi qui allègent vers la justice. Intégration du protocole de Nagoya dans le droit national ne peut pas éviter les principes généraux du droit. Par conséquent, ce chapitre considère que les principes de l'intégration du protocole de Nagoya dans les législations nationales. Certains principes de base du droit international sont la souveraineté, la coopération, le souci commun de l'humanité. Des principes juridiques du droit international de l'environnement sont analysés par des principes de fond et les principes du processus. Pour les principes de fond, ce chapitre examine trois aspects: les principes généraux du droit de l'environnement, les principes pour l'examen de la loi des ressources naturelles, des principes équitables. Les principes généraux de droit de l'environnement

comprend: les principes de prévention, pollueur-payeur, de précaution et un nouveau principe de droit de l'environnement est le principe de non-régression. Principes pour l'examen de la loi des ressources naturelles comprennent la conservation et l'utilisation durable des ressources naturelles, l'utilisation raisonnable, d'abus de droits. Les principes d'équité sont l'équité intergénérationnelle, l'utilisation équitable, le principe de responsabilités communes mais différenciées. Principes du processus comprennent le devoir de savoir, le devoir d'informer et de consulter, la participation du public.

Ce chapitre analyse également les méthodes, les mesures d'impact et d'autres facteurs à l'intégration du protocole de Nagoya dans les législations nationales, parce que, le droit international stipule que rarement la manière dont un État doit mettre en œuvre ses dispositions, en laissant à l'Etat de choisir la procédure appropriée pour le d'exécution dans leurs territoires.

L'auteur choisit d'analyser trois méthodes qui sont utiles pour l'intégration du protocole de Nagoya dans le droit national. La méthode de la législation comprend la promulgation de mesures législatives dans les lois civiles, pénales et administratives pour donner effet aux droits et obligations reconnus dans le Protocole ou soi-disant que la création du droit national. La méthode de constitution de cette norme du protocole serait incorporée dans le droit national. Une juridiction nationale ou toute autre loi-application agence a directement recours à des dispositions du Protocole. Interprétation vise également la conciliation entre le droit international et droit national.

Il y a de nombreuses mesures peuvent être envisagées pour le processus d'intégration, qui comprennent des mesures réglementaires, les mesures administratives et judiciaires, mesures techniques, mesures économiques, le suivi, la surveillance et de vérification.

Les mesures réglementaires comprennent l'établissement de normes et de restriction et les interdictions. Réglage standard comprend des normes de processus et des normes de produits. Les mesures de restriction et interdictions comprennent des limites ou des interdictions, en prenant des mesures commerciales, d'importation et restrictions à l'exportation. Les mesures administratives et judiciaires comprennent: les procédures administratives, la responsabilité civile. La compétence juridictionnelle comprend le choix de la loi, l'évaluation des dommages, l'exécution des jugements étrangers, la responsabilité et l'indemnisation, le droit pénal. Les mesures techniques comprennent l'évaluation d'impact environnemental (EIE), octroi de licences et de permis. Les mesures économiques comprennent la fiscalité, permis négociables, permis négociables et l'étiquetage. Le chapitre analyse également le suivi, la surveillance et l'audit.

Ce chapitre analyse l'impact des facteurs à l'intégration du protocole de Nagoya dans les législations nationales qui se concentre sur les facteurs culturels et linguistiques des facteurs.

Title 2 – L'accès aux ressources génétiques et le partage des avantages dans les droits nationaux – le cas du Vietnam

CHAPITRE 1 – L'accès aux ressources génétiques et le partage des avantages dans les droits nationaux d'Etats sélectionnés et les défis pour l'intégration du Protocole de Nagoya

La situation générale des droits nationaux sur l'accès aux ressources génétiques et le partage des avantages est insuffisante pour assurer la mise en œuvre du Protocole. Peu de régimes

ont été adoptés et ne permettent pas un accès et un partage des avantages, à cause d'un manque de traçabilité et une absence de recours spécifiques. La définition des droits et la propriété sur les ressources génétiques ne sont également pas claires. De plus, il existe des asymétries entre les utilisateurs et les fournisseurs, et un déficit de connaissances.

Pourtant, une fois la ratification ou l'adhésion du Protocole de Nagoya réalisée, chaque Etat est tenu de prendre des mesures appropriées et développer sa législation sur l'accès et le partage des avantages pour combler les lacunes et se conformer au Protocole. Cependant, il n'existe que peu de moyens juridiques, d'approche globale, et de mesures en ce sens. Dès lors, la plupart des suggestions de la thèse visent à développer une conscience politique, des stratégies institutionnelles, des procédures et la capacité de mettre en œuvre une législation sur l'accès et le partage des avantages. En pratique, les pays fournisseurs se fondent sur l'état de leur législation actuelle caractérisée par un manque d'uniformité, et des incertitudes, rendant incertaine une mise en œuvre effective du Protocole. Les difficultés pour les pays utilisateurs résident dans le caractère flexible et limité des dispositions du Protocole concernant la surveillance et la conformité, et il semble nécessaire d'instaurer dans les législations nationales des mesures qui permettraient et encourageraient chaque utilisateur à s'engager dans des négociations contractuelles, dans le respect des conditions convenues d'un commun accord .

Cette étude se base sur une sélection de législations nationales fondée sur des critères de reposant sur : 1-une représentativité des continents ; 2- une étude d'Etats fournisseurs et utilisateurs; 3- des Etats développés et en développement; 4- des régimes juridiques basés sur les conceptions « dualiste » et « moniste » de l'ordre juridique ; des systèmes de Common Law et de droit romain – des systèmes de droit civil napoléonien, 5- une grande expérience dans le droit de la biodiversité et dans l'accès et le développement du droit au partage des avantages. 6 - Surtout, le développement par ces Etats d'une législation sur l'accès et le partage des avantages conformément à la liste figurant dans la base de données de la CDB.

La législation sur l'accès et le partage des avantages du Brésil peut être résumée comme suit : le Brésil était le premier pays à avoir signé la CDB. Suite à la publication du décret législatif n°2 de 1994, le Brésil a ratifié la CDB, introduisant ses dispositions dans le droit national. La décision provisoire 2186-16/2001 après plusieurs rééditions, demeure le principal instrument juridique brésilien sur l'accès et le transfert du patrimoine génétique, ainsi que sur l'accès aux savoirs traditionnels. Depuis sa publication, la décision provisoire se caractérise par certains articles réglementés dans des décrets. Aucune réglementation spécifique ne traite de la propriété, mais l'État a le droit de contrôler ou d'autoriser l'utilisation des ressources génétiques. Bien qu'aucune loi n'a été adoptée au niveau fédéral, et qu'il n'existe pas de droit clairement énoncé sur le statut juridique des ressources génétiques, les Etats de l'Amapa et de l'Acre ont adopté leurs propres lois régissant l'accès à ces ressources. Dans ces deux États, les ressources génétiques sont considérées comme le patrimoine de l'Etat et se distinguent des ressources biologiques qui les contiennent et peuvent être de propriété privée ou communale.

Le Brésil prévoit que les modalités mutuellement convenues sur l'accès et le partage des avantages doivent être énoncées dans un document ou un ensemble de documents pouvant inclure des permis, des contrats et des accords de transfert du matériel. Ces mesures prévoient

généralement un partage des avantages avec l'État. Cette situation montre la diversité des modalités du partage des avantages dans la pratique, et que les dispositions flexibles de l'article 5 du Protocole peuvent être intégrées dans des lois nationales selon diverses méthodes. Ces dispositions sur le partage des avantages reflètent clairement les principes susmentionnés.

La décision provisoire du Brésil établit également certaines dispositions concernant les mesures visant les utilisateurs, bien que leur précision soit inférieure à celles relatives aux mesures des fournisseurs. Celles-ci concernent tant les utilisateurs domestiques qu'étrangers. Bien qu'une limite de la décision provisoire réside dans l'absence de loi sur l'accès et le partage des avantages approuvée par le Congrès du Brésil, elle constitue l'un des seuls instruments juridiques étatiques comprenant des dispositions sur l'utilisation.

La stratégie du Brésil apparaît clairement, en tant que premier signataire du Protocole, tout en décidant une ratification et une adaptation de sa législation ultérieurement. L'intégration du Protocole reste donc à réaliser. Elle implique notamment une amélioration du statut juridique des ressources génétiques, et une réponse aux exigences de sécurité, de clarté et de transparence dans l'accès et le partage des avantages, conformément au Protocole, pour assurer son respect.

En Afrique du Sud, la loi sur la biodiversité, qui a été promulguée en 2004, revêt une importance particulière au regard des engagements de l'Afrique du Sud concernant la CDB. La loi sur la biodiversité prévoit la gestion et la conservation de la biodiversité en Afrique du Sud et les moyens de leur réalisation, en traitant notamment de l'utilisation durable des ressources biologiques indigènes et du partage juste et équitable entre les parties prenantes des avantages découlant de la bio-prospection impliquant la biodiversité indigène.

Les ressources génétiques et leur propriété ne sont pas explicitement prises en compte par la Constitution. Cependant, en se fondant sur la Constitution, le gouvernement national et les neuf provinces se sont accordés pour concurrencer la compétence législative dans la plupart des domaines relevant de la conservation de la biodiversité.

La loi sur la biodiversité en vigueur reconnaît la propriété privée sur les ressources génétiques, par exemple, lorsqu'elles se situent sur des terres ou des propriétés privées. Le processus d'autorisation prévu par la loi exige que des négociations soient menées, et un accord conclu entre une "partie prenante" et un candidat avant que l'Etat ne délivre le permis nécessaire.

En tant que pays fournisseur, il est difficile pour l'Afrique du Sud de répondre aux exigences de sécurité, de clarté et de transparence sur l'accès et le partage des avantages de l'article 6.1.a du Protocole parce que le cadre réglementaire demeure peu clair et les relations avec les autorités compétentes et les parties prenantes n'ont pas encore été établies. Suite à l'article 5.4 du Protocole, les prestations peuvent inclure des avantages monétaires et non monétaires. Alors que la plupart des législations nationales prévoient des avantages monétaires et non monétaires, il est intéressant de noter que l'Afrique du Sud se concentre uniquement sur les avantages monétaires. La loi sur la biodiversité prévoit également la mise en place de fonds d'affectation spéciale, dans lesquels les prestations reçues par l'Etat et non distribués aux parties prenantes seront conservés. En ce qui concerne les savoirs traditionnels, il existe plusieurs bases juridiques pertinentes pour incorporer l'article 2 du Protocole et rendre le partage juste et équitable des avantages découlant de

l'utilisation de ces connaissances. Cependant, dans les faits, peu d'attention est accordée à la nécessité d'obtenir d'un consentement préalable donné en connaissance de cause des détenteurs de savoirs traditionnels. En ce qui concerne la conformité, les mesures indiquent généralement que toute infraction aux dispositions de la législation, de la réglementation ou des lignes directrices et tout accès non autorisé aux ressources génétiques ou biologiques fera l'objet de sanctions. En outre, de nombreuses mesures indiquent que le non-respect des clauses d'un accord concernant l'accès et le partage des avantages sera également sanctionné.

Au même titre que pour le Brésil, l'Afrique du Sud a choisi d'être parmi les premiers signataires du Protocole, tout en décidant une ratification et une intégration dans sa législation ultérieurement. Dès lors, la transposition de ces dispositions reste à entreprendre. Elle est nécessaire pour améliorer le droit en termes de sécurité, de clarté et de transparence, pour assurer l'accès et le partage des avantages conformément au Protocole.

Ce chapitre examine la loi type africaine comme un instrument de référence de l'Union africaine, l'Afrique du Sud, étant membre de cette organisation. Malgré tout, cette législation contient également des lacunes importantes, lorsqu'elle est replacée dans le contexte du Protocole de Nagoya et il est nécessaire de garder à l'esprit que l'un des objectifs fondamentaux de la loi type africaine était de donner effet au troisième objectif de la CDB. Néanmoins, l'adoption du Protocole de Nagoya reflète beaucoup, sinon la plupart des aspirations contenues dans la loi africaine et il est devenu nécessaire de trouver un moyen d'utiliser les caractéristiques positives de cette loi pour aider les pays africains à atteindre leurs obligations internationales dans la mise en œuvre du Protocole de Nagoya.

La France a ratifié une série de conventions internationales relatives à la conservation de la biodiversité. Afin de réaliser les objectifs politiques de protection de la biodiversité, la France a également adopté une législation et une réglementation spécifiques, régulièrement actualisées. Cependant, il n'existe pas de cadre juridique national sur l'accès et le partage des avantages dans les territoires d'outre-mer.

La législation française ne comporte aucune disposition définissant le statut juridique et la propriété des ressources génétiques. Toutefois, sur la base de dispositions du Code de l'environnement, les ressources génétiques peuvent être comprises en tant que patrimoine commun de la nation. Par conséquent, il est nécessaire de préciser qui devient « fournisseur ». Tout d'abord, en ce qui concerne l'attribution de compétence dans l'environnement, la personne publique propriétaire est considérée comme fournisseur de ressources génétiques. Ensuite, bien les ressources génétiques constituent un « bien » au sens juridique, elles ne disposent pas d'un régime juridique particulier. En d'autres termes, elles sont soumises à la propriété commune régie par la loi : les autorités compétentes pour l'accès aux ressources génétiques sont ainsi chargées de délivrer une autorisation préalable (permis ou équivalent) aux personnes individuelles ou à la collectivité fournisseuse.

Le régime juridique sur l'accès et le partage des avantages n'existe en France que dans les territoires d'outre-mer. Des exemples reflètent le développement de ce régime juridique et concernent la seule province sud de Nouvelle-Calédonie et le parc amazonien de Guyane. Les

limites de ces dispositions concernent : un champ d'application variable selon les territoires et les finalités, la difficulté pour les utilisateurs d'identifier les autorités compétentes chargées de délivrer les autorisations d'accès, et une forte demande des utilisateurs et des fournisseurs d'outre-mer pour un cadre juridique dans ce domaine.

L'accès aux ressources génétiques requiert une autorisation auprès de l'Autorité nationale compétente et / ou des fournisseurs de consentement préalable donné en connaissance de cause en tant que particuliers titulaires de droits et / ou le consentement préalable donné en connaissance de cause des communautés autochtones et locales.

Dans les territoires français d'outre-mer, il existe un manque de consensus des intervenants sur la notion de bénéfice. Ces différentes conceptions causent parfois des tensions et exacerbent un sentiment de pillage des autorités et des communautés locales. En effet, aucun régime juridique ne précise la nature des avantages découlant de l'utilisation des ressources génétiques et des savoirs traditionnels. Par conséquent, la définition des prestations est basée sur la volonté des parties prenantes et peut prendre la forme de publications, d'avantages financiers tirés de l'exploitation des ressources génétiques, une restitution, etc ...

En ce qui concerne le statut juridique des communautés autochtones et locales, leurs droits ne correspondent pas nécessairement à une véritable reconnaissance des règles et des structures coutumières de la loi de l'État. En général, le droit français ne reconnaît pas le concept de « minorités ethniques, religieuses ou linguistiques ». Il n'existe pas de référence aux « communautés autochtones et locales », en dehors d'une loi-cadre sur les étrangers de 2000. De plus, les savoirs traditionnels ne sont pas reconnus par la loi. Cependant, leur protection peut être assurée par des droits de propriété intellectuelle, mais ceux-ci s'avèrent inadaptés à leurs caractéristiques.

Concernant le respect, différentes mesures de surveillance et de contrôle existent, telles que le suivi des projets dans le temps et l'établissement des contrôles par étape. Il existe également des procédures administratives et judiciaires applicables en France permettant notamment aux demandeurs étrangers d'obtenir une réparation devant les tribunaux français. Certaines mesures procédurales peuvent encore être considérées, telles que l'arbitrage international et la coopération judiciaire prévus dans le Code de procédure civile.

La France a clairement opté pour une stratégie consistant à signer prioritairement le Protocole, tout en assurant sa ratification et sa transposition ultérieurement. Par conséquent, les dispositions du Protocole doivent être incorporées dans le droit national. L'élaboration d'une législation sur l'accès et le partage des avantages est en cours de réalisation.

Ce chapitre analyse également l'Union européenne en tant qu'utilisateur de ressources génétiques. Cependant, sur le plan politique, l'UE ne traite pas la question des ressources génétiques. Un petit nombre de mesures législatives et politiques des membres de l'UE abordent directement les dispositions de la CDB sur l'accès et le partage des avantages. Pour sa part, l'UE encourage les pays en développement à consolider leur cadre juridique sur l'accès et le partage des avantages. En tant qu'« utilisateur », les discussions se concentrent principalement sur la

divulgation de l'origine dans les demandes de brevet. La politique de l'UE permet d'assurer un lien entre le droit de propriété intellectuelle et le partage des avantages.

Les défis pour l'intégration des obligations de l'utilisateur issues du Protocole se révèlent insuffisantes dans la plupart des Etats pour assurer une sensibilisation efficace des utilisateurs de ressources génétiques. La Directive 98/44/CE, qui constitue l'instrument juridique de l'UE prenant spécifiquement en compte les dispositions de la CDB sur l'accès et le partage des avantages s'avère quant à elle peu applicable. L'entrée en vigueur du Protocole dans l'UE a compliqué la situation pour les États membres parce que ceux-ci doivent désormais mettre en œuvre et appliquer les normes juridiques émises par les institutions de l'UE ainsi que les engagements internationaux pris à l'échelon régional.

Au final, l'UE ne dispose d'aucun instrument juridique encadrant spécifiquementl'accès et le partage des avantages, mais certaines mesures législatives et politiques pourraient contribuer à la mise en œuvre du protocole. Cette transposition comporte certains défis, notamment concernant l'intégration des mesures visant les utilisateurs. Il est clair que l'Union européenne a choisi une approche de premier signataire en décidant ensuite la ratification et le développement législatif sur l'accès et le partage des avantages. En cas de ratification du Protocole, un instrument juridique spécialisé sur les questions d'accès et de partage des avantages pourrait s'avérer nécessaire.

CHAPITRE 2 – Les droits sur l'accès aux ressources génétiques et le partage des avantages au Vietnam et l'intégration du protocole de Nagoya

Le Vietnam fait parti des Etats les plus importants en termes diversité génétique et de savoirs traditionnels. Le rôle et l'importance des ressources génétiques ont beaucoup compté dans le développement socio-économique du pays ces dernières années, notamment dans les domaines de l'agriculture, de la sylviculture et de la pêche, qui représentent un pourcentage significatif de l'économie nationale. Cependant, l'extinction et la dégradation des ressources génétiques se poursuivent sans solutions efficaces.

Adhérer au Protocole contribuera à mettre en œuvre les responsabilités du Vietnam au regard de la CDB, et instituera une obligation supplémentaire pour le Vietnam afin de faciliter l'accès et assurer un partage juste et équitable des avantages découlant de l'utilisation des ressources génétiques et des savoirs traditionnels. Cette obligation pourrait inciter le Vietnam à développer des marchés pour les produits dérivés de ressources génétiques, et améliorer les impacts socio-économiques des activités liées à l'accès et au partage de ces avantages.

Avant la loi sur la biodiversité de 2008, le Vietnam ne disposait pas de règle juridique claire et complète sur l'accès et le partage des avantages. En vertu de la loi sur la biodiversité et ses règlements, l'accès et le partage des avantages est régi par l'article 1 (Articles 55-61), quelques articles connexes de la section 2 du chapitre V de la loi sur la biodiversité, et par le décret 65/2010/ND-CP du 11 juin 2010, qui établissent la base du système national vietnamien sur l'accès et le partage des avantages. Selon la loi, l'Etat, au nom du peuple du Vietnam, est l'unique propriétaire des ressources génétiques sur le territoire national (article 17 de la Constitution de 1992).

La loi sur la biodiversité du Vietnam et le décret 65/2010/ND-CP ont tous deux été publiées avant l'adoption du Protocole. Cependant, de manière générale, la législation vietnamienne sur l'accès et le partage des avantages s'avère en conformité avec son contenu.

Dans l'analyse des éléments sur l'accès et de partage des avantages, le principal problème concerne la démarcation de la compétence dans l'octroi de permis pour les ressources génétiques des espèces protégées entre la Ministère de l'Agriculture et du Développement rural et la Ministère des Ressources naturelles et de l'environnement, en cas de conflit grave ou de chevauchement entre des dispositions législatives des lois sur la biodiversité 2008, sur la protection et le développement des forêts de 2004, et la pêche de 2003. En outre, l'accès aux ressources génétiques est attaché aux savoirs traditionnels associés aux ressources génétiques, mais sous la gestion de l'Agence nationale de la propriété intellectuelle du Ministère de la Science et la Technologie (MOST). Cependant, il n'existe pas de lignes directrices plus détaillées, même avec le décret 65/2010/ND-CP, et il s'avère très difficile pour les populations locales et les responsables locaux de mettre en œuvre les dispositions sur l'accès et le partage des avantages. En outre, la loi sur la biodiversité et le décret 65/2010/ND-CP ne détaillent pas l'application de la loi. La loi sur la biodiversité et le décret 65/2010/ND-CP ont créé un cadre juridique au contenu minimum pour le partage des avantages en vertu du des conditions convenues d'un commun accord, dont les modalités d'application relèvent du contrat. Le même problème concerne le partage des avantages avec les communautés locales résidant dans les zones tampons des aires protégées qui devraient constituer des cibles prioritaires pour le partage, et être encouragées à participer aux activités de conservation. Les communautés locales résidant à l'intérieur ou autour de la zone protégée qui ne sont pas engagées dans la gestion des ressources génétiques des zones protégées ne pourront cependant pas bénéficier des avantages résultant de leur utilisation. Le décret 65/2010/ND-CP prévoit une liste de prestations comprenant des avantages monétaires et non monétaires. Un point important du décret 65/2010/ND-CP est de déterminer un ratio de bénéfice total découlant de l'accès aux ressources génétiques et d'organiser un partage entre les parties à la licence ou à l'accord, comprenant au minimum 30% de prestations devant être converties en espèces. Une grande partie de la réglementation traite également des avantages découlant de l'utilisation des ressources génétiques non soumises à l'octroi d'une licence, ou ne répondant pas au d'un consentement préalable donné en connaissance de cause et au des conditions convenues d'un commun accord .

Cependant, les dispositions sur l'accès et le partage des avantages et des bénéficies n'incluent pas les fournisseurs de savoirs traditionnels. L'article 60.2.c impose seulement de partager les avantages avec les parties liées, y compris la répartition des droits de propriété intellectuelle sur les résultats de l'invention, lorsque les droits d'auteurs sont issus de l'accès aux savoirs traditionnels. Cela signifie que les avantages ne sont partagés que lorsque les savoirs traditionnels sont protégés par des droits d'auteurs. En outre, le régime actuel ne prévoit pas de droits de propriété intellectuelle pour les savoirs traditionnels. Il existe seulement une disposition générale dans l'article 64 sur le droit d'auteur des savoirs traditionnels sur les ressources génétiques.

Au Vietnam, la licence pour l'accès aux ressources génétiques, qui est censée devenir le certificat si le Vietnam adhère au Protocole et répond aux exigences de l'article 17.2, est prévue dans l'article 59 de la loi sur la biodiversité. En comparaison avec l'article 17.4 du Protocole, il exige une information minimale pour le certificat quand il n'est pas confidentiel, différente de l'article 59.3 de la loi sur la biodiversité

La question est de savoir en cas de manquement aux obligations susmentionnées, quelle réglementation sera appliquée. En effet, le décret sur le traitement des violations administratives dans le domaine de la biodiversité demeure applicable. Ces dispositions dans le domaine de l'environnement, de la protection et du développement des pêcheries n'incluent cependant pas l'accès et le partage des avantages. Dès lors, la violation des obligations contractuelles relatives à l'accès aux ressources génétiques et au partage des avantages pourrait se fonder sur des dispositions générales du Code civil de 2005, mais celles-ci ne seront pas efficaces en l'absence de lignes directrices tenant compte des caractéristiques de l'accès et du partage des avantages.

En somme, le cadre juridique vietnamien actuel sur l'accès et le partage des avantages est basé sur des considérations générales, inapplicables sans précision spécifique, et il n'existe aucune évaluation officielle d'organismes d'État sur la mise en œuvre de l'accès et du partage des avantages. Toutefois, en parallèle au débat sur l'existence d'un régime sur l'accès national et le partage des avantages, une pratique tend à s'affirmer dans ce domaine. Elle se traduit pour l'auteur, par la transmission d'informations basées sur des études de cas, essentiellement issues de rapports étrangers ou de l'institution de recherche. La plupart de ces pratiques datent d'avant la loi sur la biodiversité de 2008. Le point focal national de la CDB du Vietnam et d'autres fournisseurs vietnamiens n'ont pas collecté de données sur l'accès et le partage de l'information ou n'ont aucune idée du régime juridique applicable dans ce domaine. Cette situation démontre que la sensibilisation sur l'accès et le partage des avantages au Vietnam est limitée, et cette très faible capacité sera un défi pour intégrer du Protocole de Nagoya dans la législation. Les études de cas montrent la diversité des intervenants impliqués, de l'utilisateur au fournisseur, la variété des types de ressources génétiques végétales pour l'alimentation et l'agriculture, des plantes pour la médecine et les produits cosmétiques, des micro-organismes, et des enzymes. Ces ressources génétiques pourraient être sur la liste des espèces protégées ou des espèces populaires, y compris des savoirs traditionnels associés aux ressources génétiques. Ces études de cas associent : 1) « Nature's Way with Panax vietnamensis », 2) l'institut national sur le cancer des États-Unis (NCI), 3) l'Université de l'Illinois-Chicago et le recherche en collaboration sur les sciences pharmaceutiques, 4) le New EnglandBio-labs (NEB) and enzymes, 5) l'institut national japonais de technologie et d'évaluation (NITE) et micro-organismes, 6) l'International Rice Research Institute et le Centre national pour les ressources phytogénétiques du Japon et de sélection de nouvelles variétés de riz, 8) « la SAPA Essential Company and Medicinal Plants Association », 9) l'OMS et des échantillons de virus H5N1.

L'intégration du protocole de Nagoya dans la législation nationale du Vietnam est orientée vers le haut avec des défis et des opportunités. Celle-ci constitue une nouvelle problématique pour le pays. La sensibilisation sur le potentiel des ressources génétiques, le partage juste et équitable des avantages qui en découlent, et la nécessité de créer un accès au marché pour les communautés,

les entreprises et les instituts, est encore limitée. Bien que le cadre juridique sur l'accès et le partage des avantages ait été introduit dans le droit national, il existe de nombreuses lacunes, des conflits et des chevauchements empêchant une application de la réglementation dans la pratique. Pour rendre le régime efficace, il faudra des efforts concertés de toutes les parties prenantes.

Conclusion

Bien que son but soit de mettre en œuvre des dispositions sur l'accès et le partage des avantages de la CDB, le Protocole lui-même semble constituer un accord-cadre avec de nombreuses ambiguïtés et des lacunes intentionnelles, notamment en matière de flexibilité dans le partage des avantages et des mécanismes facultatifs de mise en conformité, entrainant un faible respect à l'origine du détournements de ressources génétiques. Cette situation est à l'origine de réticences étatiques concernant sa ratification et les 50 ratifications nécessaires à son entrée en vigueur seront difficiles à atteindre.

Différents scénarios sont envisageables pour le Protocole. Dans le premier, il disposerait de 92 signatures, sans pour autant bénéficier des 50 instruments de ratifications, et ne pourrait donc pas entrer en vigueur. Il ne constituerait alors qu'une obligation légale indirecte. Le second scénario serait l'entrée en vigueur avec un nombre minimum de ratification, sans transposition pour autant de tous les Etats signataires. Dans ce cas, les effets juridiques seraient également limités.

Deux stratégies d'adoption du Protocole sont envisageables par les Etats. Dans la première, ils disposent d'une bonne législation nationale en conformité avec le Protocole, et décident ensuite de le signer et de le ratifier. Dans ce cas, une évolution de la législation nationale ne sera pas nécessaire suite à l'adoption. Dans la seconde, les Etats décident de signer le protocole, et ensuite de le ratifier et de prendre les mesures nationales requises.

Dans les quatre pays sélectionnés, le Brésil, l'Afrique du Sud et la France ont déjà signé le protocole, contrairement au Vietnam. Ce dernier a choisi la première stratégie visant à améliorer l'accès et le partage dans sa législation avant d'adhérer au Protocole. Il constitue le bon moyen pour ne pas gaspiller le temps des pays membres de la CDB, en permettant aux Etats de prendre le temps d'améliorer le droit interne sur l'accès et le partage des avantages, puis en considérant l'opportunité de ratifier ou adhérer au Protocole.

ANNEX I

NAGOYA PROTOCOL ON ACCESS TO GENETIC RESOURCES AND THE FAIR AND EQUITABLE SHARING OF BENEFITS ARISING FROM THEIR UTILIZATION TO THE CONVENTION ON BIOLOGICAL DIVERSITY[1184]

The Parties to this Protocol,

Being Parties to the Convention on Biological Diversity, hereinafter referred to as ―the Convention□,

Recalling that the fair and equitable sharing of benefits arising from the utilization of genetic resources is one of three core objectives of the Convention, and *recognizing* that this Protocol pursues the implementation of this objective within the Convention,

Reaffirming the sovereign rights of States over their natural resources and according to the provisions of the Convention,

Recalling further Article 15 of the Convention,

Recognizing the important contribution to sustainable development made by technology transfer and cooperation to build research and innovation capacities for adding value to genetic resources in developing countries, in accordance with Articles 16 and 19 of the Convention,

Recognizing that public awareness of the economic value of ecosystems and biodiversity and the fair and equitable sharing of this economic value with the custodians of biodiversity are key incentives for the conservation of biological diversity and the sustainable use of its components,

Acknowledging the potential role of access and benefit-sharing to contribute to the conservation and sustainable use of biological diversity, poverty eradication and environmental sustainability and thereby contributing to achieving the Millennium Development Goals,

Acknowledging the linkage between access to genetic resources and the fair and equitable sharing of benefits arising from the utilization of such resources,

Recognizing the importance of providing legal certainty with respect to access to genetic resources and the fair and equitable sharing of benefits arising from their utilization,

Further recognizing the importance of promoting equity and fairness in negotiation of mutually agreed terms between providers and users of genetic resources,

Recognizing also the vital role that women play in access and benefit-sharing and *affirming* the need for the full participation of women at all levels of policymaking and implementation for biodiversity conservation,

Determined to further support the effective implementation of the access and benefit-sharing provisions of the Convention,

Recognizing that an innovative solution is required to address the fair and equitable sharing of benefits derived from the utilization of genetic resources and traditional knowledge associated with genetic resources that occur in transboundary situations or for which it is not possible to grant or obtain prior informed consent,

Recognizing the importance of genetic resources to food security, public health, biodiversity conservation, and the mitigation of and adaptation to climate change,

Recognizing the special nature of agricultural biodiversity, its distinctive features and problems needing distinctive solutions,

Recognizing the interdependence of all countries with regard to genetic resources for food and agriculture as well as their special nature and importance for achieving food security worldwide and for sustainable development of agriculture in the context of poverty alleviation and climate change and acknowledging the fundamental role of the

[1184] Available at http://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf

International Treaty on Plant Genetic Resources for Food and Agriculture and the FAO Commission on Genetic Resources for Food and Agriculture in this regard,

Mindful of the International Health Regulations (2005) of the World Health Organization and the importance of ensuring access to human pathogens for public health preparedness and response purposes,

Acknowledging ongoing work in other international forums relating to access and benefit-sharing,

Recalling the Multilateral System of Access and Benefit-sharing established under the International Treaty on Plant Genetic Resources for Food and Agriculture developed in harmony with the Convention,

Recognizing that international instruments related to access and benefit-sharing should be mutually supportive with a view to achieving the objectives of the Convention,

Recalling the relevance of Article 8(j) of the Convention as it relates to traditional knowledge associated with genetic resources and the fair and equitable sharing of benefits arising from the utilization of such knowledge,

Noting the interrelationship between genetic resources and traditional knowledge, their inseparable nature for indigenous and local communities, the importance of the traditional knowledge for the conservation of biological diversity and the sustainable use of its components, and for the sustainable livelihoods of these communities,

Recognizing the diversity of circumstances in which traditional knowledge associated with genetic resources is held or owned by indigenous and local communities,

Mindful that it is the right of indigenous and local communities to identify the rightful holders of their traditional knowledge associated with genetic resources, within their communities,

Further recognizing the unique circumstances where traditional knowledge associated with genetic resources is held in countries, which may be oral, documented or in other forms, reflecting a rich cultural heritage relevant for conservation and sustainable use of biological diversity,

Noting the United Nations Declaration on the Rights of Indigenous Peoples, and

Affirming that nothing in this Protocol shall be construed as diminishing or extinguishing the existing rights of indigenous and local communities,

Have agreed as follows:

ARTICLE 1

OBJECTIVE

The objective of this Protocol is the fair and equitable sharing of the benefits arising from the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components.

ARTICLE 2

USE OF TERMS

The terms defined in Article 2 of the Convention shall apply to this Protocol. In addition, for the purposes of this Protocol:

(a) “Conference of the Parties” means the Conference of the Parties to the Convention;

(b) “Convention” means the Convention on Biological Diversity;

(c) “Utilization of genetic resources” means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention;

(d) “Biotechnology” as defined in Article 2 of the Convention means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use;

(e) “Derivative” means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity.

ARTICLE 3

SCOPE

This Protocol shall apply to genetic resources within the scope of Article 15 of the Convention and to the benefits arising from the utilization of such resources. This Protocol shall also apply to traditional knowledge associated with genetic resources within the scope of the Convention and to the benefits arising from the utilization of such knowledge.

ARTICLE 4

RELATIONSHIP WITH INTERNATIONAL AGREEMENTS AND INSTRUMENTS

1. The provisions of this Protocol shall not affect the rights and obligations of any Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity. This paragraph is not intended to create a hierarchy between this Protocol and other international instruments.

2. Nothing in this Protocol shall prevent the Parties from developing and implementing other relevant international agreements, including other specialized access and benefit-sharing agreements, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol.

3. This Protocol shall be implemented in a mutually supportive manner with other international instruments relevant to this Protocol. Due regard should be paid to useful and relevant ongoing work or practices under such international instruments and relevant international organizations, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol.

4. This Protocol is the instrument for the implementation of the access and benefit-sharing provisions of the Convention. Where a specialized international access and benefit-sharing instrument applies that is consistent with, and does not run counter to the objectives of the Convention and this Protocol, this Protocol does not apply for the Party or Parties to the specialized instrument in respect of the specific genetic resource covered by and for the purpose of the specialized instrument.

ARTICLE 5

FAIR AND EQUITABLE BENEFIT-SHARING

1. In accordance with Article 15, paragraphs 3 and 7 of the Convention, benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization shall be shared in a fair and equitable way with the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention. Such sharing shall be upon mutually agreed terms.

2. Each Party shall take legislative, administrative or policy measures, as appropriate, with the aim of ensuring that benefits arising from the utilization of genetic resources that are held by indigenous and local communities, in accordance with domestic legislation regarding the established rights of these indigenous and local communities over these genetic resources, are shared in a fair and equitable way with the communities concerned, based on mutually agreed terms.

3. To implement paragraph 1 above, each Party shall take legislative, administrative or policy measures, as appropriate.

4. Benefits may include monetary and non-monetary benefits, including but not limited to those listed in the Annex.

5. Each Party shall take legislative, administrative or policy measures as appropriate, in order that the benefits arising from the utilization of traditional knowledge associated with genetic resources are shared in a fair and equitable way with indigenous and local communities holding such knowledge. Such sharing shall be upon mutually agreed terms.

ARTICLE 6

ACCESS TO GENETIC RESOURCES

1. In the exercise of sovereign rights over natural resources, and subject to domestic access and benefit-sharing legislation or regulatory requirements, access to genetic resources for their utilization shall be subject to the prior informed consent of the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention, unless otherwise determined by that Party.

2. In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that the prior informed consent or approval and involvement of indigenous and local communities is obtained for access to genetic resources where they have the established right to grant access to such resources.

3. Pursuant to paragraph 1 above, each Party requiring prior informed consent shall take the necessary legislative, administrative or policy measures, as appropriate, to:

(a) Provide for legal certainty, clarity and transparency of their domestic access and benefit-sharing legislation or regulatory requirements;

(b) Provide for fair and non-arbitrary rules and procedures on accessing genetic resources;

(c) Provide information on how to apply for prior informed consent;

(d) Provide for a clear and transparent written decision by a competent national authority, in a cost-effective manner and within a reasonable period of time;

(e) Provide for the issuance at the time of access of a permit or its equivalent as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms, and notify the Access and Benefit-sharing Clearing-House accordingly;

(f) Where applicable, and subject to domestic legislation, set out criteria and/or processes for obtaining prior informed consent or approval and involvement of indigenous and local communities for access to genetic resources; and

(g) Establish clear rules and procedures for requiring and establishing mutually agreed terms. Such terms shall be set out in writing and may include, *inter alia*:

(i) A dispute settlement clause;

(ii) Terms on benefit-sharing, including in relation to intellectual property rights;

(iii) Terms on subsequent third-party use, if any; and

(iv) Terms on changes of intent, where applicable.

ARTICLE 7

ACCESS TO TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES

In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that traditional knowledge associated with genetic resources that is held by indigenous and local communities is accessed with the prior and informed consent or approval and involvement of these indigenous and local communities, and that mutually agreed terms have been established.

ARTICLE 8

SPECIAL CONSIDERATIONS

In the development and implementation of its access and benefit-sharing legislation or regulatory requirements, each Party shall:

(a) Create conditions to promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries, including through simplified measures on access for non-commercial research purposes, taking into account the need to address a change of intent for such research;

(b) Pay due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health, as determined nationally or internationally. Parties may take into consideration the need for expeditious access to

genetic resources and expeditious fair and equitable sharing of benefits arising out of the use of such genetic resources, including access to affordable treatments by those in need, especially in developing countries;

(c) Consider the importance of genetic resources for food and agriculture and their special role for food security.

ARTICLE 9

CONTRIBUTION TO CONSERVATION AND SUSTAINABLE USE

The Parties shall encourage users and providers to direct benefits arising from the utilization of genetic resources towards the conservation of biological diversity and the sustainable use of its components.

ARTICLE 10

GLOBAL MULTILATERAL BENEFIT-SHARING MECHANISM

Parties shall consider the need for and modalities of a global multilateral benefit-sharing mechanism to address the fair and equitable sharing of benefits derived from the utilization of genetic resources and traditional knowledge associated with genetic resources that occur in transboundary situations or for which it is not possible to grant or obtain prior informed consent. The benefits shared by users of genetic resources and traditional knowledge associated with genetic resources through this mechanism shall be used to support the conservation of biological diversity and the sustainable use of its components globally.

ARTICLE 11

TRANSBOUNDARY COOPERATION

1. In instances where the same genetic resources are found *in situ* within the territory of more than one Party, those Parties shall endeavour to cooperate, as appropriate, with the involvement of indigenous and local communities concerned, where applicable, with a view to implementing this Protocol.

2. Where the same traditional knowledge associated with genetic resources is shared by one or more indigenous and local communities in several Parties, those Parties shall endeavour to cooperate, as appropriate, with the involvement of the indigenous and local communities concerned, with a view to implementing the objective of this Protocol.

ARTICLE 12

TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES

1. In implementing their obligations under this Protocol, Parties shall in accordance with domestic law take into consideration indigenous and local communities' customary laws, community protocols and procedures, as applicable, with respect to traditional knowledge associated with genetic resources.

2. Parties, with the effective participation of the indigenous and local communities concerned, shall establish mechanisms to inform potential users of traditional knowledge associated with genetic resources about their obligations, including measures as made available through the Access and Benefit-sharing Clearing-House for access to and fair and equitable sharing of benefits arising from the utilization of such knowledge.

3. Parties shall endeavour to support, as appropriate, the development by indigenous and local communities, including women within these communities, of:

(a) Community protocols in relation to access to traditional knowledge associated with genetic resources and the fair and equitable sharing of benefits arising out of the utilization of such knowledge;

(b) Minimum requirements for mutually agreed terms to secure the fair and equitable sharing of benefits arising from the utilization of traditional knowledge associated with genetic resources; and

(c) Model contractual clauses for benefit-sharing arising from the utilization of traditional knowledge associated with genetic resources.

4. Parties, in their implementation of this Protocol, shall, as far as possible, not restrict the customary use and exchange of genetic resources and associated traditional knowledge within and amongst indigenous and local communities in accordance with the objectives of the Convention.

ARTICLE 13

NATIONAL FOCAL POINTS AND COMPETENT NATIONAL AUTHORITIES

1. Each Party shall designate a national focal point on access and benefit-sharing. The national focal point shall make information available as follows:

(a) For applicants seeking access to genetic resources, information on procedures for obtaining prior informed consent and establishing mutually agreed terms, including benefit-sharing;

(b) For applicants seeking access to traditional knowledge associated with genetic resources, where possible, information on procedures for obtaining prior informed consent or approval and involvement, as appropriate, of indigenous and local communities and establishing mutually agreed terms including benefit-sharing; and

(c) Information on competent national authorities, relevant indigenous and local communities and relevant stakeholders.

The national focal point shall be responsible for liaison with the Secretariat.

2. Each Party shall designate one or more competent national authorities on access and benefit-sharing. Competent national authorities shall, in accordance with applicable national legislative, administrative or policy measures, be responsible for granting access or, as applicable, issuing written evidence that access requirements have been met and be responsible for advising on applicable procedures and requirements for obtaining prior informed consent and entering into mutually agreed terms.

3. A Party may designate a single entity to fulfil the functions of both focal point and competent national authority.

4. Each Party shall, no later than the date of entry into force of this Protocol for it, notify the Secretariat of the contact information of its national focal point and its competent national authority or authorities. Where a Party designates more than one competent national authority, it shall convey to the Secretariat, with its notification thereof, relevant information on the respective responsibilities of those authorities. Where applicable, such information shall, at a minimum, specify which competent authority is responsible for the genetic resources sought. Each Party shall forthwith notify the Secretariat of any changes in the designation of its national focal point or in the contact information or responsibilities of its competent national authority or authorities.

5. The Secretariat shall make information received pursuant to paragraph 4 above available through the Access and Benefit-sharing Clearing-House.

ARTICLE 14

THE ACCESS AND BENEFIT-SHARING CLEARING-HOUSE AND INFORMATION-SHARING

1. An Access and Benefit-sharing Clearing-House is hereby established as part of the clearing-house mechanism under Article 18, paragraph 3, of the Convention. It shall serve as a means for sharing of information related to access and benefit-sharing. In particular, it shall provide access to information made available by each Party relevant to the implementation of this Protocol.

2. Without prejudice to the protection of confidential information, each Party shall make available to the Access and Benefit-sharing Clearing-House any information required by this Protocol, as well as information required pursuant to the decisions taken by the Conference of the Parties serving as the meeting of the Parties to this Protocol. The information shall include:

(a) Legislative, administrative and policy measures on access and benefit-sharin

(b) Information on the national focal point and competent national authority or authorities; and

(c) Permits or their equivalent issued at the time of access as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms.

3. Additional information, if available and as appropriate, may include:

(a) Relevant competent authorities of indigenous and local communities, and information as so decided;

(b) Model contractual clauses;

(c) Methods and tools developed to monitor genetic resources; and

(d) Codes of conduct and best practices.

4. The modalities of the operation of the Access and Benefit-sharing Clearing-House, including reports on its activities, shall be considered and decided upon by the Conference of the Parties serving as the meeting of the Parties to this Protocol at its first meeting, and kept under review thereafter.

ARTICLE 15

COMPLIANCE WITH DOMESTIC LEGISLATION OR REGULATORY REQUIREMENTS ON ACCESS AND BENEFIT-SHARING

1. Each Party shall take appropriate, effective and proportionate legislative, administrative or policy measures to provide that genetic resources utilized within its jurisdiction have been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the other Party.

2. Parties shall take appropriate, effective and proportionate measures to address situations of non-compliance with measures adopted in accordance with paragraph 1 above.

3. Parties shall, as far as possible and as appropriate, cooperate in cases of alleged violation of domestic access and benefit-sharing legislation or regulatory requirements referred to in paragraph 1 above.

ARTICLE 16

COMPLIANCE WITH DOMESTIC LEGISLATION OR REGULATORY REQUIREMENTS ON ACCESS AND BENEFIT-SHARING FOR TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES

1. Each Party shall take appropriate, effective and proportionate legislative, administrative or policy measures, as appropriate, to provide that traditional knowledge associated with genetic resources utilized within their jurisdiction has been accessed in accordance with prior informed consent or approval and involvement of indigenous and local communities and that mutually agreed terms have been established, as required by domestic access and benefit-sharing legislation or regulatory requirements of the other Party where such indigenous and local communities are located.

2. Each Party shall take appropriate, effective and proportionate measures to address situations of non-compliance with measures adopted in accordance with paragraph 1 above.

3. Parties shall, as far as possible and as appropriate, cooperate in cases of alleged violation of domestic access and benefit-sharing legislation or regulatory requirements referred to in paragraph 1 above.

ARTICLE 17

MONITORING THE UTILIZATION OF GENETIC RESOURCES

1. To support compliance, each Party shall take measures, as appropriate, to monitor and to enhance transparency about the utilization of genetic resources. Such measures shall include:

(a) The designation of one or more checkpoints, as follows:

(i) Designated checkpoints would collect or receive, as appropriate, relevant information related to prior informed consent, to the source of the genetic resource, to the establishment of mutually agreed terms, and/or to the utilization of genetic resources, as appropriate;

(ii) Each Party shall, as appropriate and depending on the particular characteristics of a designated checkpoint, require users of genetic resources to provide the information specified in the above paragraph at a designated checkpoint. Each Party shall take appropriate, effective and proportionate measures to address situations of non-compliance;

(iii) Such information, including from internationally recognized certificates of compliance where they are available, will, without prejudice to the protection of confidential information, be provided to relevant national authorities, to the Party providing prior informed consent and to the Access and Benefit-sharing Clearing-House, as appropriate;

(iv) Check points must be effective and should have functions relevant to implementation of this subparagraph (a). They should be relevant to the utilization of genetic resources, or to the collection of relevant information at, *inter alia*, any stage of research, development, innovation, pre-commercialization or commercialization.

(b) Encouraging users and providers of genetic resources to include provisions in mutually agreed terms to share information on the implementation of such terms, including through reporting requirements; and

(c) Encouraging the use of cost-effective communication tools and systems.

2. A permit or its equivalent issued in accordance with Article 6, paragraph 3 (e) and made available to the Access and Benefit-sharing Clearing-House, shall constitute an internationally recognized certificate of compliance.

3. An internationally recognized certificate of compliance shall serve as evidence that the genetic resource which it covers has been accessed in accordance with prior informed consent and that mutually

agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the Party providing prior informed consent.

4. The internationally recognized certificate of compliance shall contain the following minimum information when it is not confidential:

(a) Issuing authority;

(b) Date of issuance;

(c) The provider;

(d) Unique identifier of the certificate;

(e) The person or entity to whom prior informed consent was granted;

(f) Subject-matter or genetic resources covered by the certificate;

(g) Confirmation that mutually agreed terms were established;

(h) Confirmation that prior informed consent was obtained; and

(i) Commercial and/or non-commercial use.

ARTICLE 18

COMPLIANCE WITH MUTUALLY AGREED TERMS

1. In the implementation of Article 6, paragraph 3 (g) (i) and Article 7, each Party shall encourage providers and users of genetic resources and/or traditional knowledge associated with genetic resources to include provisions in mutually agreed terms to cover, where appropriate, dispute resolution including:

(a) The jurisdiction to which they will subject any dispute resolution processes;

(b) The applicable law; and/or

(c) Options for alternative dispute resolution, such as mediation or arbitration.

2. Each Party shall ensure that an opportunity to seek recourse is available under their legal systems, consistent with applicable jurisdictional requirements, in cases of disputes arising from mutually agreed terms.

3. Each Party shall take effective measures, as appropriate, regarding:

(a) Access to justice; and

(b) The utilization of mechanisms regarding mutual recognition and enforcement of foreign judgments and arbitral awards.

4. The effectiveness of this article shall be reviewed by the Conference of the Parties serving as the meeting of the Parties to this Protocol in accordance with Article 31 of this Protocol.

ARTICLE 19

MODEL CONTRACTUAL CLAUSES

1. Each Party shall encourage, as appropriate, the development, update and use of sectoral and cross-sectoral model contractual clauses for mutually agreed terms.

2. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall periodically take stock of the use of sectoral and cross-sectoral model contractual clauses.

ARTICLE 20

CODES OF CONDUCT, GUIDELINES AND BEST PRACTICES AND/OR STANDARDS

1. Each Party shall encourage, as appropriate, the development, update and use of voluntary codes of conduct, guidelines and best practices and/or standards in relation to access and benefit-sharing.

2. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall periodically take stock of the use of voluntary codes of conduct, guidelines and best practices and/or standards and consider the adoption of specific codes of conduct, guidelines and best practices and/or standards.

ARTICLE 21

AWARENESS-RAISING

Each Party shall take measures to raise awareness of the importance of genetic resources and traditional knowledge associated with genetic resources, and related access and benefit-sharing issues. Such measures may include, *inter alia*:

(a) Promotion of this Protocol, including its objective;

(b) Organization of meetings of indigenous and local communities and relevant stakeholders;

(c) Establishment and maintenance of a help desk for indigenous and local communities and relevant stakeholders;

(d) Information dissemination through a national clearing-house;

(e) Promotion of voluntary codes of conduct, guidelines and best practices and/or standards in consultation with indigenous and local communities and relevant stakeholders;

(f) Promotion of, as appropriate, domestic, regional and international exchanges of experience;

(g) Education and training of users and providers of genetic resources and traditional knowledge associated with genetic resources about their access and benefit-sharing obligations;

(h) Involvement of indigenous and local communities and relevant stakeholders in the implementation of this Protocol; and

(i) Awareness-raising of community protocols and procedures of indigenous and local communities.

ARTICLE 22

CAPACITY

1. The Parties shall cooperate in the capacity-building, capacity development and strengthening of human resources and institutional capacities to effectively implement this Protocol in developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition, including through existing global, regional, subregional and national institutions and organizations. In this context, Parties should facilitate the involvement of indigenous and local communities and relevant stakeholders, including non-governmental organizations and the private sector.

2. The need of developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition for financial resources in accordance with the relevant provisions of the Convention shall be taken fully into account for capacity-building and development to implement this Protocol.

3. As a basis for appropriate measures in relation to the implementation of this Protocol, developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in

transition should identify their national capacity needs and priorities through national capacity self-assessments. In doing so, such Parties should support the capacity needs and priorities of indigenous and local communities and relevant stakeholders, as identified by them, emphasizing the capacity needs and priorities of women.

4. In support of the implementation of this Protocol, capacity-building and development may address, *inter alia*, the following key areas:

(a) Capacity to implement, and to comply with the obligations of, this Protocol;

(b) Capacity to negotiate mutually agreed terms;

(c) Capacity to develop, implement and enforce domestic legislative, administrative or policy measures on access and benefit-sharing; and

(d) Capacity of countries to develop their endogenous research capabilities to add value to their own genetic resources.

5. Measures in accordance with paragraphs 1 to 4 above may include, *inter alia*:

(a) Legal and institutional development;

(b) Promotion of equity and fairness in negotiations, such as training to negotiate mutually agreed terms;

(c) The monitoring and enforcement of compliance;

(d) Employment of best available communication tools and Internet-based systems for access and benefit-sharing activities;

(e) Development and use of valuation methods;

(f) Bioprospecting, associated research and taxonomic studies;

(g) Technology transfer, and infrastructure and technical capacity to make such technology transfer sustainable;

(h) Enhancement of the contribution of access and benefit-sharing activities to the conservation of biological diversity and the sustainable use of its components;

(i) Special measures to increase the capacity of relevant stakeholders in relation to access and benefit-sharing; and

(j) Special measures to increase the capacity of indigenous and local communities with emphasis on enhancing the capacity of women within those communities in relation to access to genetic resources and/or traditional knowledge associated with genetic resources.

6. Information on capacity-building and development initiatives at national, regional and international levels, undertaken in accordance with paragraphs 1 to 5 above, should be provided to the Access and Benefit-sharing Clearing-House with a view to promoting synergy and coordination on capacity-building and development for access and benefit-sharing.

ARTICLE 23

TECHNOLOGY TRANSFER, COLLABORATION AND COOPERATION

In accordance with Articles 15, 16, 18 and 19 of the Convention, the Parties shall collaborate and cooperate in technical and scientific research and development programmes, including biotechnological research activities, as a means to achieve the objective of this Protocol. The Parties undertake to promote and encourage access to technology by, and transfer of technology to, developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition, in order to enable the development and strengthening of a sound and viable technological and scientific base for the attainment of the objectives of the Convention and this Protocol. Where possible and appropriate such collaborative activities shall take place in and with a Party or the Parties providing genetic resources that is the country or are the countries of origin of such resources or a Party or Parties that have acquired the genetic resources in accordance with the Convention.

ARTICLE 24

NON-PARTIES

The Parties shall encourage non-Parties to adhere to this Protocol and to contribute appropriate information to the Access and Benefit-sharing Clearing-House.

ARTICLE 25

FINANCIAL MECHANISM AND RESOURCES

1. In considering financial resources for the implementation of this Protocol, the Parties shall take into account the provisions of Article 20 of the Convention.

2. The financial mechanism of the Convention shall be the financial mechanism for this Protocol.

3. Regarding the capacity-building and development referred to in Article 22 of this Protocol, the Conference of the Parties serving as the meeting of the Parties to this Protocol, in providing guidance with respect to the financial mechanism referred to in paragraph 2 above, for consideration by the Conference of the Parties, shall take into account the need of developing country Parties, in particular the least developed countries and small island developing States among them, and of Parties with economies in transition, for financial resources, as well as the capacity needs and priorities of indigenous and local communities, including women within these communities.

4. In the context of paragraph 1 above, the Parties shall also take into account the needs of the developing country Parties, in particular the least developed countries and small island developing States among them, and of the Parties with economies in transition, in their efforts to identify and implement their capacity-building and development requirements for the purposes of the implementation of this Protocol.

5. The guidance to the financial mechanism of the Convention in relevant decisions of the Conference of the Parties, including those agreed before the adoption of this Protocol, shall apply, *mutatis mutandis*, to the provisions of this Article.

6. The developed country Parties may also provide, and the developing country Parties and the Parties with economies in transition avail themselves of, financial and other resources for the implementation of the provisions of this Protocol through bilateral, regional and multilateral channels.

ARTICLE 26

CONFERENCE OF THE PARTIES SERVING AS THE MEETING OF THE PARTIES TO THIS PROTOCOL

1. The Conference of the Parties shall serve as the meeting of the Parties to this Protocol.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, decisions under this Protocol shall be taken only by those that are Parties to it.

3. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, any member of the Bureau of the Conference of the Parties representing a Party to the Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from among the Parties to this Protocol.

4. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall keep under regular review the implementation of this Protocol and shall make, within its mandate, the decisions necessary to promote its effective implementation. It shall perform the functions assigned to it by this Protocol and shall:

(a) Make recommendations on any matters necessary for the implementation of this Protocol;

(b) Establish such subsidiary bodies as are deemed necessary for the implementation of this Protocol;

(c) Seek and utilize, where appropriate, the services and cooperation of, and information provided by, competent international organizations and intergovernmental and non-governmental bodies;

(d) Establish the form and the intervals for transmitting the information to be submitted in accordance with Article 29 of this Protocol and consider such information as well as reports submitted by any subsidiary body;

(e) Consider and adopt, as required, amendments to this Protocol and its Annex, as well as any additional annexes to this Protocol, that are deemed necessary for the implementation of this Protocol; and

(f) Exercise such other functions as may be required for the implementation of this Protocol.

5. The rules of procedure of the Conference of the Parties and financial rules of the Convention shall be applied, *mutatis mutandis*, under this Protocol, except as may be otherwise decided by consensus by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

6. The first meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be convened by the Secretariat and held concurrently with the first meeting of the Conference of the Parties that is scheduled after the date of the entry into force of this Protocol. Subsequent ordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held concurrently with ordinary meetings of the Conference of the Parties, unless otherwise decided by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

7. Extraordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held at such other times as may be deemed necessary by the Conference of the Parties serving as the meeting of the Parties to this Protocol, or at the written request of any Party, provided that, within six months of the request being communicated to the Parties by the Secretariat, it is supported by at least one third of the Parties.

8. The United Nations, its specialized agencies and the International Atomic Energy Agency, as well as any State member thereof or observers thereto not party to the Convention, may be represented as observers at meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol. Any body or agency, whether national or international, governmental or non-governmental, that is qualified in matters covered by this Protocol and that has informed the Secretariat of its wish to be represented at a meeting of the Conference of the Parties serving as a meeting of the Parties to this Protocol as an observer, may be so admitted, unless at least one third of the Parties present object. Except as otherwise provided in this Article, the admission and participation of observers shall be subject to the rules of procedure, as referred to in paragraph 5 above.

ARTICLE 27

SUBSIDIARY BODIES

1. Any subsidiary body established by or under the Convention may serve this Protocol, including upon a decision of the Conference of the Parties serving as the meeting of the Parties to this Protocol. Any such decision shall specify the tasks to be undertaken.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of any such subsidiary bodies. When a subsidiary body of the Convention

serves as a subsidiary body to this Protocol, decisions under this Protocol shall be taken only by Parties to this Protocol.

3. When a subsidiary body of the Convention exercises its functions with regard to matters concerning this Protocol, any member of the bureau of that subsidiary body representing a Party to the Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from among the Parties to this Protocol.

ARTICLE 28

SECRETARIAT

1. The Secretariat established by Article 24 of the Convention shall serve as the secretariat to this Protocol.

2. Article 24, paragraph 1, of the Convention on the functions of the Secretariat shall apply, *mutatis mutandis*, to this Protocol.

3. To the extent that they are distinct, the costs of the secretariat services for this Protocol shall be met by the Parties hereto. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, decide on the necessary budgetary arrangements to this end.

ARTICLE 29

MONITORING AND REPORTING

Each Party shall monitor the implementation of its obligations under this Protocol, and shall, at intervals and in the format to be determined by the Conference of the Parties serving as the meeting of the Parties to this Protocol, report to the Conference of the Parties serving as the meeting of the Parties to this Protocol on measures that it has taken to implement this Protocol.

ARTICLE 30

PROCEDURES AND MECHANISMS TO PROMOTE COMPLIANCE WITH THIS PROTOCOL

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, consider and approve cooperative procedures and institutional mechanisms to promote compliance with the provisions of this Protocol and to address cases of non-compliance. These procedures and mechanisms shall include provisions to offer advice or assistance, where appropriate. They shall be separate from, and without prejudice to, the dispute settlement procedures and mechanisms under Article 27 of the Convention.

ARTICLE 31

ASSESSMENT AND REVIEW

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall undertake, four years after the entry into force of this Protocol and thereafter at intervals determined by

the Conference of the Parties serving as the meeting of the Parties to this Protocol, an evaluation of the effectiveness of this Protocol.

ARTICLE 32

SIGNATURE

This Protocol shall be open for signature by Parties to the Convention at the United Nations Headquarters in New York, from 2 February 2011 to 1 February 2012.

ARTICLE 33

ENTRY INTO FORCE

1. This Protocol shall enter into force on the ninetieth day after the date of deposit of the fiftieth instrument of ratification, acceptance, approval or accession by States or regional economic integration organizations that are Parties to the Convention.

2. This Protocol shall enter into force for a State or regional economic integration organization that ratifies, accepts or approves this Protocol or accedes thereto after the deposit of the fiftieth instrument as referred to in paragraph 1 above, on the ninetieth day after the date on which that State or regional economic integration organization deposits its instrument of ratification, acceptance, approval or accession, or on the date on which the Convention enters into force for that State or regional economic integration organization, whichever shall be the later.

3. For the purposes of paragraphs 1 and 2 above, any instrument deposited by a regional economic integration organization shall not be counted as additional to those deposited by member States of such organization.

ARTICLE 34

RESERVATIONS

No reservations may be made to this Protocol.

ARTICLE 35

WITHDRAWAL

1. At any time after two years from the date on which this Protocol has entered into force for a Party, that Party may withdraw from this Protocol by giving written notification to the Depositary.

2. Any such withdrawal shall take place upon expiry of one year after the date of its receipt by the Depositary, or on such later date as may be specified in the notification of the withdrawal.

ARTICLE 36

AUTHENTIC TEXTS

The original of this Protocol, of which the Arabic, Chinese, English, French, Russian and Spanish texts are equally authentic, shall be deposited with the Secretary-General of the United Nations.

IN WITNESS WHEREOF the undersigned, being duly authorized to that effect, have signed this Protocol on the dates indicated.

DONE at Nagoya on this twenty-ninth day of October, two thousand and ten.

Annex

MONETARY AND NON-MONETARY BENEFITS

1. Monetary benefits may include, but not be limited to:

(a) Access fees/fee per sample collected or otherwise acquired;

(b) Up-front payments;

(c) Milestone payments;

(d) Payment of royalties;

(e) Licence fees in case of commercialization;

(f) Special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity;

(g) Salaries and preferential terms where mutually agreed;

(h) Research funding;

(i) Joint ventures;

(j) Joint ownership of relevant intellectual property rights.

2. Non-monetary benefits may include, but not be limited to:

(a) Sharing of research and development results;

(b) Collaboration, cooperation and contribution in scientific research and development programmes, particularly biotechnological research activities, where possible in the Party providing genetic resources;

(c) Participation in product development;

(d) Collaboration, cooperation and contribution in education and training;

(e) Admittance to *ex situ* facilities of genetic resources and to databases;

(f) Transfer to the provider of the genetic resources of knowledge and technology under fair and most favourable terms, including on concessional and preferential terms where agreed, in particular, knowledge and technology that make use of genetic resources,

including biotechnology, or that are relevant to the conservation and sustainable utilization of biological diversity;

(g) Strengthening capacities for technology transfer;

(h) Institutional capacity-building;

(i) Human and material resources to strengthen the capacities for the administration and enforcement of access regulations;

(j) Training related to genetic resources with the full participation of countries providing genetic resources, and where possible, in such countries;

(k) Access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies;

(l) Contributions to the local economy;

(m) Research directed towards priority needs, such as health and food security, taking into account domestic uses of genetic resources in the Party providing genetic resources;

(n) Institutional and professional relationships that can arise from an access and benefit-sharing agreement and subsequent collaborative activities;

(o) Food and livelihood security benefits;

(p) Social recognition;

(q) Joint ownership of relevant intellectual property rights.

PROTOCOLE DE NAGOYA SUR L'ACCÈS AUX RESSOURCES GÉNÉTIQUES ET LE PARTAGE JUSTE ET ÉQUITABLE DES AVANTAGES DÉCOULANT DE LEUR UTILISATION RELATIF À LA CONVENTION SUR LA DIVERSITÉ BIOLOGIQUE[1185]

Les Parties au présent Protocole, Étant Parties à la Convention sur la diversité biologique, ci-après dénommée « la Convention »,

Rappelant que le partage juste et équitable des avantages découlant de l'utilisation des ressources génétiques est l'un des trois objectifs centraux de la Convention et reconnaissant que le présent Protocole poursuit la réalisation de cet objectif dans le cadre de la Convention,

Réaffirmant les droits souverains des États sur leurs propres ressources naturelles et conformément aux dispositions de la Convention,

Rappelant en outre l'article 15 de la Convention,

Conscientes de l'importante contribution au développement durable du transfert de technologie et de la coopération dans ce domaine en vue de renforcer les capacités de recherche et d'innovation et d'ajouter de la valeur aux ressources génétiques dans les pays en développement conformément aux articles 16 et 19 de la Convention,

Reconnaissant que la sensibilisation du public à la valeur économique des écosystèmes et de la diversité biologique, et le partage juste et équitable de cette valeur économique avec les gardiens de la diversité biologique sont d'importantes mesures d'incitation disponibles pour la conservation de la diversité biologique et l'utilisation durable de ses éléments constitutifs,

Reconnaissant la contribution potentielle de l'accès et du partage des avantages à la conservation et à l'utilisation durable de la diversité biologique, à l'éradication de la pauvreté et à un environnement durable, contribuant ainsi à la réalisation des Objectifs du millénaire pour le développement,

Conscientes des liens qui existent entre l'accès aux ressources génétiques et le partage juste et équitable des avantages découlant de l'utilisation de ces ressources,

Reconnaissant l'importance d'assurer la sécurité juridique en ce qui concerne l'accès aux ressources génétiques et le partage juste et équitable des avantages découlant de leur utilisation,

Reconnaissant en outre l'importance de promouvoir l'équité et la justice dans la négociation de conditions convenues d'un commun accord entre les fournisseurs et les utilisateurs de ressources génétiques,

Reconnaissant également le rôle capital que jouent les femmes en matière d'accès et de partage des avantages et affirmant la nécessité d'assurer leur pleine participation à tous les niveaux aux décisions politiques concernant la conservation de la diversité biologique et à leur application,

Fermement décidées à appuyer davantage l'application effective des dispositions de la Convention relatives à l'accès et au partage des avantages,

Reconnaissant qu'une solution novatrice est nécessaire relativement au partage juste et équitable des avantages découlant de l'utilisation des ressources génétiques et des connaissances traditionnelles associées aux ressources génétiques dans des situations transfrontalières ou pour lesquelles il n'est pas possible d'accorder ou d'obtenir le consentement préalable donné en connaissance de cause,

Reconnaissant l'importance des ressources génétiques pour la sécurité alimentaire, la santé publique, la conservation de la diversité biologique, et l'atténuation des changements climatiques et l'adaptation à ceux-ci,

Reconnaissant la nature spéciale de la diversité biologique agricole, ses traits distinctifs et ses problèmes nécessitant des solutions particulières,

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[1185] Available at http://www.cbd.int/abs/doc/protocol/nagoya-protocol-fr.pdf

Reconnaissant l'interdépendance de tous les pays en ce qui a trait aux ressources génétiques pour l'alimentation et l'agriculture ainsi que leur nature et leur importance particulières pour assurer la sécurité alimentaire à l'échelle mondiale et pour le développement durable de l'agriculture dans le contexte de l'atténuation de la pauvreté et des changements climatiques, et reconnaissant le rôle fondamental du Traité international sur les ressources phytogénétiques pour l'alimentation et l'agriculture et de la Commission des ressources génétiques pour l'alimentation et l'agriculture de la FAO à cet égard,

Tenant compte du Règlement sanitaire international (2005) de l'Organisation mondiale de la santé et de l'importance d'assurer l'accès aux pathogènes humains aux fins de préparation et d'intervention pour la santé publique,

Reconnaissant les travaux en cours sur l'accès et le partage des avantages dans d'autres instances internationales,

Rappelant le Système multilatéral d'accès et de partage des avantages créé en vertu du Traité international sur les ressources phytogénétiques pour l'alimentation et l'agriculture développé en harmonie avec la Convention,

Reconnaissant que les instruments internationaux relatifs à l'accès et au partage des avantages devraient être complémentaires en vue d'atteindre les objectifs de la Convention,

Rappelant l'article 8 j) de la Convention, tel qu'il a trait aux connaissances traditionnelles associées aux ressources génétiques et au partage juste et équitable des avantages découlant de l'utilisation de ces connaissances,

Notant le lien d'interdépendance entre les ressources génétiques et les connaissances traditionnelles, le fait que ces ressources et ces connaissances sont indissociables pour les communautés autochtones et locales, et l'importance des connaissances traditionnelles pour la conservation de la diversité biologique et l'utilisation durable de ses éléments constitutifs, ainsi que pour la pérennité des moyens de subsistance des communautés concernées,

Reconnaissant la diversité des contextes dans lesquelles les connaissances traditionnelles associées aux ressources génétiques sont détenues ou possédées par les communautés autochtones et locales,

Sachant que les communautés autochtones et locales ont le droit d'identifier les détenteurs légitimes de leurs connaissances traditionnelles associées aux ressources génétiques au sein de leurs communautés,

Reconnaissant également les formes particulières sous lesquelles certains pays possèdent des connaissances traditionnelles associées aux ressources génétiques, que ces formes soient orales, documentaires ou autres, et qui reflètent un riche patrimoine culturel présentant un intérêt pour la conservation et l'utilisation durable de la diversité biologique,

Prenant note de la Déclaration des Nations Unies sur les droits des peuples autochtones,

Affirmant qu'aucune disposition du présent Protocole ne peut être interprétée comme entraînant la diminution ou l'extinction de droits que les communautés autochtones et locales ont déjà,

Sont convenues de ce qui suit :

Article Premier

OBJECTIF

L'objectif du présent Protocole est le partage juste et équitable des avantages découlant de l'utilisation des ressources génétiques, notamment grâce à un accès satisfaisant aux ressources génétiques et à un transfert approprié des technologies pertinentes, compte tenu de tous les droits sur ces ressources et aux technologies et grâce à un financement adéquat, contribuant ainsi à la conservation de la diversité biologique et à l'utilisation durable de ses éléments constitutifs.

Article 2

EMPLOI DES TERMES

Les termes définis à l'article 2 de la Convention s'appliquent au présent Protocole. En outre, aux fins du présent Protocole, on entend par :

a) « Conférence des Parties » la Conférence des Parties à la Convention;

b) « Convention » la Convention sur la diversité biologique;

c) « Utilisation des ressources génétiques » les activités de recherche et de développement sur la composition génétique et/ou biochimique de ressources génétiques, notamment par l'application de la biotechnologie, conformément à la définition fournie à l'article 2 de la Convention;

d) « Biotechnologie » toute application technologique qui utilise des systèmes biologiques, des organismes vivants, ou des dérivés de ceux-ci, pour réaliser ou modifier des produits ou des procédés à usage spécifique, conformément à la définition fournie dans l'article 2 de la Convention;

e) « Dérivé » tout composé biochimique qui existe à l'état naturel résultant de l'expression génétique ou du métabolisme de ressources biologiques ou génétiques, même s'il ne contient pas d'unités fonctionnelles de l'hérédité.

Article 3

CHAMP D'APPLICATION

Le présent Protocole s'applique aux ressources génétiques qui entrent dans le champ d'application de l'article 15 de la Convention ainsi qu'aux avantages découlant de l'utilisation de ces ressources. Le présent Protocole s'applique également aux connaissances traditionnelles associées aux ressources génétiques qui entrent dans le champ d'application de la Convention et aux avantages découlant de l'utilisation de ces connaissances.

Article 4

RELATION AVEC LES ACCORDS ET INSTRUMENTS INTERNATIONAUX

1. Les dispositions du présent Protocole ne modifient en rien les droits et obligations découlant pour une Partie d'un accord international existant, sauf si l'exercice de ces droits ou le respect de ces obligations devait causer des dommages graves à la diversité biologique ou constituer pour elle une menace grave. Le présent paragraphe n'a pas pour objet de créer une hiérarchie entre le présent Protocole et d'autres instruments internationaux.

2. Rien dans le présent Protocole n'empêche les Parties d'élaborer et d'appliquer d'autres accords pertinents, y compris d'autres accords spéciaux en matière d'accès et de partage des avantages, à condition qu'ils favorisent les objectifs de la Convention et du présent Protocole et n'aillent pas à leur encontre.

3. Le présent Protocole s'applique dans un esprit de complémentarité réciproque avec les autres instruments internationaux pertinents. Les travaux ou pratiques utiles et pertinents en cours dans le cadre de ces instruments internationaux et organisations internationales compétentes devraient être dûment pris en compte, à condition qu'ils favorisent les objectifs de la Convention et du présent Protocole et n'aillent pas à leur encontre.

4. Le présent Protocole est l'instrument d'application des dispositions de la Convention relatives à l'accès et au partage des avantages. Lorsqu'un instrument international spécial sur l'accès et le partage des avantages s'applique, est conforme aux objectifs de la Convention et du présent Protocole et ne va pas à l'encontre de ces objectifs, le présent Protocole ne s'applique pas pour la ou les Partie(s) à cet instrument spécial en ce qui concerne la ressource génétique spécifique couverte par ledit instrument et pour les besoins de celui-ci.

Article 5

PARTAGE JUSTE ET ÉQUITABLE DES AVANTAGES

1. Conformément aux paragraphes 3 et 7 de l'article 15 de la Convention, les avantages découlant de l'utilisation des ressources génétiques et des applications et de la commercialisation subséquentes sont partagés de manière juste et équitable avec la Partie qui fournit lesdites ressources et qui est le pays d'origine de ces ressources ou une Partie qui a acquis les ressources génétiques conformément à la Convention. Ce partage est soumis à des conditions convenues d'un commun accord.

2. Chaque Partie prend des mesures législatives, administratives ou de politique générale, selon qu'il convient, dans le but d'assurer que les avantages découlant de l'utilisation des ressources génétiques qui sont détenues par les communautés autochtones et locales, conformément à la législation interne relative aux droits établis desdites

communautés sur ces ressources, sont partagés de manière juste et équitable avec ces communautés selon des conditions convenues d'un commun accord.

3. Chaque Partie prend les mesures législatives, administratives ou de politique générale, selon qu'il convient, pour appliquer le paragraphe 1.

4. Les avantages peuvent inclure mais ne sont pas limités aux avantages monétaires et non monétaires énumérés à l'annexe.

5. Chaque Partie prend les mesures législatives, administratives ou de politique générale, selon qu'il convient, afin que les avantages découlant de l'utilisation des connaissances traditionnelles associées aux ressources génétiques soient partagés de manière juste et équitable avec les communautés autochtones et locales détentrices de ces connaissances. Ce partage s'effectue selon des conditions convenues d'un commun accord.

Article 6

ACCÈS AUX RESSOURCES GÉNÉTIQUES

1. Dans l'exercice de ses droits souverains sur ses ressources naturelles et conformément aux dispositions législatives ou réglementaires internes en matière d'accès et de partage des avantages, l'accès aux ressources génétiques en vue de leur utilisation est soumis au consentement préalable donné en connaissance de cause de la Partie qui fournit lesdites ressources, qui est le pays d'origine desdites ressources ou une Partie qui les a acquises conformément à la Convention, sauf décision contraire de cette Partie.

2. Conformément à son droit interne, chaque Partie prend, selon qu'il convient, les mesures nécessaires pour s'assurer que le consentement préalable donné en connaissance de cause ou l'accord et la participation des communautés autochtones et locales sont obtenus pour l'accès aux ressources génétiques, dès lors que leur droit d'accorder l'accès à ces ressources est établi.

3. Conformément au paragraphe 1 ci-dessus, chaque Partie qui exige le consentement préalable donné en connaissance de cause prend, selon qu'il convient, les mesures législatives, administratives ou de politique générale appropriées pour :

a) Assurer la sécurité juridique, la clarté et la transparence de ses dispositions législatives ou réglementaires internes en matière d'accès et de partage des avantages;

b) Prévoir des règles et procédures équitables et non arbitraires sur l'accès aux ressources génétiques;

c) Mettre à disposition des informations sur la manière de solliciter un consentement préalable en connaissance de cause;

d) Prévoir une décision écrite d'une autorité nationale compétente, qui soit rendue de façon claire et transparente, sans engendrer de coûts excessifs, et dans un délai raisonnable;

e) Prévoir la délivrance, au moment de l'accès aux ressources génétiques, d'un permis ou d'un document équivalent attestant de l'adoption de la décision d'accorder le consentement préalable en connaissance de cause et de la conclusion de conditions convenues d'un commun accord, et notifier le Centre d'échange sur l'accès et le partage des avantages en conséquence;

f) S'il y a lieu et conformément à la législation interne, établir des critères et/ ou procédés pour l'obtention du consentement préalable en connaissance de cause ou l'accord et la participation des communautés autochtones et locales à l'accès aux ressources génétiques;

g) Établir des règles et des procédures claires relatives à la demande et à l'établissement de conditions convenues d'un commun accord. Ces conditions doivent être arrêtées par écrit et peuvent inclure, entre autres :

i) Une clause sur le règlement des différends;

ii) Les conditions de partage des avantages, compte tenu également des droits de propriété intellectuelle;

iii) Les conditions de l'utilisation ultérieure par des tiers, le cas échéant; et

v) Les conditions de changement d'intention, le cas échéant.

Article 7

ACCÈS AUX CONNAISSANCES TRADITIONNELLES ASSOCIÉES AUX RESSOURCES GÉNÉTIQUES

Conformément à son droit interne, chaque Partie prend, selon qu'il convient, les mesures appropriées pour faire en sorte que l'accès aux connaissances traditionnelles associées aux ressources génétiques détenues par les communautés autochtones et locales soit soumis au consentement préalable donné en connaissance de cause ou à l'accord et à la participation de ces communautés autochtones et locales, et que des conditions convenues d'un commun accord soient établies.

Article 8

CONSIDÉRATIONS SPÉCIALES

En élaborant et en mettant en oeuvre ses dispositions législatives ou réglementaires en matière d'accès et de partage des avantages, chaque Partie :

a) Crée des conditions propres à promouvoir et encourager la recherche qui contribue à la conservation de la diversité biologique et à son utilisation durable, en particulier dans les pays en développement, notamment par des mesures simplifiées d'accès pour la recherche à des fins non commerciales, compte tenu de la nécessité de prendre en considération le changement d'intention quant aux objectifs de cette recherche;

b) Prend dûment en considération les situations d'urgence actuelles ou imminentes qui menacent ou nuisent à la santé humaine, animale ou végétale, telles que définies au niveau national ou international. Les Parties peuvent prendre en considération la nécessité d'accélérer l'accès aux ressources génétiques et le partage juste et équitable des avantages découlant de leur utilisation, y compris l'accès à des traitements abordables pour ceux qui sont dans le besoin, en particulier dans les pays en développement;

c) Tient compte de l'importance des ressources génétiques pour l'alimentation et l'agriculture et du rôle spécial qu'elles jouent pour la sécurité alimentaire.

Article 9

CONTRIBUTION À LA CONSERVATION ET À L'UTILISATION DURABLE

Les Parties encouragent les utilisateurs et les fournisseurs à affecter les avantages découlant de l'utilisation des ressources génétiques à la conservation de la diversité biologique et à l'utilisation durable de ses éléments constitutifs.

Article 10

MÉCANISME MULTILATÉRAL MONDIAL DE PARTAGE DES AVANTAGES

Les Parties examinent la nécessité et les modalités d'un mécanisme multilatéral mondial de partage des avantages pour traiter le partage juste et équitable des avantages résultant de l'utilisation des ressources génétiques et des connaissances traditionnelles associées aux ressources génétiques qui se trouvent dans des situations transfrontières ou pour lesquelles il n'est pas possible d'accorder ou d'obtenir le consentement préalable donné en connaissance de cause. Les avantages partagés au moyen de ce mécanisme par les utilisateurs de ressources génétiques et de connaissances traditionnelles associées aux ressources génétiques sont utilisés pour favoriser la conservation de la diversité biologique et l'utilisation durable de ses éléments constitutifs à l'échelle mondiale.

Article 11

COOPÉRATION TRANSFRONTIÈRE

1. Lorsque les mêmes ressources génétiques sont situées in situ sur le territoire de plus d'une Partie, les Parties concernées s'efforcent de coopérer, selon qu'il convient, en vue d'appliquer le présent Protocole, avec la participation des communautés autochtones et locales concernées, s'il y a lieu.

2. Lorsque les mêmes connaissances traditionnelles associées à des ressources génétiques sont partagées par des communautés autochtones et locales différentes dans plusieurs Parties, ces Parties s'efforcent de coopérer, selon qu'il convient, avec la participation des communautés autochtones et locales concernées en vue de réaliser l'objectif du présent Protocole.

Article 12

CONNAISSANCES TRADITIONNELLES ASSOCIÉES AUX RESSOURCES GÉNÉTIQUES

1. En mettant en oeuvre les obligations qui leur incombent en vertu du présent Protocole, les Parties, en conformité avec leur droit interne, tiennent compte, s'il y a lieu, du droit coutumier des communautés autochtones et locales ainsi que de leurs protocoles et procédures, pour tout ce qui concerne les connaissances traditionnelles associées aux ressources génétiques.

2. Avec la participation active des communautés autochtones et locales concernées, les Parties établissent des mécanismes pour informer les utilisateurs potentiels de connaissances traditionnelles associées aux ressources génétiques de leurs obligations, y compris les mesures diffusées par le biais du Centre d'échange sur l'accès et le partage des avantages en matière d'accès à ces connaissances et de partage juste et équitable des avantages découlant de leur utilisation.

3. Les Parties s'efforcent d'appuyer, selon qu'il convient, l'élaboration par les communautés autochtones et locales, y compris les femmes de ces communautés, de :

a) Protocoles communautaires relatifs à l'accès aux connaissances traditionnelles associées aux ressources génétiques et au partage juste et équitable des avantages découlant de leur utilisation;

b) Conditions minimales pour la négociation de conditions convenues d'un commun accord afin d'assurer le partage juste et équitable des avantages découlant de l'utilisation des connaissances traditionnelles associées aux

ressources génétiques; et

c) Clauses contractuelles types pour le partage des avantages découlant de l'utilisation des connaissances traditionnelles associées aux ressources génétiques.

4. En appliquant le présent Protocole, les Parties, dans la mesure du possible, ne limitent pas l'utilisation coutumière ou l'échange de ressources génétiques et de connaissances traditionnelles associées au sein des communautés autochtones et locales et entre elles, conformément aux objectifs de la Convention.

Article 13

CORRESPONDANTS NATIONAUX ET AUTORITÉS NATIONALES COMPÉTENTES

1. Chaque Partie désigne un correspondant national pour l'accès et le partage des avantages. Le correspondant national fournit les renseignements suivants :

a) Aux demandeurs d'accès aux ressources génétiques, des informations sur les procédures d'obtention du consentement préalable donné en connaissance de cause et sur l'établissement de conditions convenues d'un commun accord, y compris le partage des avantages;

b) Aux demandeurs d'accès aux connaissances traditionnelles associées aux ressources génétiques, dans la mesure du possible, des informations sur les procédures d'obtention du consentement préalable donné en connaissance de cause ou l'accord et la participation, selon qu'il convient, des communautés autochtones et locales, et sur l'établissement de conditions convenues d'un commun accord, y compris le partage des avantages; et c) Des informations sur les autorités nationales compétentes, les communautés autochtones et locales et les parties prenantes concernées.

Le correspondant national est responsable de la liaison avec le Secrétariat.

2. Chaque Partie désigne une ou plusieurs autorités nationales compétentes en matière d'accès et de partage des avantages. Les autorités nationales compétentes, en conformité avec les mesures législatives et administratives ainsi que les politiques nationales applicables, sont chargées d'accorder l'accès ou, s'il y a lieu, de délivrer une preuve écrite que les conditions d'accès ont été respectées, et de fournir des conseils sur les procédures et les conditions

d'obtention du consentement préalable donné en connaissance de cause et de conclusion de conditions convenues d'un commun accord.

3. Une Partie peut désigner une seule entité pour cumuler les fonctions de correspondant national et d'autorité nationale compétente.

4. Chaque Partie communique au Secrétariat, au plus tard à la date d'entrée en vigueur du présent Protocole pour elle, les coordonnées de son correspondant national et de son autorité ou ses autorités nationales compétentes. Lorsqu'une Partie désigne plus d'une autorité nationale compétente, elle indique au Secrétariat, avec sa notification à cet effet, quels sont les domaines de responsabilité respectifs de ces autorités. Le cas échéant, il sera au moins précisé quelle est l'autorité compétente responsable des ressources génétiques sollicitées. Chaque Partie notifie immédiatement au Secrétariat toute modification de la désignation de son correspondant national ou des coordonnées ou des responsabilités de son ou ses autorités nationales compétentes.

5. Le Secrétariat met cette information à disposition en vertu du paragraphe 4 ci-dessus par le biais du Centre d'échange sur l'accès et le partage des avantages.

Article 14

CENTRE D'ÉCHANGE SUR L'ACCÈS ET LE PARTAGE DES AVANTAGES ET ÉCHANGE D'INFORMATIONS

1. Un Centre d'échange sur l'accès et le partage des avantages est créé dans le cadre du mécanisme d'échange prévu au paragraphe 3 de l'article 18 de la Convention. Il sert de moyen de partage d'informations relatives à l'accès et au partage des avantages. En particulier, il permet d'accéder aux informations pertinentes que fournit chaque Partie pour l'application du présent Protocole.

2. Sans préjudice de la protection des informations confidentielles, chaque Partie communique au Centre d'échange sur l'accès et le partage des avantages toute information qu'elle est tenue de fournir en vertu du présent Protocole et des décisions prises par la Conférence des Parties siégeant en tant que réunion des Parties au présent Protocole. Ces informations comprennent notamment :

a) Les mesures législatives, administratives et de politique générale en matière d'accès et de partage des avantages;

b) Les informations concernant le correspondant national et l'autorité ou les autorités nationales compétentes; et

c) Les permis ou documents équivalents délivrés au moment de l'accès pour attester de la décision d'accorder le consentement préalable en connaissance de cause et de la conclusion de conditions convenues d'un commun accord.

3. Des informations supplémentaires, le cas échéant et selon qu'il convient, peuvent inclure :

a) Les autorités compétentes pertinentes des communautés autochtones et locales, et des renseignements, selon qu'il en est décidé;

b) Les clauses contractuelles types;

c) Les méthodes et outils développés pour surveiller les ressources génétiques; et

d) Les codes de conduite et les meilleures pratiques.

4. Les modalités de fonctionnement du Centre d'échange sur l'accès et le partage des avantages, y compris ses rapports d'activité, sont examinées et arrêtées par la Conférence des Parties siégeant en tant que réunion des Parties au présent Protocole à sa première réunion et font l'objet d'examens ultérieurs.

Article 15

RESPECT DES DISPOSITIONS LÉGISLATIVES OU RÉGLEMENTAIRES INTERNES SUR L'ACCÈS ET LE PARTAGE DES AVANTAGES

1. Chaque Partie prend des mesures législatives, administratives ou de politique générale appropriées, efficaces et proportionnées afin de garantir que l'accès aux ressources génétiques utilisées sous sa juridiction a fait l'objet d'un consentement préalable donné en connaissance de cause et que des conditions convenues d'un commun accord ont été

établies, conformément à la législation ou aux dispositions législatives ou réglementaires internes relatives à l'accès et au partage des avantages de l'autre Partie.

2. Les Parties prennent des mesures appropriées, efficaces et proportionnées pour traiter des situations de non-respect des mesures adoptées conformément au paragraphe 1 ci-dessus.

3. Les Parties coopèrent, dans la mesure du possible et selon qu'il convient, en cas de violation présumée des dispositions législatives ou réglementaires internes relatives à l'accès et au partage des avantages mentionnées au paragraphe 1 ci-dessus.

Article 16

RESPECT DES DISPOSITIONS LÉGISLATIVES OU RÉGLEMENTAIRES INTERNES RELATIVES À L'ACCÈS ET AU PARTAGE DES AVANTAGES PORTANT SUR LES CONNAISSANCES TRADITIONNELLES ASSOCIÉES AUX RESSOURCES GÉNÉTIQUES

1. Chaque Partie prend des mesures législatives, administratives ou de politique générale appropriées, efficaces et proportionnées, selon qu'il convient, afin de garantir que l'accès aux connaissances traditionnelles associées aux ressources génétiques utilisées sous sa juridiction a été soumis au consentement préalable donné en connaissance de cause ou à l'accord et à la participation des communautés autochtones et locales et que des conditions convenues d'un commun accord ont été établies, conformément aux dispositions législatives ou réglementaires internes relatives à l'accès et au partage des avantages de l'autre Partie où ces communautés autochtones et locales sont situées.

2. Chaque Partie prend des mesures appropriées, efficaces et proportionnées pour traiter des situations de non-respect des mesures adoptées conformément au paragraphe 1 ci-dessus.

3. Les Parties coopèrent, dans la mesure du possible et selon qu'il convient, en cas de violation présumée des dispositions législatives ou réglementaires internes en matière d'accès et de partage des avantages mentionnées au paragraphe 1 ci-dessus.

Article 17

SURVEILLANCE DE L'UTILISATION DES RESSOURCES GÉNÉTIQUES

1. Afin de favoriser le respect des règles applicables, chaque Partie prend des mesures appropriées pour surveiller l'utilisation des ressources génétiques et augmenter la transparence concernant cette utilisation. Ces mesures comprennent :

a) La désignation d'un ou plusieurs points de contrôle, comme suit :

i) Les points de contrôle désignés recueillent et reçoivent selon qu'il convient, les informations pertinentes concernant l'obtention du consentement préalable donné en connaissance de cause, la source de la ressource génétique, l'existence de conditions convenues d'un commun accord et/ou l'utilisation des ressources génétiques, le cas échéant;

ii) Chaque Partie, s'il y a lieu et selon les caractéristiques particulières du point de contrôle désigné, exige que les utilisateurs de ressources génétiques fournissent à un point de contrôle désigné les renseignements précisés dans le paragraphe ci-dessus. Chaque Partie prend des mesures appropriées, efficaces et proportionnées pour traiter les situations de non-respect;

iii) Ces renseignements, y compris ceux provenant de certificats de conformité reconnus à l'échelle internationale lorsqu'ils sont disponibles, doivent être donnés aux autorités nationales compétentes, à la Partie qui donne le consentement préalable en connaissance de cause et au Centre d'échange sur l'accès et le partage des avantages, selon qu'il convient et sans préjudice des informations confidentielles;

iv) Les points de contrôle doivent être opérationnels et leurs fonctions devraient correspondre à l'application des dispositions du présent alinéa a). Ils devraient être en lien avec l'utilisation des ressources génétiques ou avec la collecte d'informations pertinentes, entre autres, à tout stade de la recherche, du développement, de l'innovation, de la précommercialisation ou de la commercialisation.

b) L'encouragement des utilisateurs et des fournisseurs de ressources génétiques à inclure, dans les conditions convenues d'un commun accord, des clauses relatives au partage de l'information concernant la mise en oeuvre de ces conditions, y compris en prévoyant l'obligation de présenter un rapport;

c) L'encouragement de l'utilisation d'outils et de systèmes de communication efficaces et économiques.

2. Un permis ou un document équivalent délivré conformément au paragraphe 3 e) de l'article 6 et mis à la disposition du Centre d'échange sur l'accès et le partage des avantages constitue un certificat de conformité reconnu à l'échelle internationale.

3. Un certificat de conformité reconnu à l'échelle internationale prouve que l'accès à la ressource génétique dont il traite a fait l'objet d'un consentement préalable donné en connaissance de cause et que des conditions convenues d'un commun accord ont été établies, conformément aux dispositions législatives ou réglementaires internes relatives à l'accès et au partage des avantages de la Partie accordant le consentement préalable donné en connaissance de cause.

4. Le certificat de conformité reconnu à l'échelle internationale contient au minimum les renseignements suivants lorsqu'ils ne sont pas confidentiels :

a) L'autorité de délivrance;

b) La date de délivrance;

c) Le fournisseur;

d) L'identifiant unique du certificat;

e) La personne ou entité à laquelle le consentement préalable en connaissance de cause a été donné;

f) Le sujet ou les ressources génétiques auxquels se rapporte le certificat;

g) Une confirmation que des conditions convenues d'un commun accord ont été établies;

h) Une confirmation que le consentement préalable en connaissance de cause a été obtenu; et

i) L'utilisation à des fins commerciales et/ou non commerciales.

Article 18

RESPECT DES CONDITIONS CONVENUES D'UN COMMUN ACCORD

1. En appliquant le paragraphe 3 g) i) de l'article 6 et l'article 7, chaque Partie encourage les fournisseurs et les utilisateurs de ressources génétiques et/ou de connaissances traditionnelles associées aux ressources génétiques à inclure dans les conditions convenues d'un commun accord des dispositions pour couvrir, le cas échéant, le règlement des différends, notamment :

a) La juridiction à laquelle ils soumettront les procédures de règlement des différends;

b) Le droit applicable; et/ou

c) La possibilité de recourir à d'autres modes de règlement des différends, tels que la médiation et l'arbitrage.

2. Chaque Partie veille à garantir la possibilité de recours dans son système juridique, conformément aux règles juridictionnelles applicables, en cas de différend concernant les conditions convenues d'un commun accord.

3. Chaque Partie prend, selon qu'il convient, des mesures effectives concernant :

a) L'accès à la justice; et

b) L'utilisation de mécanismes de reconnaissance mutuelle et d'application des décisions arbitrales et des jugements étrangers.

4. La Conférence des Parties siégeant en tant que réunion des Parties au présent Protocole évalue l'efficacité de cet article, conformément à l'article 31 du présent Protocole.

Article 19

CLAUSES CONTRACTUELLES TYPES

1. Chaque Partie encourage, selon qu'il convient, l'élaboration, la mise à jour et l'utilisation de clauses contractuelles types sectorielles et intersectorielles pour les conditions convenues d'un commun accord. 2. La Conférence des Parties siégeant en tant que réunion des Parties au présent Protocole examine périodiquement l'utilisation de clauses contractuelles types sectorielles et intersectorielles.

Article 20

CODES DE CONDUITE, LIGNES DIRECTRICES ET BONNES PRATIQUES ET/OU NORMES

1. Chaque Partie encourage, selon qu'il convient, l'élaboration, la mise à jour et l'utilisation de codes de conduite volontaires, de lignes directrices et bonnes pratiques et/ou normes relatifs à l'accès et au partage des avantages.

2. La Conférence des Parties siégeant en tant que réunion des Parties au présent Protocole examine périodiquement l'utilisation de codes de conduite volontaires, de lignes directrices et bonnes pratiques et/ou normes et envisage l'adoption de codes de conduite, lignes directrices et bonnes pratiques et/ou normes spécifiques.

Article 21

SENSIBILISATION

Chaque Partie prend des mesures pour sensibiliser le public à l'importance des ressources génétiques et des connaissances traditionnelles associées aux ressources génétiques, et aux questions liées à l'accès et au partage des avantages. Ces mesures peuvent inclure, entre autres :

a) La promotion du présent Protocole, y compris de son objectif;

b) L'organisation de réunions de communautés autochtones et locales et de parties prenantes concernées;

c) La mise en place et le maintien de bureaux d'assistance pour les communautés autochtones et locales, et les parties prenantes concernées;

d) La diffusion d'informations par le biais d'un centre d'échange national;

e) La promotion de codes de conduite volontaires, de lignes directrices et bonnes pratiques et/ou normes en consultation avec les communautés autochtones et locales et les parties prenantes concernées;

f) La promotion d'échanges d'expérience aux niveaux national, régional et international, selon qu'il convient;

g) L'éducation et la formation des utilisateurs et des fournisseurs de ressources génétiques et de connaissances traditionnelles associées aux ressources génétiques concernant leurs obligations en matière d'accès et de partage des avantages;

h) La participation des communautés autochtones et locales et des parties prenantes concernées à l'application du présent Protocole; et

i) La sensibilisation aux protocoles communautaires et aux procédures des communautés autochtones et locales.

Article 22

CAPACITÉS

1. Les Parties coopèrent à la création et au développement de capacités et au renforcement des ressources humaines et des capacités institutionnelles en vue de l'application effective du présent Protocole dans les pays en développement Parties, en particulier dans les pays les moins avancés et dans les petits États insulaires en développement parmi eux, ainsi que dans les Parties à économie en transition, y compris par l'intermédiaire des institutions et organisations mondiales, régionales, sous-régionales et nationales. Dans ce contexte, les Parties devraient faciliter la participation des communautés autochtones et locales et des parties prenantes concernées, y compris les organisations non gouvernementales et le secteur privé.

2. Les besoins des pays en développement Parties, en particulier ceux des pays les moins avancés et des petits États insulaires en développement parmi eux, ainsi que des Parties à économie en transition en matière de ressources

financières conformément aux dispositions pertinentes de la Convention, sont pleinement pris en compte dans la création et le renforcement des capacités aux fins de l'application du présent Protocole.

3. Pour servir de base à l'adoption de mesures appropriées pour l'application du présent Protocole, les pays en développement Parties, en particulier les pays les moins avancés et les petits États insulaires en développement parmi eux, ainsi que les Parties à économie en transition devraient identifier leurs besoins et leurs priorités en matière de capacités nationales au moyen d'autoévaluations des capacités nationales. Ce faisant, ces Parties devraient soutenir les besoins et les priorités des communautés autochtones et locales et des parties prenantes concernées en matière de capacités recensés par celles-ci, en mettant l'accent sur les besoins de capacités et les priorités des femmes.

4. Pour favoriser l'application du présent Protocole, la création et le renforcement des capacités pourraient viser notamment les domaines essentiels suivants :

a) La capacité d'appliquer le présent Protocole et de satisfaire aux obligations qui en résultent;

b) La capacité de négocier des conditions convenues d'un commun accord;

c) La capacité d'élaborer, de mettre en oeuvre et de faire respecter des mesures législatives, administratives ou de politique générale internes en matière

d'accès et de partage des avantages; et

d) La capacité des pays de développer leurs capacités endogènes de recherche afin d'ajouter de la valeur à leurs propres ressources génétiques.

5. Les mesures prises en application des paragraphes 1 à 4 ci-dessus peuvent inclure, entre autres :

a) Le développement juridique et institutionnel;

b) La promotion de l'équité et de la justice dans les négociations, par exemple

par la formation en matière de négociation de conditions convenues d'un commun accord;

c) La surveillance du respect des règles et la mise en conformité avec celles-ci;

d) L'emploi des meilleurs outils de communication et systèmes Internet disponibles pour les activités relatives à l'accès et au partage des avantages;

e) L'élaboration et l'utilisation de méthodes d'évaluation;

f) La bioprospection, la recherche associée et les études taxonomiques;

g) Le transfert de technologie ainsi que les infrastructures et la capacité technique permettant d'en assurer la pérennité;

h) L'augmentation de la contribution des activités d'accès et de partage des avantages à la conservation de la diversité biologique et à l'utilisation durable de ses éléments constitutifs;

i) Des mesures spéciales de renforcement des capacités des parties prenantes concernées en matière d'accès et de partage des avantages; et

j) Des mesures spéciales de renforcement des capacités des communautés autochtones et locales en mettant l'accent sur les capacités des femmes de ces communautés, en matière d'accès aux ressources génétiques et/ou aux connaissances traditionnelles associées aux ressources génétiques.

6. Les informations sur les initiatives de création et de renforcement des capacités prises aux niveaux national, régional et international en application des paragraphes 1 à 5 devraient être communiquées au Centre d'échange sur l'accès et le partage des avantages afin de favoriser les synergies et la coordination de la création et du renforcement des capacités en matière d'accès et de partage des avantages.

Article 23

TRANSFERT DE TECHNOLOGIE, COLLABORATION ET COOPÉRATION

Conformément aux articles 15, 16, 18 et 19 de la Convention, les Parties collaborent et coopèrent aux programmes de recherche et de développement techniques et scientifiques, y compris les activités de recherche biotechnologique, afin de réaliser l'objectif du présent Protocole. Les Parties s'engagent à appuyer et à encourager l'accès des pays en développement Parties à la technologie et le transfert de technologie à ces pays, en particulier les pays les moins avancés et les petits États insulaires en développement parmi eux, ainsi que les Parties à économie en transition, afin de favoriser le développement et le renforcement d'une base technologique et scientifique solide et viable pour la réalisation des objectifs de la Convention et du présent Protocole. Dans la mesure du possible et selon qu'il convient, ces activités de collaboration ont lieu sur le territoire et avec la participation de la Partie ou des Parties fournissant les ressources génétiques, qui sont les pays d'origine de ces ressources, ou des Parties qui les ont acquises conformément à la Convention.

Article 24

NON-PARTIES

Les Parties encouragent les non-Parties à respecter le présent Protocole et à communiquer au Centre d'échange sur l'accès et le partage des avantages des renseignements appropriés.

Article 25

MÉCANISME DE FINANCEMENT ET RESSOURCES FINANCIÈRES

1. Lorsqu'elles examinent la question des ressources financières destinées à l'application du présent Protocole, les Parties tiennent compte des dispositions de l'article 20 de la Convention.

2. Le mécanisme de financement de la Convention est le mécanisme de financement du présent Protocole.

3. En ce qui concerne la création et le renforcement des capacités visés à l'article 22 du présent Protocole, la Conférence des Parties siégeant en tant que réunion des Parties au présent Protocole tient compte, lorsqu'elle fournit des orientations concernant le mécanisme de financement visé au paragraphe 2 ci-dessus pour examen par la Conférence des Parties, du besoin de ressources financières des pays en développement Parties, en particulier des pays les moins avancés et des petits États insulaires en développement parmi eux, et des Parties à économie en transition, ainsi que des besoins de capacités et des priorités des communautés autochtones et locales, y compris les femmes de ces communautés.

4. Dans le cadre du paragraphe 1 ci-dessus, les Parties tiennent également compte des besoins des pays en développement Parties, en particulier ceux des pays les moins avancés et des petits États insulaires en développement parmi eux, ainsi que ceux des Parties à économie en transition, lorsqu'elles s'efforcent de déterminer et satisfaire leurs besoins en matière de création et de renforcement de capacités aux fins de l'application du présent Protocole.

5. Les orientations fournies au mécanisme de financement de la Convention dans les décisions pertinentes de la Conférence des Parties, y compris celles qui ont été approuvées avant l'adoption du présent Protocole, s'appliquent, mutatis mutandis, aux dispositions du présent article.

6. Les pays développés Parties peuvent aussi fournir des ressources financières et autres ressources pour l'application des dispositions du présent Protocole, par des voies bilatérales, régionales et multilatérales, dont les pays en développement Parties et les Parties à économie en transition pourront user.

Article 26

CONFÉRENCE DES PARTIES SIÉGEANT EN TANT QUE RÉUNION DES PARTIES AU PRÉSENT PROTOCOLE

1. La Conférence des Parties siège en tant que réunion des Parties au présent Protocole.

2. Les Parties à la Convention qui ne sont pas Parties au présent Protocole peuvent participer en qualité d'observateur aux travaux de toute réunion de la Conférence des Parties siégeant en tant que réunion des Parties au présent Protocole. Lorsque la Conférence des Parties siège en tant que réunion des Parties au présent Protocole, les décisions qui sont prises en vertu du présent Protocole le sont seulement par les Parties au présent Protocole.

3. Lorsque la Conférence des Parties siège en tant que réunion des Parties au présent Protocole, tout membre du Bureau de la Conférence des Parties représentant une Partie à la Convention qui n'est pas Partie au présent Protocole à ce moment-là est remplacé par un nouveau membre qui est élu par les Parties au présent Protocole parmi elles.

4. La Conférence des Parties siégeant en tant que réunion des Parties au présent Protocole suit régulièrement l'application du présent Protocole et prend, dans le cadre de son mandat, les décisions nécessaires pour en favoriser l'application effective. Elle s'acquitte des fonctions qui lui sont assignées par le présent Protocole et :

a) Formule des recommandations sur toute question concernant l'application du présent Protocole;

b) Crée les organes subsidiaires jugés nécessaires pour faire appliquer le présent Protocole;

c) Fait appel et recourt, en tant que de besoin, aux services, à la coopération et aux informations fournis par les organisations internationales et les organes intergouvernementaux et non gouvernementaux compétents; d) Détermine la présentation et la périodicité de la transmission des informations à communiquer en application de l'article 29 du présent Protocole et examine ces informations ainsi que les rapports soumis par tout organe subsidiaire;

e) Examine et adopte, en tant que de besoin, les amendements au Protocole et à son annexe, ainsi que toutes annexes additionnelles au Protocole, jugés nécessaires pour son application; et

f) Exerce toute autre fonction que pourrait exiger l'application du présent Protocole.

5. Le règlement intérieur de la Conférence des Parties et les règles de gestion financière de la Convention s'appliquent mutatis mutandis au présent Protocole, à moins que la Conférence des Parties siégeant en tant que réunion des Parties au présent Protocole n'en décide autrement par consensus.

6. La première réunion de la Conférence des Parties à la Convention siégeant en tant que réunion des Parties au présent Protocole est convoquée par le Secrétariat et tenue concurremment avec la première réunion de la Conférence des Parties qui se tiendra après la date d'entrée en vigueur du présent Protocole. Par la suite, les réunions ordinaires de la Conférence des Parties siégeant en tant que réunion des Parties au présent Protocole se tiendront concurremment avec les réunions ordinaires de la Conférence des Parties, à moins que la Conférence des Parties siégeant en tant que réunion des Parties au présent Protocole n'en décide autrement.

7. Des réunions extraordinaires de la Conférence des Parties siégeant en tant que réunion des Parties au présent Protocole peuvent avoir lieu à tout autre moment si la Conférence des Parties siégeant en tant que réunion des Parties au présent Protocole le juge nécessaire, ou à la demande écrite d'une Partie, sous réserve que cette demande soit appuyée par un tiers au moins des Parties dans les six mois suivant sa communication aux Parties par le Secrétariat.

8. L'Organisation des Nations Unies, ses institutions spécialisées et l'Agence internationale de l'énergie atomique, ainsi que tout État membre desdites organisations ou tout observateur auprès desdites organisations qui n'est pas Partie à la Convention, peuvent être représentés en qualité d'observateur aux réunions de la Conférence des Parties siégeant en tant que réunion des Parties au présent Protocole. Tout organe ou institution, à caractère national ou international, gouvernemental ou non gouvernemental, compétent dans des domaines visés par le présent Protocole et ayant informé le Secrétariat de son souhait d'être représenté en qualité d'observateur à une réunion de la Conférence des Parties siégeant en tant que réunion des Parties au présent Protocole, peut être admis en cette qualité à moins qu'un tiers au moins des Parties présentes ne s'y opposent. L'admission et la participation d'observateurs sont régies par le règlement intérieur visé au paragraphe 5 ci-dessus, sauf disposition contraire du présent article.

Article 27

ORGANES SUBSIDIAIRES

1. Tout organe subsidiaire créé par, ou en vertu de, la Convention peut s'acquitter de fonctions au titre du présent Protocole, y compris sur décision de la Conférence des Parties siégeant en tant que réunion des Parties au présent Protocole. Une telle décision précise les tâches à entreprendre.

2. Les Parties à la Convention qui ne sont pas Parties au présent Protocole peuvent participer, en qualité d'observateur, aux travaux de toute réunion d'un tel organe subsidiaire. Lorsqu'un organe subsidiaire de la Convention agit en tant

qu'organe subsidiaire du présent Protocole, les décisions relevant du présent Protocole sont prises uniquement par les Parties au présent Protocole.

3. Lorsqu'un organe subsidiaire de la Convention exerce ses fonctions sur des questions concernant le présent Protocole, tout membre du Bureau de cet organe subsidiaire représentant une Partie à la Convention qui n'est pas Partie au présent Protocole à ce moment-là est remplacé par un nouveau membre qui est élu par les Parties au présent Protocole parmi elles.

Article 28

SECRÉTARIAT

1. Le Secrétariat établi en vertu de l'article 24 de la Convention fait fonction de Secrétariat du présent Protocole.

2. Le paragraphe 1 de l'article 24 de la Convention relatif aux fonctions du Secrétariat s'applique mutatis mutandis au présent Protocole.

3. Pour autant qu'ils sont distincts, les coûts des services de secrétariat afférents au présent Protocole sont pris en charge par les Parties au présent Protocole. La Conférence des Parties siégeant en tant que réunion des Parties au présent Protocole prend, à sa première réunion, les dispositions financières nécessaires à cet effet.

Article 29

SUIVI ET ÉTABLISSEMENT DES RAPPORTS

Chaque Partie veille au respect des obligations qui sont les siennes en vertu du présent Protocole et, à des intervalles réguliers et sous la forme décidés par la Conférence des Parties siégeant en tant que réunion des Parties au présent Protocole, fait rapport à la Conférence des Parties siégeant en tant que réunion des Parties au présent Protocole sur les mesures qu'elle a prises pour en appliquer les dispositions.

Article 30

PROCÉDURES ET MÉCANISMES PROPRES À ENCOURAGER LE RESPECT DES DISPOSITIONS DU PRÉSENT PROTOCOLE

La Conférence des Parties siégeant en tant que réunion des Parties au présent Protocole examine et approuve, à sa première réunion, des procédures et des mécanismes institutionnels de coopération propres à encourager le respect des dispositions du présent Protocole et à traiter les cas de non-respect. Ces procédures et mécanismes comportent des dispositions visant à offrir des conseils ou une assistance, le cas échéant. Ils sont distincts et sans préjudice de la procédure et des mécanismes de règlement des différends prévus à l'article 27 de la Convention.

Article 31

ÉVALUATION ET EXAMEN

La Conférence des Parties siégeant en tant que réunion des Parties au présent Protocole procède, quatre ans après l'entrée en vigueur du présent Protocole, puis ensuite à des intervalles déterminés par la Conférence des Parties siégeant en tant que réunion des Parties au présent Protocole, à une évaluation de son efficacité.

Article 32

SIGNATURE

Le présent Protocole est ouvert à la signature des Parties à la Convention au Siège de l'Organisation des Nations Unies à New York du 2 février 2011 au 1er février 2012.

Article 33

ENTRÉE EN VIGUEUR

1. Le présent Protocole entre en vigueur le quatre-vingt-dixième jour suivant la date de dépôt du cinquantième instrument de ratification, d'acceptation, d'approbation ou d'adhésion, par les États ou les organisations régionales d'intégration économique qui sont Parties à la Convention.

2. Le présent Protocole entre en vigueur pour un État ou une organisation régionale d'intégration économique qui le ratifie, l'accepte, l'approuve ou y adhère après le dépôt du cinquantième instrument ainsi qu'il est entionné au paragraphe 1 ci-dessus, soit le quatre-vingt-dixième jour après la date de dépôt, par cet État ou cette organisation régionale d'intégration économique, de son instrument de ratification, d'acceptation, d'approbation ou d'adhésion, soit au moment où la Convention entre en vigueur pour cet État ou cette organisation régionale d'intégration économique, la date la plus tardive étant retenue.

3. Aux fins des paragraphes 1 et 2 ci-dessus, aucun des instruments déposés par une organisation régionale d'intégration économique n'est considéré comme venant s'ajouter aux instruments déjà déposés par les États membres de ladite organisation.

Article 34

RÉSERVES

Aucune réserve ne peut être faite au présent Protocole.

Article 35

DÉNONCIATION

1. A l'expiration d'un délai de deux ans à compter de la date d'entrée en vigueur du présent Protocole à l'égard d'une Partie, cette Partie peut dénoncer le présent Protocole par notification écrite au Dépositaire.

2. Cette dénonciation prend effet à l'expiration d'un délai d'un an à compter de la date de sa réception par le Dépositaire, ou à toute date ultérieure qui pourra être spécifiée dans ladite notification.

Article 36

TEXTES FAISANT FOI

L'original du présent Protocole, dont les textes anglais, arabe, chinois, espagnol, français et russe font également foi, sera déposé auprès du Secrétaire général de l'Organisation des Nations Unies.

EN FOI DE QUOI les soussignés, à ce dûment habilités, ont signé le présent Protocole aux dates indiquées.

FAIT à Nagoya, le vingt-neuf octobre deux mil dix.

Annexe

AVANTAGES MONÉTAIRES ET NON MONÉTAIRES

1. Les avantages monétaires peuvent comprendre ce qui suit sans y être limités :

a) Droits d'accès/droits par échantillon collecté ou autrement acquis;

b) Paiements initiaux;

c) Paiements par étapes;

d) Paiement de redevances;

e) Droits de licence en cas de commercialisation;

f) Droits spéciaux à verser à des fonds d'affectation spéciale en faveur de la conservation et de l'utilisation durable de la diversité biologique;

g) Salaires et conditions préférentielles s'il en est convenu d'un commun accord;

h) Financement de la recherche;

i) Coentreprises;

j) Copropriété des droits de propriété intellectuelle pertinents.

2. Les avantages non monétaires peuvent comprendre ce qui suit sans y être limités :

a) Partage des résultats de la recherche et de la mise en valeur;

b) Collaboration, coopération et contribution aux programmes de recherche scientifique et de mise en valeur, notamment aux activités de recherche biotechnologique, autant que possible dans la Partie qui fournit les ressources génétiques;

c) Participation au développement de produits;

d) Collaboration, coopération et contribution à l'éducation et à la formation;

e) Accès aux installations de conservation ex situ de ressources génétiques et aux bases de données;

f) Transfert, au fournisseur des ressources génétiques, des connaissances et technologies à des conditions équitables et qui soient les plus favorables, y compris à des conditions privilégiées et préférentielles s'il en est ainsi convenu, en particulier des connaissances et de la technologie qui utilisent les ressources génétiques, y compris la biotechnologie, ou qui ont trait à la conservation et à l'utilisation durable de la diversité biologique;

g) Renforcement des capacités en matière de transfert de technologie;

h) Renforcement des capacités institutionnelles;

i) Ressources humaines et matérielles nécessaires au renforcement des capacités pour l'administration et l'application des règlements d'accès;

j) Formation relative aux ressources génétiques avec la pleine participation des pays qui les fournissent et, autant que possible, dans ces pays;

k) Accès à l'information scientifique ayant trait à la conservation et à l'utilisation durable de la diversité biologique, y compris les inventaires biologiques et les études taxonomiques;

l) Apports à l'économie locale;

m) Recherche orientée vers les besoins prioritaires, tels que la sécurité alimentaire et la santé, compte tenu des utilisations internes des ressources génétiques dans la Partie qui fournit les ressources génétiques;

n) Relations institutionnelles et professionnelles qui peuvent découler d'un accord d'accès et de partage des avantages et des activités de collaboration ultérieures;

o) Avantages en matière de sécurité alimentaire et de moyens de subsistance;

p) Reconnaissance sociale;

q) Copropriété et droits de propriété intellectuelle pertinents.

ANNEX II

ACCESS TO GENETIC RESOURCES AND BENEFIT-SHARING - RELATED LEGISLATION INSTRUMENTS IN SELECTED COUNTRIES

I. Brazil

Constitution of the Federative Republic of Brazil, 1988, and amendment 52, enacted on March 8th 2006, available at *http://www.v-brazil.com/government/laws/constitution.html*, last accessed May 10, 2012

Decree 98.830 of 15 January 1990

Decree No. 2 in 1994, Brazil ratified the CBD

Provisional Ruling 2052, June 2000

Provisional Ruling 2186-16/2001

Decree 3945 of September 2001

Decree 5949 of June 7, 2005

Decree 6040 of February 7, 2007

Decree 6915 of July 2009

Acre State Law No 1235/97

Amapá Law No 388/97, 1998.

Amapá Decree No 1624, June, 1999

II. South Africa

Constitution of the Republic of South Africa, No.108 of 1996 and amendment 2003 Available at ***http://www.info.gov.za/documents/constitution/1996/a108-96.pdf***, last accessed May 10, 2012

National Environmental Management Act, 107 of 1998

South Africa Biodiversity Act, No 10, 2004

Protected Areas Act, No 57, 2003

Patents Amendment Act, No. 20 of 2005

Trust Laws of South Africa.

Adjustment of Fines Act, No.101 of 1991

2001 African Model Law for the Protection of the Rights of the Local Communities, Farmers and Breeders and for the Regulation of Access to Biological Resources (the African Model Law)

III. France and European Union

France

La Constitution du 4 octobre 1958 et dernière modification : révision constitutionnelle du 23 juillet 2008 available at ***http://www.conseil-constitutionnel.fr/conseil-constitutionnel/francais/la-constitution/la-constitution-du-4-octobre-1958/la-constitution-du-4-octobre-1958.5071.html*** last accessed May 10, 2012

Constitutional Charter for the environment 2004, available at ***http://www.conseil-constitutionnel.fr/conseil-constitutionnel/english/constitution/charter-for-the-environment.103658.html*** last accessed May 10, 2012

Law of 1st July 1957

Law of 2nd May 1930

Law of 22nd July 1960

Law of 10th July 1976

Law of 2nd February 1995

Rural Code 1989

Law No 91-1266, 18 December 1991

Organic Law of 1999

Law on Orientation for overseas (Law 2000-1207 of 13, December 2000)

Environment Code of September, 2000.

National Biodiversity Strategy and Action Plan Overseas 2006-2010,

Environmental Code of 14 April 2006

Civil Code

Civil Code of Procedure

Deliberation 06-2009 of 18 February 2009 of Southern Province of New Caledonia

European Union (EU)

Direction 79/409 dated 2/4/1979 on conservation of wild bird

Regulation CEE No 3626/82 dated 3/12/1982 on the application of the Convention CITES within space of community.

Direction 92/43/CEE dated 21/5/1992 on the conservation of natural habitats and wild fauna and flora.

Council Regulation No 2081/92 (14 July 1992) on geographic indications

Council Regulation No 2982/92 of 14 July 1992 on certificates of specific character for agricultural products and foodstuffs;

Protocol No 3 on the Sami people[1186] of the Act of Accession of Austria, Finland and Sweden to the EU (1994)

Council Regulation No 2100/94 (27 July 1994) on Community Plant Variety Rights

Directive 96/9/EC of the European Parliament and of the Council (11 March 1996)

Directive 98/44/EC, (6 July 1998) on the legal protection of biotechnological innovations

Directive 98/95/EC on conservation varieties (14 December 1998);

Council Regulation on the conservation, characterisation, collection, utilisation of genetic resources in agriculture and amending Regulation (EC) 1258/1999

1998 European Community Biodiversity Strategy (COM(98)042) - 5th Environmental Action Program

The 2002 EC Biodiversity Action Plan for Economic and Development Cooperation

IV. Vietnam

Constitution of the Socialist Republic of Vietnam 1992 and amendment 2001, available at *http://vbqppl.moj.gov.vn/vbpq/en/Lists/Vn%20bn%20php%20lut/View_Detail.aspx?ItemID=10450*, last accessed May 29 2012

The Biodiversity law of Vietnam, available at *http://vbqppl.moj.gov.vn/vbpq/en/Lists/Vn%20bn%20php%20lut/View_Detail.aspx?ItemID=10503*, last accessed May 30, 2012

Legal texts issued by the National Assembly

Fisheries Law 2003

[1186] Indigenous peoples of Northern Norway, Sweden and Finland

Ordinance on Plant Varieties 2004

Ordinance on Livestock Breeds 2004

Law on Forest Protection and Development, 2004

Law on Intellectual Property, 2005

Civil Code 2005

Law on the issuance of legal texts 2008

Biodiversity Law 2008

Legal texts issued by the Government and Prime Minister

Decree 32/2006/ND-CP of dated 30 March 2006 on the management of endangered forest fauna and flora;

Decree 82/2006/ND-CP of 10 August 2006 on the management of the import, export, re-export, introduction from the sea, transit, breeding, rearing and artificial propagation of endangered species of wild fauna and flora

Decree 104/2006/ND-CP dated 22 September 2006 on guiding implementation of the Law on Intellectual Property Rights to plant varieties

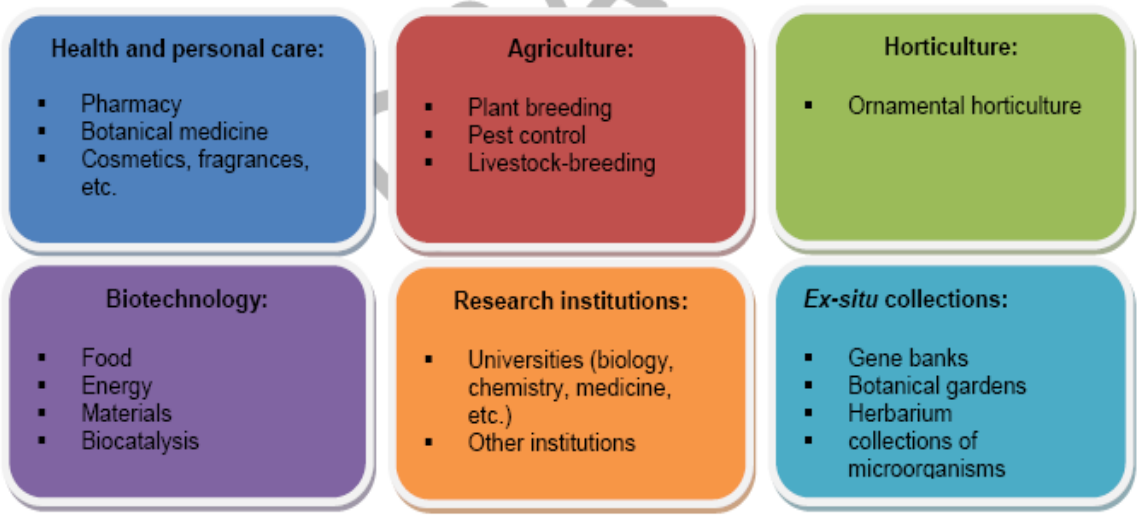
Decree 25/2008/ND-CP of 4 March 2008 on the functions, responsibilities, powers and structure of Ministry of Natural Resources and Environment

Decision 132/2008/QD-TTg of 30 September 2008 of the Vietnam Environment Administration which is part of Ministry of Natural Resources and Environment

Decree 65/2010/ND-CP of 11 June 2010 guiding implementation of the Biodiversity Law

ANNEX III[1187]

Figure 1: Potential Users of Genetic Resources



Source: Own illustration, based on Holm-Müller, K., Richerzhagen, C. and Täuber, S. *Users of Genetic Resources in Germany – Awareness, Participation and Positions regarding the Convention on Biological Diversity*. BfN-Skripten 126 (BfN: Bonn, 2005). p. 18.

Table 1: Market Sectors Dependent on Genetic Resources

Sector	Size of market	Comment
Pharmaceutical	US$ 643 billion (in 2006)	A significant share derived from genetic resources (e.g. 47 % of cancer drugs over period 1981-2006)
Biotechnology	US $ 70 billion (in 2006 from public companies alone)	Many products derived from genetic resources (enzymes, micro-organisms)
Crop protection products	US $ 30 billion (in 2006)	Some derived from genetic resources
Agricultural seeds	US $ 30 billion (in 2006)	All derived from genetic resources
Ornamental horticulture	Global import value US $ 14 billion (in 2006)	All derived from genetic resources
Personal care, botanical, and food and beverage industries	US $ 22 billion for herbal supplements US $ 12 billion for personal cares US $ 31 billion for food products (all in 2006)	Some products derived from genetic resources: represents natural component of the market
Source: Own illustration, based on Markandya, A. and Nunes, P. *Sharing benefits derived from genetic resources*. In ten Brink, P. (ed.) *The Economics of Ecosystems and Biodiversity in National and International Policy Making*. (Earthscan: London and Washington, 2011).		

[1187] Based on IUCN, An Explanatory Guide to the Nagoya Protocol on Access and Benefit-sharing , Draft 1.1,at http://cmsdata.iucn.org/downloads/iucn_explanatory_guide_to_the_nagoya_protocol_draft_1_1.pdf

ANNEX IV –
COUNTRIES MEMBER OF DIFFERENT TREATIES IN COMPARISON

Country Name	Nagoya Protocol/Signature	FAO's international Treaty /Members	UPOV/Members	WTO/TRIPs /Members
Afghanistan		2006-11-09		
Albania		2010-05-12	2005-10-15	2000-09-08
Algeria	2011-02-02	2002-12-13		
Andorra				
Angola		2006-03-14		1996-11-23
Antigua and Barbuda	2011-07-28			1995-01-01
Argentina	2011-11-15		1994-12-25	1995-01-01
Armenia		2007-03-20		2003-02-05
Australia	2012-01-20	2005-12-12	1989-03-01	1995-01-01
Austria	2011-06-23	2002-06-06	1994-07-14	1995-01-01
Azerbaijan			2004–12-09	
Bahamas				
Bahrain				1995-01-01
Bangladesh	2011-09-06	2003-11-14		1995-01-01
Barbados				1995-01-01
Belarus			2003-01-05	
Belgium	2011-09-20	2007-10-02	1976-12- 05	1995-01-01
Belize				1995-01-01
Benin	2011-10-28	2006-02-24		1996-02-01
Bhutan	2011-09-20	2003-09-02		
Bolivia (Plurinational State of)			1999-05-21	1995-09-12
Bosnia and Herzegovina				
Botswana				1995-05-31
Brazil	2011-02-02	2006-05-22	1999-05-23	1995-01-01
Brunei Darussalam				1995-01-01
Bulgaria	2011-06-23	2004-12-29	1998-04-24	1996-12-01
Burkina Faso	2011-09-20	2006-12-05		1995-06-01
Burundi		2002-06-10		1995-07-23
Cambodia	2012-02-01	2002-06-11		2004-10-13
Cameroon		2005-12-29		1995-12-13
Canada		2002-06-10	1991-04-03	1995-01-01
Cape Verde	2011-09-26			2008-07-23
Central African Republic	2011-04-06	2003-08-04		1995-05-31
Chad	2012-01-31	2006-03-14		1996-10-19
Chile			1996-04-23	1995-01-01
China			1999-23-04	2001-12-11
Colombia	2011-02-02		1996-09-13	1995-04-30
Comoros				
Congo	2011-09-23	2004-09-14		1997-03-27
Cook Islands		2004-12-02		
Costa Rica	2011-07-06	2006-11-14	2009-01-12	1995-01-01
Côte d'Ivoire	2012-01-25	2003-06-25		1995-01-01
Croatia		2009-05-08	2001-09-01	2000-11-30
Cuba		2004-09-16		1995-04-20
Cyprus	2011-12-29	2003-09-15		1995-07-30
Czech Republic	2011-06-23	2004-03-31	1993-01-01	1995-01-01
Democratic People's Republic of Korea		2003-07-16		
Democratic Republic of the Congo	2011-09-21	2003-06-05		1997-01-01
Denmark	2011-06-23	2004-03-31	1968-10-06	1995-01-01
Djibouti	2011-10-19	2006-05-08		1995-05-01
Dominica				1995-01-01
Dominican Republic	2011-09-20		2007-06-16	1995-03-09
Ecuador	2011-04-01	2004-05-07	1997-08-08	1996-21-01
Egypt	2012-01-25	2004-03-31		1995-06-30
El Salvador	2012-02-01	2003-07-09		1995-05-07
Equatorial Guinea				
Eritrea		2002-06-10		
Estonia		2004-03-31	2000-09-24	1999-11-13
Ethiopia		2003-06-18		
European Union	2011-06-23	2004-03-31	2005-07-29	1995-01-01
Fiji		2008-07-09		1996-01-14
Finland	2011-06-23	2004-03-31	1993-04-16	1995-01-01
France	2011-09-20	2005-07-11	1971-10-03	1995-01-01
Gabon	2011-05-13	2006-11-13		1995-01-01
Gambia				1996-10-23
Georgia			2008-11-29	2000-06-14

Germany	2011-06-23	2004-03-31	1968-08-10	1995-01-01
Ghana	2011-05-20	2002-10-28		1995-01-01
Greece	2011-09-20	2004-03-31		1995-01-01
Grenada	2011-09-22			1996-02-22
Guatemala	2011-05-11	2006-02-01		1995-07-21
Guinea	2011-12-09	2002-06-11		1995-10-25
Guinea-Bissau	2012-02-01	2006-02-01		1995-05-31
Guyana				1995-01-01
Haiti				1996-01-30
Holy See				
Honduras	2012-02-01	2004-01-14		1995-01-01
Hungary	2011-06-23	2004-03-04	1983-04-16	1995-01-01
Iceland		2007-08-07	2006-05-03	1995-01-01
India	2011-05-11	2002-06-10		1995-01-01
Indonesia	2011-05-11	2006-03-10		1995-01-01
Iran (Islamic Republic of)		2006-04-28		
Iraq				
Ireland	2012-02-01	2004-03-31	1981-11-08	1995-01-01
Israel			1979-12-12	1995-01-01
Italy	2011-06-23	2004-05-18	1977-07-01	1995-01-01
Jamaica		2006-03-14		1995-03-09
Japan	2011-05-11		1982-09-03	1995-01-01
Jordan	2012-01-10	2002-05-30	2004-10-24	2000-04-11
Kazakhstan				
Kenya	2012-02-01	2003-05-27	1999-05-13	1995-01-01
Kiribati		2005-12-13		
Kuwait		2003-09-02		1995-01-01
Kyrgyzstan		2009-06-01	2000-06-26	1998-12-20
Lao People's Democratic Republic		2006-03-14		
Latvia		2004-05-27	2002-08-30	1999-02-10
Lebanon	2012-02-01	2004-05-06		
Lesotho		2005-11-21		1995-05-30
Liberia		2005-11-25		
Libya		2005-04-12		
Liechtenstein				1995-09-01
Lithuania	2011-12-29	2005-21-06	2003-12-10	2001-05-31
Luxembourg	2011-06-23	2004-03031		1995-01-01
Madagascar	2011-09-22	2006-03-13		1995-11-17
Malawi		2002-07-04		1995-05-31
Malaysia		2003-05-05		1995-01-01
Maldives		2006-03-02		1995-05-31
Mali	2011-04-19	2005-05-05		1995-05-31
Malta				1995-01-01
Marshall Islands				
Mauritania	2011-05-18	2003-02-11		1995-05-31
Mauritius		2003-03-27		1995-01-01
Mexico	2011-02-24	2012-05-16	1997-08-09	1995-01-01
Micronesia (Federated States of)	2012-01-11			
Monaco				
Mongolia	2012-01-26			1997-01-29
Montenegro		2010-07-21		2012-04-29
Morocco	2011-12-09	2006-07-14	2006-10-08	1995-01-01
Mozambique	2011-09-26			1995-08-26
Myanmar		2002-12-04		1995-01-01
Namibia		2004-10-07		1995-01-01
Nauru				
Nepal		2009-10-19		2004-04-23
Netherlands	2011-06-23	2005-11-18	1968-08-10	1995-01-01
New Zealand			1981-11-08	1995-01-01
Nicaragua		2002-11-22	2001-09-06	1995-09-03
Niger	2011-09-26	2004-10-27		1996-12-03
Nigeria	2012-02-01			1995-01-01
Niue				
Norway	2011-05-11	2004-08-03	1993-09-13	1995-01-01
Oman		2004-07-14	2009-11-22	2000-11-09
Pakistan		2003-09-02		1995-01-01
Palau	2011-09-20	2008-08-05		
Panama	2011-05-03	2006-03-13	1999-05-23	1997-09-06
Papua New Guinea				1996-06-09
Paraguay		2003-01-03	1997-02-08	1995-01-01
Peru	2011-05-04	2003-06-05	2011-08-08	1995-01-01
Philippines		2006-09-28		1995-01-01
Poland	2011-09-20	2005-02-07	1989-11-11	1995-07-01
Portugal	2011-09-20	2005-11-07	1995-10-14	1995-01-01
Qatar		2008-07-01		1996-01-13

Republic of Korea	2011-09-20	2009-01-20	2002-01-07	1995-01-01
Republic of Moldova	2012-01-25		1998-10-28	2001-07-26
Romania	2011-09-20	2005-05-31	2001-03-16	1995-01-01
Russian Federation			1998-04-24	
Rwanda	2011-02-28 /2012-03-20	2010-10-14		1996-05-22
Saint Kitts and Nevis				1996-02-21
Saint Lucia		2003-07-16		1995-01-01
Saint Vincent and the Grenadines				
Samoa		2006-03-09		2012-05-10
San Marino				
Sao Tome and Principe		2006-04-07		
Saudi Arabia		2005-10-17		2005-12-11
Senegal	2012-01-26	2006-10-25		1995-01-01
Serbia	2011-09-20			
Seychelles	2011-04-15 /2012-04-20	2006-05-30		
Sierra Leone		2002-11-20		1995-07-23
Singapore			2004-07-30	1995-01-01
Slovakia		2010-06-08	1993-01-01	1995-01-01
Slovenia	2011-09-27	2006-01-11	1999-07-29	1995-07-30
Solomon Islands				1996-07-26
Somalia	2012-01-09			
South Africa	2011-05-11		1977-11-06	1995-01-01
South Sudan				
Spain	2011-07-21	2004-03-31	1980-05-18	1995-01-01
Sri Lanka				1995-01-01
Sudan	2011-04-21	2002-06-10		
Suriname				1995-01-01
Swaziland				1995-01-01
Sweden	2011-06-23	2004-03-31	1971-12-17	1995-01-01
Switzerland	2011-05-11	2004-11-22	1977-07-10	1995-01-01
Syrian Arab Republic		2003-08-26		
Tajikistan	2011-09-20			
Thailand	2012-01-31			1995-01-01
The former Yugoslav Republic of Macedonia			2011-05-04	2003-04-04
Timor-Leste				
Togo	2011-09-27	2007-10-23		1995-05-31
Tonga				2007-07-27
Trinidad and Tobago		2004-10-27	1998-06-30	1995-03-01
Tunisia	2011-05-11	2004-06-08	2003-08-31	1995-03-29
Turkey		2007-06-07	2007-11-18	1995-03-26
Turkmenistan				
Tuvalu				
Uganda		2003-03-25		1995-01-01
Ukraine	2012-01-30		1995-11-03	2008-05-16
United Arab Emirates		2004-02-16		1996-04-10
United Kingdom of Great Britain and Northern Ireland	2011-06-23	2004-03-31	1968-08-10	1995-01-01
United Republic of Tanzania		2004-04-30		1995-01-01
United States of America			1981-11-08	1995-01-01
Uruguay	2011-07-19	2006-03-01	1994-11-13	1995-01-01
Uzbekistan			2004-11-14	
Vanuatu	2011-11-18			
Venezuela (Bolivarian Republic of)		2005-05-17		1995-01-01
Viet Nam			2006-12-24	2007-01-11
Yemen	2011-02-02	2006-03-01		
Zambia		2006-03-13		1995-01-01
Zimbabwe		2005-07-05		1995-03-05
TOTAL	92	127	70	155

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INDEX

A

B

C

D

E

F

G

H

I

J

L

M

N

O

P

R

S

T

U

V

W

TABLES OF CONTENTS

Genetic resources are not only component of nature that need be protected but also has economic, social, cultural values for development. Approaching genetic resources under those two aspects of ‘conservation’ and ‘development’, one of three objectives of Convention on Biological Diversity (CBD) and the goal of the Nagoya Protocol is ‘Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization’.

The Nagoya Protocol adopted in October 2010 by the 10th Conference of the Parties to the CBD, is a landmark for the international governance of biodiversity and a milestone in the development of the international regime governing biodiversity. However, the Protocol has been criticized as “imperfect” and “incomplete” because of ambiguities, gaps and generalities. Each country that becomes a Party to the Protocol will need to develop national legislation to meet its obligations under the Protocol, filling in gaps with national legislation in accordance with its particular situation. The integration of the Protocol into national law is important in both meanings of the first process and the bridge of putting the legal provisions of the Protocol into practice. However, there are many problems that need defined and analyzed as the bases to find solutions.

The first part of this thesis contributes analysis of problems of the Protocol in the international context, relations with the others relevant international treaties and all the contents, intrinsic problems of the Protocol in both legal and technical, scientific aspects. The part 2 of the thesis clarifies all related legal problems of integration into national law such as weakness of international law, legal points of views: dualism and monism, non-self executive treaties, the principles, methods, measures and other factors. Then, it provides case studies of national laws of Brazil, South Africa, France and takes a closer look in to practice of national legislation of Vietnam.

Les ressources génétiques sont une composante de la nature qui doit être protégée pour ses valeurs économiques, sociales, et culturelles. En approchant des ressources génétiques en vertu des deux aspects de la «conservation» et du «développement», l'un des trois objectifs du Protocole de Nagoya est l'accès aux ressources génétiques à la Convention sur la diversité biologique (CDB) et un partage juste et équitable des avantages découlant de leur utilisation.

Le Protocole de Nagoya adopté en octobre 2010 lors de la 10e Conférence des Parties à la CDB, marque un tournant pour la gouvernance internationale de la biodiversité et un jalon dans le développement du régime international régissant la biodiversité. Toutefois, le Protocole a été qualifié d’ «imparfait» et d’ «incomplet» en raison d‘ambiguïtés, de lacunes et de généralités. Chaque Etat partie au Protocole doit élaborer une législation nationale pour répondre à ses obligations, et combler les lacunes par une mise en conformité avec celui-ci. L'étude de l’intégration du protocole dans le droit national est importante parce qu’il s’agit du premier instrument juridique dans ce domaine et que l’analyse de sa transposition met en lumière les différentes voies envisageables. Cependant, celle-ci peut soulever de nombreux problèmes et nécessite de définir et d'analyser ces bases pour trouver des solutions.

La première partie de cette thèse propose une analyse des problèmes du Protocole dans le contexte international, les relations avec les autres traités internationaux pertinents et tous les problèmes intrinsèques du Protocole dans ses aspects juridiques, scientifiques et techniques. La seconde partie de la thèse clarifie tous les problèmes juridiques pertinents de l'intégration dans la législation nationale et traite de la faiblesse du droit international au regard des systèmes juridiques monistes et dualistes, les traités non-auto-exécutoires, les principes, méthodes et mesures. Elle analyse également les droits nationaux du Brésil, d’Afrique du Sud, de la France et un regard plus proche dans la pratique avec la législation nationale du Vietnam.