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Navigating Nagoya: Will CBD COP 10 deliver an ABS Protocol?

From 18 to 29 October, the 193 Parties to the Convention on Biological Diversity (CBD) and an uncountable number of civil society actors are expected to meet in Nagoya, Japan for the "Kyoto conference for all living things" - the CBD's 10th Conference of the Parties (COP). It is a meeting that the biodiversity community has been waiting for with as much anticipation as climate change negotiators awaited Copenhagen last year. Hopefully though, it will be remembered as a more successful event. Despite the slow pace of negotiations over the past year, some observers still say COP 10 has the potential to be the birth place of the long-awaited international protocol that would implement an effective system for access and benefit sharing (ABS). Also, with the latest strategic plan phasing out this year, the issue at stake is nothing less than the outlook for global efforts on conserving biodiversity over the next 10 years.

Forty percent of the world's economy depends directly or indirectly on biological resources. The natural goods and services biodiversity provides are a key source of food, water, shelter, incomes, and livelihoods for billions of people. The rural poor especially depend on biological resources for up to 90 percent of their daily needs. With biodiversity continuing to decline and species being extinct at 1000 times the natural rate, protection of biodiversity calls for immediate action.

This call is by no means new, given the adoption of the CBD in 1992. It contains three core objectives: 1) the protection of biodiversity, 2) the sustainable use of its components, and 3) the fair and equitable sharing of benefits arising from the use of genetic resources. Already during COP 6 held in 2002, Members agreed on a first strategic plan to put these objectives into practice. Amongst other milestones, 2010 was declared the international year of biodiversity, the year by which members wanted to substantially reduce the loss of biodiversity.

As pointed out in the CBD's Global Biodiversity Outlook 3, the 2010 target has been missed. However, even if 2010 will not be the year that the loss of biodiversity was halted,

it still has the potential to be the year in which governments launch a real strategy to put the Convention into action. To achieve this aim, COP 10 will need to design a new strategic plan outlining priority areas and viable means to achieve for the next decade and establish an expert body to the UN on biodiversity. More importantly, governments will need to match the strategic plan with a robust resource mobilisation strategy - an issue that is likely to stir up talks. The 2010 biodiversity targets were missed partly as a consequence of "a lack of adequate financial resources and under-development of relevant financial mechanisms," as the CBD Secretariat and various expert reports indicate. The global financial crisis has further aggravated this, as governmental development assistance targeted at biodiversity issues has experienced a precipitous decline over the last two years.

Most controversial however, are the ongoing negotiations on an international protocol to ensure that the benefits arising from the use of genetic resources, often found on indigenous peoples' land, are shared in a fair and equitable manner with the holders of such resources. Members have set COP 10 as the target for adopting the ABS protocol, putting a successful end to the protracted negotia-



tions. The issue thus finds itself in the spotlight at Nagoya. "Reaching a consensus on an ABS Protocol is essential for a successful meeting in Nagoya," Izabella Teixeira, Brazil's Minister of Environment, said in an interview with PR Newswire.

Access and benefit sharing has long been an important priority on the agenda of developing countries. The interest mainly stems from the fact that the most biodiverse countries in the world are developing countries while the users of genetic resources - such as pharmaceutical companies and cosmetic firms - are traditionally situated in the richest economies. Moreover, dynamics have been highly influenced by a feeling of historical injustice caused by misappropriation by technologically advanced countries in a number of biodiversity rich but considerably poor countries.

As BioRes previously reported, ABS negotiations intensified after a first draft text was introduced by the Chairs of the ABS Working Group in March of this year. Building on what was conceived as a momentum to conclude negotiations, members resumed the March meeting twice in Montreal in July and September respectively. "The time has come to demonstrate good will and to show that we want to adopt and implement a concise, effective and fair protocol", Timothy Hodges, Co-Chair of the ABS Working Group said in the July meeting.

However, though deliberations were generally constructive and member states were able to move ahead in the negotiations, a long list of issues remains unresolved - the most critical among them. "There is still a lot of work to be done" and the time remaining might prove too short to finalise the Protocol," Timothy Hodges and Fernando Casas, Co-Chairs of the meeting, warned during the September meeting. Developing countries and indigenous and local communities have expressed concerns about this development and the fact that the implementation of the Convention's objective with the most value to them remains in limbo due to political differences. In fact, some groups were considering refraining from agreeing to a new strategic plan if no progress is made on the ABS Protocol.

Difficulties seem to arise from two points. Firstly, political differences, and secondly, the topic's highly technical and complex character. The latter issue has become apparent in particular during the last round of talks. Negotiations continued to circle around an acceptable definition for "genetic resource," its "derivates," and "utilisation of genetic resources." The already politically sensitive issue is complicated by the fact that legal implications of certain terminology and constellations are not always fully understood as effects may differ depending on the actors involved (institutions on law, environmental governance, intellectual property, etc.) and on the country concerned.

The clarification of scope of the agreement is further addressed in provisions on scope, including exemptions, and on the inclusion of associated traditional knowledge. Various aspects of enforcement, a second core element of the Protocol, are then addressed in a number of provisions on monitoring and tracking and on compliance.

To inform discussions to take place before and during COP 10, this issue of the BioRes Review features articles by experts on some of the most critical issues related to the negotiations. The aim is to provide sound, yet not necessarily complete or definitive, legal analysis on the latest draft of the

ABS Protocol as a result of the 21 September Interregional Negotiation Group of the ABS Working Group. A number of personal suggestions and recommendations are also provided by the authors to address outstanding points in the negotiations on these topics. Though a large number of topics would undoubtedly benefit from such analysis, this issue's feature articles will concentrate on the following selected issues:

Utilisation - The wording of the CBD's third objective to ensure the fair and equitable sharing of benefits arising from the utilisation of genetic resources has proven unfortunate and presented a major stumbling block to negotiation of an effective international regime on ABS. A literal definition of genetic resources would, in effect, exclude from the remit of any regime biochemical compounds, which do not contain functional units of heredity. Developing countries have long argued that any regime must deal with not only genetic resources but also proteins, metabolites and other so-called derivatives of genetic resources. Latest developments on this issue are addressed by Kabir Bavikatte and Brendan Tobin.

Exemptions - While Parties continue to engage in heated discussions regarding the appropriate definition and meaning of genetic resources, its derivatives, use and continued use, a long list of possible exemptions adds further ambiguity to the substantive scope of the protocol. This is particularly true for genetic resources for food and agriculture, and genetic resources with human pathogen potential - two issues that are further complicated by the fact that other international organisations and agreements have their own say in this field. The sharing of human pathogen material is addressed by Fredrick Abbott while Claudio Chiarolla discusses the standing of genetic resources on food and agriculture.

Traditional Knowledge - The inclusion of traditional knowledge associated with genetic resources is of critical importance for any meaningful international ABS regime as access to genetic resources often occurs through the use of associated traditional knowledge. Accordingly, the most recent draft ABS Protocol includes several provisions relating to traditional knowledge in the form of either bracketed or unbracketed text which leave, however, a large number of important issues unresolved. Daniel Robinson and Brendan Tobin address the various outstanding issues on this matter.

Disclosure of Origin - To solve problems related to the monitoring and traceability of genetic resources, ABS negotiations have focused on the development of some form of certificate of origin/source/legal provenance - more recently called a "certificate of compliance." Closely linked to this tool is the discussion on a requirement to disclose the origin of genetic resources and associated traditional knowledge in intellectual property applications. The disclosure requirement and the international certificate are discussed by Jorge Cabrera and Oliver Rukundo.

We hope that this compilation of articles will inform the negotiations and, together with the innumerable efforts undertaken by member states and civil society organisations, create the drive needed to make Nagoya a success.

In addition to the potential ABS protocol, this issue of the BioRes Review addresses two other topics where trade policy can influence biodiversity outcomes in an important way, namely fisheries and agriculture. In two brief pieces, Malena Sell and Jonathan Hepburn explore the channels of impact - both positive and negative.

Cutting the Gordian Knot: Resolving conflicts over the term “utilisation”

By Kabir Bavikatte and Brendan Tobin

The wording of the CBD's third objective - to ensure the fair and equitable sharing of benefits arising from the utilisation of genetic resources - has proven unfortunate and presented a major stumbling block to negotiation of an effective international regime on ABS. A literal definition of genetic resources would, in effect, exclude from the remit of any regime biochemical compounds, which do not contain functional units of heredity. Developing countries have long argued that any regime must deal with, not only genetic resources but also proteins, metabolites, and other so-called derivatives of genetic resources.

After years of relatively fruitless endeavours to clarify what resources are to be covered by an ABS regime, recent meetings in Montreal have led to an interesting potential solution. During the July meeting of the Interregional Negotiation Group (ING) it became increasingly clear that the way forward was not to define genetic resources but rather to focus on a definition of the “utilisation of genetic resources.” A “small group” was formed to develop such a definition, though it was not given the mandate to negotiate but rather any outcome was to be negotiated in the ING. The small group relied upon the report of the Meeting of the Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches (GLTE) that met in Windhoek, Namibia in December 2008.

The GLTE effectively cut the Gordian Knot of deadlocked ABS negotiations by stating in its report that the ABS Protocol is about implementing Article 15 of the Convention on Biological Diversity (CBD) which focuses on the “utilisation of genetic resources.” This implied that rather than trying to define “genetic resources,” which would have different interpretations depending on whether one is a lawyer, scientist, or an anthropologist, it makes more sense to list out what constitutes the utilisation for the purposes of the ABS Protocol. The GLTE also provided a list of possible uses of genetic resources in its report.

The working definition of “utilisation of genetic resources” that was developed by the small group in the July ING Meeting foresaw an Annex that would list out the different uses of genetic resources which would also include “derivatives,” thus making it unnecessary to define the latter term. Negotiations on this utilisation definition were reopened at the September ING meeting. In this context, Canada stated that capital instructions required them to bracket the term wherever it appears in the draft ABS Protocol until the definition was negotiated and agreed to. This position effectively halted the negotiations with the Like Minded Mega Diverse Countries (LMMC) and the Like Minded Asia Pacific Group (Asia Pacific Group) who refused to continue the negotiations unless the issue was resolved. The Co-Chairs of the ING, after closed-door consultations with key negotiators at the ING, re-convened the small group to further refine the July definition of “utilisation of genetic resources.” Parties agreed that this definition would be bracketed with a footnote stating that it had not been negotiated.

The small group eventually came up with a new working definition for the disputed term along with a working definition of “derivatives”:

“Utilization of genetic resources” means to conduct research and development on the genetic and biochemical composition of genetic material/

biological resources/genetic resources, 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 genetic resources, even if they do not contain functional units of heredity.

There were two significant concerns that the small group sought to address. First, the inclusion of naturally occurring biochemical compounds such as resins that do not contain functional units of heredity. This is especially important since genetic material under the CBD is defined as containing plant, animal, microbial, or other material containing “functional units of heredity.” Second, the importance of addressing the issue of “proximity” (i.e., at what point does the utilisation end for the purposes of the ABS Protocol? Or how significant should the use of a genetic resource be for it to be considered utilisation?).

Interestingly references to the Annex that was to list out the different uses of genetic resources were dropped, as the definition itself was considered comprehensive enough to cover all possible uses of genetic resources.

Moreover, the definition of derivatives was kept, as the Group of Latin American Countries (GRULAC) requested to keep the text until they were satisfied with the outcome of the negotiations on the new utilisation definition. Finally, GRULAC insisted on the inclusion of biochemical compounds or metabolites that do not contain functional units of heredity in the definition of “utilisation of genetic resources.”

The September meeting of the ING ended with an understanding that the definition of utilisation developed by the small group would be the definition that would be negotiated by Parties in Nagoya, Japan.

With this understanding we may be no closer to a categorical definition of genetic resources but for now a working solution may be on the table.

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Adding ambiguity: A long list of exemptions

While Parties continue to engage in heated discussions regarding the appropriate definition and meaning of genetic resources, its derivatives, use and continued use, a long list of possible exemptions adds further ambiguity to the substantive scope of the Protocol. This is particularly true for genetic resources for food and agriculture, and genetic resources with human pathogen potential - two issues that are further complicated by the fact that other international organizations and agreements have their own say in this field.

In addition to Article 2 and 3 (1) (see discussion above), the scope of the draft protocol is defined in Article 3 (2), which contains an exclusive list of limitations. These address, in addition to temporal limitations (such as “acquired before the entry into force of this Protocol”) the following:

- Geographical exemptions: that is, genetic resources beyond national jurisdictions (b) or from the Antarctic Treaty area (g), and
- Substantive exemptions: that is, human genetic resources (a) and human pathogens (b); genetic resources covered by the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) (c); and genetic resources utilized solely as commodities (d).

At this stage, all exemptions are bracketed. Moreover, an alternative paragraph (2) provides for a list of inclusions, thus the opposing idea. That list also contains two categories mentioned in the first alternative, namely resources from the Antarctic Treaty area and from marine areas beyond jurisdiction.

Irrespective of their different characters, all these exclusions add a degree of uncertainty or ambiguity to the Protocol. This is because every exemption provides an additional basis upon which users can argue that the resources they used fall outside the Protocol’s scope. Thus, only if the exclusions are drafted in a clear manner, leaving as little space as possible for deliberation and argumentation, can they be effective and meaningful and pose no threat to the functionality of the agreement.

However, even clear limitations can hamper the implementation of the agreement. This is particularly true for any geographical

exemption, such as the one regarding the Antarctic Treaty area and genetic resources beyond jurisdiction, which mainly concerns marine areas beyond jurisdiction. In the case of such exemptions, users of genetic resources can invoke these clauses to argue that their resources were found in these areas, and thus fall outside the Protocol’s scope. Such argument would reverse the burden of proof and place the burden to prove that the resources are indeed covered by the Protocol on the provider country. That means that country would have to show that the resources have been accessed on its territory and that they are covered by the scope of ABS legislation.

Considering how activities of accessing and utilising genetic resources take place and that genetic resources tend to be endemic in a number of countries rather than just one countries, it naturally, is much more difficult to provide such evidence than for a user to prove that he is legally operating outside the system. The latter are in a much more comfortable situation to collect data and documentation clearly showing where resources have been accessed.

For this reason it is of outmost importance that the exclusions are not only drafted in a clear manner but that the Parties to the Protocol agree on procedures applicable to such situations. One option would be to request users to provide evidence that they are legally operating outside the system irrespective of whether a specific exclusion clause is invoked. Moreover, for the exemptions relating to resources used solely as commodities, it appears necessary to discuss that provision in the light of the general definitions and the use of terms.

In addition to these uncertainty concerns, two provisions might result in further difficulties due to their close relation to other international agreements, namely, those dealing with plant genetic resources and human pathogen material.

ARTICLE 3 SCOPE

[...]

[[Consistent with the Convention, the following genetic resources are excluded]] [This Protocol does not apply to]:

[(a) Human genetic resources;]

(b) Genetic resources beyond national jurisdictions;

(c) Genetic resources [contained in Annex I of the International Treaty on Plant Genetic Resources for Food and Agriculture provided they are used for the purposes of the International Treaty on Plant Genetic Resources for Food and Agriculture][under the Multilateral System of the International Treaty on Plant Genetic Resources for Food and Agriculture, both current and as may be amended by the Governing Body of the International Treaty on Plant Genetic Resources for Food and Agriculture];

(d) [Genetic resources when utilized solely as a commodity][Commodities in trade [used solely for final consumption]][when utilized solely as commodities];

(e) Genetic resources and traditional knowledge associated with genetic resources acquired prior to the entry into force of the Protocol;

(f) [Human pathogens][A genetic resource when it constitutes a serious and direct danger to the health of humans as described in the International Health Regulations, and it is covered by and for the purpose of a specialised instrument as described in paragraph (b) of Article 6];

(g) Genetic resources located in the Antarctic Treaty Area, which is the area south of latitude 60° South.]

[The Protocol also applies to:

(a) Benefits arising from the continuing uses of genetic resources and associated traditional knowledge acquired before the entry into force of the Convention;

(b) Benefits arising from new uses of genetic resources and associated traditional knowledge acquired before the entry into force of the Convention;

(c) Genetic resources from the Antarctic Treaty Area, which is the area south of latitude 60° South; and

(d) Genetic resources from marine areas beyond national jurisdiction.

[...]

Exception #1: Plant genetic resources for food and agriculture

By Claudio Chiarolla

The status of genetic resources for food and agriculture (GRFA) is a category for which matters in the ABS Working Group are complicated by existing rules, procedures and practices. The UN Food and Agriculture Organization (FAO) International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) provides an internationally agreed framework for the conservation and sustainable use of crop diversity and the fair and equitable sharing of benefits, in accordance with the CBD. Should the ABS Protocol thus explicitly exclude PGRFA under the ITPGRFA's Multilateral System or is there a need for a more flexible regulation of GRFA?

The ITPGRFA facilitates access to PGRFA through its Multilateral System (MLS) and sets out specific ABS rules in the Standard Material Transfer Agreement (SMTA).¹ While the International Treaty itself applies to all PGRFA, the Multilateral System only facilitates access to 64 crops and forages. The species of included crops are listed in Annex I of the ITPGRFA. However, these pooled resources are available under the facilitated access mechanism of the MLS only if access is requested for the purpose of utilization and conservation for research, breeding and training for food and agriculture. This means that national ABS legislation, the CBD and the ensuing ABS Protocol may apply if recipients intend to use Annex I PGRFA for other purposes, “such as chemical, pharmaceutical and/or other non-food/feed uses.”²

The current draft ABS Protocol provides for different options regulating its relationship with the FAO International Treaty and the Protocol's scope regarding PGRFA. These can be found in Article 3 and Article 3 bis of the draft ABS Protocol.

Whether the emerging ABS Protocol will provide enough flexibility to accommodate the needs of agricultural research and plant breeding, and how it will manage to do so are open questions. An obvious solution would be to allow the future expansion of the FAO Multilateral System. However, such expansion is unlikely to occur in the short-term, because most countries of origin of excluded crops are unlikely to make any concessions given their high

expectations from, and emphasis on, the draft ABS Protocol to be adopted in Nagoya.

Currently, there are two alternative PGRFA-related exclusions in Article 3 of the draft ABS Protocol, namely: I) genetic resource contained in Annex I of the ITPGRFA provided they are used for the purposes of the ITPGRFA; or II) genetic resources under the Multilateral System of the ITPGRFA, both current and as may be amended by its Governing Body. The scope of the first option is narrower than the second one, since the latter makes no reference to purpose-of-use-related requirements for the actual inclusion of PGRFA into the Multilateral System. On the other hand, the second option also envisages the potential expansion of the Multilateral System's coverage to other crops and forages not currently listed in Annex I. Because of this, the second option may be preferred to allow for the future expansion of the MLS.

As regards the materials collected before the entry into force of the CBD and held in the ex situ collections of the Consultative Group on International Agricultural Research (CGIAR), the solution envisaged by the Governing Body of the ITPGRFA was to replace the use of interim Material Transfer Agreements with a new Agreement along the lines of the Standard Material Transfer Agreement of the ITPGRFA which includes benefit sharing provisions.³ The issue of whether the SMTA needs to be modified for its use with non-

1 Chiarolla (2008), ‘Plant Patenting, Benefit Sharing and the Law Applicable to the FAO Standard Material Transfer Agreement’, The Journal of World Intellectual Property, 11 (1), 1-28.

2 Article 12.3(a).

3 FAO (2007), ‘Consideration of the Material Transfer Agreement to be Used by the International Agricultural Research Centers of the CGIAR and other relevant International Institutions, for PGRFA not Included in Annex I of the Treaty’, IT/GB-2/07/13 Rev 1, FAO, Rome, Italy, (29 October - 2 November 2007).

ARTICLE 3 bis

[1. The provisions of this Protocol shall not affect the rights and obligations of any Contracting Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biodiversity.

This paragraph is not intended to [create a hierarchy between this][subordinate the] Protocol [and][to] other international instruments.]

2. Nothing in this Protocol shall prevent the Parties from developing and implementing other relevant international agreements, including other specialised 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 and other international instruments relevant to this Protocol shall be implemented in a mutually supportive manner, [[without prejudice to][bearing in mind] ongoing work or practices under relevant international organizations and conventions.]

4. This Protocol is the instrument for the implementation of the access and benefit sharing provisions of the Convention. 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 of this Protocol, this Protocol does not apply for the Contracting Party or Parties to the specialised instrument in respect of the specific genetic resource covered by and for the purpose of the specialised instrument.

Annex I crops has been discussed by the Governing Body of the ITPGRFA at its third meeting in Tunis, Tunisia in June 2009. No substantial changes have been made to the SMTA and such Agreement is currently used for the transfer of non-Annex I crops.⁴

During recent ABS negotiations, a common understanding emerged that the finalization of the Protocol may entail the deletion of both alternative options under letter (c) of Article 3, while the provision on the Protocol's relationship with other instruments contained in paragraph 4 of Article 3 bis would be retained. Although the ITPGRFA and its MLS are not directly referred to in its wording, there is no doubt that they are in fact the only existing "specialized ABS instrument" consistent with the CBD. Therefore, it is important to examine the legal implications of paragraph 4 of Article 3 bis. The latter provision is drafted in broad terms that allow for the voluntary use of the Standard Material Transfer Agreement including for the transfer of non-Annex I PGRFA between providers and recipients. In particular, it provides scope for using the SMTA for the transfer of materials held in the ex situ collections of CGIAR, including non-Annex I PGRFA, in accordance with the ITPGRFA Governing Body's decision.⁵ It also allows for the transfer of PGRFA from providers under the jurisdiction of an ITPGRFA Party to recipients under the jurisdiction of non-parties.⁶

Thus, the choice to delete the explicit exclusion contained in Article 3 (paragraph 2, letter c) of the draft ABS Protocol, while retaining paragraph 4 of Article 3 bis, appears neither to affect the rights and obligations of any Contracting Party

deriving from any existing international agreement nor to prevent the Parties from developing new specialised ABS agreements. On the other hand, the Protocol's potential application to benefits arising from "continuing" and "new uses" of genetic resources "acquired before the entry into force of the Convention,"⁷ which is strongly supported by the African Group, would require reconsidering the current practice, which the ITPGRFA's Governing Body has collectively endorsed, to make available all PGRFA held in the ex situ Consultative Group on International Agricultural Research collections through the Standard Material Transfer Agreement.⁸

Beyond the realm of plant genetic resources, life patenting and associated equity and benefit sharing issues have emerged in all agricultural genetic resource sectors including, inter alia, Microbial Genetic Resources and Animal Genetic Resources for Food and Agriculture. In particular, the FAO Commission on Genetic Resources for Food and Agriculture (CGRFA) has discussed the desirability of sectoral approaches, which could be envisaged in accordance with paragraph 2 of Article 3 bis of the draft Protocol. The further elaboration of cross-sectoral ABS issues relevant to food and agriculture as well as the relationship between the work of the CGRFA and that of the forthcoming ABS Protocol's governing body are critically important for genetic resources for food and agriculture covered by the Protocol and for food security.

7 Article 3, not numbered paragraph 3, letters a) and b).

8 See: IT/GB-3/09/Report at Paragraphs 38-39 and IT/GB-3/09/Inf. 15.

4 FAO (2009), 'Report of the Third Session of the Governing Body of the International Treaty on Plant Genetic Resources for Food and Agriculture', GB-3/09/Report, Tunis, Tunisia (1-5 June 2009), at paragraphs 38 and 39.

5 See: IT/GB-2/07/Report, paragraph 68.

6 This interpretation is supported by the utilization of the expression "[...] this Protocol does not apply for the Contracting Party or Parties to the specialised instrument [...]", where specific reference is made to either "Contracting Party or Parties" vis-à-vis a single reference to Contracting Parties.

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* The author would like to thank Daniele Manzella for his feedback on an earlier version of this article.

ARTICLE 6

[[CONSIDERATIONS RELEVANT TO [NON-COMMERCIAL] RESEARCH AND EMERGENCY SITUATIONS]][SPECIAL CONSIDERATIONS][^[1]

In the development and implementation of their national legislation on access and benefit-sharing, [and on the basis of the sovereign right of Parties who regulate access to genetic resources and its derivatives,] Parties 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; and

[(b) [Pay due regard to emergency situations including serious threats to public health, food security or biological diversity, according to national legislation.][Provide immediate access to [pathogens][genetic resources] falling also under the scope of relevant international organizations and conventions, such as the World Health Organization, the International Plant Protection Convention, or the World Animal Health Organization, and which are of particular public concern for the health of humans, animals or plants, in ways and for uses provided for in existing and future rules, procedures or practices on the sharing of pathogens and related benefits established under those international organizations and conventions[, taking into consideration [the legal, structural and/or administrative obstacles to the optimal implementation of] the World Trade Organization paragraph 6 system]]];]

(c) Consider the importance of genetic resources for food and agriculture and their special role for food security and climate change adaptation and mitigation;

(d) Consider sectoral approaches in the implementation and further development of this Protocol.]

[This Protocol shall provide no special consideration for any sector or any use of genetic resources or associated traditional knowledge without adequate provisions for fair and equitable benefit-sharing and compliance;]

[Pay due regard that the domestic access and benefit-sharing laws, policies or measures will not affect biological resources that are traded and used as commodities.]

[1] The following text was at the proposal of one Party and was neither agreed nor negotiated: [The first meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall adopt guidance to support Parties in implementing this Article.]

Exception #2: Sharing human pathogens

By Fredrick Abbott

Access to biological material with human pathogenic potential is important, as research aimed at the development of new drugs and vaccines is dependent on scientific analysis of the underlying causes of disease. In the circumstance of a potential pandemic, issues surrounding access take on particular urgency.

During the past several years, Member States of WHO have negotiated toward an agreement on sharing of influenza viruses with human pandemic potential in the Intergovernmental Meeting on Pandemic Influenza Preparedness (IGM-PIP). These negotiations arose out of controversy surrounding withholding by a developing country of virus samples from WHO researchers based on concern over reciprocal access to resulting vaccines and treatments, and relevant technologies. While WHO negotiations regarding influenza viruses are progressing slowly, there is also recognition at WHO that eventually the sharing of biological materials with human pathogenic potential more broadly will need to be addressed.

Biological materials with human pathogenic potential are potentially also the subject matter of the CBD and/or the draft Protocol. At present, the treatment of such materials by the draft Protocol is problematic and, depending on the approach chosen, adoption of the Protocol could lead to a situation of substantial legal insecurity.

The current draft Protocol provides three alternatives. Either potentially pathogenic materials are included and treated largely as any other genetic resource, they are explicitly exempted, or the Protocol provides for special regulation. The draft Protocol addresses its potential integration with existing and future WHO rules in Article 6 on Emergency Situations.

Up until the most recent negotiators' meeting in Montréal, "human pathogens" was the sole alternative in Article 3(f). Presumably this reference was intended to refer to external pathogens that may be harmful to humans, and not to pathogens that are human. During the last resumed session of the CBD's ABS Working Group, Parties suggested an alternative text for Article 3(f). The alternative text refers to "A genetic resource when it constitutes a serious and direct danger to the health of humans as described in the International Health Regulations, and it is covered by and for the purpose of a specialised instrument as described in paragraph (b) of Article 6". Such clarification would begin to reduce the ambiguity of the exemption, but it would leave important questions unanswered.

The wording "serious and direct danger to the health of humans" entails an immediate threat, but threat assessment based on probabilities for genetic mutation is an inherently uncertain exercise, as for example in the case of the H5N1 (avian flu) virus. It would be preferable to use language that does not entail a requirement of direct immediate threat. A formulation such as "with human pathogenic potential" might serve this purpose.

Article 6 provides for a specific mechanism applicable to pathogen/genetic resources, but its relationship to Article 3(f) and to WHO mechanisms seems to raise more questions than it answers.

The first bracketed option would create a general, non-specific obligation to take external circumstances regarding pathogen materials into account in formulating and implementing national legislation. This option would do little to clarify the relationship between the ABS Protocol and/or the CBD, on one side, and interests involving WHO on the other.

The second bracketed option is substantially more specific, although it leaves significant questions. Unless pathogen materials are expressly excluded from the scope of the ABS Protocol, this provision does not remove them from regulation under the draft Protocol. If the new bracketed exclusion from scope under Article 3(f) is adopted, this would cross-reference Article 6(b), but the two provisions almost certainly encompass different subject matter. The first clause of Article 6(b) refers to providing "immediate access", but it does not explain how that obligation would relate to other obligations in the draft ABS Protocol, such as the obligations in Article 5 for obtaining prior informed consent and negotiating the terms of benefit-sharing.

The phrase "in ways and for uses provided for in existing and future rules, procedures or practices on the sharing of pathogens and related benefits established under those international organisations and conventions" may be intended to signal that WHO rules will take priority over ABS Protocol rules. By leaving the relevant pathogen materials subject to the ABS Protocol, the provision appears to constitute the ABS Protocol and the CBD as the "default regime" regarding access to pathogen materials in the event Member States are unable to reach alternative agreements at the WHO. It might also serve as a "gap filler" when WHO rules do not cover a specific issue. If pathogen materials are excluded from the scope of the ABS Protocol under the current formulation of draft Article 3(f), they might remain subject to the CBD (but not the Protocol), mooted application of Article 6 of the draft ABS protocol, with greater uncertainty all around.

While ABS Protocol negotiators have recognised some of the potential issues raised by overlapping subject matter addressed at WHO, there is a lack of clarity as to precisely what they think ought to be done about it. In that regard, before adoption, negotiators in the ABS Protocol forum and at the WHO in the IGM-PIP should focus attention on concrete ideas concerning how the two systems are expected to operate simultaneously with respect to the same subject matter. This does not appear to be a situation in which "constructive ambiguity" will operate for the public benefit.

Professor Fredrick Abbott is Edward Ball Eminent Scholar Professor of International Law, Florida State University College of Law. This piece is based, in part, on a more comprehensive study published by ICTSD and authored by F. Abbott, entitled "An International Legal Framework for the Sharing of Biological Materials with Human Pathogenic Potential: Issues and Challenges", ICTSD 2010.

Dealing with Traditional Knowledge under the ABS Protocol

By Daniel Robinson and Brendan Tobin

Access to and use of genetic resources is often facilitated through traditional knowledge held by indigenous and local communities. The inclusion of measures to secure protection of traditional knowledge is thus of critical importance for any meaningful international ABS regime. Mention is made of traditional knowledge at various places in the draft protocol, though not in Article 1 on Objectives.

The lack of reference to traditional knowledge in the draft Protocol's Objective is a glaring omission given the mandate of COP 7 Dec VII/19D, calling for the effective implementation of Article 8(j). However, the most recent draft Protocol does include several key Articles relating to traditional knowledge in the form of either bracketed or unbracketed text. The relevant articles are Article 3 (in part), Article 5 and Article 9.

According to Article 3 (Scope) of the draft Protocol text: "This Protocol shall apply to genetic resources [and associated traditional knowledge] within the scope of [Article 15 of] the Convention on Biological Diversity and to the benefits arising from the [utilisation] of such resources [that were acquired after the entry into force of this Protocol for a Party with Parties providing such resources] [or its derivatives]." This provision is likely to be limited to traditional knowledge associated with genetic resources acquired after entry into force of the Protocol, but may apply to benefits arising from the continued use of traditional knowledge acquired before the Protocol or to new uses of such knowledge, as associated with genetic resources - this has been subject to intense debate.

There are several important considerations here regarding the scope of traditional knowledge in the Protocol. Much traditional knowledge may be considered to be in the 'public domain', it may be seen as documented national heritage (e.g., Ayurvedic TK in India), or may already be used by researchers and/or companies. On the one hand, many indigenous and local communities (ILCs) and developing countries are keen to see that 'continued' and 'new' uses of already acquired traditional knowledge are subject to obligations for prior informed consent and fair and equitable benefits. On the other hand, many of the most industrialised countries only want the Protocol to apply to genetic resources (and associated traditional knowledge) acquired after the entry into force of the Protocol. The prospect of applying benefit-sharing obligations to TK collected prior to the entry into force of the protocol is likely to prove not only controversial but very complex, if not impossible in some cases.

Questions remain over what it means to say that traditional knowledge is 'associated' with genetic resources. When quizzed about bioprospecting cases, many in industry have argued that ILCs would actually very rarely have had 'traditional' knowledge of 'genetic' resources, but rather would have traditional knowledge of the use of plants, animals and their products or parts (and derivatives/biochemical extracts) more broadly. The CBD's use of 'genetic' resources in the context of ABS is quite limiting. Some national ABS systems have expanded the scope of their laws to also require fair and equitable benefit sharing for 'biological' resources more

broadly (e.g., the South African bioprospecting regulations and the Australian state and federal biodiscovery laws), for the derivatives of these, and for associated traditional knowledge.¹ Therefore, it is very important for traditional knowledge holders that the ABS Protocol includes all use of TK related to utilisation of 'biological resources', 'genetic resources' and their 'derivatives' (which currently are in brackets in the draft, in Article 2 'Use of Terms') to avoid any ambiguity. It is noteworthy that negotiators at the It is noteworthy that negotiators at the Interregional Negotiating Group (ING), established by the WGABS to negotiate the text of the draft Protocol have now opted to define 'utilization of genetic resources' rather than 'genetic resources' themselves for the purpose of identifying obligations on PIC and benefit sharing. Negotiators in the CBD ABS Working Group may find that defining utilisation of TK associated with genetic resources may prove more useful than attempting to define what 'associated with genetic resources' means of itself. The scope of the word 'traditional' is also problematic, and the users and competent national authorities are likely to grapple with this when the Protocol enters into force.

Some commentators have criticised that fact that the provisions for access and prior informed consent (PIC) would be subject to national legislation in the draft Protocol (e.g. in the bracketed text in Article 5).² This is one of the key points raised by the Indigenous Peoples Forum on Biodiversity. Many developing country governments will take years to develop adequate national ABS regimes, and thus the Protocol should specify that access should be subject to PIC from competent national authorities and traditional knowledge holders, irrespective of the presence of national legislation. The repeated mention in the draft of 'subject to national legislation' threatens to undermine the effective implementation of the Protocol, rendering TK as something that only really is recognised at the discretion of governments. This is highly problematic from the perspective of many indigenous groups.

Article 5 *bis* of the ABS draft Protocol details access to traditional knowledge associated with genetic resources. Paragraph 1 requires Parties to take legislative, administrative

¹ According to the CBD, "'Genetic material' means any material of plant, animal, microbial or other origin containing functional units of heredity" and "'Genetic resources' means genetic material of actual or potential value." These functional units of heredity (DNA) can be found in many different types of cells within organisms. Genetic resources might include seeds, cuttings, cell cultures and other types of genetic material. A broader interpretation of 'genetic resources' to include biological resources (even if they do not contain functional units of heredity) is preferable when considering the rights of traditional knowledge-holders over various plant-based or biological products. Whether or not a broad interpretation is taken will be spelled out in Article 2 of the Protocol, which is still partially bracketed.

² See Swiderska, K. Sept. 2010. 'Equitable Benefit-Sharing or Self-Interest' IIED, London.

or policy measures to ensure that traditional knowledge associated with genetic resources (or its derivatives) 'held' by ILCs is accessed with their PIC. One conceivable issue here relates to how stakeholders and users will identify who 'holds' traditional knowledge. This will be especially difficult where traditional knowledge is held orally (i.e. where there is no publicly written record), and will likely be a common problem around the world. Thus, strong non-compliance measures (discussed below) would be particularly important so that ILCs can report the misappropriation of privately or secretly held traditional knowledge to authorities for appropriate action. From the perspective of ILCs it would be preferable to also have text in Article 5 *bis* relating to the respect of customary laws and protocols. Such reference is made in Article 9, discussed below.

Paragraph 2 of Article 5 *bis* requires appropriate and effective measures to ensure access has been sought in accordance with paragraph 1. This implies monitoring of access and benefit-sharing arrangements as detailed in Article 13, and should allow for recourse where indigenous groups feel that negotiations have not been on mutually agreed terms (MAT, see Art. 14). Substantial commitments from national authorities and other relevant parties towards observance and compliance of users with certificates of compliance (a disclosure requirement) will be required. Paragraphs 3 and 4 of Article 5 *bis* deal with non-compliance of paragraph 1, and the relatively weak phrasing seems to be the only text vaguely dealing with misappropriations of traditional knowledge. This section needs to be strengthened considerably, including by adding a definition of misappropriation and procedures for remedying it. In addition, reference could be made to Article 31 of the UN Declaration on the Rights of Indigenous Peoples (UNDRIP), which asserts that indigenous communities own and control their knowledge.

Article 9 of the current negotiating text contains important details relating to the treatment of traditional knowledge in the Protocol. Paragraph 1 contains bracketed text on consideration of community level procedures, indigenous and local community laws, customary laws, community protocols and procedures. The wording 'take into consideration' is extremely weak and falls short of the provisions of UNDRIP which require due respect, due recognition, and due consideration of customary law in recognition and adjudication of resource and land rights and dispute resolution relating to indigenous peoples rights.³ It is vitally important that ILC's customary laws, decision making procedures and protocols are followed by users of genetic resources, derivatives and associated traditional knowledge. Revision of Article 9 paragraph 1 of the draft Protocol text to ensure that prior informed consent processes requires observance of and due respect and recognition for community level procedures, customary laws, and community protocols is considered vital to secure protection of indigenous peoples and local communities human rights and their cultural integrity.⁴ There are concerns from some developing and developed countries about the definition of customary laws, community protocols and procedures. This makes the following paragraph of the draft Protocol (article 9, paragraph 3) even more important.

Article 9, paragraph 3 of the current negotiating text

3 See Tobin, B. (2010) "The Law Giveth and the Law Taketh Away": The Case for Recognition of Customary Law in International ABS and Traditional Knowledge Governance." Policy Matters 17, pp16-25. IUCN.

4 Ibid.

also makes important provisions for Parties to provide support towards the development, by indigenous and local communities, of community protocols in relation to access to traditional knowledge associated with genetic resources (or derivatives) and benefit sharing, minimum requirements for mutually agreed terms, and model contractual clauses for benefit sharing. By supporting the development of community protocols, ILCs will be empowered to control access procedures on their own terms and on the basis of their values and customs, but the strength of this ILC control will be in line with whatever text is agreed upon in Paragraph 1.

Paragraph 4 of Article 9 contains an important provision for the prevention of restrictions on customary use and exchange of genetic resources, derivatives and associated traditional knowledge. This provision seems relevant in circumstances where - such as in the case of the Indian Plant Variety Protection and Farmer's Rights Act - local communities can register for protection of domestically bred plant varieties (potentially to the exclusion of other local breeders). Some have suggested that this has or will cause an 'anticommons tragedy'.⁵ It may also be important to ensure that traditional medicines can still freely be used and exchanged, and that there are limitations on exclusive or monopolistic control.

Lastly, Paragraph 5 of Article 9 is still heavily bracketed. This is a contentious provision related to publicly available or already obtained traditional knowledge associated with genetic resources. In fact, contention over publicly available 'traditional' knowledge of ILCs has been a very common occurrence in many cases claimed as 'biopiracy.' This paragraph encourages 'reasonable measures' towards fair and equitable benefit-sharing arrangements with the [rightful] holders of this knowledge. Industry is likely to have some objections to the requirement that they enter into benefit-sharing arrangements retrospectively or for use of publicly available information. The weaker terms used (i.e. 'reasonable measures') may make this paragraph more palatable to industry. However, to be effective, this paragraph and/or Articles 13, 13 *bis* and 14 must require declaration of the use of TK and demonstration of measures taken to enter into fair and equitable benefit-sharing agreements (this is something that should ultimately link to patent disclosure requirements). Depending upon the terms chosen, it is important that users are required to establish benefit sharing arrangements where publicly available traditional knowledge is used. If this is not a requirement, then one could reasonably assume that users will continue to claim that they are simply using 'public domain' knowledge and that they have no obligation to share benefits with ILCs - irrespective of whether these communities willingly made their knowledge publicly available or if it was misappropriated (documented and acquired without PIC).

5 See Ramanna, A. and Smale, M. (2004) "Rights and Access to Plant Genetic Resources Under India's New Law" in Development Policy Review, 22 (4): 423-442.

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Monitoring compliance: Disclosure requirements and the international certificate

By Jorge Cabrera Medaglia and Olivier Rukundo

To solve problems related to the monitoring and traceability of genetic resources, ABS negotiations have focused on the development of some form of certificate of origin/source/legal provenance - more recently called a “certificate of compliance.” Closely linked to this tool is the discussion on a requirement to disclose the origin of genetic resources and associated traditional knowledge in intellectual property (IP) applications.

The current draft protocol addresses both the certificate and the disclosure of origin in the same article. The issues are grouped under the heading of monitoring and tracking the utilisation of genetic resources and associated traditional knowledge - a provision that is heavily bracketed.

General considerations

The idea and premise of the certificate is to prevent or minimise problems generated by the existence of two different jurisdictions for ABS arrangements - that of the place where the material is collected and that of the place where research and development activities are carried out. Such an internationally recognised document would make it possible to check the legality of access at the place where the activity (patent application, product approval, etc.) generates value and to follow the subsequent use of the resources and corresponding benefit sharing. At the same time, this approach supposedly would favour the creation of simpler access systems in provider countries. Existing control mechanisms would be applied, via the certificate, at the later stages of research and development, thus helping to make the regulations on access more flexible. This implies that the documentation would need to pass through the various buyers, while the monitoring points would be reserved only for certain milestones in the research and development process. These monitoring points could be related to - among others - product approval, intellectual property right (IPRs) applications, publications and the presentation of funding proposals.

Decision VIII/4C of the CBD Conference of the Parties established a Group of Technical and Legal Experts (GTLE) tasked with considering and developing an internationally recognised certificate of origin/source/legal provenance. The GTLE agreed that the basic role of any certificate system would be to provide evidence of compliance with national ABS legislation. This could be achieved by establishing a system of national certificates with standard features that would allow for their recognition internationally. The GTLE identified a number of points common to all proposals for a certificate. One such commonality among proposals was a requirement that the certificate be presented at specific checkpoints in the user countries, such as in conjunction with patent applications and IP applications in general. Most certificate proposals also envisaged a system of checkpoints at which disclosure of the certificate of origin would be required for the purposes of processing IP applications, among other things. Compliance with disclosure requirements would thus be facilitated, since an internationally recognised certificate could act as evidence of conformity with national and international law.

The inclusion and discussion of disclosure requirements and the use of the certificate in patent applications have both been contentious issues during the protocol negotiations. This naturally touches on trade related intellectual property issues and the WTO Agreement on Trade-Related Intellectual Property Rights (TRIPS). In this context, developing countries in particular have suggested that the TRIPS Agreement should be amended to require patent applicants to disclose one or more of the following: the source and origin of any genetic material and/or any related traditional knowledge used in a claimed invention; evidence of prior informed consent (PIC) from the competent authority of the country of origin; and evidence of fair and equitable benefit sharing.

Proponents of disclosure requirements argue that this would help support compliance with the CBD provisions on access to genetic resources and benefit sharing. In response, other countries have expressed contrary views. In their opinion, a modification is unnecessary, as the CBD requirements should be implemented through corresponding contracts at the national level, and the TRIPS Agreement is not the appropriate instrument to regulate ABS. In any case, this discussion continues to influence the ongoing protocol negotiations, and the relationship between the TRIPS Agreement and the future protocol is likely to shape the actual design of a disclosure requirement mandated by the ABS Protocol.

Similarly, the certificate, depending on its design, may raise international trade issues. Considering that the certificate could be a document accompanying the transfer/export (international trade) of genetic resources, its role should also be analysed in the context of the relevant rules of the WTO. These rules include those related to nondiscrimination (the most-favored nation principle and the national treatment principle) as well as the appropriate measures in the Agreement on Technical Barriers to Trade (TBT). The TBT Agreement governs the elaboration and use of technical regulations, standards and conformity assessment procedures, specifying that they should not create unnecessary obstacles to international trade.

The international certificate of compliance

Despite the fact that the certificate has been generally accepted as a potential tool for monitoring the use of genetic resources, its actual design is still far from clear. In fact, paragraph five of Article 13 calls for the “[first] Conference of the Parties serving as the meeting of the Parties to this Protocol [after the entry into force of this Protocol] to [decide on the minimum content][consider additional modalities] of

the internationally recognised certificate of compliance [system], taking into account the need to minimise transaction costs and to ensure feasibility, practicality and flexibility].”

Moreover, the actual design critically depends on the domestic implementation processes. Some countries have already taken first steps towards a certificates system by, for example, providing an on-line searchable database of access permits granted (Australia), or including provisions in their ABS laws allowing the grant of certificates (e.g., Bhutan, Costa

Rica). These countries need to ensure that the final protocol does not run counter to their efforts, but allows the use of their approach. Other countries that have not yet implemented domestic legislation, on the other hand, need to ensure that no future decisions are impeded by the protocol. In that regard, Article 13 provides a list of “example” measures that [could] or [shall] be taken, “as appropriate” (in different ordering depending on the paragraphs). While this approach provides for the necessary flexibility, such wording also results in a high degree of ambiguity and has been criticised for

ARTICLE 13

MONITORING[, TRACKING] AND REPORTING THE [UTILIZATION] OF GENETIC RESOURCES [AND ASSOCIATED TRADITIONAL KNOWLEDGE]

1. Parties shall take measures, as appropriate, to monitor[, track and report] the [utilization] of genetic resources[, its derivatives and associated traditional knowledge] to support, inter alia, [the requirement to obtain prior informed consent and mutually agreed terms][compliance [with prior informed consent requirements and mutually agreed terms][with domestic access and benefit-sharing legislation and regulatory requirements] [to support implementation] [under Article 12(1)] [in order to enhance transparency [and build trust between providers and users]]]. Such measures [could][shall] include:
 - (a) The identification and establishment of [effective][mandatory compliance] check points [[and [mandatory] [transparency][disclosure][information] requirements][to [disclose][provide] pertinent information] [at[, for example]:
 - (i) Competent national authority in the user country;
 - (ii) Research institutions subject to public funding;
 - (iii) Entities publishing research results relating to the [utilization] of genetic resources;
 - (iv) [Intellectual property examination][Patent and plant variety] offices; and
 - (v) Authorities providing regulatory or marketing approval of products [derived from genetic resources][resulting from the use of genetic resources or its derivatives];]
 - (v bis) [Indigenous and local communities, including their relevant competent authorities, that may grant access to traditional associated with genetic resources.]

[The [mandatory] disclosure requirement shall be met by providing [bona fide] evidence that a [permit or] certificate was granted [at the time of access] in accordance with [Article 5, paragraph 2 (d)]] [prior informed consent and mutually agreed terms as provided by national legislation];]

 - (b) [Requiring][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 for monitoring [, tracking and reporting] the [utilization] of genetic resources.
 - (d) [Where appropriate,] [establishing] Databases containing information about genetic resources [that have been or [may][can] be provided].]
2. [The][Any] [permit[, or]] certificate [or equivalent] issued [at the time of access] in accordance with Article 5, paragraph 2 (d) and [registered with][made available to] the [Access and Benefit-sharing] Clearing-House, [in accordance with [Article 5 paragraph 3][Article 11, paragraph 2(c)]] shall constitute an internationally recognized certificate of compliance [with national law].
3. The internationally recognized certificate of compliance shall serve as evidence that the genetic resource in question has been [[obtained/obtained,] accessed [and used] in accordance][acquired] with prior informed consent[, where applicable] and that mutually agreed terms have been entered into, as specified in the national legislation on access and benefit-sharing of the [country][Party] [providing][of origin of] the genetic resource [or its derivatives]. [[Mandatory] Disclosure requirements shall be met by providing an internationally recognized certificate.]
4. The internationally recognized certificate of compliance [or equivalent] [shall][may] contain the following minimum information [when it is not confidential]:
 - (a) Issuing national authority;
 - (b) Details of the provider;
 - (c) [A codified unique alphanumeric identifier]
 - (d) [Details of the [relevant indigenous and local communities who are] [rights holders][rightful holder] of associated traditional knowledge [within indigenous and local communities], as appropriate;]
 - (e) Details of the user;
 - (f) [Subject-matter][Genetic resources and/or derivatives] covered by the certificate [or equivalent];
 - (g) [Geographic location [and/or georeference] of the access activity;]
 - (h) [Link to][Confirmation that] mutually agreed terms [were entered into];
 - (h bis) [Confirmation that prior informed consent was obtained, where applicable;]
 - (i) Uses permitted and restrictions of use[, where applicable];
 - (j) Conditions of transfer to third parties;
 - (k) Date of issuance.]
5. The [first] Conference of the Parties serving as the meeting of the Parties to this Protocol [after the entry into force of this Protocol] shall [decide on the minimum content][consider additional modalities] of the internationally recognized certificate of compliance [system], taking into account the need to minimize transaction costs and to ensure feasibility, practicality and flexibility.]

[ARTICLE 13 bis

NON-COMPLIANCE WITH MANDATORY DISCLOSURE REQUIREMENTS

If the user fails or refuses to disclose pertinent information on the country of origin or source in cases and where the claim is directly based on genetic resources and associated traditional knowledge:

- (a) A user should be given the possibility to remedy the omission within a specific time fixed under the relevant law;
- (b) If the user continues to fail to make any declaration then the application shall not be further processed.]

lacking concrete requirements. This is particularly true for the use of the wording “as appropriate” and a reference to “domestic legislation.” If the international certificate and/or the disclosure requirement are only directed at showing that prior informed consent and mutually agreed terms requirements have been met “in accordance with domestic/national legislation” and not international law, the objectives of the protocol might be met only in the remote future, as the design of such legislation in many countries might take years. This is particularly true for countries with fewer resources and/or less stable domestic legal and political systems.

In that regard, several important aspects of the certificate still require further negotiation, including, *inter alia*, the following:

- The specific check points, including the role of IP offices;
- Details of the content of the certificate, (e.g., the mandatory or indicative minimum content);
- Design (whether a unique identifier would be required, etc) and operation of the certificate (whether it would be registered or made available to the ABS-Clearing House Mechanism, its relation with the ABS permit, etc);
- Coverage of the certificate: whether to include, in addition to genetic resources, associated traditional knowledge;
- The nature of the certificate: a voluntary or mandatory mechanism, the different values of each option, and
- Sanctions in cases of non-compliance (regulated in Article 13 *bis*).

Even if parties address these outstanding issues, a number of challenges - both from the perspective of the user and provider - remain with regard to the successful implementation of the certificate. Firstly, it is important that countries have a clear understanding of the certificate’s role and function in achieving benefit sharing. The certificate does not guarantee, *per se*, the fair and equitable distribution of benefits or the fairness of a negotiation covered by a certificate. This aspect will require further measures that need to be carefully aligned. Moreover, from the perspective of the country granting the certificates, the issuance of the instrument must not create unnecessary (and additional) obstacles and delays to the ABS permitting system or impede or complicate the flow of genetic resources. Capacity building will be required to achieve this objective. Thirdly, check-points and credible sanctions in case of non-compliance that would induce compliance need to be carefully determined. Finally, from the perspective of the country where the check points would be located, further clarity is required on when a certificate should be presented and what would trigger its presentation. This last point might also require capacity building efforts.

The disclosure requirement

The current bracketed language of the draft protocol refers to “disclosure of relevant information” and assumes the existence of “appropriate check points”. This is most visible in Article 13 as shown above. In addition, Article 12 of the draft protocol intentionally includes the disclosure requirements in IP applications (patents and plant varieties), but mixes it with general provisions regarding disclosure of information. Here, a number of relevant issues still need to be decided, *inter alia*: the nature of the disclosure requirements (mandatory or voluntary); the appropriate check points (e.g., IP offices as the relevant check point for the disclosure of origin,

as has been previously proposed); and the sanctions in case of non-compliance.

However, the draft wording used so far is rather vague with regard to some key elements of the disclosure of origin. For instance, what information is supposed to be disclosed? What is the source or origin of the genetic resources? There is no reference to other elements to be checked - except if the certificate of compliance is utilised as a mechanism to comply with the disclosure requirements - such as proof of PIC, mutually agreed terms and benefit sharing provisions. Sanctions for non-compliance seem to be targeting IP applications due to the use of the words “claims” and “application.” They do not, however, address the possible cancellation, revocation or declaration of non enforceability of the IP if the disclosure requirement has not been complied with and the IP title was (wrongly) granted.

In practice, a “soft version” of the disclosure - if compared with what has been proposed previously by developing countries in the ABS Working Group or at the WTO - is currently included in the protocol. The purpose may be to accommodate some countries that already are opposed to disclosure requirements (both in the WTO and the CBD). The drafting of the disclosure requirements in Article 13 of the draft protocol could respond to this approach.

The potential inclusion - even of this soft version of the disclosure requirements in the ABS Protocol - may impact the current negotiations at the WTO. The possibility, exact scope, and precise content of a potential amendment of the WTO is still uncertain - whether sanctions for noncompliance will fall outside patent law or not, the necessity of proving compliance with PIC and benefit sharing, etc. - as well as the amendment *per se*. Considering the large membership of the WTO and its economic relevance for the contracting parties, this amendment would promote a more effective integration of the disclosure of origin in the IP system (and in the national laws) and would promote broad implementation of the instrument. It would also be subject to the WTO Dispute Settlement procedures. In this case, the CBD may provide assistance and coordination in developing and implementing disclosure requirements by clarifying terms and instruments, including the role of the certificate of compliance in disclosure.

Finally, the disclosure of origin could have limited impact in preventing misappropriation of genetic resources unless it is accompanied by other relevant user measures, such as access to justice and the creation of collaborative mechanisms between countries to address cases of non-compliance with national ABS legislation and agreements. As a disclosure requirement will not be sufficient alone as it should be complemented by clear and articulated benefit sharing obligations in the protocol. Thus, unlike some other outstanding issues in the protocol, the international certificate and the related - yet distinctive - disclosure requirement are issues that might take shape only at a later stage and during the actual implementation.

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The WTO fisheries negotiations: An opportunity for marine biodiversity

By Malena Sell

The WTO fisheries negotiations are often said to provide the single greatest opportunity for the environment under the faltering Doha Round. The focus is on cutting the subsidies that allow for the overexploitation of fisheries, and thus on safeguarding the resource itself and the significant economic and livelihood gains this would bring for people around the world and in developing countries in particular. In addition, the phase-out of destructive subsidies would open up the possibility of re-channelling subsidies into carefully crafted management schemes, as well as into conservation initiatives such as Marine Protected Areas. As such, the benefits for ocean biodiversity as a whole could be rich and generate positive outcomes for generations to come.

Subsidies in the fisheries sector have been, and continue to be applied in a number of different ways and for a number of objectives. For example, direct support for vessel building has played an important role in developing the global fishing industry. There is clear evidence that these subsidies can cause market distortions and encourage overcapacity, ultimately contributing to the depletion of fish stocks. On the other hand, subsidies to resource management or capacity reduction might have positive effects on trade, natural resources and biodiversity. The same holds true for support measures for monitoring, control, and surveillance of illegal fishing activities. Still other subsidies are designed to assist small-scale and artisanal fishing communities that rely on fishing activities for their livelihood and food security.

Overfishing has led to negative effects on marine ecosystems as a whole. Many of the prized top predators - such as tuna and sword fish - are keystone species that strongly affect the balance of the ecosystem. As these larger fish are being fished out, the world fleets have turned to the smaller fish that they feed on, so called forage fish. A response, clearly visible on a global scale, is the increase in jellyfish as the number of fish decline. Furthermore, bottom trawling, the use of large-scale driftnets and other destructive fishing practices lead to destruction of marine habitats with negative effects that reach far beyond the target species.

Currently, marine areas are far less protected than terrestrial ecosystems - only 0.8 percent of the high seas are protected, while the figure is 6 percent for territorial waters. In 1995, Parties to the Convention on Biological Diversity (CBD) adopted the Jakarta Mandate on Marine and Coastal Biodiversity, staking out a road towards addressing the major threats to marine biodiversity, including through better and more effective implementation of integrated marine and coastal area management in the context of the ecosystem approach. In 2002, Parties agreed to a target to significantly reduce the rate of biodiversity loss by 2010 and to develop representative networks of marine protected areas (MPAs) by 2012. So far, governments are far from being on track, and will have a heavy agenda when they meet at COP-10 in Nagoya, seeking ways to turn this trend around.

In these efforts, negotiations under the Doha mandate can help promote some of the same overarching goals. In the rules negotiations, the focus is on cutting subsidies that lead to overfishing. The draft text, which has been under discussion since late 2007, would ban a long list of subsidies that boost fishing capacity or create other incentives to fish. Some subsidies would be permissible for all countries, in-

cluding payments aimed at reducing the fishing capacity and environmental impact of fishing.

This is where the link to fishery management schemes comes in. In order to provide the subsidies still allowed, countries would have to show that they have effective, international-standard management systems in place. In addition, developing countries would be allowed to provide certain otherwise forbidden subsidies under Special & Differential treatment if they have effective fishery management schemes in place. From a biodiversity perspective, the important issue will be that the management schemes are effective and work in practice, without being too complex and expensive.

In the current fisheries draft under discussion, a number of requirements with regards to fisheries management systems are fleshed out. The systems should be based on internationally-recognised best practices, such as the UN Fish Stocks Agreement for the implementation of the provisions of the Law of the Sea relating to conservation and management of straddling fish stocks. The management measures should include, inter alia: regular science-based stock assessment; capacity and effort management measures; vessel registries; and the establishment and allocation of fishing rights. The systems would be notified to and reviewed by a UN FAO body.

Funds going towards the establishment and maintenance of MPAs are not considered a subsidy in the current draft text. They are generally handled by ministries other than those disbursing the more traditional fisheries subsidies or handling the negotiations at the WTO. Therefore, cutting traditional subsidies would not imply automatic rechanneling into measures safeguarding marine biodiversity. When discussing the subsidies currently exempted from cuts, such as early retirement and retraining programmes, possible links could be made to new initiatives and jobs related to the establishment and maintenance of MPAs and related economic activities such as coastal and marine ecotourism.

In addition, when considering subsidies in the context of small and artisanal fishers - often engaged in traditional fishing practices and providing important food security, livelihoods and incomes - potential biodiversity benefits deriving from their sustainable use of the resource should be kept in mind.

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Biodiversity: Why do farm trade policies matter?

By Jonathan Hepburn

As negotiators head to Nagoya for another high-level meeting of the Convention on Biological Diversity, they will be well behind on their target to halt biodiversity loss by 2010. However, beyond the discussions this week at the CBD, policies and rules on farm trade will also have a major impact on the prospects for biodiversity and other public policy goals in both rich and poor countries.

Talks on draft CBD disciplines represent only one part of an emerging constellation of rules that could affect the relationship between farming and biodiversity. The provisions of the UN Food and Agriculture Organisation's international treaty on agrobiodiversity¹, those of the UPOV plant-breeding convention, WTO rules on intellectual property and discussions at the World Intellectual Property Organisation all potentially influence the extent to which farming affects the diversity of life forms on the planet, both directly and indirectly - although these different legal instruments embody widely varying underlying notions of how different public policy objectives should be achieved.

While the relationships between these accords has now been explored extensively by negotiators and policy analysts², less attention has been focused on how farm trade rules currently under negotiation in the WTO's faltering Doha Round could affect biodiversity - despite the fact that the ongoing trade talks could have far-reaching implications in this area. Proposed new ceilings on trade-distorting farm support and new rules on agricultural market access could affect biodiversity because of the implications they have for the competitiveness of different farm types and for different production systems in rich and poor countries.

Subsidies: A critical question

Subsidies that are linked to production levels, market price support or input subsidies can all reduce biodiversity through incentivising production techniques involving the destruction of habitats such as forests, wetlands or hedgerows; by encouraging intensive use of fertilisers, pesticides and herbicides; or by leading farmers to adopt unsustainable stocking densities for livestock. In a variety of ways, trade-distorting farm support can therefore be linked to biodiversity loss in agricultural ecosystems and those to which they are related.

In addition to the environmental damage such subsidies can cause, they are arguably also responsible for undermining food security and livelihoods in the developing world: the massive amounts of trade-distorting support provided in recent decades have contributed to the long term decline in agricultural productivity growth in poor countries, by creating disincentives for investment in farming³.

Proposed new WTO rules will cap this support at a historical low - around \$14.5 billion in the US, and around €22.1 billion in the EU - with potentially positive impacts on biodiversity, and on food security and livelihoods in poor countries.

However, the draft Doha deal places few restrictions on another category of support, known as 'green box' payments at the WTO: these will be exempt from cuts or any ceiling, on the basis that they cause no more than minimal distortion to farm production and trade. While experts tend to concur that these payments are generally less trade-distorting than payments that are directly linked to production levels, controversy continues over the extent to which they continue to affect farmers' production decisions.

Decoupled 'green box' support now represents over 90 percent of US farm subsidies, and a large and growing share in the EU - almost two thirds of support, according to the trading bloc's latest official report to the WTO. While some payments in this category are believed to promote biodiversity, such as some kinds of payments under environmental programmes, others may be neutral or even damaging.

For example, farmers may receive support under programmes that are explicitly targeted at biodiversity outcomes - such as sheep farmers whose grazing land may be important as a home to rare butterflies. In other cases, environmental payments may be awarded for activities such as afforestation, which may replace biodiversity-rich landscapes with forest monocultures. At the root of the problem may be the lack of clear objectives, targets and monitoring for many subsidy programmes.

Support payments may also be disproportionate to the costs of implementing environmental standards, including those relating to biodiversity. One study has found that a farm in Cambridgeshire in the UK incurred costs of around €75 for respecting environmental regulations, but received €27,000 in direct payments, prompting some critics to query whether such subsidies are in fact merely a disguised form of income support⁴.

While some developing countries such as China are using green box subsidies to pursue environmental objectives in areas such as forestry and for combating desertification, many still lack the financial resources to devote substantial support to farming, and remain concerned that the large and growing amounts of decoupled support in the developed world may provide producers in these countries with a competitive advantage over their own farmers.

Market access and biodiversity

Proposed new WTO rules on market access could also affect biodiversity outcomes, although the impact of the draft agriculture deal is harder to establish in this area. National rules and policies may be particularly important in determining

1 The FAO International Treaty on Plant Genetic Resources for Food and Agriculture

2 See, for example, Tansey, G and Rajotte, R (2008) "The Future Control of Food". Earthscan, UK.

3 ICTSD (2009), "Ensuring trade policy supports food security goals". <http://ictsd.org/i/publications/59176/>

4 Cited in Brunner, A, and Huyton, H (2009) "The environmental impact of EU green box subsidies". In Meléndez-Ortiz, R, Bellmann, C and Hepburn, J, "Agricultural subsidies in the WTO green box: Ensuring coherence with sustainable development goals". Cambridge University Press, UK.

whether tariff reductions for farm products are good or bad for biodiversity - an issue that has been largely absent from negotiators' considerations during the trade talks.

Many developing countries are home to large numbers of subsistence farmers that are often ill-equipped to compete with cheap and sometimes subsidised exports from large-scale industrialised farming elsewhere: at the WTO, a coalition of these nations have sought to exempt key products from tariff cuts, and to establish safeguard mechanisms to protect their farmers from import surges and sudden price depressions, on the basis of food security, the protection of livelihoods and rural development concerns. The proposed flexibilities that developing countries are likely to be granted in these areas may in practice serve to safeguard traditional farming practices that are more supportive of biodiversity, even though this issue has not featured explicitly in the WTO debate.

More complex is the relationship between trade expansion and biodiversity. Many of the poorest developing countries are heavily dependent on the export of just a few unprocessed agricultural commodities: for these, greater access to lucrative markets elsewhere could be critical for economic growth and poverty reduction, but the impact on biodiversity may depend heavily on national environmental policies and regulations, and on countries' ability to enforce these effectively.

There is growing interest in commercialising and trading goods that are derived from native biodiversity in developing countries - often through the use of labelling and certification schemes targeted at environmentally-conscious consumers. While such initiatives may offer a partial solution to the challenge of biodiversity loss, there is arguably a risk that they remain focused on a relatively limited number of 'niche' market products; furthermore, they are by their very nature unable to provide a systemic solution to the broader market failure in this area at the global level.

Trade in higher-value organic agriculture products may provide more broad-based economic benefits, as well as helping stem biodiversity loss: however, technical standards and health and safety requirements in developed countries may continue to hinder organic exports from the developing world. While under many circumstances organic agriculture may require support in order to remain economically viable, both developed and developing countries may still be able to generate positive impacts on biodiversity by reviewing national regulations and policies on input use, and investing in agricultural extension services in order to share expertise with farmers on ecological production techniques.

Biodiversity and farm trade: Towards a holistic approach

Climate change, population growth and changes in dietary patterns due to rising average incomes in the developing world are expected to place increased pressure on land and other resources in the years ahead - trends which may also be exacerbated by poor policy design in areas such as biofuels. Changes in farm trade policies that foster productivity enhancements in poor countries and increase the value of local production will be key to addressing food security and employment needs whilst also ensuring that these pressures do not have negative impacts on biodiversity.

Many developing countries may need to take action to ensure that their national environmental, social and economic objectives are established and implemented in national level development strategies if they are to ensure that agricultural trade negotiations at the WTO are indeed supportive of their biodiversity goals. However, developed country agricultural trade policy reform must be a critical counterpart in order to ensure that such measures are effective. Refocusing farm subsidies on clear and measurable public policy goals, including biodiversity, must be a priority in this respect.

Irrespective of whether governments can agree to conclude the troubled Doha Round negotiations at the WTO, opportunities for pursuing these reforms are close at hand. The EU has already begun to consider the future shape of its Common Agricultural Policy, a discussion which could have important implications for biodiversity loss and other public public goals both at home and beyond. The US is soon to begin a similar discussion ahead of the next Farm Bill, the omnibus legislation that determines agricultural support programmes for everything from cotton to corn and rice. The active engagement of constituencies that are concerned about biodiversity will be essential if agricultural trade rules are to foster its conservation and sustainable use in the years and decades to come.

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Bridges Trade BioRes Review

Published by:
The International Centre for Trade
and Sustainable Development

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Additional support provided
by Marie Wilke.

This publication is made possible
through the financial contribution
of the Government of the United
Kingdom (DFID) and the Dutch
Ministry of Foreign Affairs (DGIS).

The opinions expressed in the
signed contributions to the BioRes
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full academic citation.

ISSN 1996-9198

Bridges Trade BioRes

CBD COP 10 events & resources

Select COP 10 Side Events

Date	Time	Event	Venue
Tuesday 19 th	13:15-14:45	ICTSD side event on “Intellectual Property, Trade, and Sustainability: A South South Exchange”	Room 233B - Bldg 2, 3 rd floor
	18:15-19:45	Berne Declaration, African Center for Biosafety, Natural Justice, Third World Network and EED side event on “Ongoing Biopiracy and Lessons for an ABS Protocol”	Room 234A - Bldg 2, 3 rd floor
	18:15-19:45	UNCTAD side event on “Greening Trade for Biodiversity Conservation”	Room 231B - Bldg 2, 3 rd floor
Wednesday 20 th	18:15-19:45	Natural Justice: Lawyers for Communities and the Environment side event on “CBD and REDD: Whose Rights, Who’s Wronged?”	Room 231B - Bldg 2, 3 rd floor
Thursday 21 st	13:15-14:45	Peruvian Society for Environmental Law and IDRC side event on “New Approaches for Benefit Sharing in the Context of the International Regime on ABS”	Room 236 - Bldg 2, 3 rd floor
	16:30-18:00	Fridtjof Nansen Institute side event on “Recent Developments in Patent Law Relevant for Genetic Resources”	Room 231 - Bldg 2, 3 rd floor
Friday 22 nd	18:15-19:45	WIPO side event on “Intellectual Property and Biodiversity in the WIPO IGC: Identifying Links Between the CBD and WIPO”	Room 210A - Bldg 2, 1 st floor
Monday 23 rd	16:30-18:00	IUCN and ESARO side event on “Improving PA Governance for Secure Livelihoods and PoWPA Implementation in Southern Africa”	Room 232 - Bldg 2, 3 rd floor
Tuesday 26 th	13:15-14:45	GTZ and CBD Secretariat side event on “ABS Communication”	Room 232 - Bldg 2, 3 rd floor
	16:30-18:00	Searice side event on “Farmers Sustaining Agriculture in a Warming World”	Room 136 - Bldg 1, 3 rd floor
	18:15-19:45	Natural Justice: Lawyers for Communities and the Environment, COMPAS, UNU-IAS, ABS, Capacity Initiative for Africa, UNEP and Equator Initiative side event on “Demystifying Community Protocols”	Room 236 - Bldg 2, 3 rd floor

Biodiversity-Related Resources

ICTSD resources

GEOGRAPHICAL INDICATIONS AND THE OBLIGATION TO DISCLOSE THE ORIGIN OF BIOLOGICAL MATERIALS: IS A COMPROMISE POSSIBLE UNDER TRIPS? By Carlos M. Correa. ICTSD Programme on Intellectual Property. Issue Paper No. 8, September 2010.

THINKING OUTSIDE THE BOX INNOVATIVE OPTIONS FOR AN OPERATIONAL REGIME ON ACCESS AND BENEFIT SHARING. By Manuel Ruiz Muller. ICTSD Programme on Environment and Natural Resources. Issue Paper No. 1, June 2010.

THE POLITICAL ECONOMY OF THE INTERNATIONAL ABS REGIME NEGOTIATIONS. By Jorge Cabrera Medagliua. ICTSD Programme on Environment and Natural Resources. Issue Paper No. 2, June 2010.

THE DISCLOSURE OF ORIGIN REQUIREMENT IN CENTRAL AMERICA: LEGAL TEXTS, PRACTICAL EXPERIENCE AND IMPLEMENTATION CHALLENGES. By Jorge Cabrera Medagliua. ICTSD Programme on Environment and Natural Resources. Issue Paper No. 3, June 2010.

BIODIVERSITY RELATED INTELLECTUAL PROPERTY PROVISIONS IN FREE TRADE AGREEMENTS. By David Vivas-Eugui and Maria Julia Oliva. ICTSD Programme on Environment and Natural Resources. Issue Paper No. 4, September 2010.

DISCLOSURE OF ORIGIN AND LEGAL PROVENANCE: THE EXPERIENCE AND IMPLEMENTATION PROCESS IN SOUTH AMERICA. By Manuel Ruiz Muller. ICTSD Project on Genetic Resources. Policy Brief No. 7, June 2010.

BRAZIL’S PRACTICAL EXPERIENCE WITH ACCESS AND BENEFIT SHARING AND THE PROTECTION OF TRADITIONAL KNOWLEDGE. By Eduardo Vélez. ICTSD Project on Genetic Resources. Policy Brief No. 8, June 2010.

Other resources

TRIGGERING THE SYNERGIES BETWEEN INTELLECTUAL PROPERTY RIGHTS AND BIODIVERSITY. By Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ).

UEBT NOTE 2 OF 4 ON TRENDS IN PATENTING. Union for Ethical BioTrade. October 12, 2010.