Implications for BioTrade of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization

UNITED NATIONS

New York and Geneva, 2011

UNCTAD/DITC/TED/2011/9

For further information on UNCTAD's BioTrade Initiative please consult the following website:
http://www.unctad.org/biotrade
or contact: biotrade@unctad.org

Acknowledgements

This publication was prepared for the UNCTAD BioTrade Initiative by Carlos Correa.

The author is grateful for the comments received from Sonia Peña Moreno, David Vivas, Maria Julia Oliva, Claudio Chiarolla and the staff of UNCTAD's BioTrade Initiative.

UNCTAD gratefully acknowledges the support of the Swiss State Secretariat for Economic Affairs (SECO) for this publication.

Contents

Acronyms

ABS	access and benefit sharing
CEBLAW	Centre of Excellence for Biodiversity Law (University of Malaya)
CBD	Convention Biological Diversity
CSD	Commission on Sustainable Development
GE	genetically engineered
MDG	Millennium Development Goal
PIC	prior informed consent
SECO	Swiss State Secretariat for Economic Affairs

Introduction

The BioTrade Initiative, launched by UNCTAD in 1996, has been working to promote trade and investment in biological resources to further sustainable development. The Initiative aims at enabling rich biodiversity-based countries to achieve some of their development objectives through the exploitation of the growth opportunities generated by the use of biodiversity[1]. A key feature of this Initiative is the adherence to a number of principles that may simultaneously create 'business opportunities, growth and sustainable livelihoods for rural populations, while allowing the conservation and sustainable use of biodiversity'[2].

The Convention on Biological Diversity (CBD) is one of the international frameworks that guide the implementation of BioTrade activities[3]. In order to advance one of the objectives of the CBD -ensuring the fair and equitable sharing of the benefits arising out of the utilization of genetic resources- through greater legal certainty and transparency for both providers and users of genetic resources[4], a protocol to the CBD was adopted in October 2010 by the Conference of the Parties (COP 10) of the CBD[5].

By enabling the implementation of the third objective of the CBD, the Nagoya Protocol is expected to play an important role in promoting the conservation and sustainable use of biodiversity. Notably, as discussed below, it does not only refer to 'genetic resources' but also to their 'biochemical composition' and to "derivatives" resulting from the genetic expression or metabolism of biological or genetic resources.

The purpose of this paper is to discuss the possible implications that the Nagoya Protocol may have for the UNCTAD BioTrade Initiative as well as for BioTrade actors at different points of the value chain. It examines, in particular:

1. What activities are considered to be 'BioTrade'
2. How BioTrade activities may be treated under the CBD
3. What new obligations are imposed by the Nagoya Protocol and how they relate to the CBD
4. What 'utilization' of genetic resources means under the Nagoya Protocol and implications of this concept particularly in relation to 'derivatives'
5. Whether Principle 3 of the 'BioTrade principles and criteria', which already incorporates the principle of benefit sharing, needs to be adapted in the light of the Nagoya Protocol.

[1] UNCTAD/UNDP (2010*), Biotrade Potential for Growth and Sustainability*, Geneva, p. 5.
[2] Id.
[3] UNCTAD/UNDP (2010), p. 6 -7.
[4] See Secretariat of the Convention on Biological Diversity (2011), *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization. Text and Annex*, Montreal, p. 1.
[5] Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (hereinafter 'the Nagoya Protocol').

The paper elaborates on differences between access and benefit sharing in the context of BioTrade under the CBD and the Nagoya Protocol in order to elucidate whether the implementation of the Nagoya Protocol would introduce changes in the way BioTrade operates and, in particular, whether it would impose new obligations on parties engaged in its activities. The complexity of the issues was highlighted by strong divergences seen during the negotiation process, resulting in a number of ambiguities in the text that make the interpretation of some provisions problematic and perhaps controversial. This paper attempts to provide an interpretation based on the method prescribed by the Vienna Convention on the Law of the Treaties (articles 31 and 32).

What are BioTrade activities?

BioTrade activities include the collection/production, transformation, and commercialization of goods and services derived from native biodiversity (species and ecosystems) under criteria of environmental, social and economic sustainability. It involves a wide range of activities broadly associated with the development of a product and the various stages along its supply chain. BioTrade products include those ranging from live organisms (e.g. wildlife for pets) to man-made industrial or artisanal products (e.g. handicrafts), as well as services (ecotourism) [6]. The common denominator of these activities is their *reliance on biodiversity as the source of origin for the product or service* (i.e. biological materials and their parts of plant, animal or microbiological origin), as shown in Box 1.

Box 1

Biodiversity-based products and services supported

Natural ingredients and products for cosmetics: essential oils, natural dyes, soaps, cream and butters, moisturizers, etc.

Natural ingredients and products for pharmaceuticals: extracts and infusions from medicinal plants, natural medicine capsules, etc.

Natural ingredients and products for food: fruits, cereals, grains, tuberous, nuts, cocoa, fish products, jams, sweets and snacks, jellies, pulps and juices, spices and sauces, teas and infusions, food supplements, crocodile meat, etc.

Leather and garments: skin from *Caiman yacare* and Nile crocodile, etc.

Wildlife for pets: butterflies, chameleons, snakes, tortoise, etc.

Flowers and foliage: heliconias and other tropical flowers.

Fish products: paiche (*Arapaima gigas*).

[6] This paper will concentrate on BioTrade transactions involving *products*, and will not address the case of trade in services relating to the biodiversity, such as ecotourism.

Natural ingredients used in handicrafts: furniture, decoration objects, jewelry and garments.
Sustainable tourism: ecotourism, nature-based tourism, bird watching,

Source: UNCTAD/UNDP (2010), BioTrade Potential for Growth and Sustainability, Geneva, p. 8.

BioTrade is characterized both by its reliance on biodiversity as well as by the particular *framework* under which such trade takes place. In accordance with the framework set by the UNCTAD/ BioTrade Initiative, BioTrade activities should meet the following principles:

1. Conservation of biodiversity;

2. Sustainable use of biodiversity;

3. Fair and equitable sharing of benefits derived from the use of biodiversity;

4. Socio-economic sustainability (productive, financial and market management);

5. Compliance with national and international regulations;

6. Respect for the rights of actors involved in BioTrade activities;

7. Clarity about land tenure, use and access to natural resources and knowledge.[7]

BioTrade activities are performed by a variety of value chain actors, such as producers/hunters/collectors, intermediaries, processors, distributors and traders. BioTrade relates to the utilization of biological resources and the products derived therefrom, but not necessarily of the genetic information contained in genetic resources[8].

The definition of what constitutes BioTrade alludes to 'goods and services *derived* from biodiversity'[9]. However, the term 'derived' is used in this context in a general sense, meaning 'resulting from' or 'based on'. It does not indicate that *all* BioTrade relates to 'derivatives' in the sense specified by the Nagoya Protocol, since some products are directly obtained from biodiversity, (e.g. wildlife for pets, leather, dried butterflies) and are traded without any derivation.

Benefit sharing in the context of the CBD

[7] UNCTAD/ BioTrade Initiative (2007), *BioTrade Principles and Criteria*, New York & Geneva, p. 1, available at http://www.unctad.org/en/docs/ditcted20074_en.pdf

[8] See *Posibles implicaciones del Protocolo de Nagoya sobre "Acceso a los recursos genéticos y la participación justa y equitativa en los beneficios que se deriven de su utilización" para el Biocomercio. Insumos para discusión* (2011) (unpublished).

[9] UNCTAD/ BioTrade Initiative (2007), p. 1 (emphasis added).

The BioTrade framework is based on a set of core Principles and Criteria that respond to the objectives and principles of the CBD[10], the Commission on Sustainable Development (CSD) and the Millennium Development Goals (MDGs)[11]. Principle 3 of the BioTrade Initiative is intended to be in line, in particular, with the third objective of the CBD regarding the fair and equitable sharing of benefits derived from the use of genetic resources, as articulated by article 15 of the CBD. Prior informed consent (PIC) and benefit sharing are basic conditions that need to be complied with to obtain support for specific activities under the BioTrade Initiative.

In accordance with article 15.7 of the CBD,

> Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21 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 genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.

Benefit sharing arises, in accordance with this provision, in the case of 'commercial and other utilization of genetic resources'. Two important aspects of this provision need to be considered: what is meant, on the one hand, by 'genetic resources' and by 'commercial and other utilization', on the other.

Article 2 of the CBD defines key notions regarding the resources whose utilization triggers the benefit sharing obligation:

> "Genetic resources" means genetic material of actual or potential value, and
>
> "Genetic material" means any material of plant, animal, microbial or other origin containing functional units of heredity.

Article 2 of the CBD also defines 'biological resources':

> "Biological resources" includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity.[12]

[10] The CBD objectives are: 1) conservation of biological resources; 2) sustainable use of its components; and 3) fair and equitable sharing of the benefits arising from the utilization of genetic resources.

[11] UNCTAD (2007), p. 1.

[12] A decision of the Second meeting of the Conference of Parties of the CBD in 1995 indicated that the Convention did not apply to human genetics resources. There has been significant controversy regarding whether the CBD covers *pathogens*. A Declaration of the Group of Like-Minded Megadiverse Countries made at the Access and Benefit Sharing negotiations of the Convention on Biological Diversity (CBD) on 8 April 2009 in Paris, reaffirmed the sovereign right of States over their biological resources and stated, for instance, that "Virus and other pathogenic organisms are biological resources and therefore are included in the scope of the CBD". For the USA and European

It is worth mentioning that the definitions contained in article 2 of the CBD were the subject of protracted negotiations in the early 1990's and that, given the time constraints, at the end of the process there was little discussion on the definition of "genetic resources". In fact, this concept substituted at a very late stage of the negotiations for the originally used expression of "biological resources" or "genetic material."[13]

Article 15.7 means, in the light of these definitions, that the CBD signatories decided to apply the benefit sharing obligations to all cases in which access was provided to 'genetic resources', that is, to biological resources that contain 'functional units of heredity'. As noted in one analysis of the CBD,

> While the Convention [on Biological Diversity] in almost all articles speaks of "biological resources", also when dealing with traditional knowledge, it refers to "genetic resources" in the ABS [access and benefit sharing]-relevant Art.15…
> Now, 16 years after Rio, it is apparent that so far isolated genes from organisms covered by the CBD do not play an important role in the development of biotech medicines and GE [genetically engineered] seeds, to name the two most prominent examples where large (monetary) benefits were predicted. [14]

'Functional' in the context of article 2 of the CBD may be understood as 'having a special purpose; making it possible for somebody to do something or for something to happen'.[15] Consequently, the benefit sharing obligation may be deemed inapplicable when a biological resource is used for purposes other than reproduction or regeneration, such as the use of biochemical compounds for the production of medicines, food, etc.

However, this interpretation may be excessively narrow and omit textual elements of particular relevance. Genetic materials/resources are defined as those 'containing'

Union, instead, they are outside the scope of the CBD. See Sangeeta Shashikant (2009), *WHO: Key elements of virus and benefit-sharing framework still unresolved*, SUNS #6703, 19 May, available at http://www.twnside.org.sg/title2/intellectual_property/info.service/2009/twn.ipr.info.090506.htm; Frederick Abbott (2010), *An International Legal Framework for the Sharing of Pathogens: Issues and Challenges*, ICTSD Programme on IPRs and Sustainable Development, Issue Paper No. 30, Geneva.

[13] 'At that point, the negotiators were under significant time pressure to finalize the draft in time for the [Rio] Summit, and all definitions and concepts that were still controversial were either deleted or cut down to the "lowest common denominator" (i.e., language that was acceptable to everyone but was generally legally ambiguous). For this reason, there was little discussion on the definition of "genetic resources". The process of proposing and adopting a definition was to simply cut down the language to the point that no party found it objectionable. Because at this point the negotiations were at a very late stage, it appears that no scientists or experts in biotechnology were consulted and no detailed analysis of the potential administrative and political interpretations of the term was undertaken' (Sachin Chaturvedi et.al (2009), *Concentric Circles of the Benefit Sharing Debate and Disconnects with Technology: Challenges for a Global ABS,* paper presented at the conference on 'Genomics and Benefit Sharing with Developing Countries – From Biodiversity to Human Genomic's, November 6 2009, organised by GenBenefit and Sixth Framework Programme, Montreal, Canada.

[14] Berne Declaration, ECOROPOA, Seed, TWN (2009), *The International ABS Regime. Scope and definitions is a key issue for the fate of fair and equitable benefit-sharing*, available at http://www.evb.ch/cm_data/ABSWG-7-NGO-Definition.pdf.

[15] Oxford Advanced Learner's Dictionary, http://www.oxfordadvancedlearnersdictionary.com/dictionary/functional

functional units of heredity, but this does not mean that their utilization (as referred to in article 15) should necessarily be restricted to situations in which such units of heredity *perform* their function[16]. The commercial or other exploitation of such resources may be based on other forms of value creation, such as, for instance, the isolation of biochemical compounds of particular interest.

In fact, the key for understanding the scope of the benefit sharing obligations under article 15 of the CBD is provided by the concept of 'commercial and other utilization' of genetic resources. While 'genetic resources' contain, by definition, functional units of heredity, their utilization is not necessarily limited to research on or manipulation of the genetic information, or the use of the materials for reproductive purposes. 'Utilization' in article 15.7 refers to the 'genetic resources' and not to such units of heredity. Therefore, it may encompass testing, pre-marketing, commercialization and other activities relating to any material of plant, animal, or microbial origin that has been accessed with the purpose of exploiting its genetic value. Clearly, this does not include trade in commodities.

Admittedly, the wording in article 15 of the CBD is susceptible to different interpretations and the scope of the benefit sharing obligation has been controversial. This explains why developing countries sought (and finally obtained through the Nagoya Protocol) an implementation of said article to clearly cover the utilization of components of genetic resources (other than the genetic information as such) that provide critical inputs for the production of medicines, cosmetics, food supplements, agrochemicals, etc.

Finally, it is to be noted that article 15 applies with regard to genetic resources supplied by a country which is Party to the Convention where such resources 'exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties'[17] (CBD, article 2). It also applies to genetic resources supplied by 'Parties that have acquired the genetic resources in accordance with this Convention' (CBD, article 15.3).

The Nagoya Protocol

While the CBD established a mechanism for benefit sharing, reported cases of 'bio-piracy' and the limited flow of benefits towards developing countries that provided genetic resources, prompted these countries to demand the development of a more

[16] Although in a different context, article 9 of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions provides an example of distinction between situations in which a genetic material is merely *contained* from those where it *performs* its function (Article 9: 'The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, save as provided in Article 5(1), in which the product is incorporated and in which the genetic information is contained and performs its function'). The legal relevance of the distinction between 'containing' and 'performing its function' was confirmed in a decision by the European Court of Justice in 'Monsanto Technology LLC v Cefetra BV and Others', 6 July 2010. See also the Opinion of the General Advocate of 9 March 2010.

[17] This may refer, for instance, to characteristics developed through natural selection or incorporated through breeding practices in a particular geographical area.

specific and effective international regime. The World Summit on Sustainable Development in 2002 at Johannesburg called for the establishment of international rules on the matter; the 7th meeting of the Conference of the Parties to the Convention on Biological Diversity (CBD) held in Kuala Lumpur in 2004 adopted the mandate to initiate negotiations which concluded in Nagoya, Japan in October 2010.

The objective of the Nagoya Protocol is limited to one single purpose: implementing the benefit sharing provision under the CBD. Article 1 of the Protocol states:

> 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 4.4 of the Nagoya Protocol further indicates that '[T]his Protocol is the instrument for the implementation of the access and benefit-sharing provisions of the Convention'[18]. This means that the Protocol was conceived, within the context of the CBD, as a means to implement one of its objectives, and not as a separate or self-standing treaty[19].

Hence, the Nagoya Protocol is not intended to expand the scope of the CBD but to further develop some of its provisions, notably article 15 dealing with access to genetic resources. In accordance with article 3 of the Protocol,

> 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.

The wording 'within the scope of Article 15 of the Convention' was contested by a large group of developing countries during the negotiations of the Nagoya Protocol.[20]. Developing countries' concern essentially was that the provision could be read as limiting the Protocol to materials where 'functional units of heredity' perform their function and thereby exclude benefit sharing arising from 'derivatives'.[21] This would not be the case, however, if, as argued above, 'genetic resources' is understood to contain but not to be limited to genetic information.

Articles 5 and 6 of the Nagoya Protocol elaborate on the benefit sharing and access provisions, respectively, contained in the CBD. In both provisions, the concept of

[18] Accordingly, the 2nd paragraph of the Preamble states: '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,…'
[19] The Nagoya Protocol is only open for signature by Parties to the CBD (article 32).
[20] See Nijar, Ceblaw, p. 7.
[21] Id. p. 21-22.

'utilization' (introduced and defined by the Protocol)[22] is included. As discussed below, this may have significant implications for the interpretation of benefit sharing and PIC obligations with regard to 'derivatives' and, hence, for BioTrade activities.

Importantly, the Nagoya Protocol requires Parties to enact PIC legislation as a condition to invoke compliance by other Parties regarding access and benefit sharing obligations (article 15 of the Nagoya Protocol). This condition may provide a strong incentive for effectively implementing the CBD; so far, a relatively small number of Contracting Parties have enacted such legislation.

Article 7 of the Protocol complements Article 8(j) of the CBD, as it aims at 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'. Parties are bound to adopt legislation to this end.[23] This may also have important implications, in some cases, for BioTrade activities. While some national laws implementing the CBD had provided for PIC by indigenous and local communities, the Convention only alluded to PIC by the providing country, where certain conditions regarding the genetic resources to be accessed were met.

Articles 15 to 18 of the Nagoya Protocol contain what may be considered its core elements: specific provisions on compliance and monitoring that were absent in the CBD. As noted by Nijar,

> 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[24].

In order to understand the implications of the Nagoya Protocol, particularly in connection with access and benefit sharing, it is essential to examine the concept of 'utilization' mentioned above, and the changes that its incorporation may entail for BioTrade activities. These issues are explored in the following section.

'Utilization' of genetic resources

The Nagoya Protocol relies on the definitions contained in the CBD. In accordance with article 2 ('Use of terms'), '[T]he terms defined in Article 2 of the Convention shall apply to this Protocol'. This means, in particular, that the Protocol is based on the

[22] See the next section.

[23] Article 6. 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'.

[24] Gurdial Singh Nijar (2011), *The Nagoya Protocol on Access and Benefit Sharing of Genetic Resources: Analysis and Implementation Options for Developing Countries*, Research Paper 36, South Centre, Geneva, p. 5.

same concept of 'genetic resources' defined by the CBD, as reproduced above. However, article 2 of the Protocol adds the following:

> In addition, for the purposes of this Protocol:
> …
> (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.

These three concepts ('utilization', 'biotechnology' and 'derivative') are key to understand what the Nagoya Protocol actually adds to the CBD regime and what implications the Protocol will have for BioTrade. The interpretation of these terms is complicated, however, by some ambiguities in the text and by the way in which they appear in the Protocol. For instance, 'derivative/s' is only used in article 2(d) of the Protocol, despite its likely importance for the effective realization of the benefit sharing objective.

It is generally recognized that a major part of the economic benefits arising from the exploitation of genetic resources is based on the biochemical compounds obtained from those resources (plants, microbes, marine organisms, mammalian sources etc.), such as chemicals with therapeutic properties for the manufacture of medicines (e.g. enzymes), cosmetics (e.g., flavonoids) or food (e.g., alkaloids)[25].

Not surprisingly, negotiations on this matter were central and one of the most controversial in the long process leading to the conclusion of the Nagoya Protocol. Given that the concept of 'derivative/s', as defined in article 2(e), is only used in article 2(d) (as part of the definition of 'biotechnology') the three concepts defined in article 2(c) to (e) need to be considered in conjunction.

"Utilization of genetic resources", as defined in article 2(c) of Nagoya Protocol is a key concept in the whole architecture of the Protocol. It is used or alluded to in several provisions. As reported by a negotiator of the Protocol, 'the common understanding among all Parties was that the definition of "Utilization of genetic resources" held the key to determining whether the scope covered derivatives or not'[26]

Two aspects of this definition need to be considered:

[25] See, e.g., Union for Ethical BioTrade (UEBT), *Nagoya Protocol on Access and Benefit Sharing Technical Brief*, available at http://ethicalbiotrade.org/news/wp-content/uploads/UEBT_ABS_Nagoya_Protocol_TB.pdf.
[26] Nijar, Ceblaw Brief, p. 22.

a) The *type* of activities that 'utilization' comprises of is 'research and development'.

b) The *matter* on which utilization takes place is 'the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention'.

The definition of the *type* of activities is quite narrow, since genetic resources (and its derivatives) can be utilized in the course of productive and commercial activities. This issue is further discussed below.

Interestingly, this definition alludes to research and development on the 'biochemical composition' of genetic resources, that is, the arrangement of the chemistry of the compounds of living tissues and the processes in a living organism, and not to research and development on biochemical *compounds* as such. It may be understood, however, that any study of a 'biochemical composition' may include that of the individual components. In addition, the reference to 'biotechnology' and, through its definition, of 'derivative' clearly indicates that research and development on particular biochemical compounds is covered.

In effect, 'biotechnology' includes any technological application that, *inter alia*, uses 'derivatives' of living organisms (article 2(d)), while 'derivative' means a 'naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources' (article 2(e)), with the clarification that the concept encompasses biochemical compounds that do not contain 'functional units of heredity'.

A 'biochemical compound' is any chemical compound naturally occurring in living organisms. It may be used without separation from the biological resource to which it belongs (e.g. dried plants) or isolated and even synthetized. Currently available techniques allow researchers to precisely detect, isolate and structurally characterize bioactive natural compounds. 'Naturally occurring' may be interpreted in this context as meaning that a biochemical compound is the result of processes at the cellular level, unaltered by human intervention, that have taken place *in vivo* or *in vitro*. This would include, hence, compounds obtained at laboratories or production facilities.

There is no universally accepted definition of 'research and development'. The concept, as used for statistical purposes[27], includes basic and applied research as well as 'experimental development' understood as 'systematic work, drawing on existing knowledge gained from research and/or practical experience, that is directed to producing new materials, products or devices, to installing new processes, systems and services, or to improving *substantially* those already produced or installed'[28]. The ordinary meaning of the concept[29] seems to more broadly encompass improvements on existing products.

[27] See OECD (2002), Frascati Manual 2002 .Proposed Standard Practice for Surveys on Research and Experimental Development, OECD, Paris,

[28] Emphasis added. See http://www.nsf.gov/statistics/randdef/iorg.cfm.

[29] See, e.g. Cambridge Dictionaries (on line) at http://dictionary.cambridge.org/dictionary/british/re-search-and-de-velopment.

This set of definitions seems to leave little doubt that the Nagoya Protocol does cover the utilization of genetic resources *as such*, as well as of their 'derivatives', understood as the biochemical compounds present in such resources. This interpretation is confirmed by the negotiating history of the text:

Firstly, developing countries successfully rejected a definition of utilization that alluded to 'research and development on the genetic and/or biochemical composition of genetic *material*' (emphasis added). They insisted on the need to refer to genetic *resources*, on the argument that 'genetic material', as defined by Article 2 of the CBD would exclude derivatives[30].

Secondly, developing countries also refused references in the definition of '"research and development *on the functional units of heredity* as well as on the biochemical compounds *resulting from the gene expression* contained in genetic material…"'[31] (emphasis added). This wording was also perceived by those countries as an attempt to exclude the application of the Protocol to 'derivatives', since it could have been interpreted as limiting benefit sharing to situations where only genetic information is utilized[32].

As noted by the Union for Ethical BioTrade,

> [T]he Nagoya Protocol now clearly encompasses research and development to identify new bioactive compounds and natural ingredients for food, supplement and cosmetics products…Research on the properties of extracts and molecules from plants, for example, and their development and commercialization as ingredients in pharmaceuticals, cosmetics or nutraceuticals would thus now be distinctly subject [to] access and benefit sharing requirements.[33]

It has been argued that developing countries failed to achieve the inclusion of derivatives in the Nagoya Protocol. In accordance with one commentator,

> developing countries were keen to ensure that biochemical derivatives of genetic resources were included in the scope, since these are used commercially as much as genetic resources (eg. for screening medically active compounds to develop new drugs). In the end, derivatives were not included in the scope, but they were defined as biochemicals, which at least provides the basis for further negotiation[34].

This interpretation, however, seems to be based on a concept of 'derivatives' broader than that adopted by the Nagoya Protocol. In fact, the definition of 'derivative' in the Protocol is narrow, as it only encompasses 'a naturally occurring biochemical compound'. 'Derivative' is often understood more broadly as including products

[30] Nijar, South Centre, p.13.
[31] Nijar, Ceblaw, p. 23-24.
[32] Id.
[33] UEBT, op. cit.
[34] Krystyna Swiderska (2010), *What happened at Nagoya?*, available at http://www.iied.org/natural-resources/key-issues/biodiversity-and-conservation/what-happened-nagoya.

based on or elaborated with such biochemical compounds[35]. For instance, the draft ASEAN Framework Agreement on Access to Biological and Genetic Resources (February 2000)[36] defined 'derivatives' as

> something extracted from biological and genetic resources such as blood, oils, resins, genes, seeds, spores, pollen and the like as well as the products derived from, patterned on, or incorporating manipulated compounds and/or genes (article 3).

This means that while the benefit sharing obligations under the Nagoya Protocol clearly apply in relation to naturally occurring biochemical compounds, the extent to which it would apply to downstream products derived, in turn, from such compounds[37] is less clear. However, the benefit sharing obligation could apply in cases where a product (e.g. for cosmetic use) contains biochemical compounds,[38] to the extent that those compounds add value to the product.

Legal commentators will probably discuss whether the coverage of 'naturally occurring biochemical compounds' under the Nagoya Protocol means an expansion (a 'CBD-plus' provision) or an interpretation of the concept of 'genetic resources' as contained in the CBD[39]. As mentioned above, it may be argued that the Protocol was conceived and adopted to develop some of the CBD's provisions and not to create a new, independent international framework. Hence, the negotiating parties, in accepting the final text of the Protocol, have in fact agreed on an interpretation of the scope of Article 15 of the CBD.

While this may be an interesting legal discussion, for the purposes of determining the implications of the Nagoya Protocol for BioTrade activities, the important point is that it clarifies the concept of 'utilization' and unequivocally requires benefit sharing for the utilization of the biochemical compounds found in genetic resources covered by the CBD[40].

There are a number of issues that require further exploration, namely: a) whether the obligations relating to biochemical compounds apply both to access and benefit sharing, or only to the latter; b) whether 'utilization' is limited to research and development or encompasses other ensuing activities, such as commercialization of the products resulting from such research and development; and c) whether the

[35] In accordance with the Oxford Learner's Dictionary, 'derivative' is 'a word or thing that has been developed or produced from another word or thing', at http://www.oxfordadvancedlearnersdictionary.com/dictionary/derivative_1

[36] Available at http://www.iprsonline.org/legalinstruments/docs/asean_framework_agreement.pdf

[37] For instance, many patents on derivatives from taxol (isolated from *Taxus brevifolia*) have been applied for by pharmaceutical companies (e.g. US Patents No. 5,352,806 and 5,248,796).

[38] It might be argued that an 'isolated' biochemical compound is not 'naturally occurring'. However, isolation does not change the chemical composition and such a differentiation would be unwarranted.

[39] See Nijar, South Centre, p. 14, who argues that the Nagoya Protocol relies on an 'evolutionary' interpretation of the concept of 'genetic resources'.

[40] The clarification of whether or not the Nagoya Protocol goes beyond the CBD with regard to biochemical compounds would have, however, important implications. In particular, if the thesis that the Protocol is not 'CBD-plus' prevails, it would mean that benefit sharing under the CBD would be mandatory in respect of biochemical compounds, even if not specifically mentioned in the Convention. Hence, countries that are Parties to the CBD but not to the Nagoya Protocol would have the right to implement access and benefit sharing provisions accordingly.

Protocol will apply to the exploitation of genetic resources/derivatives accessed, without PIC and mutually agreed terms, before its entry into force. These issues are addressed in the following sub-sections.

Access to biochemical compounds

Paragraphs 1, 2 and 5 of Article 5 of the Protocol ('Fair and Equitable Benefit-Sharing') refer to 'benefits arising from the utilization of genetic resources'. Hence, benefits need to be ensured whether they derive from the exploitation of the genetic information as such or of naturally occurring biochemical compounds.

While there seems to be no room for controversy regarding the applicability of *benefit sharing* provisions in relation to such compounds, the extent to which *access* thereto is also subject to the Nagoya Protocol -and hence PIC required- seems more controversial. Thus, it has been held that

> the Protocol does not support self-standing prior informed consent requirements for access to biochemicals that are not anymore contained in genetic material.[41]

Article 5.1 of the Nagoya Protocol states that '…access to genetic resources for their utilization shall be subject to the prior informed consent of the Party …'. In accordance with Nijar,

> applying the definition of 'utilization of genetic resources', which refers to 'genetic and/or biochemical composition of genetic resources', derivatives which do not contain functional units of heredity are also included in this Article [5.1]. This means that there must be PIC obtained for access to such derivatives… The person who first extracts the biochemical composition of the genetic resource would no doubt have to obtain the PIC of the provider country that is the country of origin. Similarly, any person accessing the extract from wherever – the naturally occurring biochemical composition (and not the genetic resource) – for R&D would need to ascertain the country of origin and obtain PIC. Note that 'naturally occurring' derivatives excludes products.[42]

This is an important issue that the Conference of the Parties to the CBD may need to clarify in order to provide certainty to those working with derivatives as defined in the Nagoya Protocol. The extension of PIC, if required, to biochemical compounds may require the adoption of new procedures at the national level, in those countries that have already implemented the CBD, and the design of appropriate domestic measures in the countries that have not implemented the CBD so far.

Under the CBD system (and, hence, the Nagoya Protocol) benefit sharing is based on the 'mutually agreed terms' (article 15.7, CBD) established between the providing Party and the recipient of the genetic resources as a result of the process of granting PIC. Consequently, since benefit sharing is mandatory under the Protocol for derivatives (as defined), it seems inevitable to consider that PIC needs to be

[41] Council of the European Union, DS 1803/10, Brussels, 12November 2010, p. 3.
[42] Nijar, South Centre, p. 14-15.

requested in order for the providing party to be able to determine the conditions for such benefit sharing.

Scope of 'utilization'

In accordance with the above-mentioned definition, '"utilization of genetic resources" means to conduct research and development on the genetic and/or biochemical composition of genetic resources' (article 2(c), Nagoya Protocol).

The ordinary meaning of 'research and development' '(in industry, etc.) is work that tries to find new products and processes or to improve existing ones'.[43] Under this definition, access and benefit sharing obligations would apply to those persons seeking genetic resources/derivatives for investigative purposes and the development of a new product or process, or the improvement of existing products and processes.

However, commercial benefits are not directly obtained from research and development as such, but from the commercialization of its outcomes through, for instance, licensing agreements or the sale of products resulting from research. Article17 ('Monitoring the utilization of genetic resources') recognize this as it refers to check points with functions 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.

A narrow interpretation of 'research and development' would deprive the benefit sharing obligation from much of its content. Article 17 provides contextual elements for understanding what 'utilization' means. Its interpretation also needs to take into account that the specific object and purpose of the Nagoya Protocol[44] is ensuring benefit sharing. It is possible to interpret, hence, that 'utilization' in article 6.1 means that while only parties seeking access to genetic resources for the purpose of undertaking research and development are obliged to obtain the providing Party's PIC, the benefit sharing obligation applies in respect to benefits arising from stages following research and development, including the commercialization of technologies or products.

Temporal scope

In accordance with generally accepted principles of international law, a treaty does 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' (article 28, Vienna Convention on the Law of the Treaties). Derogations to this principle, however, are possible if that were the intention of the parties. Despite intense debates on the subject during the negotiations, the Nagoya Protocol does not

[43] Oxford Advanced Learner's Dictionary, at http://www.oxfordadvancedlearnersdictionary.com/dictionary/research-and-development.

[44] See article 31.1 of the Vienna Convention on the Law of the Treaties, which mandates interpretation of the terms of a treaty 'in their context' and in the light of the treaty's 'object and purpose'.

specifically address the problem of temporal scope, except indirectly and partially in article 10[45].

Nevertheless, applying the Nagoya Protocol to the consequences of situations that arose in the past, including the continued use or new uses of previously accessed resources, may not be deemed contrary to the principle of treaty non-retroactivity codified by the referred to Vienna Convention. Depending on national constitutional rules, hence, Parties might request the review of 'mutually agreed terms' or seek benefit sharing based on the Protocol's new rules. Thus, while the Nagoya Protocol may not retroactively apply to situations where access was not sought or granted in accordance with article 15 of the CBD, benefit sharing provisions might apply to the utilization of genetic resources the access to which took place before the entry into force of said Protocol.

Impact on BioTrade

As mentioned above, different views may be held regarding whether or not the Nagoya Protocol goes beyond the CBD with regard to access and benefit sharing. In any case, the implementation of the Protocol may entail several changes in respect to BioTrade activities that involve the utilization of genetic resources, their derivatives, or associated traditional knowledge.

First, since the Nagoya Protocol makes compliance by other Parties conditional upon the enactment and implementation of domestic PIC and benefit sharing legislation (article 15), it may trigger the enactment of implementing legislation in a larger number countries that would need to be observed in conducting some BioTrade activities.

Second, the Nagoya Protocol requires Parties to enact PIC and benefit sharing legislation regarding traditional knowledge associated with genetic resources. This may also trigger the establishment of new regulations on the subject that would need to be complied with in undertaking some BioTrade activities.

Third, PIC requirements (including the need for 'mutually agreed terms') may be interpreted as not only applying to access to genetic resources as such, but also to naturally occurring biochemical compounds. Hence, PIC may need to be obtained when parties aim at investigating and developing products based on such compounds. Since Parties may need to develop procedures to deal with requests of this kind, interested parties may be advised to seek clarification from the relevant national authority on how to proceed.

Fourth, benefit sharing obligations apply in relation to the commercial or other utilization of genetic resources and/or their naturally occurring biochemical compounds. Since the primary object of 'utilization' (as defined in the Nagoya

[45] Article 10: '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'.

Protocol) is research and development (including improvements on existing products), those participating in the value chain who intend to conduct such activities on genetic resources, their biochemical composition, or individual biochemical compounds are obliged to seek PIC and share the corresponding benefits. Other actors in the value chain (e.g. traders) should seek the relevant information necessary to responsibly confirm compliance with PIC and benefit sharing obligations by those actors in the chain value obliged to do so.

Fifth, Parties may impose benefit sharing on the continuous or new utilization of 'derivatives' that were accessed before the entry into force of the Nagoya Protocol, in a way that does not affect the principle of non-retroactivity of treaties' obligations. This will depend, however, on national legislation and government practices.

Sixth, it is worth noting that only those Parties that have implemented domestic legislation for PIC and mutually agreed terms may seek to enforce the compliance provisions under article 15 of the Nagoya Protocol in the jurisdiction of another Party where the accessed genetic resources are utilized.

Finally, the Nagoya Protocol would not affect activities relating to products that do not consist of or derive from genetic resources subject to the CBD (for instance, regarding plant genetic resources obtained from a country that is not a country of origin under the Convention) nor to activities that may not be deemed the 'utilization' of genetic resources in accordance with article 2 of the Protocol, such as trade in leather or flour of a local bean. Similarly, in cases where genetic resources (e.g. seeds) are sought in order to undertake further research and breeding, the transfer of materials would be normally covered by the CBD, or the FAO International Treaty on Plant Genetic Resources for Food and Agriculture, in the case of crops included in Annex I of the Treaty. The Nagoya Protocol will have no significant implications in such cases.

In summary, the Nagoya Protocol is likely to provide more legal certainty and transparent regulations on access and benefit sharing and thereby benefit the conduct of a range of BioTrade activities.

Once the Protocol enters into force and is implemented in a particular country, in which situations will the Protocol provisions affect BioTrade? [46] Some examples may be useful to clarify the Protocol's implications:

-In cases where bio-prospecting is conducted or access to certain type of plants or other materials is required to evaluate them and detect, extract and eventually commercialize (for instance, as pigments, flavoring, antioxidants, etc.) biochemical compounds contained therein, the Nagoya Protocol will clearly apply.

[46] Note that in some countries approved international treaties are self-executing, while in others they only become operative when implemented through domestic legislation.

-When the properties of a biochemical compound contained in a biological material are already known, access to the relevant materials for subsequent processing (drying, extraction, purification, etc.) and commercialization of the compound would not be subject to the Nagoya Protocol. Thus, the supply of, for instance, Aloe Vera (cosmetics), Shea nut (cosmetics, food), Papain (tenderizer), Warburgia (antimalarial), Pyrethrum (insecticide), and Neem (insecticide, dentifrice, etc.) as raw materials to prepare powders, essential oils, etc. would normally be outside the scope of the Nagoya Protocol. Benefit sharing should take place through a fair price paid to farmers or collectors as the value of those materials in terms of biochemical compounds is already known.

The following table elaborates on the possible applicability of the Nagoya Protocol to different types of BioTrade activities indicated in Box 1 above.

Table 1. BioTrade under the Nagoya Protocol

Biodiversity-based products and services	**Applicability of the Nagoya Protocol**
Natural ingredients and products for cosmetics: essential oils, natural dyes, soaps, cream and butters, moisturizers, etc.	Yes, if access is sought to undertake R&D to eventually extract and commercialize natural ingredients or products containing them.
Natural ingredients and products for pharmaceuticals: extracts and infusions from medicinal plants, natural medicine, capsules, etc.	See above
Natural ingredients and products for food: fruits, cereals, grains, tuberous, nuts, cocoa, , jams, sweets and snacks, jellies, pulps and juices, spices and sauces, teas and infusions, food supplements, crocodile meat, etc.	See above
Leather and garments: skin from Caiman yacare and Nile crocodile, etc.	No, since no research and development or other utilization of naturally occurring biochemical compounds takes place ; a price is paid for the value of the traded materials
Wildlife for pets: butterflies, chameleons, snakes, tortoise, etc.	See above
Flowers and foliage: heliconias and other tropical flowers.	See above
Fish products: paiche (Arapaima gigas).	No, unless fish is used for further breeding
Handicrafts: furniture, decoration objects, jewelry and garments.	Not applicable

Implementing the Nagoya Protocol

In view of the above discussion, Principle 3 of the BioTrade Initiative on 'Equitable benefit-sharing'[47] may need to be updated. This principle is one of the key 'BioTrade Principles and Criteria'. It calls for BioTrade activities to equitably share the benefits derived from the use of biodiversity, which entails informed, transparent, and inclusive interaction among all actors involved in the production and commercialization of biodiversity-based products. In accordance with UNCTAD,

> This principle responds to a fundamental facet of the conservation and sustainable use of biodiversity under the Convention on Biological Diversity, of which the third objective is the fair and equitable sharing of benefits arising from the use of genetic resources. Article 15 thus requires access to and the distribution of the benefits related to genetic resources to be based on prior informed consent and mutually agreed terms. When BioTrade activities involve the commercialization of genetic resources, this principle supports these objectives and requirements. Equitable benefit sharing also arises in the context of the second objective of the Convention: the sustainable use of biodiversity. Benefit-sharing is therefore also important in activities dealing with biological resources, which form the vast majority of BioTrade activities.

The formulation of this principle should be adapted to the new framework established by the Nagoya Protocol, with regard to the access to and the sharing of benefits resulting from the utilization of naturally occurring biochemical compounds, as discussed above. Although the Nagoya Protocol has not entered into force yet, those participating in BioTrade activities may wish to start to voluntarily apply the new framework.

It is necessary to consider, however, that from a legal point of view the obligations under the Nagoya Protocol will be enforceable only after their effective implementation at the national level. This will require, first, the entry into force of the Protocol once fifty ratifications are notified and, second, the internalization of its provisions through domestic legislation. In some countries, the provisions of international treaties whose content is deemed self-sufficient for their direct application, can be considered 'self-executing', that is, they would not need to be incorporated through national legislation to become operative. Most provisions of the Nagoya Protocol will require, however, implementing legislation (e.g. PIC and procedures to determine 'mutually agreed terms'; measures to implement PIC by traditional and local communities, where appropriate) since they would not be operative without the adoption of the relevant measures.

There may be situations where BioTrade involves one or more actors domiciled in a country that has ratified and implemented the Nagoya Protocol, on the one hand, and actors in one or more countries that have not, on the other. In such situations, the Protocol will not be fully operative. For instance, if certain biological materials are

[47] Other principles addressing access and benefit sharing may also need to be reviewed to take the new legal framework into account.

obtained in a country where the Protocol is enforceable, but 'utilization' thereof takes place in a non-Party, it would not be possible to invoke the compliance provisions contained in the Protocol.

Conclusions

The text of the Nagoya Protocol makes evident, particularly in article 2, the enormous divergences and difficult compromises that the negotiating parties had to overcome to reach an agreement.

Despite this, an interpretation of the treaty language guided by the Convention on the Law of the Treaties seems to leave little doubt that a) the 'utilization' of genetic resources includes research and development on the biochemical composition of such resources as well as on the individual compounds ('derivatives') contained therein; b) the commercial exploitation of the outcomes of such research and development is subject to the Protocol's benefit sharing provisions, and c) access to genetic resources with the purpose of exploiting the commercial value of 'derivatives' is also subject to the Protocol. 'Derivatives', however, are defined in a narrow manner.

While many of the BioTrade activities fall outside the Nagoya Protocol, its impact will be particularly important -once the Protocol becomes enforceable in particular jurisdictions- for new research and development on genetic resources aimed at identifying and commercially exploiting biochemical compounds of interest for industrial use.