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GROUP OF TECHNICAL AND LEGAL EXPERTS ON COMPLIANCE IN THE CONTEXT OF THE INTERNATIONAL REGIME ON ACCESS AND BENEFIT-SHARING
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Item 3 of the provisional agenda*

COMPILATION OF SUBMISSIONS BY PARTIES, GOVERNMENTS, INTERNATIONAL ORGANIZATIONS, INDIGENOUS AND LOCAL COMMUNITIES AND RELEVANT STAKEHOLDERS ON COMPLIANCE IN THE CONTEXT OF THE INTERNATIONAL REGIME ON ACCESS AND BENEFIT-SHARING

Note by the Executive Secretary

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INTRODUCTION

1. In its decision IX/12, paragraph 11, the Conference of the Parties decided, *inter alia*, to establish a group of technical and legal experts to further examine the issue of compliance in order to assist the Ad Hoc Open-ended Working Group on Access and Benefit-sharing in the elaboration and negotiation of the international regime on access and benefit-sharing.

2. In the same decision, the Conference of the Parties requested the Expert Group to provide legal and, as appropriate, technical advice, including, where appropriate, options and/or scenarios. The terms of reference for the Group, set out in section A of annex II to the decision, are as follows:

"The expert group will address the following questions:

(a) What kind of measures are available, or could be developed, in public and private international law to:

(i) Facilitate, with particular consideration to fairness and equity, and taking into account cost and effectiveness:

a) Access to justice, including alternative dispute resolution;

b) Access to courts by foreign plaintiffs;

(ii) Support mutual recognition and enforcement of judgments across jurisdictions; and

(iii) Provide remedies and sanctions in civil, commercial and criminal matters;

in order to ensure compliance with national access and benefit-sharing legislation and requirements, including prior informed consent, and mutually agreed terms;

(b) What kind of voluntary measures are available to enhance compliance of users of foreign genetic resources;

(c) Consider how internationally agreed definitions of misappropriation and misuse of genetic resources and associated traditional knowledge could support compliance where genetic resources have been accessed or used in circumvention of national legislation or without setting up of mutually agreed terms;

(d) How could compliance measures take account of the customary law of indigenous and local communities?

(e) Analyse whether particular compliance measures are needed for research with non-commercial intent, and if so, how these measures could address challenges arising from changes in intent and/or users, particularly considering the challenge arising from a lack of compliance with relevant access and benefit-sharing legislation and/or mutually agreed terms."

3. In paragraph 15 of decision IX/12, the Conference of the Parties invited Parties, Governments, international organizations, indigenous and local communities and relevant stakeholders to provide information and views related to the issues to be addressed by each expert group six weeks prior to the convening of each group.

4. Further to that request, notification 2008-116 of 12 September 2008 was sent to Parties, Governments, international organizations, indigenous and local communities and relevant stakeholders and a reminder notification 2008-146 (extension of a deadline) was sent on 31 October 2008.

5. The present document provides a compilation of submissions provided by Parties, Governments, international organizations, indigenous and local communities and relevant stakeholders on compliance in the context of the international regime on access and benefit-sharing. The contributions have been reproduced in the form and language in which they were received. In addition, contributions provided in a language other than English have been translated into English.

I. SUBMISSIONS FROM PARTIES

CANADA

Introduction

Canada has provided its comments, for ease of reference, under the headings of each aspect of the terms of reference that the Compliance Technical Experts Group (TEG) will be examining.

As regards terminology, "compliance" refers to a state of adherence to norms, whether they be international or national, voluntary or otherwise. The nature of the international regime has not yet been decided and the approach to the Terms of Reference in the TEG should take this into account.

In considering questions of compliance, a number of general points are relevant for the TEG to consider:

- Compliance efforts can only be effectively targeted if it is clear which norms one is seeking compliance with
- Voluntary compliance measures can contribute to enhancing compliance with national ABS laws (including PIC), and mutually agreed terms (MAT). Such measures can be taken at the national level and the international level.
- All Parties will be providers of genetic resources and will have users within their jurisdiction
- All Parties will have to implement any "user" measures which are agreed, regardless of their nature
- Foreign and domestic users should be treated the same
- The range and variety of sectors utilizing genetic resources should be taken into account when designing compliance measures, which may have to vary by sector or sub-sector
- Compliance measures should be consistent with other relevant international obligations, including trade rules.
- It should be noted that non-compliance with an ABS regime will be driven significantly by lack of awareness. The consequences of non-compliance could reflect this fact.

The topic of genetic resources and compliance with related norms (national ABS laws, contracts, or the CBD) poses particular challenges:

- The intangible aspect of GR
- The reality of numerous transactions
- The variety of provider jurisdiction approaches to access and benefit-sharing
- Many jurisdictions have no explicit national ABS laws
- The fact that most benefits will likely be of a non-monetary nature (for example under the form of increased knowledge of biodiversity).
- Scope of the term "genetic resources"
- The need for pragmatic, cost-effective approaches that can be applied flexibly across national legal systems and property law approaches
- The need to tailor compliance measures to the typical users.

Question (a): What kind of measures are available, or could be developed, in public and private international law to:

(i) facilitate, with particular consideration to fairness and equity, and taking into account cost and effectiveness:

a. access to justice, including alternative dispute resolution
b. access to courts by foreign plaintiffs

(ii) support mutual recognition and enforcement of judgments across jurisdictions; and

(iii) provide remedies and sanctions in civil, commercial and criminal matters;

in order to ensure compliance with national access and benefit-sharing legislation and requirements, including prior informed consent, and mutually agreed terms;

Input for Question (a):

Private International Law

Meaning of private international law

The expression private international law, also called conflict of laws, refers to the body of domestic principles and rules applicable to transborder cases involving private relationships that contain at least one legally relevant foreign element. It is used to answer questions such as: What is the law applicable to a contract when the parties have their residence in different countries? Is a judge competent when the defendant does not have his residence in the judge's forum? Can a judgment from a foreign court or a foreign arbitral award be recognised in the judge's forum?

Private international law is part of the internal law of each State and in that sense, differs from public international law that regulates the relations among sovereign States and international organisations.

Some private international law rules have been harmonised at the international level by way of multilateral or bilateral treaties.

In Canada, private international law rules are part of the law of the provinces and territories and differ from one Canadian jurisdiction to another.

1. Access to justice and alternative dispute resolution

In terms of facilitating alternative dispute resolution mechanisms, Canada is one of the 143 States party to the *United Nations Convention on the Recognition and Enforcement of Foreign Arbitral Awards* (New York Convention) and the Convention is implemented in all Canadian jurisdictions. This Convention is widely recognized as a foundation instrument of international arbitration and requires courts of contracting States to give effect to an agreement to arbitrate when seized of an action in a matter covered by an arbitration agreement and also to recognize and enforce awards made in other States, subject to specific limited exceptions.

Moreover, all Canadian jurisdictions implemented the UNCITRAL *Model Law on International Commercial Arbitration* on arbitral procedure and one Canadian province, Nova Scotia, has implemented the UNCITRAL *Model Law on International Commercial Conciliation* regarding the conciliation process.

We consider the above Convention important for the Compliance Technical Experts Group to consider in its work.

In addition, the TEG should also examine the International Chamber of Commerce Rules of Arbitration and the Permanent Court of Arbitration Optional Rules for Arbitration to determine whether these can provide approaches that achieve the "fairness and equity" referred to in the question.

2. Access to courts by foreign plaintiffs

Canadian and foreign citizens have equal access to courts as Canadian citizenship is not a prerequisite. However, in commercial and civil matters, foreign citizens do not have access to free legal aid.

Judicial cooperation among States is key to facilitate the judicial process for foreign applicants. Canada is among the 57 States party to the Hague *Convention on the Service Abroad of Judicial and Extrajudicial Documents in Civil or Commercial Matters* which facilitate the service of documents abroad. Canada is also a party to many bilateral treaties on judicial cooperation regarding service of documents and taking of evidence abroad.

3. Mutual recognition and enforcement of judgments

Under the Canadian Constitution, the recognition and enforcement of foreign judgments falls under the legislative authority of provinces and territories, with the possible exception of matters within the jurisdiction of the Federal Court. This means that in considering whether a foreign judgment is enforceable in Canada, one must look to the law of the particular province or territory where enforcement is sought.

It can be said that, generally in Canada, the recognition and enforcement of foreign judgments in civil and commercial matters is relatively easy to obtain, although there are indirect jurisdictional controls and procedural rules to consider.

Canada is a party to one bilateral treaty on the recognition and enforcement of judgments in civil and commercial matters, that is the 1984 *Convention between Canada and the United Kingdom of Great Britain and Northern Ireland providing for the Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters* that is in force and was implemented by legislation adopted in all Canadian jurisdictions except Quebec.

It should be noted that several provinces in Canada have adopted reciprocal enforcement of judgments acts that enable the enforcement of judgments from specific jurisdictions on a reciprocal basis.

In 2005, the Hague Conference on Private International Law adopted the *Convention on Choice of Court Agreements*. This Convention sets rules for when a court must take jurisdiction or refuse to do so where commercial parties have entered into an exclusive choice of court agreement. The Convention also provides for the recognition and enforcement of resulting judgments, with an option for States party to agree on a reciprocal basis to recognize judgments based on a choice of court agreement that was not exclusive. In Canada, the Uniform Law Conference of Canada will soon be drafting a uniform implementing act to be proposed to the provinces and territories for adoption.

Again, we consider this Convention something that the Compliance TEG should consider in its work.

4. Civil and commercial remedies in contractual matters

There are mainly two areas where private international law rules may intervene in the case of a contractual dispute where one of the parties is not resident in the forum State or if there was any other foreign element. First, the forum court would have to decide on its jurisdiction and secondly, it would have to determine the applicable law.

4.1 Jurisdiction of the forum court

Common law courts in Canada have jurisdiction when the defendant is present in the forum. They also have jurisdiction where there is a real and substantial connection between the contract and the forum. Examples of real and substantial connection to the forum are found in the rules of court in the common law provinces permitting the service of defendants outside the territory of the forum and also in the jurisprudence. In addition, British Columbia and Saskatchewan adopted the Uniform Law Conference of Canada's *Court Jurisdiction and Proceedings Transfer Act* that provides a list of presumptive real and substantial connections to the forum.

For example, in Alberta rules of court, courts would have jurisdiction where the proceeding is to enforce, rescind, resolve, annul or otherwise affect a contract or to recover damages or obtain any other relief in respect of the breach of a contract, being a contract made within the forum, made by or through an agent trading or residing within the forum on behalf of a principal trading or residing out of the forum or which is by its terms, or by implication governed by the forum law, or in which the parties thereto agreed that the forum courts shall have jurisdiction to entertain any action in respect of the contract.

Quebec courts have jurisdiction in personal actions of a contractual nature where: 1) the defendant has his domicile or his residence in Quebec; 2) the defendant is a legal person, is not domiciled in Québec but has an establishment in Quebec, and the dispute relates to its activities in Quebec; 3) a fault was committed in Quebec, damage was suffered in Quebec, an injurious act occurred in Quebec or one of the obligations arising from a contract was to be performed in Quebec; 4) the parties have by agreement submitted to it all existing or future disputes between themselves arising out of a specified legal relationship; or 5) the defendant submits to its jurisdiction.

However, Quebec courts have no jurisdiction where the parties, by agreement, have chosen to submit all existing or future disputes between themselves relating to a specified legal relationship to a foreign authority or to an arbitrator, unless the defendant submits to the jurisdiction of the Quebec authority.

4.2 Applicable law

Canadian private international law rules on determining the applicable law in contractual matters promote party autonomy and the justifiable expectations of the contracting parties, subject to the need to protect weaker parties.

4.2.a Express choice made by the parties

In common law provinces, when the parties have expressly chosen an applicable law in their contract, that law would govern the contract given the choice is bona fide, legal and there is no reason for avoiding it on public policy grounds. In the leading case, Vita Food Products Inc. v. Unus Shipping Co., the Privy Council held that the parties' expressed intention should determine the proper law of a contract, provided that the application of that law is not contrary to public policy, and the choice was bona fide and legal. However, courts will disregard the choice of a law expressly made to evade the system of law with which the transaction, objectively considered, is most closely connected. The choice of the parties may be inferred from the circumstances.

In Quebec, the court is bound by the express choice made by the parties, even if the contract has no foreign element. However, in the case where there is no foreign element, the contract remains subject to the mandatory provisions of the law of the country which would apply if no law was chosen.

4.2.b No express choice made by the parties

Where the parties have not selected a governing law and it cannot be inferred from the circumstances, the common law courts will apply the system of law with which the transaction has its closest and most real connection or "the proper law of the contract".

There are facts that may influence the determination by the judge of the law that is the most closely connected to the transaction. The court would look, for example, at such factors as the place of performance, the place of residence or business of the parties and the nature and subject matter of the contract.

In Quebec, Article 3112 of the Quebec Civil Code is to the effect that if no law is designated in the contract, the courts apply the law of the country with which the act is most closely connected, in view of its nature and the attendant circumstances and Article 3113 presumes an contract to be most closely connected with the law of the country where the party who is to perform the obligation which is characteristic of the act has his residence or, if the act is made in the ordinary course of business of an enterprise, his establishment.

The foregoing illustrates that detailed private international law rules are already in existence and currently regulate transborder cases involving private relationships that contain at least one legally relevant foreign element.

Violations of National ABS Laws, including PIC

Although partly addressed under question (c), there are some aspects of question (a) that touch upon matters of criminal or quasi-criminal law. In particular, (a)(iii) refers to "sanctions…in criminal matters" in the context of ensuring compliance with national ABS legislation and requirements, including prior informed consent. A key point is that if measures are sought for the international regime to address compliance with national ABS laws, these are going to be substantially different than those addressing contract (MAT) compliance concerns.

At the current time, it appears that many jurisdictions around the world have not yet enacted explicit national laws regulating access to genetic resources and therefore issues of non-compliance with such laws do not yet exist for them. Other jurisdictions have enacted approaches which are quite different from each other. These two facts need to be taken into account when approaching the issue of compliance with national ABS laws.

At the national level, national ABS legislation could be subject to a range of tools to promote compliance, from voluntary compliance promotion measures such as educating providers and users, to inspections, investigations, warnings and prosecution, the latter possibly resulting in sanctions.

Where wrongdoing crosses borders, national extradition and mutual legal assistance laws exist to facilitate international cooperation. Canada's commitment to mutual legal assistance is well-established at both the investigative and prosecutorial levels. Canada is party to the *Convention against Transnational Organized Crime* which provides a basis for international cooperation in the absence of a specific bilateral treaty. This treaty contains provisions regarding extradition and mutual legal assistance, enforcement cooperation, and confiscation and seizure. The treaty applies to certain defined crimes as well as other serious offences which are transnational in nature and involve an organized criminal group.

Serious offence is defined as conduct which is punishable by at least four years of imprisonment while organized criminal group is defined as a group of three or more persons, existing for a period of time and acting in concert with the aim of committing one or more serious crimes in order to obtain a financial or other material benefit.

Canada has bilateral and multilateral treaties dealing wholly or partially with mutual legal assistance. Canada's *Mutual Legal Assistance in Criminal Matters Act* is the legislation which enables Canadian authorities to give effect to treaty requests to obtain search warrants, evidence gathering orders and other warrants available under the *Criminal Code* on behalf of a requesting state, assuming the legal and evidential basis for the order exists.

The *Extradition Act*, along with the relevant extradition agreements, provides the legal framework to extradite persons from Canada on the request of an extradition partner for the purposes of prosecuting that person, imposing a sentence upon them or enforcing a sentence imposed on that person. Generally, the offence in respect of which the extradition is requested must be punishable by imprisonment of at least two years. Canada cooperates with other countries to extradite individuals in appropriate cases, including its own nationals, when trafficking offences are committed abroad.

Without necessarily supporting its use for genetic resources, given that the Working Group has not agreed to work from a criminal law framework at this time, Canada would at least expect that the *Convention against Transnational Organized Crime* would be examined by the compliance TEG as an existing tool in public international law that could be relevant. It touches on the issue of criminalization, extradition and mutual legal assistance, enforcement cooperation, confiscation and seizure, forfeiture and witness protection.

Where national ABS laws include minimum benefit-sharing standards, this could involve an inappropriate use of the criminal law to enforce civil contracts; this is not generally considered to be an acceptable use of criminal law, which should not be used lightly. Conduct should only be declared criminal and associated with punitive consequences if there exists no other less restrictive means of social control to engage in such behaviour.

Further comments on the criminal law can be found in the Input to Question (c).

Other Measures that could be developed

Under the heading of measures that "could be developed", two measures have been proposed which are worthy of commentary at this time in order to support the work of the TEG: patent application disclosure and the possibility of a national certificate of compliance.

Patent Application Disclosure

In recent years and in various *fora*, developing countries have called for the adoption of a disclosure regime, whereby patent applicants would be required to identify the source/origin of any genetic material contained in their invention. According to its proponents, there are two main objectives to implementing a disclosure requirement. First, disclosure of the source/origin of genetic resources (GR) in patent applications is advocated as a compliance measure/checkpoint for access and benefit-sharing arising from the utilization of such resources. Second, the introduction of a disclosure requirement could improve prior art searches. Canada would offer the following comments on patent disclosure:

- **A disclosure requirement that would invalidate patents could entail legal uncertainty:**

Some proponents of the disclosure requirement argue that failure to comply should result in the invalidation of the patent. However, this would undermine the certainty of patents as they would be

subject to attack by third parties over the accuracy and completeness of the disclosure making. The biotechnology sector relies heavily on capital investment to fund research and innovation. Without a reasonable degree of certainty, such capital investment is likely to decrease and result in lower research and development efforts[1].

Other disclosure proposals have also been advanced, including some in which penalties for non-compliance would lie outside of the patent system. However, such options would still require legislative changes to implement a disclosure obligation in patent legislation and it could be possible to challenge a patent on the grounds of wrongful or insufficient disclosure with existing legal mechanisms under patent law. In addition, it could lead to an increase of the workload of patent offices.

- **Patents only cover a limited proportion of GR uses:**

Not all GR-derived products and uses are patented or even patentable. For example, the botanical medicine industry, which makes a direct use of GR does not rely on the patent system yet it was worth $40 billion dollars in 1997.[2] A disclosure requirement in the patent system would not facilitate the sharing of benefits arising from the use of GR in such an industry.

- **Patents are not a measure of commercial success**

Because of the "first to file" practice of most patent legislation, patents are filed long before actual commercialisation could occur. In fact, obtaining a patent is no guarantee of actual commercial success. Only 3000 out of the 1.5 million patents in force in the US are commercially viable, for a success rate of 0.2%[3]. In the absence of any commercial exploitation/success (and thus benefits), it is difficult to see how a disclosure requirement linked to the patent system can ensure sharing of monetary benefits.

Many patented GR are used as research tools and may be far removed from the commercial product. In this case, it is unclear how a disclosure requirement linked to the patent system can ensure proper monetary benefit sharing when the patent GR is not a significant part, if at all, of the commercialised product.

- **A disclosure requirement is unlikely to achieve its stated goals:**

If insufficient or wrongful disclosure can lead to the invalidation of the patent, the original right holder over the genetic resources will not have any benefits to share. Likewise, the decrease in investments resulting from a decreased certainty of the patent system will reduce the potential benefits arising from the use of GR.

From a prior art search perspective, it is unclear how disclosure of the country of origin/source will achieve better prior art searches. Very few countries hold GR databases that would facilitate searches. Moreover, GR are seldom limited to one source country, therefore limiting the prior art search to the source country may in fact reduce the scope of the search.

Moreover, even some of the supporters of a disclosure requirement agree that it would not be sufficient by itself to ensure the sharing of benefits arising from the use of GR[4].

[1] Bio, BIOTECanada, EuropaBio and CropLife, letter to the members of the TRIPS council, WTO, October 23, 2006. http://bio.org/ip/letters/20061023.pdf

[2] Worldwide figures; ten Kate and Laird in "The commercial use of biodiversity", p. 78-79

[3] "Avoiding the Inventors Lament", Business Week, November 10, 2005.

[4] WTO, The relationship between the trips agreement and the convention on biological diversity (CBD) and the protection of traditional knowledge, Submission from Brazil and India IP/C/W/443

National Certificates of Compliance

Another measure that has recently been raised as a possibility is a national certificate of compliance, currently a "brick" in our negotiations. Our understanding of this is that these would be certificates that would indicate that a genetic resource was obtained in compliance with any national ABS laws that may exist within a country. Such certificates could be used in a wide range of future transactions in order for the user to be able to have some legal certainty about the genetic resource that has been access. This could be a very useful tool for the Technical experts Group to examine further, including the following issues:

- How could the system allow for a distinction between resources coming from a territory requiring a certificate and those originating from territories without such a requirement?
- Would those participating in the international regime be placed at a competitive disadvantage to those not so participating?
- How could minimum standards or requirements regarding access be addressed under this system?
- The need for a cost-benefit analysis, including in particular the cost of administrative implementation
- An impact assessment on human and financial resources in developing countries
- The identification of effective checkpoints
- Identification of new technologies that could be used and an assessment of capacity needs in countries in relation to this.

Canada considers that any system incorporating a certificate of compliance should respect and recognize the Standard Material Transfer Agreements of the International Treaty on Plant Genetic Resources for Food and Agriculture as the certificate concerning materials that were obtained under that Treaty's Multilateral System for ABS.

Question (b): What kind of voluntary measures are available to enhance compliance of users of foreign genetic resources:

Input to Question (b):

Compliance means conformity with norms, which can include both voluntary and legal norms. Nor does compliance with even legal norms necessarily have to be addressed using only legal sanctions and mechanisms. Voluntary measures may be a means to achieve the goal of having users comply with ABS requirements when accessing foreign genetic resources. Voluntary tools that can be used to enhance compliance of users of foreign genetic resources range from education and awareness-raising initiatives to guidelines, codes of conduct and best practice, to voluntary certification schemes. Voluntary measures can be taken at both the national and international levels.

Education and awareness-raising

One of the main gaps relating to compliance with access and benefit-sharing requirements is the general lack of awareness of the Convention on Biological Diversity (CBD) and its third objective and the ABS requirements in different countries. This gap, as identified in document UNEP/CBD/WG-ABS/5/3, appears to be confirmed in Canada by the results of a recent survey among users of genetic resources developed by the Quebec government[5] and could represent the principal explanation for non-compliance

[5] Hélène Gilbert, *Portrait de l'usage des ressources génétiques au Québec : Résultats et analyse d'un sondage auprès des utilisateurs de ressources génétiques*, Québec, Société Provancher d'histoire naturelle du Canada, 2008, 61 pp.

with foreign legislation on ABS. Awareness-raising and communication tools on ABS are probably one of the most cost-effective ways of improving compliance of foreign users of genetic resources.

In Canada, a number of workshops have been held over the last few years[6] with different stakeholders and a government website dedicated to ABS was launched in May 2007[7].

Yet, the awareness level among Canadian users of genetic resources remains generally poor. Countries that have enacted ABS legislation could endeavour to ensure a sufficient level of information is readily available to those who want to obtain access to their genetic resources, for both the user and the provider.

Incentives

Incentives are a potentially useful tool to increase compliance of users accessing foreign genetic resources. Such incentives could include, for example, enhanced grants for research organizations that comply with ABS rules. Incentives have a number of advantages such as encouraging proactive behaviours, providing more flexibility than regulation and potentially requiring less time for implementation[8].

Voluntary measures for compliance promotion

Statements of principles, guidelines, codes of conduct, best practice and eventually third-party certification are all voluntary measures that have been implemented to enhance compliance**.** A number of guidelines, codes of conduct and best practice examples already do exist with respect to ABS. While some of these voluntary tools have been developed by governments (sometimes with collaboration of other stakeholders)[9], some also have been elaborated by individual stakeholders or associations of stakeholders[10]. The effectiveness of these voluntary tools is however difficult to assess in the absence of third-party verification. Third-party assessment is a process by which an independent organization assesses the level of compliance with a set of standards or norms. Such a system strongly contributes to the credibility of codes of conduct or guidelines. Unbiased assessments are supported by operational independence[11].”

[6] Science and Technology Experts Workshop (Ottawa, December 2004), Northern Workshop on Access to Genetic Resources and Associated Traditional Knowledge and Benefit-sharing (Whitehorse, March 2005), Workshop on Genetic Resources in Canadian Agriculture (Saskatoon, November 2005), Workshop on Forest Genetic Resources (Fredericton, February 2006).

[7] http://www.ec.gc.ca/apa-abs

[8] Kathleen Segerson and Thomas Miceli, “Voluntary Environmental Agreements: Good or Bad News for Environmental Protection?”, *Journal of Environmental Economics and Management*, no. 36, 1998, p. 110

[9] See among others, the *Guidelines for Access to Genetic Resources for Users in Japan,* (METI and JBA, 2006), the *ABS Management Tool - Best Practice Standard and Handbook for Implementing Genetic Resources Access and Benefit-sharing Activities* (Stratos and Swiss Department of Economic Affairs, 2007), *Access and Benefit-sharing, Good practice for academic research on genetic resources* (Swiss Academy of Sciences, 2006)

[10] See among others the *Guidelines for BIO Members Engaging in Bioprospecting* (Biotechnology Industry Organization, 2005), the *Principles on Access to Genetic Resources and Benefit-sharing* (Botanical Garden Conservation International, 2000) or the *Guidelines for IFPMA Members on Access to Genetic Resources and Equitable Sharing of the Benefits Arising out of their Utilization* (International Federation of Pharmaceutical Manufacturers and Associations, 2007). Some individual companies have developed or publicly committed themselves to respect ABS requirement: e.g. GlaxoSmithKline (http://www.gsk.com/responsibility/cr_issues/ei_biodiversity.htm), NovoNordisk Guiding Principles (http://www.novonordisk.com/old/press/environmental/er97/bio/biodiversity.html).

[11] Lyle Glowka, *Towards a Certification system for Bioprospecting Activities*, Berne (Switzerland), Secrétariat d’État à l’économie, 2001, p. 10

Third-party voluntary certification for compliance

A further compliance promotion measure is third-party voluntary certification. Certification can be defined as "a method for verifying compliance with a set of agreed standards[12]." In third-party certification, compliance is assessed independently and certified. This type of system has gained great popularity in recent years, and particularly in the area of environmental policy, where certification standards enacted by ISO and the Forestry Stewardship Council (FSC), among others, have seen relatively good adoption rates[13].

Under such a certification scheme, a bioprospector or researcher would obtain certification that they complied with the appropriate ABS standards. Voluntary certification schemes have the advantage of providing flexibility for their implementation. Advantages of such a system could include enhanced trust facilitating access for certified users, defence from biopiracy claims, facilitating review of GR management systems and potential to attract investment from socially and environmentally responsible investors[14].

A requirement for a voluntary certification scheme would be common agreement on standards and norms from stakeholders (business, researchers and academics, and providers of genetic resources, including indigenous and local communities and governments).

Electronic Databases

The TEG should consider the value of electronic databases in support of monitoring and enhancing compliance of users of foreign genetic resources.

Question (c): Consider how internationally agreed definitions of misappropriation and misuse of genetic resources and associated traditional knowledge could support compliance where genetic resources have been accessed or used in circumvention of national legislation or without setting up of mutually agreed terms;

Input for Question (c):

All countries have the sovereignty to regulate and enforce matters within their own territorial jurisdiction, but lack the capacity to enforce their laws within the jurisdiction of another sovereign state. "T[t]he enforcement jurisdiction of a state is in fact *limited* to its territory absent some special rule of international law or other basis permitting the exercise of such jurisdiction abroad."[15]

Thus, as noted under Question (a), individual states have the power to take steps to ensure that their own ABS laws are enforced, but cannot enforce their laws within other states.

[12] Charles Victor Barber, Sam Johnston and Brendan Tobin, *User Measures: Options for Developing Measures in User Countries to Implement the Access and Benefit-Sharing Provisions of the Convention on Biological Diversity*, Tokyo, United Nations University/Institute of Advanced Studies (UNU/IAS), 2003, p. 23

[13] The International Organization for Standardization (ISO) published the first set of environmental management standards ISO 14000 and ISO 14001in 1996. The Forest Stewardship Council (FSC) founded in 1993 certifies sustainable forest management. It is now the most important voluntary certification scheme in the forestry sector in the world with over 100 millions hectares of certified forests in more than 80 countries.

[14] Lyle Glowka, *Op. Cit.* p. 45

[15] John H. Currie, *Public International Law*, 2d ed. (Toronto, 2008), at 335.

This question appears to be an attempt to address the concerns of those who have proposed that each country would agree to enforce, within its territory, the laws of other states. It would be unusual in criminal matters to agree to enforce the unexamined criminal or quasi-criminal laws of any state around the world; rather, where a criminal law framework is desired, the typical approach is that the international community agrees on a common "harm" that is the subject of criminalization and then attaches related obligations around extradition, mutual legal assistance, etc. It is also important to note that of those jurisdictions which have national ABS laws, the approaches vary substantially, and many countries may not wish to change them to adapt to an internationally agreed approach.

Question (c) suggests that should there be a desire to consider whether to approach this issue internationally from a criminal law framework, an internationally agreed definition of the proscribed act would be the starting point for any such approach. With an internationally agreed approach, each country would then be simply enforcing its own laws within its jurisdiction.

Question (d): How could compliance measures take account of the customary law of indigenous and local communities?

Input to Question (d):

At the domestic level, the Government of Canada presently takes a circumstance and purpose specific approach to the recognition and incorporation of the customary laws of the Aboriginal peoples of Canada in mainstream Canadian law, rather than a full scale incorporation and recognition of the customary laws of Aboriginal peoples of Canada. This is because of a number of considerations, including the largely oral form of transmission of customary laws, the diversity of indigenous legal traditions across the country and the complexities involved in their recognition and incorporation into mainstream Canadian law. However, Canada continues to be engaged in discussions with various Aboriginal groups to explore options and opportunities for the recognition and incorporation of some customary laws in mainstream Canadian law. As such, the customary laws of the Aboriginal peoples of Canada have been recognized, in specific circumstances and for specific purposes, into various statutes, the common law (i.e. marriage and adoption), self-government agreements or governmental initiatives.

For example, a number of federal, provincial and territorial statutes make references to or have attempted to incorporate customary laws to a certain extent. For example, the federal *Indian Act* recognizes some form of indigenous legal traditions such as customary elections and the adoption of membership codes in some cases. Other statutes have attempted to include principles of customary laws or traditional knowledge, mostly in relation to the environment and wildlife (i.e. *Canadian Environmental Assessment Act*, *Species at Risk Act*, the Nunavut *Wildlife Act*).

Further, self-government agreements that have been concluded between federal and/or provincial and territorial governments and Aboriginal groups (and the implementing statutes), or are in the process of being negotiated, may recognize that Aboriginal communities may choose to incorporate their customary laws in certain areas of jurisdiction that are defined in those agreements. However, it is important to clarify that federal, provincial and territorial laws continue to apply and prevail, subject to the terms of any negotiated agreement specifically providing that laws enacted by an Aboriginal community will prevail in the event of a conflict.

Customary laws of the Aboriginal peoples of Canada are also being taken into account in the delivery of community justice programs and services, such as the programs funded through the Department of Justice's Aboriginal Justice Strategy. Further, the values and principles underlying the customary laws of Aboriginal communities have found their expression in resource co-management agreements as well as negotiated protocols and agreements related to benefit-sharing.

At present, there is a lack of common understanding about what constitutes customary laws and there is therefore much uncertainty about the nature and scope of customary laws, both at the domestic and international levels. It is also unclear whether "taking account" of the customary laws of indigenous and local communities would require the recognition of the customary laws of those groups within Canada, and would also require the recognition of the customary laws of indigenous groups in other countries. Would recognition of customary laws imply that Parties are being asked to ensure extra-territorial compliance with the customary laws of indigenous and local communities of foreign countries? Recognition and incorporation of those customary laws would be overly ambitious and extremely challenging in light of the present uncertainty.

Canada is committed to engaging Aboriginal peoples on the development of a national ABS policy. However, policy decisions have yet to be made as to how the customary laws and/or traditional knowledge of Aboriginal peoples will be incorporated under the Canadian policy.

The TEG should consider whether the issue of customary law is best left to national ABS implementation rather than as a compliance measure for the international regime.

Question (e): Analyse whether particular compliance measures are needed for research with non-commercial intent, and if so, how these measures could address challenges arising from changes in intent and/or users, particularly considering the challenge arising from a lack of compliance with relevant access and benefit-sharing legislation and/or mutually agreed terms.

Input to Question (e):

Compliance measures are best determined and implemented at the domestic level, to reflect the national ABS regime. They will depend on several factors, including: the nature of the domestic regime, the process for granting access and the specific content of the mutually agreed terms. The specific mechanics of compliance for commercial and non-commercial access to genetic resources should be left to implementation at the national level. Research is the foundation of many major scientific discoveries and innovations and, to the extent possible, should not be impeded by a regime on access and benefit sharing.

Commercial and non-commercial intent

Most *in situ* genetic resources are primarily accessed by non-commercial research oriented organizations, for example, university professors and students, biologists working for public research institutes, taxonomists etc[16]. However, it is impossible to predict at the outset of research whether subsequent study and analysis of the collected samples will result in potential commercial applications or not. For direct commercial activity many large firms are licensing, or forming partnerships with, small companies and universities in the initial steps of product discovery from natural products discovery research. Sometimes commercial applications may result after a number of transfers of the genetic resource to third-parties from the original accessor (e.g. other researchers, private company laboratories)[17]. In these circumstances, it becomes very complex to distinguish non-commercial from commercial research.

The operations of commercial and non-commercial users in accessing genetic resources can be very similar. For instance, the International Chamber of Commerce notes that small and medium-sized enterprises "face margins and economic realities more akin to those encountered by non-commercial

[16] Kerry ten Kate and Sarah A. Laird *The commercial use of biodiversity*, London, Earthscan, 1999, p. 5

[17] Sarah A. Laird and Rachel Weinberg, *The Commercial Use of Biodiversity: An Update on the Current Trends in Demand for Access to Genetic Resources and Benefit-Sharing, and Industry Perspectives on ABS Policy Implementation*, December 2005, UNEP/CBD/WG/4/INF/5, p. 10

researchers than larger firms. Accordingly, a regime that draws a line between commercial and non-commercial use may erect barriers that preclude activities by the important SME segment."[18] This further suggests that separate compliance mechanisms, in particular relating to access, are not needed. The value of research (whether it is taking place with commercial or non-commercial intent) is knowledge generation, innovation and improvement.

Both non-commercial and commercial researchers will be expected to comply with the domestic requirements for obtaining prior informed consent (PIC) to access a genetic resource in countries that have enacted them. Minimally, non-compliance with PIC could constitute trespass, theft or a contract violation and would be dealt with under domestic law.

Strong consideration should be given to voluntary measures that address compliance issues and complement the Bonn Guidelines. For example, sectoral menus, model clauses, material transfer agreements, codes of conduct for users, and identification of best practices have been demonstrated to be practical and effective mechanisms for promoting compliance in many sub-sectors.

Change of intent

It is difficult to foresee with any accuracy if or when non-commercial research would become applied research with commercial intent. Specifically, it would be difficult to identify scenarios where research undertaken would never have potential commercial value, in particular once knowledge has entered the public domain and others are free to use it to generate further innovation. Furthermore, while in early stages of research the intended outcome may be strictly non-commercial, it is impossible to predict whether this research could be used for different purposes that could not have been foreseen in earlier stages.

Nevertheless, whether the final use of the research is for commercial or non-commercial purposes, compliance is enhanced where there are transparent, non-discriminatory, and practical access and benefit-sharing arrangements in advance of access and the commencement of research, although approaches do vary from sector to sector.

Although it is difficult to ensure research would only strictly have either commercial or non-commercial uses, domestic regimes are best placed to determine whether any specific compliance measures are needed for certain purposes. There are a number of existing national laws which provide examples on how change of intent can be addressed. Provisions for compliance relating to change of intent or transfer to third-party could be included in national ABS regimes as part of the legal requirements for the PIC procedure and/or they could be negotiated between the provider and user of genetic resources under the MAT.

Example: Addressing change of intent and transfer to third-party under prior informed consent (PIC)

Change of intent or third party users can be addressed under the procedure to obtain PIC. The Australian procedure for obtaining prior informed consent for access to genetic resources requires the applicant to indicate if the access is being sought for non-commercial or commercial or *potentially* commercial purposes. If the research is for non- commercial application there is a statutory declaration that the applicant will not use the biological resources for commercial purposes, not transfer any sample without

[18] International Chamber of Commerce "Access and Benefit Sharing: Sectoral approaches, Concepts, Terms, Working Definitions" (Submission to the Technical Experts Group on Concepts, Terms, Working Definitions and Sectoral Approaches. Paris. October 2008)

permission of the Commonwealth of Australia and not allow others to carry out research or development for commercial purposes unless a benefit-sharing agreement is entered into[19].

Example: Addressing change of intent and transfer to third-party under mutually agreed terms (MAT)

Provisions relating to change of intent are also typically included under MAT. Under the model Cooperative Research and Development Agreement (CRADA), prepared by the United States National Park Service for collection of genetic resources in U.S. National Parks, the user (the *Collaborator*) is given the choice to negotiate benefit-sharing agreements/arrangements at the time of access or to defer negotiation until such time as they wish to use their research results for *Commercial Purposes*:

> Collaborator agrees to provide written notification to NPS when any Progeny, Unmodified Derivatives, Modifications, Subject Invention or Product is to be used for any Commercial Purpose not less than sixty (60) days prior to such use to ensure compliance with the provisions of paragraph 5.1 [sharing of the benefits] of this CRADA.[20]

The user is prohibited from using any research results for commercial purposes until a benefit-sharing agreement is completed. Other provisions in the model NPS CRADA that address change of intent are the requirement for periodic reports on the research activities, NPS audits[21] and requirement to disclose to the National Park Service any *Subject Invention* that may be patentable *or otherwise protectable*[22].

Clauses relating to transfer to third-parties and sublicensing are a common feature of Mutually Agreed Terms and Material Transfer Agreements. In some cases, the prior consent of the original provider of the material is required. In the case of the Cooperative Research and Development Agreement (CRADA) of the United States National Park Service, the third-party must assume in writing the performance of the terms and conditions of the CRADA[23]. In other cases, a new agreement has to be concluded with the third-party normally with particular conditions to ensure consistency between both agreements[24].

Pre-existing obligations and practices

Compliance measures should be respectful of pre-existing treaty obligations and the work and expertise of other international bodies; for example, any new measures should recognize that plant genetic resources for food and agriculture are already covered by the *International Treaty on Plant Genetic Resources for Food and Agriculture* (ITPGRFA) under the United Nation's Food and Agriculture Organization (FAO).

The ITPGRFA promotes cooperative and effective operational mechanisms to promote compliance with its Standard Material Transfer Agreement. These include "monitoring, offering advice or assistance, including legal advice or legal assistance, when needed, in particular to developing countries and countries with economies in transition."

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[19] *Statutory Declaration* form available at: http://www.environment.gov.au/biodiversity/science/access/pubs/stat-dec.doc, Consulted November 6th, 2008.

[20] National Park Service U.S. Department of the Interior, *Benefits-sharing Draft Environmental Impact Statement Article 5*, September 2006, p. 194

[21] *Ibid.* Article 4.1 and 4.4, p. 192-193

[22] *Ibid.* Article 7.1, p. 195-196

[23] *Ibid.* Article 15.1, p. 204

[24] Australian National Botanic Gardens, *Model Material Acquisition Agreement Between [Partner Institution] and [Participating Garden]*, Article 4.3, http://www.chabg.gov.au/chabg/cpg-kew/Model-Material-Acquisition-Agreement.html, Consulted November 6th, 2008

Existing practices in the agricultural sector, for example, also demonstrate that compliance can be achieved successfully for research with commercial and non-commercial intent by enhancing trust and sharing, ensuring transparency in the requirements for Prior Informed Consent, and agreeing on the sharing of benefits through mutually-agreed upon terms between Contracting Parties.

Example: Compliance within the Plant Herbaria Community of Practice in Canada

The National Collection of Vascular Plants (DAO) is part of an international cooperative network involving loans of preserved specimens and exchange of information for taxonomic research. The Collection operates with conditions for use and formal loan terms which aim to facilitate access as well as ensure the safe keeping of materials for future uses.

Data and specimens provided by DAO are provided for research purposes, and their use is the responsibility of both the lending curator and the borrowing curator representing an institution and an individual using the borrowed material. There are specific guidelines on how specimens must be stored, handled, and how they must be referenced in publications. Specimen loans for projects of a specifically commercial nature require permission from the DAO. In this instance, "commercial purposes" does not include the sale of publications derived from research that are in public domain. It does include the sale, or transfer or transmission of unpublished information (e.g. list or databases of specimens or taxon attributes) or images, to third parties.

To ensure compliance with the conditions for use (either commercial or non-commercial) of specimens, the loan agreement states: "The consequences of any lack of attention to these conditions, for example leading to unreasonable damage to specimens, will result in limited future access." Although neither regulatory nor legally binding, this provides considerable incentive for the receiving institution or individual to comply with the loan conditions. Between 1 April 2007 and 31 March 2008, the DAO loaned out 2,798 specimens, representing 30 individual loans and exchanges without any cases of non-compliance.

EUROPEAN COMMUNITY AND ITS MEMBER STATES

EU submission in response to Notification 2008-116 to the ABS Group of Legal and Technical Experts on Compliance – Tokyo 27-30 January 2009

INTRODUCTION

The "International Regime"-Annex to CBD Decision IX/12 includes a range of components in Section III.C. on Compliance. Components that Parties agreed to further elaborate with the aim of incorporating them in the international regime are tools to encourage, monitor and enforce compliance, for instance, awareness-raising activities, mechanisms for information exchange or an internationally recognized certificate issued by a competent domestic authority. Other tools that Parties agreed to further consider are tools to encourage, monitor and enforce compliance, for instance, sectoral menus of model clauses for material transfer agreements, disclosure requirements, codes of conducts for important groups of users, an international understanding of misappropriation as well as information technology for tracking. The experts participating in this group are mandated to look at a fairly generic set of questions. It would therefore be useful if the experts were to identify in their report, where appropriate, specific consequences that flow from their more generic discussion for specific components under consideration in the ABS WG. This would be in line with the mandate given to the experts to "assist" the ABS Working Group in the further negotiation of the international ABS regime and to "provide legal and, as appropriate, technical advice, including where appropriate, options and/ or scenarios."

The EU looks forward to the deliberations of the experts in this ad hoc technical expert group and expects to benefit from the advice of the experts particularly regarding the following issues:

- The relevance of sectoral menus of model clauses for potential inclusion in Material Transfer Agreements to support compliance with ABS requirements;
- The role of existing agreements and mechanisms under public and private international law in supporting ABS compliance;
- The relevance of national decision-making on access for compliance with ABS requirements set out in prior informed consent decisions and mutually agreed terms;
- The relationship between measures taken by Parties to support compliance of users under their jurisdiction to national decision-making on access to genetic resources in parties providing genetic resources under the international ABS regime.

TERMS OF REFERENCE OF THE ABS LEGAL AND TECHNICAL EXPERTS ON COMPLIANCE

What kind of measures are available or could be developed under **private and public international law** to facilitate access to justice/courts; facilitate recognition and enforcement of judgments and provide remedies.

Public international law covers the relationships between States. The main sources of public international law are international conventions, international custom, as evidence of a general practice accepted as law, and the general principles of law recognized by civilized nations[1].

[1] International Court of Justice Statute, Article 38

In contrast, private international law regulates relationships between private entities across borders. In particular, it seeks to regulate (1) which jurisdiction applies to a dispute; (2) which laws apply to the dispute and (3) whether and how eventual decisions or judgments are recognized and may be enforced in another jurisdiction. Each State has its own national rules on conflicts of laws, but some of these may have been harmonized through conventions, guidelines, and model laws. With respect to EC Member States, the rules on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters have been harmonized through Regulation (EC) No. 44/2001[2].

The relevance of public international law to the issue of ABS stems from Article 15 of the CBD in which Parties are required to implement Article 15 at the national level. Any dispute among Parties concerning the interpretation or application of Article 15 would be a matter of public international law and settled in accordance with Article 27 of the CBD.

The operation of Article 15 at national level could give rise to private international law issues considering that Mutually Agreed Terms (MAT) will normally be set out in a civil law contract.

1. Private international law

There are three main organizations involved in the harmonization of private international law, namely the Hague Conference on Private International Law[3], the International Institute for the UN Commission on International Trade Law (UNCITRAL)[4] and the Unification of International Law (UNIDROIT)[5].

The Hague Conference was established in 1893 and has 69 members. Its mandate is to work for the progressive unification of private international law and its work encompasses commercial law, banking law and international civil law procedures as well as family law. It has adopted a range of Conventions, the ones of most relevance to ABS being the 1971 Convention on the Recognition and Enforcement of Foreign Judgments in Civil and Commercial Matters, the 1970 Convention on the Taking of Evidence Abroad in Civil or Commercial Matters, the 1986 Convention on the Law Applicable to Contracts for the Sale of Goods, the 2005 Convention on the Choice of Courts and the 1980 Convention on International Access to Justice.

UNCITRAL was established by the UN General Assembly in 1966 with the mandate to further the progressive harmonization and unification of the law of international trade. It has a Commission composed of 60 members, who are appointed on an equitable geographical balance. It has produced various Conventions and soft law instruments, including the UN Convention on Contracts for the International sale of Goods plus rules on arbitration. While not developing the 1958 UN Convention on the Recognition and Enforcement of Foreign Arbitral Awards (the New York Convention), UNCITRAL actively promotes it.

The third organization UNIDROIT is an independent intergovernmental organization with 61 members. Its basic statutory duty is to prepare modern and, where appropriate, harmonized rules of private international law. Its primary focus is on substantive rules, and only includes conflict of law rules incidentally. It prepares conventions, model law and guidelines, the most relevant for the purpose of this discussion being the UNIDROIT Principles of International Commercial Contracts.

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[2] OJ L 012, 16/01/2001 p. 1-23. This Regulation binds all Member States apart from Denmark.
[3] http://www.hcch.net/index_en.php
[4] http://www.uncitral.org/
[5] http://www.unidroit.org/

Some of the instruments developed by these organizations have only a small number of Parties and therefore only limited application or are not yet in force. In addition they mainly apply, in some cases exclusively, to commercial transactions.

- ***Access to justice (including alternative conflict resolution)***

Contractual arrangements usually determine the way in which a dispute should be settled and include appropriate dispute settlement clauses. Such clauses provide legal certainty to the parties of a contract. An international regime could facilitate the enforcement of contractual obligations by encouraging the inclusion of (an) appropriate dispute settlement clause(s) in material transfer agreements and also, provide parties to an ABS contract with a (menu of) relevant model clause(s).

The choice of the jurisdiction is a critical issue when looking at a national law approach. The location of the defendant and his/her assets, the place of the breach, the extent of relevant national laws and the ability to enforce a judgment in another jurisdiction will, to a large extent, determine whether parties to ABS contracts bring a case in the provider or in the user country. The 2005 Convention on Choice of Court Agreements adopted under the Hague Conference, once in force, will become relevant within the jurisdiction of states that are Parties.

Where a contract, expressing MAT does not provide for a dispute settlement clause, the party seeking redress will fall back on national law rules on conflicts of laws and applicable private international rules.

From EU's perspective, a distinction could be observed between 1) judgments rendered within the Member States of the EU and 2) judgments rendered by third countries. In the first situation, the Brussels Convention of September 1968 on simplified procedures of Exequatur was concluded between EU Member States. Moreover, the Council Regulation (EC) No. 44/2001 is the EU legal basis for the recognition of judgments among Member States (except for Denmark). If a Member State recognized a foreign judgment within its jurisdiction, it has "*force obligatoire*" (can be enforced) within all Member States. However, Regulation 44/2001 does not apply to arbitral awards. In the second situation the recognition of judgments is possible according to national legislation and international agreements (bilateral / multilateral agreements mentioned above).

If an aggrieved party has been able to get access to justice and obtains a judgment in its favor, the next step is enforcement. This only becomes an issue when the defendant refuses to respect the Courts judgment. The Hague Conference's Convention on the Recognition and Enforcement of Foreign Judgments in Civil and Commercial Matters provides a mechanism for enforcement between Parties to it. But it has a limited membership of 4 Parties. Otherwise, enforcement would depend on national laws but would only cover civil law matters, and not criminal or similar public law measures.

Where a court has jurisdiction, the next issue would be to identify a cause of action and the applicable law. These issues would largely be decided by national law, which would also determine the available remedies.

In addition, the notion of 'access to justice' is underpinned by social equity issues, which look beyond purely procedural matters. This is to address the concerns of some Parties as to the high costs of litigating, especially in a developed country. In this regard the Hague Conference has adopted a Convention on International Access to Justice, which provides that nationals of any Contracting State shall be entitled to legal aid for court proceedings in civil or commercial matters on the same conditions as if they were nationals. The Convention is in force but has limited number of Parties (24

largely developed countries). In addition the Convention on Civil Procedures (45 Parties) also has provisions on legal aid.

- ***Alternative Dispute Resolution***

Alternative Dispute Resolution (ADR) covers a wide range of mechanisms which allow parties to resolve differences without recourse to national courts. Mediation and arbitration are both types of ADR. Mediation refers to a non-adversary, non-judicial process whereby a neutral third party attempts to steer parties to a mutually agreed settlement. It can be effective where both parties are acting in good faith to agree a mutually acceptable settlement. Arbitration is also a non-judicial process. It is a formalised series of rules and procedures which can be used by State, public bodies or private individuals. Parties must consent to arbitration (either upfront or after a contractual conflict has risen) and, where so agreed, the final arbitration award is binding on the parties.

Arbitration has become the preferred method of dispute resolution in many commercial sectors. It provides a flexible mechanism for parties to resolve disputes without recourse to national legal systems. This avoids some of the uncertainties associated with litigation in terms of jurisdiction, choice of law and enforcement and the resultant unpredictability on costs and time. One of the major benefits of arbitration is that it can be tailored to the needs of the parties. In this regard, specialist arbitrators, who are familiar with the area of dispute, can be selected.

There are numerous types of arbitration and arbitration bodies. A dispute may be submitted to an administered arbitration body or to an unadministered arbitration body (ad hoc) or parties to a contract may decide to establish a new 'standing' arbitration mechanism and rules, but this could be a costly and time-consuming exercise.

There are a number of well known and respected arbitration bodies, such as the ICC International Court of Arbitration, the London Court of International Arbitration (LCIA)[6], and the Permanent Court of Arbitration. These bodies could service the whole arbitration procedure, including service of documents and appointment of arbitrators. In addition, there is also a WIPO Arbitration and Mediation Centre[7] which deals with the resolution of international commercial disputes between private parties. Factors such as: who are the parties to the dispute (private or State), the location of parties, preference for certain procedures and experience of disputes within their sector, will determine the choice of arbitration forum.

Parties could also agree to establish an ad hoc arbitration and apply existing arbitral rules such as UNCITRAL or the London Court of International Arbitration.

Another significant advantage of arbitration is the relative ease of enforcement of judgments due to the 1958 UN Convention on the Recognition and Enforcement of Foreign Arbitral Awards (the New York Convention). Article III of the New York Convention provides that each Contracting State shall recognize arbitral awards as binding and enforce them in accordance with the rules of procedure of the territory where the award is relied upon.

An international award originating in a country that is a Party to the New York Convention may be enforced in any other Country that is a Party. Given that the New York Convention has 142 Parties there is wide global coverage.

[6] http://www.lcia-arbitration.com/
[7] http://www.wipo.int/amc/en/index.html

In an ABS context, some existing Material Transfer Agreements already include settlement of dispute clauses based on arbitration, notably in the standard Material Transfer Agreement of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). This practice is also reflected in the African Model Law[8].

A further noteworthy issue regarding contractual disputes is Article 12.5 of the ITPGRFA: "Contracting Parties shall ensure that an opportunity to see recourse is available, consistent with applicable jurisdictional requirements, under their legal systems,…recognizing that obligations arising under MTAs rest exclusively with the parties to those MTAs."

2. Public international law

Public international law regulates the relationship between states. Article 15.1 of the CBD stated that "*recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation*". Moreover, according to Art. 15.2 each Party are furthermore obliged to endeavor to create conditions to facilitate access to genetic resources (GR) for environmentally sound uses by other Parties and not to impose restrictions that run counter to the objectives of the CBD. In addition, art. 15.7 claims that Parties are obliged to take legislative, administrative or policy measures, as appropriate, with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of GR with the Party providing such resources and such sharing shall be on mutually agreed terms.

Where a dispute arises between Parties to the CDB concerning the interpretation or application of the CBD, Article 27 would provide Parties with a means to resolve disputes by first negotiation, then mediation and if so desired, be recourse to the arbitration procedures set out in Part I to Annex II and/or the submission of the dispute to the International Court of Justice (ICJ). If the parties to the dispute have not accepted the same or any procedure, the dispute shall be submitted to conciliation in accordance with Part 2 of Annex II unless the parties otherwise agree.

Certain benefit-sharing activities , for example, the establishment of in-country laboratories to carry out certain steps of research programmes and training, may be considered "investments" and might fall under the scope of bilateral investment treaties. Such treaties, which constitute part of the body of public international law, regularly contain a clause that dispute between a foreign investor and the host country related to the treaty should be settled through arbitration.

- ***Potential Measures in Public International Law that could be developed***

An international regime could provide for a number of options which facilitate compliance, such as a commitment to establish an information exchange mechanism between national ABS focal points of Parties to support both providers and users of genetic resources. Also, mutual legal assistance in litigation could help facilitate compliance across jurisdictions.

What kind of voluntary measures are available to enhance compliance of users of foreign GR;

This section will review some of the voluntary measures that are currently available, looking at both national and user initiatives:

- The most significant voluntary measure is the Bonn Guidelines themselves.

[8] See UNEP/CBD/ABS-WG5/INF3, p.28

- In the FAO Commission, the Code of Conduct for Plant Collecting and Transfer of Germplasm[9], which was adopted in 1993.

- Commission recommendation C2008-1329 on PI management and code of conduct for universities and public research institution

- Government Initiatives: Some examples

    - A Nordic project on "Access and Rights to Genetic Resources – A Nordic Approach", mandated by the Nordic Genetic Resources Council. This project addresses various aspects related to rights and access to genetic resources in the Nordic countries[10].

    - A booklet on 'Good Practice for academic research on genetic resources[11], produced by the Swiss Academy of Sciences.

    - The Federal Department of Economic Affairs in Switzerland, in partnership with the International Institute for Sustainable Development, has produced a best practice standard and handbook for Implementing Genetic Resource Access and Benefit Sharing Activities[12.]

    - The Japanese Ministry of Economy, Trade and Industry and the Japan BioIndustry have developed 'Guidelines on Access to Genetic Resources in Japan'[13.]

- Codes of conduct such as:

    - Rules and provisions by national institutes and organizations elaborated e.g. by the German Research Foundation (Deutsche Forschungsgemeinschaft – DFG), the Leibniz Institute of Plant Genetics and Crop Plant Research (Institut für Pflanzengenetik und Kulturpflanzenforschung – IPK), the Federal Centre for Breeding Research on Cultivated Plants (Bundesanstalt für Züchtungsforschung an Kulturpflanzen (BAZ)).

    - The International Plant Exchange Network (IPEN) Code of Conduct is the unified policy of the network of botanical gardens. It covers acquisition, maintenance and supply of living plant material by the gardens as well as benefit-sharing. The Code further provides a Material Transfer Agreement (MTA) to be used for exchanges with institutions that are not member of the IPEN network for non-commercial uses.

    - Another Botanical Gardens initiative is the 'Principles on Access for Genetic Resources and Benefit Sharing for participating Institutions'[14].

[9] http://www.fao.org/biodiversity/conventionsandcodes/plantgermplasm/en/
[10] The Nordic project can be found in : http://www.norden.org/pub/sk/showpub.asp?pubnr=2003:016
[11] Found at http://abs.scnat.ch./downloads/index.php
[12]Found at http://www.iisd.org/pdf/2007/abs_mt.pdf
[13] Found at http://www.mabs.jp/information/oshirase/pdf/iden_tebiki_e.pdf

- The Belgian Co-ordinated Collections of Micro-organisms launched Micro-Organisms Sustainable use and Access regulation International Code of Conduct[15] (MOSAICC) with a number of partner organizations. MOSAICC is a voluntary Code of Conduct to support the implementation of the CBD in microbial work. Its aim is to help facilitate access to genetic resources and to help partners make appropriate agreements when transferring micro-organisms.

- The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) has established a set of 'Guidelines for IFPMA members on Access to genetic resources and Equitable Sharing of Benefits Arising out of their Utilization'[16].

Consider how internationally agreed definitions of misappropriation and misuse of GR and associated traditional knowledge could support compliance where genetic resources have been accessed or used in circumvention of national legislation or without setting up mutually agreed terms

Failure of parties to a benefit-sharing arrangement to implement obligations established in mutually agreed terms can be pursued through a well established set of national and international level rules if the mutually agreed terms are set out in contracts governed by private law.

An internationally agreed definition of misappropriation of genetic resources could help addressing situations in which mutually agreed terms do not exist. Either because genetic resources have been acquired in circumvention of national prior informed consent requirements or because mutually agreed terms have not been established.

An internationally agreed definition of "misappropration" of genetic resources could support compliance if Parties were to agree that instances of "misappropration" would trigger measures in the jurisdiction of countries where genetic resources are used.

A key challenge to developing an international understanding of misappropriation is how to approach the link between national access legislation of provider countries and eventual user country measures to pursue instances of misappropriation so that fundamental legal principles of clarity, predictability, proportionality and reciprocity are respected. Any such discussion should also address practical implementation issues such as the burden of proof in national court proceedings or the distinction between genetic resources within and outside the scope of the international ABS regime are addressed.

Against this background, the EU continues to see the need as explained in the previous EU submission of 28 April 2008, to establish international standards on national access law and practice regarding genetic resources and an international mechanism/process for assessing whether or not national access frameworks meet international standards that provide clarity, predictability, proportionality and reciprocity, as a precondition for its ability to engage in discussions on misappropriation.

[14] Found at http://www.bgci.org/abs/Downloads/
[15] Found at http://bccm.belspo.be/projects/mosaicc/
[16] Found at http://www.ifpma.org/Issues/CBD

How could compliance measures take account of customary law of indigenous and local communities?

Customary laws of indigenous peoples are the rules that govern all aspects of indigenous people lives and their communities. They define rights and responsibilities of community members, as well as relate to the cultural and spiritual life and access to and use of natural resources. These are local systems of laws, norms, and regulations that have been devised to keep social order and maintain continuity of cultural practices. Therefore, these laws are relevant also for interactions with non-community members.

A practical example of interactions between governments and indigenous peoples is the establishment of Saami parliaments in Finland, Norway and Sweden, representing the Saami people in specified affairs the domestic law of the three countries. The Saami parliaments – together with the Saami Council - have jointly established a trust, which manages certain common cultural elements of the Saami people, such as the flag and the national anthem.

While these local systems represent rules binding among the respective community, they do not bind outsiders. In addition, they differ from statutory laws in that they are often not laid down in writing and thus can change easier and more frequently than statutory laws. While this could be a practical difficulty in obtaining PIC and MAT of indigenous peoples and local communities, some communities have appointed an authority or representative for interactions with non-community members in matters of community interest.

Such an approach is one means to ensure that community level procedures are respected for instance when traditional knowledge associated with genetic resources is involved. Compliance measures discussed above, such as specific dispute settlement arrangements within MTAs and arbitration procedures could also be facilitated through reference to the appointed community representative or authority.

Analyze whether particular compliance measures are needed for research with non-commercial intent, and if so, how these measures could address challenges arising from changes in intent and/or users, particularly considering the challenge arising from a lack of compliance with relevant access and benefit-sharing legislation and/or mutually agreed terms;

The EU considers that an international ABS regime needs to address the issue of simplified access to genetic resources for non-commercial research. However, non-commercial users of genetic resources have an important responsibility in generating confidence and trust with providers of genetic resources.

This confidence can be generated through practical and meaningful steps for distinguishing non-commercial research from other, including commercial, uses of genetic resources and for ensuring that simplified access procedures for non-commercial research are established but will not be abused.

Specific steps to address the particular challenges arising from non-commercial research could include:

- the appropriate classification of research depending on its varying form and objective;
- ensuring that obligations are passed on to subsequent users;

- addressing potential changes in intent by non-commercial users, including through identification of clear reference points for changes in intent.

- The renegotiation of MAT with the provider of the genetic resource in cases of changes in intent by non-commercial users.

- preventing that users of genetic resources without obligations vis a vis the provider make use of generated scientific information (eg, through publication policies) if such use is restricted.

- measures to allow the tracking of genetic resources in cases of doubt on the fulfillment of ABS requirements by users.

- linking decisions on simplified access with adherence of researchers to Codes of Conduct and other voluntary systems applicable to the research community.

INDIA

India's initial views on issues to be addressed by ABS Expert Group on Compliance

...

Q 1: What kind of measures are available, or could be developed, in public and private international law to (i) facilitate with particular consideration to fairness and equity and taking into account cost and effectiveness, access to justice, including alternative dispute resolution, and access to courts of foreign plaintiffs? (ii) Support mutual recognition and enforcement of judgements across jurisdictions; (iii) provide remedies and sanctions in civil, commercial and criminal matters, in order to ensure compliance with national access and benefit sharing legislation and requirements, including prior informed consent, and mutually agreed terms.

A 1. At the outset it may be important to note that 'compliance procedures' are not dispute settlement or adversarial elements. The purpose of compliance measures is to facilitate an amicable review and consideration of the difficulties faced by States in fulfillment of their international obligations. The objective of compliance procedures/mechanism has always been to promote compliance and address issues of non-compliance.

Under public international law, the State represents its nationals on account of the harm/loss suffered because of the denial of access to benefit sharing of genetic resources. According to rules of state responsibility, States can bring forth claims on behalf of their nationals for the harm caused to them. Alternate modes of dispute settlement such as arbitration, mediation and conciliation are gaining currency, because of the speed, informality and party autonomy involved in dispute resolution. The Optional Rules for Arbitration of Disputes Relating to Natural Resources and or/the Environment developed by the Permanent Court of Arbitration, the UNCITRAL Arbitration Rules and other arbitral forums provide modes of dispute settlement in environmental matters.

The New York Convention on Recognition and Enforcement of Foreign Arbitral Awards, 1956 and other regional agreements provide for enforceability of judgement in other jurisdiction of contracting parties. Moreover, rules of private international law also afford the victim of transboundary harm, similar choice of forum – in the courts where damage occurred; in the place where harmful activity is located; and in the place where the defendant is domiciled. In India, the Civil Procedure Code, 1908, Section 13 (14) provides that a foreign judgement shall be conclusive as to any matter thereby directly adjudicated upon between the same parties or between parties under whom they or any of them claim litigating under the same title. However, the judgment of a foreign court is not enforceable in India in the following cases: (a) where it has not been pronounced by a court of competent jurisdiction; (b) where it has not been given on the merits of the case; (c) where it appears on the face of the proceedings to be founded on

an incorrect view of international law or a refusal to recognize the law of India in cases in which such law is applicable; (d) where the proceedings in which the judgment was contained are opposed to natural justice; (e) where it has been obtained by fraud; and (f) where it sustains a claim founded on a breach of any law in force in India.

Most legal systems provide a right to move the courts when a person's right is violated. At the international level, the UNECE Aarhus Convention on Access to Information, Participation in Decision-Making and Access to Justice in Environmental Matters, 1998 provides the public a right to access justice whereby any person can trigger the compliance procedure.

States are also free subject to their domestic laws, to ensure that legal and natural persons are held liable for offences established in which are effective, proportionate and dissuasive sanctions, including monetary sanctions.

States can also enter into agreement on mutual legal assistance in civil, administrative and criminal matters for strengthening international cooperation in law enforcement. Such cooperation could include: wide measure of mutual legal assistance in investigations, prosecutions and judicial proceedings in relation to the criminal offences.

Q. 2 What kind of voluntary measures are available to enhance compliance of users of foreign genetic resources?

One of the fundamental precepts of treaty law is that treaty obligations must be undertaken in good faith. Thus international law requires that States must undertake full compliance with treaty obligations, unless the treaty itself provides for any relaxation for a special category of Parties. A State not complying with a treaty obligation can be required to fully comply with its provisions from the date of entry into force for the Party concerned. Rules of state responsibility for violation of an international obligation also apply. If a Party is found to be in non-compliance, any party, the Secretariat or the compliance mechanism (as is the case in different treaties) can request that State to return to compliance as soon as possible.

Comments of India in response to the mandate of Article 21 of the International Treaty on Plant Genetics Resources for Food and Agriculture provide a good background for undertaking voluntary measures.

To reiterate again the objective of the compliance procedures should be to identify compliance difficulties, establish the cause of such difficulties and formulate responses and advise to correct the state of non-compliance.

Compliance procedures should be transparent and cater towards confidence building among parties. The special needs of the developing countries and diversity rich countries in particular should be identified and guidance can be provided on specific issues like institutional support, development of suitable national policy guidelines on benefit sharing, farmer rights and intellectual property rights issues.

The corrective measures like withdrawal of certain privileges to parties to non-compliance should be considered as last options. The non-compliance due to circumstances beyond the parties' control should be considered and advice to comply should be provided, before such measures are taken.

Q3 Consider how internationally agreed definitions of misappropriation and misuse of genetic resources and associated traditional knowledge could support compliance where genetic resources have been accessed or used in circumvention of national legislation or without setting up of mutually agreed terms.

A3. It may not be difficult to understand as to what would amount to misuse or abuse of a plant species under domestic law. However the same is not true of international law. The LMMC and the Latin American and Caribbean Group (GRULAC) at the last ABS Working Group Meeting demanded to "ensure the effective, fair and equitable sharing of monetary and non-monetary benefits arising from the use of genetic resources, derivatives and associated traditional knowledge, by preventing their misappropriation and misuse, and by securing compliance in user countries with national laws and requirements, including PIC and MAT of the country of origin providing such resources, or of the party that has acquired such resources in accordance with the CBD." The issue of sharing equitably and fairly genetic resources or the monetary value derived thereof would largely be dependent on the agreed definition of misuse.

The answer to this question to a large extent would depend upon what amounts to 'misappropriation and misuse of genetic resources and associated traditional knowledge' to be agreed upon/looked into by the meeting of other technical/legal expert group on 'Definitions' being held next month.

Q 4. How could compliance measures take account of the customary law of Indigenous and Local communities?

A 4. Indigenous people have always felt that emphasis on State sovereignty has undermined the gains achieved in the recognition and protection of indigenous peoples' rights in international and regional human rights fora. In fact, the CBD has already been cited in some human rights meetings as the basis for denying indigenous peoples their rights over resources found within their lands and territories.

Article 3 of the CBD, states that the understanding of sovereignty is limited by the United Nations Charter and the principles of international law. Many of the indigenous peoples and local communities want a permanent sovereignty over their natural resources and want their rights to have control over their resources recognized in an international regime on ABS. Such recognition could consist of, inter alia, requiring users of genetic resources to obtain indigenous peoples' free prior and informed consent (FPIC) before access can be granted. They also expect the State to help regulate access to genetic resources by recognizing indigenous peoples' permanent

sovereignty over their natural resources and setting up the institutional infrastructure to enforce this right.

This position has been rejected by a number of developing countries including, India. India believes that it is the State that should give PIC on behalf of communities because most them lack the capacity to grant PIC.

It may however, be necessary in some measure to understand the customary practices while speaking on their behalf. While the 'State' represents all its peoples, it may be noted that the needs of indigenous peoples must be recognized. Article 29 of the United Nations Declaration on the Rights of Indigenous Peoples, 1994 states: "Indigenous peoples are entitled to the recognition of the full ownership, control and protection of their cultural and Intellectual Property. They have the right to special measures to control, develop and protect their sciences, technologies and cultural manifestations, including human and other genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs and visual and performing arts."

Likewise the ILO Convention 169 Concerning Indigenous Peoples in Independent Countries sets a general policy of respect for the human rights of indigenous and tribal peoples, asserts their rights to land, and provides for some rules as regards labour, social security and health-related matters. Convention No. 169 may have relevance for the protection of traditional knowledge of indigenous peoples to the extent that (Article 2.2(b)) identifies the rights of those peoples to "the full realization of the social, economic and cultural rights [...] with respect for their social and cultural identity, their customs and traditions and their institutions."

It may also be noted that most modern intellectual property debates presuppose the existence of formal government and written records. However, traditional knowledge holders in indigenous and local communities cannot rely upon in practice, because indigenous and local communities often lack formal government and oral traditions lack written records. Examples can include traditional healer/s in India being individually being capable of treating patients along with prayer/mantras.

Another problem of compliance is how do we enforce IP-related rights under customary law. Say for e.g. family rights, hunting rights, etc. Their traditional justice system consists of clear set of rules that were designed to maintain harmony within the society and between the natural, animal and human worlds. The rules were carefully taught by one generation to the next and enforced by daily instruction, observation, and expectations of proper behavior. The senior members of the group dealt with offences; they judged the offence and determined what remedial actions had to be taken. In serious offences, there had to be public admission of guilt. The collective group was involved in speaking "harsh words" to the offender. Once guilt was admitted and the group the individual had to restore harmony defined appropriate remedial actions. Failure to comply resulted in shunning and, on occasion, banishment that was often seen as equivalent to the death penalty.

Q 5) Analyse whether particular compliance measures are needed for research with non-commercial intent, and if so, how these measures could address challenges arising from changes in intent and/or users, particularly considering the challenge arising from a lack of compliance with relevant access and benefit-sharing legislation and/or mutually agreed terms.

A 5. There must be compliance measures to ensure that research based intent is regulated and when converted to commercial purpose the rights of the patent holder/community are protected. However, these rules would have to be worked out considering the difference of opinion among the developing and developed on the right international for also responsible for granting of patent rights.

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NIGERIA

from: Tutu Kuye @ [illegible]

SUBMISSION ON THE ACTIVITIES OF FEDERAL REPUBLIC OF NIGERIA ON ACCESS AND BENEFIT SHARING BY USERS OF FOREIGN GENETIC RESOURCES: GROUP OF TECHNICAL AND LEGAL EXPERTS ON COMPLIANCE.

The Federal Republic of Nigeria as at present is still in its embrayonic stage of developing laws, regulations and standards relating to Access and Benefits sharing by users of Foreign Genetic Resources.

2. These legislations are the National Bio-safety Bill and the National Biodiversity Management Agency Bills. These two bills were developed by the Federal Ministry of Environment, Non Governmental Organisations (NGOs) on Environment in collaboration with relevant stakeholders in the Environment Industry. They are however being processed for enactment by the National Assembly.

3. The National Biodiversity Management Agency Bill contains provisions for the establishment of a corporate body known as the National Biodiversity Management Agency whose functions primarily is to coordinate matters concerning the conservation and management of Biodiversity including formulation of policies, rules, regulations and standards on Access to Genetic Resources and ensure equitable Benefits sharing regarding the use of Genetic Resources.

4. It also created offences and adequate penalties for offenders whose activities contravene the provision of the endangered species Act, Biosafety Act or the provision of any other Biodiversity-related laws, International Conventions, Agreement and Protocols.

5. The National Biosafety Bill on the other also contains provisions establishing the National Biosafety Committee whose main function is to be responsible for the review of applications for contained use, confirmed field act, commercial release or other form of deliberate release and recommend the conditions under which any experience and genetically modified organization shall be conducted and assist in risk assessment within the Federal Republic of Nigeria. The Committee will also consider and approve applications for permits.

6. **Part VI** of the National Biosafety Bill specifically provides for Risk Assessment and Risk Management, Institutional Risk Management, Plan and Strategy. Offences are created with adequate enforcement/compliance measures and offences/penalties made available for any contravention in the act.

7. These Bills when enacted into law will adequately accommodate all issues relating to Access and Benefit - sharing by users of Foreign Genetic Resources in the Federal Republic of Nigeria.

8. The two Bills contains, provision relating to the implementation of the provision of the convention on Biological Diversity in Nigeria. In addition to the above, the Country has its own Arbitration Act which allows Parties recourse to Arbitration procedures as alternative dispute resolutions. The International Center for Arbitration has its branch office in Lagos Nigeria which is easily accessible to both Nigeria and non-Nigerians (Foreign Litigants) that are parties to Bilateral Agreements.

9. The provisions of the National Biosafety Bill and the Biodiversity Agency Bill adequately allow easy access to justice, effective sanctions and remedies in Civil, Commercial and Criminal matters as well as mutual recognition and enforcement of judgments across jurisdiction to ensure proper compliance with National Access and Benefit-sharing Legislations and requirements including prior informal consent and mutually agreed terms.

10. The 1999 Nigerian Constitution also recognized the right of Parties to access justice when the need arises. Adequate awareness campaign programme will be embarked upon the to the villages when these bills are enacted into law to convince the populace that the compliance measures to be adopted in the bills takes account of the customary law of indigenous and local communities.

11. The two Bill contains detailed provisions on Access and Benefit sharing by users of Foreign Genetic Resources.

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NORWAY

(a) What kind of measures are available, or could be developed, in public and private international law to:

(i) Facilitate, with particular consideration to fairness and equity and taking into account cost and effectiveness, access to justice, including alternative dispute resolution, and access to courts by foreign plaintiffs

Access to justice is determined by national rules on civil procedure. Harmonized rules in this field will safeguard access to justice for foreigners. Also harmonized rules in this field will facilitate for clear rules on jurisdiction where the claimant may opt between two or more jurisdictions. Finally, rules on jurisdiction may also prevent circumvention of otherwise relevant jurisdictions – so called forum shopping.

An important factor when choosing between available jurisdictions is which law is applicable as to the substance. Harmonization in this field can be achieved either through harmonized choice of law rules, or harmonized substantial law.

Finally, rules on jurisdictions may be circumvented by agreements on settlement by arbitration. If the arbitral proceedings take place far away, this may prevent the defendant from safeguarding his interest properly. A provision stating where arbitral proceedings may take place, preferably in the same state that would otherwise have jurisdiction, will suffice.

Alternative dispute resolution

Any dispute concerning the interpretation and application of Article 15 would be a matter of public international law and settled in accordance with Article 27 of the CBD. Article 15 regulates access to genetic resources, which is subject to prior informed consent and Mutually Agreed Terms (MAT). Where such a dispute arises between Parties to the CBD Article 27 provides Parties with a means to resolve disputes by first negotiation, then mediation and finally recourse to the arbitration procedures set out in Part I of the Annex II or to the International Court of Justice (ICJ). This is, however, optional since it requires Parties to accept either arbitration of submission to the ICJ, or both, as compulsory. Parties should therefore be encouraged to accept these settlement of disputes procedures as compulsory means.

MATs are often concluded through a contract between private or public entities. Since most obligations arising under Mutually Agreed Terms will be between providers and users, disputes arising in these arrangements should be solved in accordance with the relevant contractual arrangements on access and benefit-sharing and the applicable law and practices. Alternative dispute resolution (ADR) covers a range of mechanisms which allow parties to resolve differences without recourse to national courts. In an ABS context, many MATs already include settlement of dispute clauses based on arbitration, for example the Standard Material Transfer Agreement of the ITPGRFA. Standard clauses to be included in MATs could be developed under the international regime.

(ii) Support mutual recognition and enforcement of judgments across jurisdictions

Rules on recognition and enforcement are necessary supplements to rules on jurisdiction. It is in particular unfortunate if the claimant is forced to sue in a jurisdiction where the judgment may not be enforced, and the judgment is not enforceable in the relevant jurisdiction.

Whether foreign judgments are enforceable depends upon national law. However, states may enter into agreements on recognition and enforcement of foreign judgments.

As far as arbitral judgments are concerned, the vast majority of states (143 states) are parties to the 1958 New York Convention on the Recognition and Enforcement of Foreign Arbitral Awards.

Also, recognition and enforcement of civil judgments in Europe may take place within the scope of the Lugano Convention 16 September 1988 on jurisdiction, enforcement and recognition of judgments in civil and commercial matters, eventually to be replaced by Lugano Convention 30 October 2007.

Apart from judgments falling within the scope of the above-mentioned conventions, the right to recognition and enforcement of foreign judgments in Norway is quite narrow. This may be the case in other states as well. Consequently, provisions on mutual recognition and enforcement of judgments across jurisdictions are necessary in order to facilitate for the recognition and the enforcement of foreign judgments.

(iii) Provide remedies and sanctions in civil, commercial and criminal matters, in order to ensure compliance with national access and benefit-sharing legislation and requirements, including prior informed consent, and mutually agreed terms

The Bonn Guidelines para. 61 on "Remedies" states that "Parties may take appropriate effective and proportionate measures for violations of national legislative, administrative or policy measures, implementing the access and benefit-sharing provisions of the CBD, including requirements relating to prior informed consent and mutually agreed terms". This needs to be taken into account.

This is also an issue which is addressed in the Norwegian legislative work on ABS legislation, where enforcement rules are considered necessary to ensure compliance with national rules in cases of breaches of these rules, such as coercive fines and fines.

Checkpoints are needed at the national level in order to be able to verify compliance. Genetic material should be accompanied with information on their origin and whether they have been accessed in accordance with national legislation in the provider country. For example if national legislation in the provider country requires prior informed consent for access to the material, the documentation should also specify whether such consent has been sought. This documentation could serve as a Certificate of origin/compliance and should accompany the genetic material from the collection phase until their commercialization.

However, when genetic resources covered by the International Treaty on Plant Genetic Resources for Food and Agriculture, are used for research and commercial purposes, they should be accompanied by information verifying that these resources are accessed in accordance with the Standard Material Transfer Agreement under the Treaty.

The Norwegian Act relating to the management of wild living marine resources (Marine Resources Act), Chapter 2, Section 10 regulates benefits arising out of the use of marine genetic material. It states that:

> "A permit issued under section 9 may lay down that a proportion of the benefits arising out of the use of Norwegian marine genetic material shall accrue to the State.
>
> "A permit issued under section 9 may lay down that genetic material and the results of bioprospecting activities may not be sold or communicated to others without the consent of and, if required, payment to the State.
>
> "The King may prescribe that if marine bioprospecting or the use of genetic material has taken place without a permit being issued pursuant to section 9, a proportion of the benefits such as are mentioned in the first paragraph shall accrue to the State."

This is an example of a measure in cases of non-compliance with national legislation.

The Norwegian Patent Law was amended in 2003. The amendments entered into force the 1st of February 2004. A new para. 8 (b) was included to address disclosure of origin. It states that the patent application shall include information on the country from which the inventor collected or received the biological material (the providing country). If it follows from national law in the providing country that access to

biological material shall be subject to prior consent, the application shall inform on whether such consent has been obtained.

If the providing country is not the same as the country of origin of the biological material, the application shall also inform on the country of origin. The country of origin means the country from which the material was collected from in-situ sources. If it follows from national law in the country of origin that access to biological material shall be subject to prior consent, the application shall inform on whether such consent has been obtained. If information dealt with under this subsection is not known, the applicant shall state this in the application.

Infringement of the duty to provide information is subject to penalty in accordance with the General Civil Penal Code § 166. The duty to provide information is without prejudice to the processing of patent applications or the validity of granted patents.

Norway submitted a communication dated 13 June 2006 to the TRIPS General Council, the TNC and to the Regular Session of the Council (IP/C/W/473, WT/GC/W/566 and TN/C/W/42) with a proposal to introduce an obligation in the TRIPS agreement in a new Article 29 bis to disclose the origin of genetic resources and traditional knowledge in patent applications. This proposal, if adopted, would support the aims of the CBD, and in particular the aim to ensure the equitable sharing of benefits arising out of the use of genetic resources. Such a disclosure obligation should be introduced in a new Article 29bis and should provide that patent applications should not be processed unless the required information has been submitted. However, non-compliance with the disclosure obligation discovered post-grant should not affect the validity of the patent. The specific provisions of the disclosure obligation should be fully compatible with the International Treaty on Plant Genetic Resources for Food and Agriculture and the Multilateral System established under it.

b) What kind of voluntary measures are available to enhance compliance of users of foreign genetic resources.

In Norway's view voluntary measures are not enough to ensure compliance of users of foreign genetic resources. Voluntary measures may enhance compliance, but they are not sufficient.

However, the Bonn Guidelines provide for a system of voluntary certification as a possible means to verify the transparency of the process of access and benefit-sharing. Such a system could certify that the access and benefit-sharing provisions of the Convention on Biological have been complied with.

Other voluntary measures than provided for in the Bonn Guidelines are Codes of Conduct which have been developed in some sectors.

Within the context of the international regime an internationally recognised certificate of origin/compliance. In our view, this should be an obligation for all Parties, and not only a voluntary measure. This could be a certificate accompanying the genetic resources from the collection phase until their commercialisation, as a measure to increase transparency, traceability and predictability. It should serve as a means to provide evidence of compliance with national access and benefit-sharing legislation, as may be required at specific checkpoints to be established in user countries. A certificate of origin/compliance would also make it easier to enforce the disclosure requirement in IPR applications since such a certificate could accompany the application.

Countries that cannot provide for the mandatory issuance of certificates may wish to consider its issuance on a discretionary basis in light of the benefits for both providers and users. The issuance of such certificates in the provider country could be triggered automatically by the granting of access or at the request of a user. The patent application would then serve as a checkpoint to verify whether such a certificate exists.

The certificate should be complementary to and used side by side with other internationally recognised certificates, such as the Standard Material Transfer Agreement under the International Treaty on Plant Genetic Resources for Food and Agriculture

The clearing house mechanism (CHM) could have a role as receiver of notifications of disclosure of origin in patent applications and unique identifiers of genetic resources under a system for international certificates of origin/compliance.

To conclude: Legally binding measures in user countries are needed to be able to enforce national legislation regulating access to genetic resources and benefit-sharing in provider countries and to be able to follow-up Article 15(7) of the CBD. This is also important in order to ensure predictability and legal certainty for both users and providers.

At the same time, these rules, as well as the measures they require of users, should be reasonably easy accessible and understood, and reasonably easy, fast and cheap to follow for *inter alia* small and medium sized enterprises that wish to create values based on useful information found in genetic resources and biological material around the world, in line with the central goals of the CBD.

c) Consider how internationally agreed definitions of misappropriation and misuse of genetic resources and associated traditional knowledge could support compliance where genetic resources have been accessed or used in circumvention of national legislation or without setting up of mutually agreed terms.

Norway believes that a working understanding on what we mean by "misappropriation" of genetic resources and traditional knowledge could be helpful in developing the regime and also with regard to national implementation of the regime. This could be linked to an international obligation in the regime for all parties to prohibit the use of misappropriated genetic resources/traditional knowledge. At least the following can be considered as acts or cases of misappropriation of genetic resources:

- Use of genetic resources that is not in compliance with CBD or the provisions of the international regime or relevant national legislation
- Any acquisition or utilisation of genetic resources by illegal means
- Use of genetic resources for purposes other than those for which they were accessed
- Deriving commercial benefits from the acquisition, appropriation or utilisation of genetic resources when the person using the genetic resources, knows, or is negligent to know, that these were acquired or appropriated by illegal means.

Concerning TK: Norway submitted a proposal to the WIPO dated 20 April 2006 (WIPO/GRTKF/IC/9/12 on protection against misappropriation and unfair use of Traditional Knowledge based on Article 10bis of the Paris Convention.

The legal standard in article 10 *bis* is "what an honest person would consider an act of unfair competition within a commercial or industrial context". Transposed to the WIPO committee's work the idea of behaviour contrary to honest practices or amounting to inequitable conduct could be developed to guide understanding of what constitutes an act of misappropriation or unfair use of TK. Acts that could clearly qualify as "unfair use" - would inter alia be exploitation of TK obtained by theft, bribery, coercion, fraud etc. while also other relevant acts would, depending on the circumstances in each case be covered.

It could be argued that it would be difficult for a local community to obtain a court decision in a foreign country. However, it can be argued that the mere possibility would serve as an incentive for users to obtain prior consent from TK-holders and to participate in benefit-sharing arrangements.

Norwegian proposal for a recommendation regarding protection against misappropriation and unfair use of traditional knowledge:

1. The members of the Paris Union for the Protection of Industrial Property and the World Intellectual Property Organization should assure nationals of member countries adequate and effective protection against misappropriation and unfair use of traditional knowledge (TK)

2. Any use of TK against honest practices in cultural, industrial or commercial matters should be considered as actions in breach of paragraph one.

3. TK holders should in particular be provided with effective means to ensure that:

(i) The principle of prior informed consent applies to access to TK,

(ii) Benefits arising from certain uses of TK are fair and equitable shared,

(iii) All acts of such a nature as to create confusion by any means whatever with the origin of the TK are repressed, and

(iv) All acts of such a nature that would be offensive for the holder of the TK are repressed."

(d) How could compliance measures take account of the customary law of indigenous and local communities?

The international regime should contribute to the respect for and preservation of traditional knowledge associated with genetic resources as well as to the equitable sharing of benefits arising from the use of such knowledge in accordance with Article 8(j) of the CBD. The regime needs to develop methods of cooperation with indigenous peoples and local communities in the PIC and MAT process when traditional knowledge associated with genetic resources is addressed.

In order to meet the provisions of ILO Convention No. 169 which Norway has ratified, the Norwegian Government and the Sami Parliament reached agreement on the "Procedures for Consultations between the State Authorities and the Sami Parliament of 11 May 2005" (PCSSP).

The PCSSP has several objectives. First of all, the procedures are intended to contribute to the practical implementation of the State's obligations to consult indigenous peoples under international law. Secondly, agreement shall be sought between the State authorities and the Sami Parliament whenever consideration is being given to legislative and administrative measures that may directly affect Sami interests. The third objective is to facilitate the development of a partnership perspective between State authorities and the Sami Parliament that contributes to the strengthening of Sami culture and society. Finally, the intention is to develop a common understanding of the situation and of the developmental needs of Sami society.

The scope of the agreement is extensive. The consultation procedures laid down in the PCSSP apply to the Government and its ministries, directorates and other subordinate state agencies or activities. Furthermore, they apply in matters that may affect Sami interests directly. The substantive scope of the consultations may include various issues, such as legislation, regulations, specific or individual administrative decisions, guidelines, measures and decisions. The obligation to consult the Sami

Parliament may include all material and immaterial forms of Sami culture, including music, theatre, literature, art, media, language, religion, cultural heritage, immaterial property rights and **traditional knowledge** research, land ownership, rights to use lands, matters concerning land administration, biodiversity and nature conservation etc.

The PCSSP also contains general provisions concerning the consultation procedures. The consultations shall be undertaken in good faith, with the objective of achieving agreement to the proposed measures. Furthermore, the state authorities shall as early as possible inform the Sami Parliament about the commencement of relevant matters that may directly affect the Sami, and identify those Sami interests and conditions that may be affected. After the Sami Parliament has been informed on relevant matters, the Parliament shall notify the state authority as soon as possible as to whether or not further consultations are required. The Sami Parliament may also independently identify matters which in its view should be subject to consultation. In cases where the state authorities and the Sami Parliament agree that further consultations are to be held, they shall seek to agree on a plan for such consultations. Sufficient time shall be allocated to enable the parties to carry out genuine and effective consultations and political consideration of all relevant proposals.

For further information about the PCSSP, reference is made to the link on Procedures for Consultations between the state authorities and the Sami Parliament.
http://www.regjeringen.no/en/dep/aid/Topics/Sami-policy/midtspalte/PROCEDURES-FOR-CONSULTATIONS-BETWEEN-STA.html?id=450743&epslanguage=EN-GB

(e) Analyse whether particular compliance measures are needed for research with non-commercial intent, and if so, how these measures could address challenges arising from changes in intent and/or users, particularly considering the challenge arising from a lack of compliance with relevant access and benefit-sharing legislation and/or mutually agreed terms.

Norway believes that compliance measures are needed also in the case of non-commercial research since the intended use may change. However, simplified access rules should be considered in the regime for access to biological resources to be used *exclusively* for taxonomy purposes, since this is not considered to be a utilization of a genetic resources (the aim is not to use the genetic information of the resource).

See above under (a) (iii) measures that may be imposed under the Norwegian Act relating to the management of wild living marine resources in cases of non-compliance with access- and benefit-sharing legislation.

SWITZERLAND

Non-Paper submitted by Switzerland

I. General considerations

Compliance means "according with or meeting rules or standards". If compulsory rules are not complied with, enforcement measures must be taken to compel observance of these rules. It is difficult to consider compliance measures in any detail when the rules that must be complied with are largely unknown, which is the case with regard to the IR. According to general principles for compliance and enforcement, the IR should ensure that ABS rules are practical, transparent, efficient and effective, that regulatory compliance and enforcement measures follow the rule of law and due process, and that these measures are non-discriminatory.[1] From a general perspective also, the more the IR and national **ABS measures** function **as incentives** to comply with the ABS system, the more this system becomes self-enforcing, or the less enforcement measures are necessary.

The situation is a similar one with regard to possible measures in international law for compliance with national rules (question a): It is difficult to consider compliance measures if there is a lack of a certain harmonization of substantive and procedural national rules. Such is the case with regard to existing national ABS legislation and requirements. Nevertheless, international law provides for certain compliance and enforcement measures, particularly with regard to contracts on prior informed consent (PIC) and mutually agreed terms (MAT).

II. Measures to ensure compliance with national ABS requirements (question (a))

Measures to foster and ensure compliance with ABS are a crucial element in building and maintaining trust among providers and users of genetic resources. Such measures are needed in any ABS system, on the international and national level. They may vary according to the yet to be determined legal status (legally binding, voluntary or a mix thereof) of the future IR.

Question (a) asks to identify measures in public and private international law in order to ensure compliance with national ABS legislation and requirements, including PIC and MAT. Hence, the experts' terms of reference do not refer to a discussion of measures to ensure compliance of providers and users with the IR or other international norms on ABS.

The three subquestions regarding (i) access to justice, (ii) mutual recognition and enforcement of judgments, and (iii) remedies and sanctions, all have to do with **judicial procedures and measures**. They address core challenges for legal certainty of providers.

In addressing these subquestions, a distinction has to be made between administrative and regulatory decisions/orders issued by authorities (such as PIC in form of collection permits) and contractual arrangements between two parties (such as contractual PIC/MAT for access and MAT for benefit sharing).

[1] Also see COP decision VII/19, UNEP/CBD/COP/7/21.

II.A. Administrative and Regulatory Decisions/Orders

States have many regulatory and criminal enforcement instruments at their disposal to ensure that entities **under their jurisdictions** comply with laws and administrative or regulatory decisions, also with regard to ABS. These instruments **depend on the legal system in a given State** and include awareness raising and capacity building policies, inspections, investigations or prosecution. In some jurisdictions free legal aid is granted, under certain conditions, to individuals lacking sufficient financial means to access justice and legal representation. Procedural guarantees make sure that human rights and other rights are observed.

As indicated, national compliance and enforcement instruments generally **do not have extrajurisdictional effect**. ABS cases, however, are cross-jurisdictional by definition (Art. 15 CBD), i.e. user and provider entities operate in different jurisdictions. As the **extrajurisdictional or extraterritorial application** of laws and decisions of one State is limited by the **sovereignty** of other States, enforcement of national ABS requirements is often hampered. States do not normally execute penal, administrative and regulatory decisions and apply laws of other States, unless multi- or bilateral treaties governed by public international law, such as mutual legal assistance instruments, oblige them to do so. These treaties are regularly based either on a certain level of **harmonization of the substantive national rules** governing a subject matter or on the recognition that the different national rules and laws are **substantially equal**. In some cases, international treaties introduce **standard administrative procedures and mechanisms**, which have to be implemented on the national level.

Many States are only willing to execute requests of legal assistance if the requesting State offers reciprocity. Even so, a State wants to make sure that a ruling based on foreign law it is asked to enforce or foreign law to be applied by an authority provides and respects certain minimum standards with regard to the *ordre public*. In general, **courts and administrative tribunals** will be concerned that fundamental rights and freedoms recognized by their own legal system, such as the freedom of contracts, the scientific freedom, or even the right to own property, are not infringed by the application of foreign law, or that an enforcement of a judgment which is based on foreign law does not interfere unduly with such rights.

Few States have adopted access laws, and they follow a wide range of approaches. This makes recognition and enforcement of access laws across different jurisdictions very challenging. Therefore, it would be favourable for the IR **to introduce certain minimum standards for national access laws** (such as principles with regard to non-discrimination, time efficiency and transparency) in order to facilitate the recognition and enforcement of foreign ABS laws and the conditions set out in access permits issued by foreign authorities.

For several years, there have been discussions about the usefulness of introducing an **internationally recognized certificate of legal provenance/source/origin**. According to the group of technical experts convened by the CBD in January 2007, such a certificate would serve as evidence of compliance with national ABS legislation of the provider country, as may be required to be submitted by users at specific checkpoints that need to be established by user countries.[2] One idea behind this is to oblige users to produce this certificate in administrative procedures, such as product approval procedures, in order to receive a specific permit or legal title. Hence, the inability of producing the certificate issued by the provider country would bear specific legal consequences in the user country, such as the denial of market introduction.

If such a regime was to be introduced, the certificate would connect the **access legislation** of the provider country with **user-measures legislation** of the user country. In this form, the internationally recognized

[2] UNEP/CBD/WG-ABS/5/7, annex, para. 21 and 39.

certificate would be an accord of the user country to give indirect legal effect to provisions of a provider country's ABS legislation. A user country would only be in a position to agree to such an accord if it knows the content of the access legislation of the provider countries. Otherwise, the question arises whether courts and administrative tribunals would agree with the validity of such an accord, i.e. whether they would agree with the domestic legal consequences or the recognition of the certificate issued by a foreign authority. Therefore, before agreeing **to connect both legislations**, the user country should make sure that it knows the rights and obligations of a user under foreign legislation. In other words, the internationally recognized certificate as mentioned above would only be fully operational and facilitate compliance with provider-country legislation if it was based on a **sufficient degree of international harmonization of national access laws**.

If an internationally recognized certificate of legal provenance/source/origin for genetic resources is further considered, **models of existing schemes using certificates as a basis of operation**, such as agreed upon under other international conventions, should be carefully examined.

As far as **sector specific treaties governed by public international law** are concerned, many of them, once adopted by a State, provide for legally binding mechanisms for inter-State dispute settlement, and therefore go beyond the provisions of Article 27 CBD. Probably the most prominent example is the dispute settlement system of the World Trade Organization (WTO) with its panel and Appellate Body proceedings, applicable for disputes among Member States of the WTO. Generally however, such dispute settlement systems require (again) a certain harmonization of substantial and procedural rules, and are not applicable to disputes arising from contracts involving private parties.

II.B. Contracts

Most judicial systems are substantially more flexible with regard to contracts that have parties in different jurisdictions. These contracts are governed by **private international law (conflict of laws)**. This body of law determines whether a court has jurisdiction and whether it should recognize or enforce a foreign judgment in civil or commercial matters. It concerns the questions of which jurisdiction should be permitted to hear a legal dispute between private parties (or entities acting as such), and which jurisdiction's law should be applied. Private international law is mostly governed by national law, which means that each State, and in some States each sub-national entity, has its own rules.

There are several **multilateral instruments** that aim at **harmonizing** the national private international law (conflict of laws). Most prominent are those negotiated under the auspices of the **Hague Conference on Private International Law**.[3] This forum administrates 39 conventions on matters of private international law. However, more than a quarter of these conventions are not in force while others have only a very limited number of Contracting States. This illustrates the reluctance to strive for a multilateral harmonization on subject matters related to the access to courts or mutual recognition of judicial awards and the enforcement thereof across jurisdictions. This experience indicates that it would **not be very promising for the IR to develop its own harmonization instruments** in this regard.

There are some Hague Conventions which may be of interest in relation to ABS. The following conventions should be carefully examined for their relevance to ABS:[4]

- The ***Convention of 1 March 1954 on civil procedure*** (in force; 45 Contracting States) covers issues such as cross-boarder communication of judicial and extrajudicial documents, non-discrimination in imposing security for costs or non-discriminatory free legal aid. The latter may be important in

[3] http://hcch.e-vision.nl/index_en.php.

[4] This list is indicative only; it is not necessarily complete.

enabling provider entities to take legal measures in the user State with regard to contract based PIC and MAT.

- The ***Convention of 18 March 1970 on the Taking of Evidence Abroad in Civil or Commercial Matters*** (in force; 45 Contracting States) deals with the conditions and procedures in case a court in one State needs evidence found in another State. The possibility to obtain evidence in another jurisdiction might be crucial with regard to ABS requirements.

- The ***Convention of 1 February 1971 on the Recognition and Enforcement of Foreign Judgments in Civil and Commercial Matters*** (in force; 4 Contracting States) deals with the scope of and the conditions that have to be fulfilled for cross-boarder recognition and enforcement of judgments. The small number of Contracting States makes it practically insignificant and testifies to the aforementioned reluctance of States to accept multilateral harmonization in this matter.[5]

- The ***Convention of 25 October 1980 on International Access to Justice*** (in force; 24 Contracting States) particularly renews the non-discriminating clauses of the 1954 Convention on civil procedure with regard to security for costs and free legal aid. As mentioned above, the latter may be important in enabling provider entities to take legal measures in the user State with regard to contract based PIC and MAT.

- The ***Convention of 30 June 2005 on Choice of Court Agreements*** (not in force; 1 Contracting State) provides an alternative to choosing arbitration in contracts. It provides a framework for two or more parties to agree on one or more specific courts of one Contracting State to the exclusion of the jurisdiction of any other courts.

In a contractual setting, seeking legal redress at a court is not the only option. **Alternative dispute resolution** systems include amicable dispute settlement through good faith negotiations, mediation, or arbitration. The Standard Material Transfer Agreement (SMTA) of the **International Treaty on Plant Genetic Resources for Food and Agriculture**, the only multilaterally agreed MTA, contains in its Article 8 provisions on dispute settlement. It establishes an escalation plan consisting of amicable dispute resolution, mediation, and finally arbitration.

Arbitration is widely recognized as a dispute settlement method in commercial practice, in particular in cross-border settings. It offers the parties to a contract flexibility with regard to applicable substantive law, procedures, arbitrators, and location. Of relevance to the issue of customary laws of local and indigenous communities is the fact that arbitral tribunals are normally empowered to appoint experts, including experts on such bodies of law. It is also possible to nominate representatives of indigenous and local communities as arbitrators. Arbitration is normally binding and without appeal and thus can be the more straightforward and cost effective way of dispute resolution than going to court. The **1958 New York Convention** on the Recognition and Enforcement of Foreign Arbitral Awards[6] provides for an international framework for the enforceability of arbitral awards. More than 140 States are Contracting Parties to this Convention.

[5] However, what is true on the multilateral level may not be the case for the regional level: The Lugano Convention on Jurisdiction and the Enforcement of Judgments in Civil and Commercial Matters[5] was concluded in Lugano on 16 September 1988. It is rafitied by the 15 old member states of the European Union (EU), Poland and the members of the European Free-Trade Association (EFTA). It is a parallel convention to the Brussels Convention of 27 September 1969 on the Jurisdiction and the Enforcement of Judgments in Civil and Commercial Matters.

[6] United Nations, *Treaty Series* , vol. 330, p. 3.;

http://treaties.un.org/Pages/ViewDetails.aspx?src=UNTSONLINE&tabid=2&id=464&chapter=22&lang=en.

There are **many frameworks for international arbitration**. In general, one can distinguish between non-administered and administered systems of arbitration. Non-administered systems merely provide a series of rules governing the procedure of arbitration, whereas administered systems also provide for an institutional framework to serve arbitration. The Arbitration Rules of the UN Commission on International Trade Law (UNCITRAL) is an non-administered type of arbitration. The International Chamber of Commerce (ICC),[7] in its nature a entity set up by business and industries, and the Permanent Court of Arbitration (PCA)[8] are two examples of institutions that provide administered systems of arbitration. The PCA was established in 1899 to facilitate arbitration and other forms of dispute resolution between States. Today it provides services for the resolution of disputes involving various combinations of States, State entities, intergovernmental organizations, and private parties, and has specific rules for arbitration of disputes relating to natural resources and/or the environment.[9] ICC and PCA might be well-suited to be included in the discussion on the future IR.

Thus arbitration is a well-known and established dispute settlement mechanism. This is why **the IR could promote the systematic inclusion of international arbitration clauses in contract based PIC and MAT**. It could include **model clauses** for such provisions. It could stipulate that customary law of indigenous and local communities should be taken into account, where the applicable substantive law governing the dispute foresees the application of such customary law.

III. Available voluntary measures to enhance compliance (question (b))

Members of the expert group on compliance are mandated to examine what kind of voluntary measures are available to enhance compliance of users of foreign genetic resources. The following is an indicative list of such measures, some of which are already contained in the Bonn Guidelines:

- Declarations by users of genetic resources of PIC and MAT compliance
- Certificates or declarations by providers, stating that the user has complied with PIC
- Certification, including third party certification[10]
- Sector specific codes of conducts and guidelines, such as the Best Practice Tool of the Swiss Academy of Sciences directed to academic research,[11] and other similar instruments developed by users
- Cross-sector guidelines explaining the steps and stakeholders involved in ABS, such as the ABS-Management Tool of the Swiss State Secretariat for Economic Affairs[12]
- Awareness raising and education modules
- Databases of best practices
- Establishment of an ombudsperson

[7] http://www.iccwbo.org/court/.

[8] http://www.pca-cpa.org/showpage.asp?pag_id=1027.

[9] Other administered systems include the London Court of International Arbitration, the American Arbitration Association, the China International Economic and Trade Association or the Inter-American Commercial Arbitration Commission.

[10] See for example Glowka L., Towards a Certification System for Bioprospecting Activities, Swiss Government commissioned Study, seco, Bern 2001.

[11] http://abs.scnat.ch/downloads/ABS_Brochure.pdf.

[12] http://www.iisd.org/pdf/2007/abs_mt.pdf.

IV. Role of internationally agreed definitions of misappropriation and misuse (question (c))

Cross-border compliance can be strengthened if stakeholders in different jurisdictions share a common understanding of the rules and conditions under which ABS takes place. This includes a common understanding of the concepts "misappropriation" and "misuse" of genetic resources. Moreover, an agreement on these concepts, possibly in the IR, could build up trust between all stakeholders involved in ABS operations as rightful use of genetic resources could be more easily differentiated from "misappropriation" and "misuse".

However, agreeing on the wording and interpretation of such a set of definitions might prove difficult because it will have to fit different national legal frameworks. Nonetheless, based on the CBD's existing terminology, "misappropriation" and "misuse" could be defined as follows:

- **Misappropriation** of genetic resources means the access of genetic resources without prior informed consent and/or mutually agreed terms covering these genetic resources pursuant to the relevant national laws regulating access to genetic resources of the country providing these genetic resources and in force at the time of access.

- **Misuse** of genetic resources means the use of genetic resources in infringement of the utilization clauses in the prior-informed-consent instruments issued by the country providing these genetic resources, or of the mutually agreed terms covering these genetic resources.

V. Taking account of customary law (question (d))

Arbitration mechanisms could be suitable to account for customary law of indigenous and local communities (see II.B. above). In general, this issue should be dealt with particularly by the Expert Group on traditional knowledge associated with genetic resources.[13] The IR should establish mechanisms to **facilitate the participation** of indigenous and local communities at the national and international level whenever their rights and interests are concerned.

VI. Particular compliance measures for research with non-commercial intent (question (e))

In general, ABS compliance and enforcement measures should be **non-disciminatory**, i.e. there is no reason to treat research with non-commercial intent differently from research with commercial intent with regard to compliance and enforcement per se. Either an entity complies or it does not; there are no in-betweens. An entity that conducts research with non-commercial intent has to comply with the relevant substantive rules set by PIC and MAT requirements the same way another entity conducting commercial research has to. Thus the difference is not in the compliance itself but with what a user has to comply with.

Thus, the potential need to differentiate between research with **commercial and non-commercial intent** is mainly a **question of substance**. However, as a prerequisite, criteria to differentiate among different categories of use have to be developed and agreed upon. Based on that, different substantive rules on PIC and MAT (including benefit sharing) for all categories of utilization of genetic resources can be developed. This means that particular terms and conditions on elements such as capacity building, awareness raising and conservation measures, could be distinct in different sets of ABS rules. Hence, non-commercial and commercial research and/or use could be treated differently and thus the "tools to encourage compliance"[14] would take a different shape accordingly.

[13] Decision IX/12, Annex II, C, UNEP/CBD/COP/9/29.

[14] See Decision IX/12, Annex I The International Regime, III. C. 1.1, UNEP/CBD/COP/9/29.

The difference between non-commercial and commercial research is only gradual, as every research (even basic academic research) can entail commercial activities or foster commercial processes. **Where the primary focus is non-commercial, the MAT could** (1) include the obligation to obtain permission from the access provider before passing on a sample to anyone else, (2) establish rather non-monetary benefit-sharing, and (3) stipulate a conditional monetary benefit-sharing expressed as a percentage in case the research or its results change to a commercial purpose, or alternatively, include the obligation to negotiate a monetary benefit-sharing agreement should the purpose of research change. **The IR could provide for a fixed percentage** to apply in case the MAT fail to do so or if there are no MAT.

Finally, research with non-commercial intent would need special concern if an internationally recognized **certificate of legal provenance/source/origin** was to be introduced (see II.A. above). First of all, checkpoints for research with non-commercial intent would have to be located within existing academic structures. Possible checkpoints and their feasibility and timing would have to be carefully evaluated. In particular, if the checkpoint was a funding agency, it would have to be taken account of the fact that researchers usually apply for funds months before actual research activities start. Yet access negotiations can only take place once the funds are available. Funding agencies might ask for a certificate to be submitted with the first intermediary research report and withhold the next payments if such a certificate is not provided. Additionally, other checkpoints for research with non-commercial intent would have to be evaluated, such as the obligation of declaration of origin and legitimate access for the publication of research results in academic journals.

II. SUBMISSIONS FROM NON-PARTIES

UNITED STATES OF AMERICA

NOV-26-2008 12:56 OES/ENRC 202 736 7351 P.01

United States Department of State

Bureau of Oceans and International Environmental and Scientific Affairs

Office of Ecology and Natural Resource Conservation

November 26, 2008

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Dr. Ahmed Djoghlaf
Executive Secretary
Secretariat of the Convention on Biological Diversity
United Nations Environment Program
413 Saint-Jacques Street, Suite 800
Montreal, QC H2Y 1N9
Canada

Dear Dr. Djoghlaf.

This is in response to your Notification inviting written submissions to the meeting of the group of technical experts on compliance. The United States appreciates the opportunity to contribute to these discussions, and we submit the following points for consideration by the group of technical experts with a view to advancing the work of the Working Group on Access and Benefit Sharing (ABS).

1. In examining the work assigned to the expert group on compliance there are certain background questions that should first be addressed.

   For example it would be helpful to gain a common understanding on the overall purpose of the compliance exercise. To this end there are factual questions to be addressed, such as:

   - Compliance by whom? It is important to understand whose compliance is being targeted. Private researchers? Public researchers? National governments where the genetic resources are located?

   - Compliance for what purpose? It is important to have a common understanding of the purpose of seeking compliance. Is it to facilitate access to genetic resources? Is it to ensure benefit-sharing? Is it to conserve biodiversity? Is it some or all of the above?

   - Compliance with which ABS regime? In the absence of consensus on some of the key parameters of the international ABS regime under discussion, e.g., whether it will be binding or non-binding, it will be difficult to provide relevant legal advice on compliance.

- Where is compliance most effectively enforced? At the international level? At national level?

- How can compliance be facilitated? What procedures are helpful to reduce the transaction costs to compliance with national or other relevant legislation? How are the procedures applicable to nationals applicable to foreigners? Are the procedures for facilitating compliance with access legislation different from those to facilitate compliance with obtaining mutually agreed terms?

- When is enforcement most effective? Prior to access? At some time after access when it is determined how the genetic resources will be used? Prior to commercialization?

These and other background issues must be analyzed prior to embarking on any exercise to develop compliance rules for ABS.

II. Taking into account the above questions and the tasks assigned to the upcoming expert group on compliance, it seems important to consider what is the best mechanism for enforcing compliance? Is it domestic courts? International arbitration? Treaty dispute settlement procedures? Once the mechanisms are decided, the rules and procedures for applying such mechanisms are more easily established.

From the U.S. perspective, the most straight forward mechanism is reliance on contract law, because the parties to a contract can provide how compliance issues and disputes will be resolved. For example, a contract could include references to domestic courts or arbitration. A contract could also address possible conflicts of laws.

There has been much discussion of the regime providing a roadmap for developing binding national laws on access and benefit sharing. Such laws would likely be enforced through domestic courts although they could also require application of contract law that could be enforced through domestic courts or arbitration.

To the extent an ABS treaty is developed, compliance could be enforced among parties through a treaty dispute settlement mechanism.

The "pros" and "cons" of these different mechanisms should be analyzed in the specific context of ABS rules for genetic resources.

III. It needs to be taken into account that the purpose of compliance is not merely to establish rules and procedures that allow enforcement of the ABS regime. A compliance mechanism should also provide transparency and certainty. Transparency

and certainty are necessary to give potential users confidence that they know in advance the conditions with which they must comply in order to access genetic resources. Potential users will not be willing to access materials if they will be subject to endless challenges after the fact.

Regardless of the nature of the mechanism, a root cause of compliance disputes appears to be a lack of information available to researchers regarding the rules in place in different jurisdictions for access and benefit sharing. Therefore attention should be paid to ways to increase the flow of information about existing national systems or systems that may be developed in the future. This could be done through a clearinghouse mechanism for information on different national laws. It could be achieved through public service announcements targeted at key communities.

IV. Regarding the proposal for development of internationally-agreed definitions of misappropriation and misuse of genetic resources and associated traditional knowledge, it seems that any such definitions would necessarily be linked to how these terms are understood under national law. It seems that an international body could establish a list of examples of what could be included in any such definition, but it is ultimately up to each country to define misappropriation or misuse under its own law given its own national circumstances. In other fora, e.g. discussions about "illegal logging," international bodies have settled on an illustrative list of activities that could be encompassed by the definition of "illegal logging" in domestic legislation rather than trying to develop international norms.

V. The United States has experience in this field as both a provider and user of genetic resources and has developed its national laws accordingly. For example the U.S. National Park System uses a contract based access system authorized under the National Parks Omnibus Management Act of 1998. This legislation arose in part out of a circumstance where a sample was taken from Yellowstone national park of the microbe *Thermos aquaticus* from which was developed the heat-stable enzyme Taq polymerase. The sample was taken without an access agreement. Patents for Taq polymerase use in gene amplification were issued and sold to a multinational company. Today, the National Park Service grants access to genetic resources in parks pursuant to an access agreement which is negotiated on a case-by-case basis.

Another example of a national system is found in the U. S. Lacey Act which was recently amended in the 2008 Farm Bill (16 U.S.C.A. 3371 et. al.). While the Lacey Act does not apply to a scientific specimen of plant genetic material, it does provide an interesting example of how a national law can incorporate relevant foreign laws so as to punish activities that are illegal under the national law of foreign countries, such as illegal logging.

The United States appreciates the Secretariat including our comments in the synthesis paper presented to the group of technical experts in January and we look forward to discussion of this topic in Tokyo.

Sincerely,

Sezaneh M. Seymour

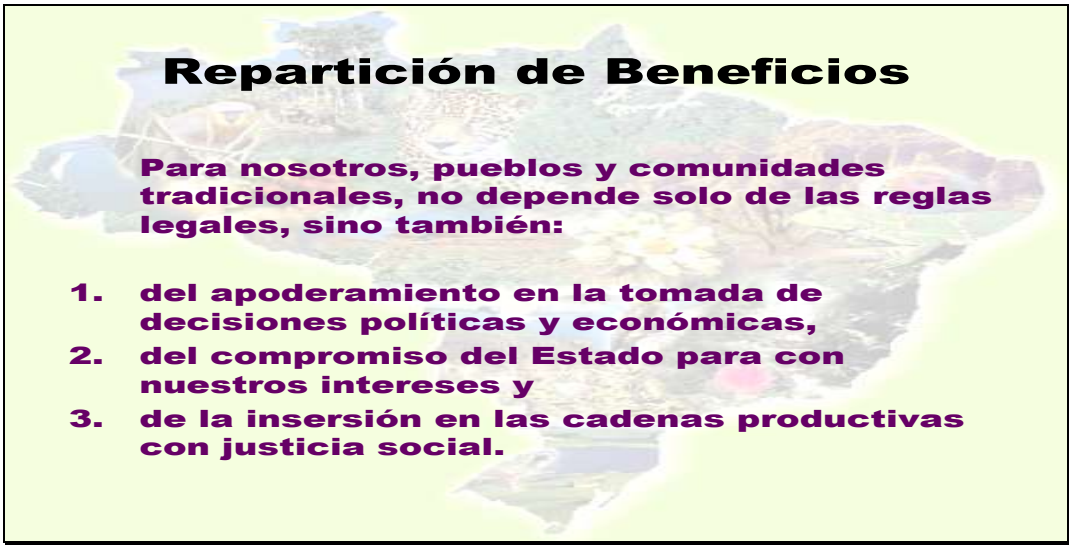
Sezaneh M. Seymour
ABS Focal Point
United States of America

III. SUBMISISONS FROM INDIGENOUS AND LOCAL COMMUNITY ORGANIZATIONS

COOPERATIVA ECOLOGICA DAS MULHERES EXTRATIVISTAS DO MARAJO, BRAZIL

Slide 1

Slide 2



English translation

Benefit-Sharing

For traditional peoples and communities, it is not just a question of legal rules, but also of:

1. Empowerment when it comes to political and economic decision-making,
2. The Government's commitment to protecting our interests and
3. Integration into chains of production, with social justice.

Slide 3

English translation

Benefit Sharing

Building on a relationship of reciprocity that facilitates, supports, makes possible, recovers, shares, recognizes, involves, communicates, and, above all,

makes a **commitment**...

Slide 4

English translation

Benefit-sharing

Commitment by the Government:

For example: on the Island of Marajó, where I come from, people still die of typhoid fever, because there is no drinking water, and no basic collective sanitation services.

The extreme poverty in the region makes traditional communities vulnerable in any kind of conflict, and exposes them to all kinds of clientelism and other deceitful relationships.

Slide 5

English translation

Benefit-sharing

Integrating Communities into Chains of Production

We want to be able to have the same degree of influence as a researcher who works in a biotechnology lab, and we want to be informed about our rights... Basically, we want to be able to decide for ourselves how we want to participate in the relationship!

Slide 6

English translation

Benefit-sharing

Before, we were treated like research subjects, and they wanted to know a bit about our

culture. Today, they don't even want that! They only care about how we gather this or that fruit or seed, what we do and how we do it, and what we use this or that for; they want to know how we plant our subsistence crops, etc.

Slide 7

English translation

Benefit-sharing

Big industrial concerns are not interested in our home-grown production methods. They are, however, very, very interested in our raw materials and millennium-old knowledge. That gets their attention!

Some companies use this input as a basis, and bring out products that have high added value, without generating any wealth for those who hold that knowledge and keep up the supplies of said resources.

Slide 8

English translation

Benefit-sharing

Some of the information arising out of the research are of no interest to the market, but are of great interest to indigenous peoples and traditional communities. That information does not get back to the grassroots community...

I have been told that good researchers publish in other languages. The way I see it, that is why people know more about us far beyond the limits of Brazil.

Slide 9

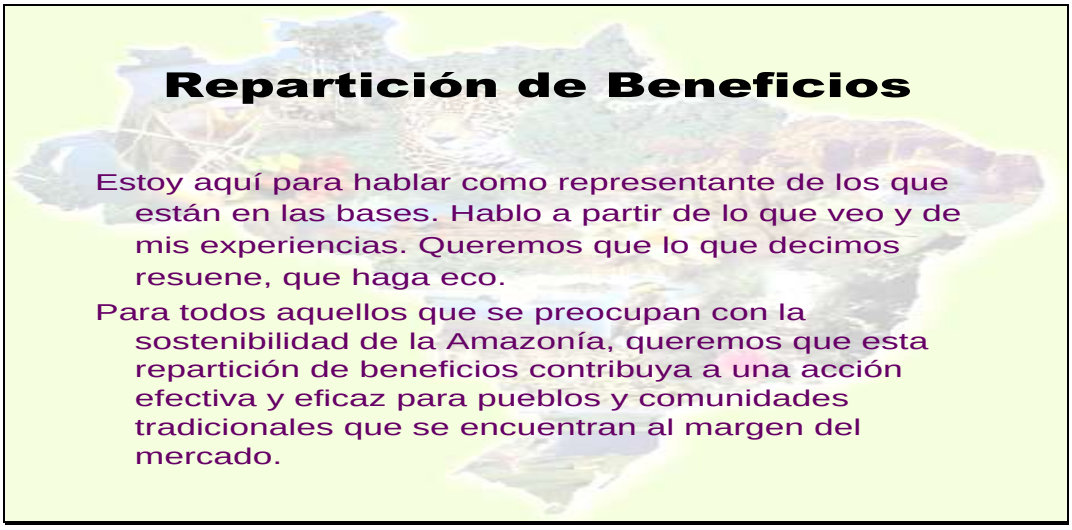
English translation

Benefit-sharing

Our integration into chains of production is intrinsically linked to our value as gatherers and providers of the raw material. The value of our traditional technology is manifested in our ancestral knowledge.

Our medicinal treatments and other traditional uses of forest resources are part of the natural selection and preservation of useful species. We must therefore be respected for the environmental services we provide, and we must be rewarded for those services.

Slide 10



English translation

Benefit-sharing

I am here to represent and speak on behalf of those at the grassroots level. I have talked about what I have seen and about my experiences. We want our message to resonate, to find an echo.

For all those who are worried about the sustainability of the Amazon region, we want benefit sharing to contribute to effective and efficient action for traditional communities and peoples who are excluded from the market.

Slide 11

PUEBLO OTOMÍ Y EL PUEBLO MAZAHUA. CONSEJO REGIONAL OTOMÍ DEL ALTO LERMA Y CONSEJO MAZAHUA DEL ESTADO DE MEXICO

(OTOMI AND MAZAHUA PEOPLES. REGIONAL COUNCIL OTOMÍ OF HIGH LERMA AND COUNCIL MAZAHUA OF THE STATE OF MEXICO)

ACCESO Y PARTICIPACIÓN EN LOS BENEFICIOS: GRUPO DE EXPERTOS TÉCNICOS Y JURÍDICOS SOBRE EL CUMPLIMIENTO – NOMINACIÓN DE EXPERTOS Y PRESENTACIÓN DE PUNTOS DE VISTA

Noviembre de 2008
Mindahi Crescencio Bastida Muñoz
Antonio Servín

México tiene una historia bien conocida de colaboración internacional, ya que su política exterior permite la participación en organismos internacionales y la celebración de acuerdos o convenios con otras naciones.

El Sistema Político Mexicano, es caracterizado por el Federalismo, que divide el poder legitimo en tres órdenes de gobierno, por lo cual corresponde la función legislativa al Poder Legislativo, mismo que tiene una estructura bicameral, siendo la Cámara de Senadores y la Cámara de Diputados (Cámara Alta y Baja, respectivamente, para otros países), correspondiendo a la primera (Articulo 76 Constitución Política de los Estados unidos Mexicanos. CPEUM):

a) Analizar la política exterior desarrollada por el Ejecutivo Federal con base en los informes anuales que el Presidente de la República y el Secretario de Relaciones Exteriores rindan al Congreso.

b) Además, aprobar los tratados internacionales y convenciones diplomáticas que el Ejecutivo Federal suscriba, así como su decisión de terminar, denunciar, suspender, modificar, enmendar, retirar reservas y formular declaraciones interpretativas sobre los mismos.

Dicha política exterior, que es conducida por el Presidente de los Estados Unidos Mexicanos, conforme el artículo 89 fracción X de la Constitución Federal, que señala las facultades y obligaciones del Presidente, establece que debe observar los siguientes principios normativos:

a) La autodeterminación de los pueblos;

b) La no intervención;

c) La solución pacífica de controversias;

d) La proscripción de la amenaza o el uso de la fuerza en las relaciones internacionales;

e) La igualdad jurídica de los Estados;

f) La cooperación internacional para el desarrollo; y

g) La lucha por la paz y la seguridad internacionales.

Lo anterior, debemos hacerlo notar para determinar cual es la vía factible para implementar en nuestro país estrategias para facilitar el acceso y participación de los beneficios derivados del Convenio sobre la Diversidad Biológica (CDB) que México suscribió el 13 de junio de 1992, en el marco de la Conferencia de Las Naciones Unidas Sobre el Medio Ambiente y el Desarrollo, celebrada en Rio de Janeiro, Brasil del 3 a 14 de Junio de 1992.

Esto, toda vez que solemos dar por hecho, sobretodo la población de la nación que corresponda, que las medidas suscritas a nivel internacional, tanto de carácter público como privado, pueden y deben aplicarse como fue convenido entre los Estados, sin mayor tramite que la sola suscripción.

Sin embargo no es directamente proporcional la relación, México posee un Orden Jerárquico Normativo en el cual la Constitución, las leyes del Congreso de la Unión que emanen de ella y todos los Tratados que estén de acuerdo con la misma, celebrados y que se celebren por el Presidente de la República, con aprobación del Senado, serán la Ley Suprema de toda la Unión. Los jueces de cada Estado se arreglarán a dicha Constitución, leyes y tratados, a pesar de las disposiciones en contrario que pueda haber en las Constituciones o leyes de los Estados.

A lo cual debemos destacar que dicha jerarquía implica que existan 2 niveles en los cuales se puede legislar, uno Federal y otro Local y ambos pueden determinar medidas de cumplimiento que respondan al derecho consuetudinario de las comunidades indígenas, pero que en todo caso depende que existan primeramente ordenamientos de carácter federal que reconozcan dichos derechos y a su vez otorgan la facultad legislativa a las Entidades Federativas o también puede reservarse exclusivamente tal facultad.

Por tanto el que en México pueda reglamentarse la aplicación y acceso a los beneficios que otorga el Convenio sobre la Diversidad Biológica, depende inicialmente de que el Congreso de la Unión, faculte a las instituciones y ciudadanos todos y proporcione los mecanismos e instrumentos para la ejecución de los acuerdos o convenios celebrados internacionalmente, toda vez rigiendo el principio de soberanía no podrían aplicarse los postulados de los mismos.

Por lo cual sigue quedando pendiente la justicia, la equidad, acceso a tribunales extranjeros, reconocimiento mutuo al menos, en tanto no se supere la resistencia de los Estados a aperturarse a la aplicación interna de los postulados internacionales si no garantizan a sus ciudadanos que las instituciones propias respetaran las decisiones de los tribunales internacionales, ya que si existen algunos mecanismos para presentar conflictos frente a ellos, pero sin embargo no se han acatado dichas resoluciones.

Consecuentemente con lo señalado en líneas previas, para los pueblos y comunidades originarias establecidas en México, es trascendente que de manera efectiva se formulen hipótesis jurídicas que reglamenten lo establecido en el artículo 8 inciso J del CDB, más allá de que la legislación nacional, *respetará, preservará y mantendrá los conocimientos, las innovaciones y las prácticas de las comunidades indígenas y locales que entrañen estilos tradicionales de vida pertinentes para la conservación y la utilización sostenible de la diversidad biológica y promoverá su aplicación más amplia, con la aprobación y la participación de quienes posean esos conocimientos, innovaciones y prácticas*. Aspectos donde si se han realizado acciones que procuran lo establecido.

No así en lo relativo a la obligación que se suscribió de fomentar que los beneficios derivados de la utilización de esos conocimientos, innovaciones y prácticas se compartan equitativamente, con las propias comunidades indígenas y locales.

La propia Constitución Federal en su artículo segundo reconoce y garantiza el derecho de los pueblos y las comunidades indígenas a la libre determinación y, en consecuencia, a la autonomía, igualmente**,** señala que la conciencia de su identidad indígena deberá ser criterio fundamental para determinar a quiénes se aplican las disposiciones sobre pueblos indígenas. A pesar de ello, y de la legislación secundaria existente no existe un procedimiento jurídico administrativo que reconozca efectivamente la personalidad de los comunidades o pueblos originarios, precisando, no de los individuos como ser y parte de pueblos originarios, sino como pueblos, es decir como colectividades, toda vez que las únicas formas de organización colectiva reconocidas son las formalmente establecidas, como lo son las sociedades mercantiles, asociaciones o sociedades civiles o los comisariados y consejos ejidales, ente otras, pero ninguna es propia de las comunidades y pueblos, por lo cual las formas tradicionales de organización carecen de personalidad jurídica.

La personalidad jurídica de la que carecen las comunidades, es el requisito (sine cuanon) sin el cual no es posible gozar de las garantías constitucionales o derechos establecidos nacional o internacionalmente.

Por ejemplo, en el Estado de México, entidad federativa de la República Mexicana, a partir del 10 de septiembre del 2002 tiene vigencia la Ley de Derechos y Cultura Indígena del Estado de México, señala en la exposición de motivos que en el capítulo segundo denominado *"Derechos fundamentales para garantizar la permanencia de los pueblos indígenas" se les reconoce la personalidad jurídica en todas las esferas del derecho y para todos los efectos y alcances que se deriven de su relación con los distintos niveles de gobierno y con terceras personas*".

Dicha formula la encontramos en el articulo 11º de la propia ley, además establece que los pueblos y comunidades indígenas tienen derecho social a vivir en libertad, paz y seguridad como pueblos diferenciados y a gozar de plenas garantías contra cualquier acto de discriminación, violencia, reacomodos o desplazamientos ilegales, separación de niñas y niños indígenas de sus familias y comunidades.

Como podemos percibir, la propia Ley determina que el tipo de derechos concedidos son de carácter social, recordemos que la división tricotónica del derecho la divide en Público, privado y Social. En consecuencia como clase social desprotegida o especifica, según se desea determinar el tipo que se conceda a las comunidades y pueblos originarios, debería de contenerse dentro de la propia legislación la forma en que pueda hacerse valida dicha personalidad, pero no es así. Revisemos que ocurre en materia del Derecho Social.

México, a nivel federal, reconoce que los Obreros y Campesinos son clases sociales desprotegidas y el Ejército una específica, por ello respecto de la doctrina y formalmente su régimen jurídico es de Derecho Social, donde se encuentran los derechos Laborales, Agrarios y Militares o Castrenses. Así los obreros tienen como forma de organización gremial para hacer valida su personalidad jurídica a los Sindicatos; los campesinos, al menos los que se encuentran dentro del régimen ejidal, realizan la defensa jurídica de sus derechos colectivos a través del Comisariado Ejidal y el Consejo de Vigilancia, y finalmente la milicia a través de sus propias Instituciones, incluso para estos principalmente y aquellos aplican principios jurídicos distintos del orden común.

Pero en estos tipos de colectivos sociales no podemos comprender a los pueblos y comunidades, ya que de origen dichas formas de organización social tienen otro objeto, por ende otra finalidad.

Citando nuevamente la Ley de Derechos y Cultura Indígena del Estado de México, ésta ley reconoce y protege a las autoridades tradicionales de las comunidades indígenas, y si bien pueden ejercer cierta representación.

También es cierto que no se encuentran legítimamente reconocido de manera plena, de tal forma que cuando una comunidad, por ejemplo, desea hacer validos los Derechos y Titulo de Obtentor, que se encuentran regulados en la Ley Federal de Variedades Vegetales, que a demás de ser de carácter federal y vigente a partir del 26 de octubre de 1996, exige que la gestión la realice el representante legal de la asociación o sociedad, incluso solicita la denominación o razón social, además dentro de los documentos que se requieren, establece como obligación presentar el Instrumento Legal que compruebe la Personalidad del Representante.

Siendo que en nuestro país el único instrumento legal de una representación, son los ofrecidos para las asociaciones o sociedades mercantiles. Por tanto debe reglamentarse la forma en que las comunidades y pueblos originarios pueden hacer validos sus derechos colectivos. Ya que esto impide que tengan acceso y participación verdadera y definitiva de los beneficios pertinente y/o sobre las condiciones mutuamente acordadas en el Convenio Sobre la Diversidad Biológica, y de la legislación Federal y Local, y demás instrumentos jurídicos internacionales, por lo cual se continua faltando al cumplimiento de la legislación sobre acceso y participación en los beneficios pertinentes y/o sobre las condiciones mutuamente acordadas.

Por tanto debemos preguntar: ¿a dieciséis años de suscrito el CDB por México, cuantos pueblos o comunidades indígenas han sido participes de los beneficios derivados de sus conocimientos tradicionales?. O bien ¿a doce años de vigencia de la Ley Federal de Variedades Vegetales, producto de la suscripción del CDB por México, cuantos pueblos o comunidades indígenas han solicitado y se les ha concedido Derechos y Titulo de Obtentor y han sido participes de los beneficios derivados de sus conocimientos tradicionales

English translation

ACCESS AND BENEFIT SHARING: GROUP OF LEGAL AND TECHNICAL EXPERTS ON COMPLIANCE – NAMING OF EXPERTS AND PRESENTATION OF POINTS OF VIEW

Mindahi Crescencio Bastida Muñoz
Antonio Servín

Mexico has a well-know history of international cooperation, with a foreign policy that enables participation in international bodies and the signing of agreements or conventions with other countries.

Mexico's political system is characterized by federalism, which distributes legitimate power among three levels of government. The legislative function is carried out by the Legislative Assembly, with its bicameral structure, namely the Senate Chamber and the Chamber of Elected Members (the Upper and Lower House, respectively, in other countries). It is responsible for (Article 76 of the Political Constitution of the United Mexican States, CPEUM):

(a) Analysing foreign policy developed by the Federal Executive, based on annual reports to Congress by the President of the Republic and the Foreign Affairs Secretary.

(b) Further, approving international treaties and diplomatic conventions signed by the Federal Executive, as well as its decision to terminate, condemn, suspend, modify, amend, withdraw caveats and make interpretative declarations regarding said treaties and conventions.

The said foreign policy is conducted by the President of the United Mexican States. article 89, section X of the Federal Constitution lists the powers and obligations of the President, and stipulates that the following normative principles must be observed:

(a) The self-determination of peoples;

(b) Non-interference;

(c) Peaceful resolution of conflicts;

(d) Proscribing the use of force, or threat thereof, in international relations;

(e) The equality of States before the law;

(f) International cooperation for development; and

(g) The struggle for international peace and security.

We have highlighted the above in order to determine a viable means of implementing strategies in our country to facilitate access and benefit sharing under the Convention on Biological Diversity (CBD) signed by Mexico on 13 June 1992, at the United Nation Conference on Environment and Development held in Rio de Janeiro, Brazil, from 3 to 14 June 1992.

This means that it is taken for granted, particularly by the people of the country in question, that internationally supported public and private measures can and must be applied as agreed among the States, without further steps than the signing itself.

However, the relationship is not directly proportional. Mexico has a hierarchical order of law-making, according to which the Constitution, Laws of Congress of the Union that arise from it, and all treaties that are in accordance with it and are signed by the President of the Republic and approved by the Senate, become the Supreme Law of the entire Union. The judges of each state must abide by said Constitution, laws and treaties, despite any provisions to the contrary that may exist in state constitutions or Laws.

We must therefore highlight the fact that said hierarchy implies that there are two levels of law-making, one federal, and the other local, and both levels can establish enforcement measures that respect the customary rights of Indigenous communities. However, this requires federal orders that recognize said rights, and either grant legislative powers to the bodies of the federation, or reserve those powers exclusively.

Therefore, the regulation and implementation of access and benefit-sharing under the Convention on Biological Diversity in Mexico initially depends on having the Congress of the Union empower all institutions and citizens, and provide the mechanisms and instruments required to carry out the international agreements and conventions that have been signed. Otherwise, the principle of sovereignty prevents the stipulations of said conventions and agreements from being applied.

That is why justice, fairness, access to foreign courts, and mutual recognition are still pending, and will be as long as States resist to opening up to the internal application of international stipulations that do not provide their citizens with a guarantee that their own institutions will respect the decisions of international courts. Mechanisms may be foreseen to dispute such stipulations, but the relevant resolutions have not been approved.

Consequently, for the indigenous peoples and communities in Mexico, it is of the utmost importance to effectively formulate legal hypotheses to regulate what is set out in Article 8(j) of the Convention on Biological Diversity, beyond stating that "*each Contracting Party shall, subject to national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge innovations and practices*". These are aspects for which steps have already been taken.

The same cannot be said for the obligation to encourage that benefits arising from the use of said knowledge, innovations and practices be shared fairly with indigenous and local communities.

Article 2 of the Federal Constitution recognizes and guarantees indigenous peoples' and communities' right to self-determination and, consequently, to autonomy. It also indicates that awareness of their indigenous identity shall be the main criteria for determining those to whom provisions regarding indigenous peoples apply. Despite this, and despite existing secondary legislation, there is no legal administrative process that effectively recognizes the legal personality of indigenous communities or peoples, not as individuals who are members of indigenous peoples, but as peoples or groups. This is because the only recognized forms of collective organisation are formally established groups, such as companies, commercial associations, or civil society organisations, or communal land councils and commissariats, among other groups. However, this does not apply to indigenous communities or peoples, which is why traditional forms of organization do not have a legal personality.

This legal personality, which communities lack, is the *sine qua non* requirement for benefiting from constitutional guarantees, and nationally or internationally established rights.

For example, in the State of Mexico, a federative body of the Mexican Republic, the Indigenous Culture and Rights Act of the State of Mexico has been in effect since September 10, 2002. The Act's statement of purpose indicates that Chapter 2, entitled "*Fundamental Rights to Guarantee the Lasting Presence of Indigenous Peoples" recognizes the legal personality (of indigenous peoples) in all areas of*

law and for all effects and to all extents in their relationship with the various levels of government and with third parties."

This language is found in Article 11 of the Act, which also establishes that indigenous peoples and communities have the social right to live in freedom, peace and security, like other various peoples, and enjoy full guarantees against any act of discrimination, violence, illegal resettling or displacement, or separation of indigenous girls and boys from their families and communities.

As we can see, the Act itself determines which granted rights are social rights, and we must remember the threefold division of law into Public, Private and Social law. Therefore, seeing as indigenous peoples and communities are a vulnerable or specific social class, depending on how they are categorized, the legislation should contain a means for validating their legal personality. However, that is not the case. Let us examine the situation with respect to Social Law.

At the federal level, Mexico recognizes workers and peasants as vulnerable social classes, and recognizes the army as a specific social class. Officially and according to doctrine, they fall under the social law system, which includes labour, agriculture, and military or armed forces laws. Workers have unions in which to organise and validate their legal personality. Peasants, at least those within the communal land system, can defend their collective rights before the law through the Communal Land Council and the Oversight Council. Finally, members of the military have their own specific institutions that apply distinct legal principles.

But these types of social groups do not include indigenous peoples and communities, seeing as these types of social organisation pursue different objectives, and therefore exist for a different purpose.

If we go back to the Indigenous Culture and Rights Act of the State of Mexico, we can see that it recognizes and protects the traditional authorities of indigenous communities, which can exercise a certain level of representation.

However, it is also true that those traditional authorities are not fully recognized. For example, this becomes evident when an indigenous community attempts to validate the Breeder's Rights and Title, as regulated under the Federal Plant Varieties Act. The Act is federal in nature, and has been in effect since 1996. The Act states that the legal representative of the association or company must handle the process, and requests a company name or title. The Act also establishes the obligation to provide, among the required documents, a legal instrument proving the representative's legal personality.

In Mexico, the only legal instruments for representation are those issued to commercial associations or companies. It is therefore necessary to regulate means by which indigenous peoples and communities can validate their collective rights. Otherwise, they cannot enjoy true and definitive access, benefit sharing and/or mutually agreed terms under the Convention on Biological Diversity. This situation also excludes them from federal and local legislation, and from other international legal instruments. Therefore, compliance with the legislation regarding access and benefit sharing, and/or mutually agreed terms continues to be found lacking.

We must therefore ask ourselves: sixteen years after Mexico signed the CBD, how many indigenous peoples have shared in the benefits arising from their traditional knowledge? Or, we could ask: twelve years after the Federal Plant Varieties Act went into effect, as a result of Mexico's signing of the CBD, how many indigenous peoples or communities have requested and obtained Plant Breeders' Rights and Titles, and have shared in the benefits arising from their traditional knowledge?

IV. SUBMISSIONS FROM INTERNATIONAL ORGANIZATIONS AND RELEVANT STAKEHOLDERS

ACCESS AND BENEFIT SHARING ALLIANCE (ABSA)

Access and Benefit Sharing Alliance

ABSA

December 1, 2008

Mr. Ahmed Djoghlaf
Executive Secretary
Convention on Biological Diversity
413 St. Jacques Street, 8th Floor
Montreal, Quebec
Canada H2Y 1N9

Dear Ahmed:

Members of the Access and Benefit Sharing Alliance (ABSA) have been working closely with the International Chamber of Commerce (ICC) as lead for the ICC's Compliance Contact Group, and with other national and regional industry advocacy organizations, on issues before the upcoming Compliance Technical Experts Group (TEG) for the ABS International Regime (IR).

In response to CBD Notification SCBD/SEL/OJ/VN/GD/64856, issued on 12 September 2008, the ABSA is writing to associate itself with the ICC's paper: "Access and Benefit Sharing: Priority Issues for the Compliance TEG; Submission to the Technical Experts Group on Compliance." In addition, we are taking this opportunity to formally submit the ABSA ABS Negotiating Principles for consideration by the CBD TEG on Compliance, scheduled for Tokyo, Japan, 27 - 30 January 2000.

As noted previously, ABSA Members remain committed to the elaboration and negotiation of the ABS IR. In this context, it is of paramount importance that the ABS IR be realistic in its jurisdictional scope and provide as much flexibility as possible for all stakeholders. As reflected in the cross-industry ICC paper, ABSA Members remain concerned that the ABS IR ensure transparency and non-discrimination in terms of commercial vs. non-commercial uses of genetic resources, with or without traditional knowledge.

Development of a transparent, non-discriminatory (i.e., domestic vs. foreign as well as commercial vs. non-commercial), and predictable ABS International Regime will enable the parties to ABS agreements to reach mutual agreed terms (MAT) in a non-bureaucratic framework for creation of meaningful benefits from sustainable uses of genetic resources.

ABSA Members look forward to continuing our close engagement on these important compliance issues in the weeks and months ahead, and I appreciate the opportunity to participate as one of the two industry experts in the Compliance TEG scheduled for January of 2009 in Tokyo.

We hope that these documents will be helpful.

Warm regards,

Susan K. Finston
Executive Director

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Access and Benefit Sharing Alliance

ABSA

ABS NEGOTIATING PRINCIPLES

INTRODUCTION:

As a core stakeholder in development of any International Regime (IR) relating to Access and Benefit Sharing (ABS), Members of the Access and Benefit Sharing Alliance (ABSA) are committed to identifying practical ABS approaches with demonstrated real-world benefits at the Convention on Biological Diversity's (CBD) Ninth meeting of the Conference of the Parties (COP 9) in Bonn, Germany.

In this practical approach, we note that a number of prior ABS approaches have fallen short of expected benefits, including policies relating to mandatory disclosure of source, origin and proof of benefit sharing. Equally important, negotiation of the ABS IR should be based on organizational principles that ensure a transparent, equitable, consistent and predictable ABS negotiating process and outcomes.

In that spirit, ABSA Members provide the following principles.

PREAMBLE:

ABSA Members:

- Reaffirm their commitment to respect the sovereign rights of CBD members over their *in situ* genetic resources (GR) and to the equitable sharing of the commercialization of GR and any related relevant traditional knowledge (TK) derived from indigenous and local communities, assuming a clear, internationally accepted definition of TK.

- Underscore industry's established track record of compliance with the Bonn Guidelines, including Prior Informed Consent (PIC), Mutually Agreed Terms (MAT) and equitable benefit sharing.

- Support development of comprehensive digital libraries or registries to help identify holders of GR; capacity building to promote best practices for IP management; and the use of model Material Transfer Agreements (MTAs) to ensure effective compliance with PIC and MAT and to provide front-loaded benefits and clarity and fairness in the disposition or sharing of intellectual property rights.

- Believe that there is an increasing recognition among the parties, indigenous communities and NGOs of industry's critical role as a key stakeholder and generator of commercial benefits from biological diversity.

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PRINCIPLES:

- An ABS International Regime (ABS IR) should include measures that ensure equitable and non-discriminatory terms for access to GR, demonstrably generate benefits, and provide positive incentives to encourage mutually beneficial and environmentally sustainable commercialization of genetic resources.

- An ABS IR should be based on reality and the actual experiences of stakeholders either at the local, regional or state level, including the actual experiences of countries, indigenous communities, NGOs, and industry.

- An ABS IR should recognize the ground realities by which businesses operate so that appropriate incentives are balanced against necessary enforcement provisions for the benefit of all stakeholders.

- To ensure a workable system, all stakeholders (countries, indigenous communities, NGOs and industry) should participate broadly in the elaboration of an ABS IR.

- NGO and industry groups should be encouraged to participate in the elaboration of an ABS IR, regardless of whether their national governments are currently CBD Members.

- Development of ABS elements should reflect the individual needs and experiences of CBD Members at various stages of economic development, which suggests a bottom-up, "cafeteria-style" approach rather than a "top down" one-size-fits-all regime based on a single legally binding instrument.

- An ABS IR should be amenable to simple and expeditious implementation, taking into account the individual needs and experiences of CBD Members.

- An ABS IR should include national regulation and enforcement mechanisms. The Parties, with the participation of stakeholders, should also consider issues of extra-territorial enforcement.

- An ABS IR should ensure transparency, predictability, consistency, durability and non-discriminatory treatment with respect to both access and compliance through the inclusion of clear definitions consistent with the terms and jurisdictional limitations of the CBD itself.

- The CBD ABS WG should continue to rely on such other international organizations as the FAO, WIPO, WTO, as appropriate, for technical input during the 2007-2010 period.

- Supporting work by other international organizations, while essential to the work of the ABS WG, should respect the CBD's unique mandate and remit for

comprehensive ABS negotiations and not prejudge the outcomes of the deliberations of the ABS WG. In this respect, the CBD should continue to rely upon the unique expertise and mandate of WIPO with regard to the harmonization of intellectual property standards.

AREAS OF CONTINUING DISAGREEMENT

- **New Additional Mandatory Disclosure Obligations**

Patent disclosure obligations enacted by CBD Members have had a documented chilling effect on bioprospecting and GR commercialization. By making patent protection for GR commercialization contingent on an *ex post* examination of the sufficiency of the disclosure, mandatory patent disclosure regimes place at risk the very basis for the recoupment of investment. [Patent disclosure obligations do not create ABS benefits, are polarizing and drive stakeholders further apart].

- **Certificates of Source, Origin and Legal Provenance**

ABSA Members do not support the development of a certificate system that would create an additional formality or condition of patentability for biotechnology inventions. They also do not view the CBD Experts Group on Certificates as fully representing the broad spectrum of views found in the biotechnology sector. The group, if reconvened in the future for additional work, should be broadened to reflect the diverse needs and experiences of industry. The CBD Experts Group on Technology Transfer may provide a model for inclusion of more than one industry representative allowing representation of different segments of the biotechnology sector.

- **Areas Beyond the Jurisdiction of the Convention**

Difficult issues for the ABSA include suggested coverage of both *in situ* and *ex situ* resources; pre-CBD vs. post 1994 GR bioprospecting; human vs. plant and animal GR; and products vs. derivatives of GR. Boundary lines should be drawn consistent with the obligations and explicit legal boundaries of the CBD Treaty, as exemplified by the Bonn Guidelines.

All stakeholders require clear boundaries to commit resources to participation in an ABS IR Without a precise understanding of important terms such as "genetic resources, products and/or derivatives," it is impossible for any private company to enter into an agreement with indigenous communities or other holders of traditional knowledge.

- **Lack of Clarity Over the Definition of Traditional Knowledge (TK)**

A precise understanding of this important term is also needed before private companies are able to enter into agreements with indigenous communities or other holders of TK. Moreover, if more than one indigenous community (within a country or

otherwise) states a claim to the same TK, there needs to be a clear approach to TK rights that does not threaten a private company that has acted in good faith and is working on the basis of PIC and MAT with one of these communities (or with a focal point of a CBD Member that has entered into good faith PIC and MAT with a community). Unless and until further international consensus is reached on the issue of TK, the ABS IR should follow the precedent established by the Bonn Guidelines.

BIOTECHNOLOGY INDUSTRY ORGANIZATION (BIO) AND THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA)

COMMENTS OF THE BIOTECHNOLOGY INDUSTRY ORGANIZATION (BIO) AND THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA) ON ISSUES TO BE ADDRESSED BY THE TECHNICAL AND LEGAL EXPERTS GROUP ON COMPLIANCE

Introduction:

Decision IX/12 of the Ninth Session of the Conference of the Parties (COP-9) of the Convention on Biological Diversity (CBD) "*[i]nvites* Parties, Governments, international organizations, indigenous and local communities and relevant stakeholders to provide information and views related to the issues to be addressed by each expert group."

The Biotechnology Industry Organization (BIO) and the Pharmaceutical Researchers and Manufacturers of America (PhRMA) appreciate this opportunity to submit comments on matters to be addressed by the Technical and Legal Experts Group on Compliance ("Compliance TEG"). BIO and PhRMA respectfully request that the experts selected for the Compliance TEG take these comments into consideration during their deliberations.

General Comments:

BIO and PhRMA members firmly believe that the proposed international regime on access and benefit-sharing should be within the scope of the CBD. It is also our strong belief that a "one size fits all" approach is not workable for the International Regime. Suppliers and recipients of genetic resources will obtain optimum economic and social benefits through the negotiation of "mutually agreed terms" for access and benefit-sharing at the "point of access," rather than applying a fixed access scheme and a fixed "basket" of benefits mandated by a treaty. Negotiations at the point of access would allow suppliers and recipients to determine the appropriate balance between "up-front" and "back-end" benefits for the relevant transaction as well as to determine an appropriate level of benefits arising from the contemplated arrangement. Compliance measures envisioned under the International Regime should be consistent with this approach.

BIO and PhRMA members support providing for effective compliance measures under the International Regime to ensure that the objectives of the CBD can be implemented in a fair and equitable manner that facilitates access. In that light, the use of existing tools, including the use of private international law mechanisms, should be further considered. Some of these tools, including mediation, arbitration and other dispute settlement mechanisms, are currently used effectively in many international business transactions and provide a good foundation for facilitating transactions relating to genetic resources. The delegation of Canada has explained the utility of such measures in their submission to the sixth session of the ABS Working Group (UNEP/CBD/WG-ABS/6/INF/3/Add.2).

Note on compliance and intellectual property. Industry strongly opposes acceptance of proposals for new disclosure requirements in patent applications relating to genetic resources. Industry is of the view that such requirements will be (a) ineffective in promoting the objectives sought (e.g., compliance with CBD principles) and (b) will introduce uncertainties into the patent system that will inhibit innovation in relevant technologies and will thereby decrease potential benefit-sharing from such efforts. Detailed and lengthy discussions in the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO) have confirmed this view. These requirements should not be included in the International Regime. Instead, promoting access and benefit-sharing through "mutually agreed terms" is the best approach. To the extent further discussion is necessary on these proposals, it should be done at WIPO, which has an intergovernmental committee (IGC) with a specific mandate to discuss matters regarding the relationship of intellectual property and genetic resources, traditional knowledge and folklore.

Specific Comments:

The terms of reference of the Compliance TEG provide that the experts group will consider and address the following questions. The questions are reproduced below and are followed by the comments of BIO and PhRMA.

(a) What kind of measures are available, or could be developed, in public and private international law to:

(i) Facilitate, with particular consideration to fairness and equity, and taking into account cost and effectiveness:

a) Access to justice, including alternative dispute resolution;

b) Access to courts by foreign plaintiffs;

(ii) Support mutual recognition and enforcement of judgments across jurisdictions; and

(iii) Provide remedies and sanctions in civil, commercial and criminal matters;

in order to ensure compliance with national access and benefit-sharing legislation and requirements, including prior informed consent, and mutually agreed terms;

Comment:

Facilitating access to justice and access to courts by foreign plaintiffs

Any enforcement measures considered by the Compliance TEG should build on existing systems.

In the case of enforcing ABS systems and facilitating access to justice, private international law offers many alternative dispute mechanisms that are currently used to enforce contractual agreements relating to international business transactions around the world.[1] Existing measures such as negotiation, mediation, arbitration and consideration of enforcement of foreign judgments should be further elaborated and adapted for use in this context. The New York Convention on the Recognition and Enforcement of Foreign Arbitral Awards (New York Convention) could provide a good starting point for discussion. The New York Convention currently has 143 members. It is truly a multilateral agreement and is an effective mechanism for settling disputes involving cross-border parties.

Mediation and arbitration offer many advantages as a model for compliance methods under the CBD. First, there are existing models for these programs. The International Chamber of Commerce (ICC) has highly developed programs in amicable dispute resolution processes, such as mediation, and has a well-recognized court of arbitration. The WIPO Arbitration and Mediation Center also provides for the resolution of international commercial disputes between private parties with highly developed procedures that are widely recognized as particularly appropriate for disputes involving intellectual property.[2]

[1] *See, e.g., Compilation of Submissions Provided by Parties, Governments, Indigenous and Local Communities, and Stakeholders on Concrete Options on Substantive Items on the Agenda of the Fifth and Sixth Meetings of the Ad Hock Open-ended Working Group on Access and Benefit-Sharing: Submission from Canada*, UNEP/CBD/WG-ABS/6/INF/3/Add. 2 (Jan. 15, 2008).

[2] *See* description of WIPO Arbitration and Mediation Center, *available at* http://www.wipo.int/amc/en/.

It is also instructive that the text of the CBD itself provides for rules of dispute settlement between the Contracting Parties that follow a multi-step negotiation-mediation-arbitration model.[3] A similar approach is also included in the standard material transfer agreement (SMTA) concluded under the Food and Agriculture Organization (FAO) International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA).

Supporting mutual recognition and enforcement of judgments across jurisdictions:

The potential to improve foreign enforcement of judgments should be studied further. However, CBD Members in the past have been reluctant to recognize judgments from other jurisdictions. Indeed, the relative failure of the 1971 Hague Convention on Recognition and Enforcement of Foreign Judgments in Civil and Commercial Matters stands in stark contrast to the wide membership of the New York Convention and is instructive as to the political difficulties of this issue.

Nonetheless, there are mechanisms in national laws that provide for the enforcement of foreign judgments in a number of CBD Parties when certain conditions are met. For example, according to the submission of Canada to the ABS Working Group,[4] the clear trend in Canadian courts is to recognize and enforce foreign judgments. In addition, the recent 2005 Hague Convention on Choice of Court Agreements may also provide a tool to be considered in this context.

Providing remedies and sanctions in civil, commercial and criminal matters:

This topic should be understood in the sense of exploring remedies and sanctions available through the dispute settlement mechanisms mentioned previously. The International Regime should not attempt to impose direct civil or criminal regulation with respect to bioprospecting or related activities at the international level. Any such specific regulation should be the domain of national laws.

Civil remedies for violation of contractual terms can include provision of damages, injunctions, or other mechanisms to address breaches of contractual terms.[5] In addition, the parties to agreement can include clauses in the mutually agreed terms providing for particular remedies if a breach occurs. The International Regime should not attempt to regulate long-held principles of contract law regarding available remedies in the various jurisdictions.

In respect of compliance with national laws on access to genetic resources, BIO and PhRMA members understand that there are significant concerns about perceived illicit bioprospecting activities and other acts that may raise concerns of "misappropriation" or "bio-piracy." In order to address these concerns, CBD Parties may provide fines or other sanctions for violation of ABS laws. Civil remedies also may be available in jurisdictions providing a cause of action for torts, such as conversion, that can address wrongful acts in respect of genetic resources.

In addition, more work should be done in respect of studying the scope of these perceived activities. Industry supports a fact-based consideration of this issue in order to identify the magnitude of any such perceived acts and any evident gaps in national ABS regimes that may result in particular problems. However, it appears that most perceived instances of misappropriation result either from the lack of appropriate national ABS regimes or lack of information to researchers working in-region. Punitive measures, therefore, will likely not address the perceived problems but may instead exert a significant chilling effect on legitimate researchers seeking to engage in activities in those countries. In that light,

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[3] CBD Article 27 provides that parties seek to resolve disputes first by negotiation, then mediation by a third party and, if those efforts fail, it provides for arbitration. CBD Article 27.3(b) also provides an option for submission of the dispute to the International Court of Justice. However, we do not view this as a workable model for disputes relating to ABS agreements concluded pursuant to the International Regime that may involve private parties.

[4] UNEP/CBD/WG-ABS/6/INF/3/Add.2, *supra* note 1.

[5] *See, e.g.*, E. ALLAN FARNSWORTH, FARNSWORTH ON CONTRACTS, Vol. III, §12.2, pp. 153-154 (1998).

overly punitive measures would be contrary to the requirements of the CBD to facilitate access and should be avoided.

The International Regime should focus instead on measures for increasing awareness of national ABS requirements by those engaging in bioprospecting activities, as well as capacity building efforts for countries developing effective ABS regimes.

(b) What kind of voluntary measures are available to enhance compliance of users of foreign genetic resources;

Comment:

Awareness-raising measures aimed at those engaging in bioprospecting activities, as well as capacity building efforts for countries developing effective ABS regimes are voluntary measures that would enhance compliance of users of foreign genetic resources. It is our belief that the vast majority of researchers and others seeking access to genetic resources are good-faith actors that intend to fully comply with local ABS laws. These methods would be highly effective at enhancing compliance of these actors.

In addition, there are currently voluntary industry guidelines that seek to formalize "best practices." BIO has published guidelines to educate and assist its members on access and benefit-sharing practices.[6] BIO has also published a model material transfer agreement (MMTA).[7] In addition, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) has also published guidelines for its members in this area.[8] While not intended to be standard agreements or mandatory codes of conduct, these guidelines help identify "best practices" in the industry and also are intended to be updated as practices change.

(c) Consider how internationally agreed definitions of misappropriation and misuse of genetic resources and associated traditional knowledge could support compliance where genetic resources have been accessed or used in circumvention of national legislation or without setting up of mutually agreed terms;

Comment:

BIO and PhRMA members are strongly of the view that the International Regime must be within the scope of the CBD. In that light, providing a definition of "misappropriation" or "misuse" in the International Regime itself may not be appropriate as these terms are not found in the CBD.

However, a further understanding of the concept of "misappropriation" or "misuse" or other terms might be helpful for discussion purposes in the ABS Working Group. In that light, greater convergence by CBD members regarding the meaning of these terms for purposes of discussion could be helpful. It is noted that, in certain jurisdictions, "misappropriation" and "misuse" have particular meanings within the context of unfair competition and anti-competition laws, respectively, which further adds to confusion and, perhaps, may indicate that different terminology should be used to capture notions of illicit acts undertaken in respect of genetic resources.

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[6] Guidelines for BIO Members Engaging in Bioprospecting, *available at* http://www.bio.org/ip/international/200507guide.asp

[7] BIO Model Material Transfer Agreement, *available at* http://www.bio.org/ip/international/BIO_Model_MTA.pdf

[8] Guidelines for IFPMA Members on Access to Genetic Resources and Equitable Sharing of Benefits Arising Out of Their Utilization, *available at* http://www.ifpma.org/Issues/fileadmin/templates/ifpmaissues/pdfs/2008_05_22_Guidelines_Genetic_Resources_EN.pdf

Any definition should be linked to compliance with national ABS laws. In other words, if there is no violation of national law, there can be no "misappropriation." This is a concept that has not reached a level of common understanding in the Working Group. As noted in the submission of ICC for the Concepts TEG,[9] the International Regime cannot remedy gaps in national legislation; failure of countries to fulfill CBD obligations in developing ABS regimes will directly lead to non-fulfillment of ABS objectives.

(d) How could compliance measures take account of the customary law of indigenous and local communities?

Comment:

Compliance measures that take into account the customary law of indigenous and local communities should be developed at the national level. The vast differences in customary law approaches within and among States make it impossible to design a "one size fits all" approach that would be functional at the international level. The International Regime should include provisions that articulate guidance for national ABS regimes, such as the identification of clear points-of-contact to ensure that legal certainty, clarity and transparency are maintained. In this manner, recipients of genetic resources will know what requirements apply to obtaining genetic resources, whether these requirements are derived from customary law or not.

If the national ABS regime does not fully comply with customary law principles, it is the State that should be held accountable and the laws changed. As noted, the International Regime cannot remedy gaps in national legislation, whether these gaps relate to customary law or other matters.

(e) Analyse whether particular compliance measures are needed for research with non-commercial intent, and if so, how these measures could address challenges arising from changes in intent and/or users, particularly considering the challenge arising from a lack of compliance with relevant access and benefit-sharing legislation and/or mutually agreed terms.

Comment:

It is not clear whether particular compliance measures under the International Regime would be needed for research with non-commercial intent. Generally speaking, the type of research envisioned will likely drive the terms that are to be mutually agreed between the relevant parties. For such cases, a specific set of rules under the International Regime would not be necessary. The agreements themselves would limit the research to non-commercial uses, commercial uses or a combination of the two, and would address benefit-sharing terms accordingly. BIO and PhRMA members view this as the optimal approach.

Nonetheless, there may be some CBD Parties that envision a split system with different rules of access for non-commercial research. It will be very difficult to specifically define this activity. If such an approach is considered by the Working Group, any such work should full address the ability to "convert" from non-commercial to commercial research. This is likely highly fact-specific and would be workable if, and only if, a clear definition for what is intended by "non-commercial" research is developed and how this may transition to "commercial" applications.

It should be noted that even where a country may pursue a bifurcated system, the compliance measures previously described would be applicable to all cases of unauthorized access. Countries may choose to apply only a particular subset of such measures to behavior that can objectively be determined to have

[9] *Good Business Practices and Case-Studies on Biodiversity: Report Submitted by the International Chamber of Commerce*, UNEP/CBD/ABS/GTLE/1/INF/1 (Oct. 31, 2008).

been in pursuit of "non-commercial" research objectives. In any case efforts should be made to ensure that the compliance measures in question are effective to enforce ABS requirements while facilitating access consistent with CBD and do not become barriers to access themselves.

CONSORTIUM FOR THE BARCODE OF LIFE

Submission of views from an International Workshop on "Access and Benefit-sharing in Non-Commercial Biodiversity Research", Bonn, 17-19 November 2008

Introduction

Governments and researchers in both industrialized and developing nations agree that non-commercial research contributes to the CBD goals of conservation and sustainable use of biodiversity. Non-commercial research can also generate non-monetary benefits and can lead to commercial development that will produce economic benefits for both provider and user countries. Access to genetic resources is critical to achieving these benefits, and for this reason non-commercial biodiversity research deserves to be recognized and promoted under the International Regime for Access and Benefit Sharing.

Ten national science agencies and international organizations involved in biodiversity research[1] convened a workshop at the Zoological Research Museum Alexander Koenig Museum in Bonn, Germany, on 17-19 November 2008, to address the issue "Access and Benefit Sharing in Non-commercial Biodiversity Research". Fifty-one participants were invited with the goal of gathering expert opinions with a balanced representation among geographic and disciplinary perspectives (see table, below). The researchers were primarily drawn from the community of taxonomists, museum and herbarium scientists, ecologists, conservationists, breeders, and genome scientists. The emphasis was on whole-organism research (as opposed to biochemistry, biophysics, or developmental biology, for example) because it is closer to the goals of CBD and the missions of the workshop's sponsors. Participants were asked to provide their personal perspectives and they did not participate as official representatives of their respective agencies, institutions, or research communities.

Sector			Geographic Region				
Research	**Agency**	**Other**	**OECD**	**Africa**	**Latin America**	**Asia**	**Pacific**
29	10	12	28	8	4	9	2
56.9%	19.6%	23.5%	54.9%	15.7%	7.8%	17.6%	3.9%

Prior to and during the workshop, participants were given access to documents related to CBD (including but not limited to the decisions of COP-9), the ABS Working Group, preparations for the upcoming meetings of the Ad Hoc Technical Expert Groups [AHTEGs] in Namibia and Japan). In addition to preparing a workshop report on the overall topic of the relationship between non-commercial research and the International ABS Regime, participants were asked to prepare responses to the questions addressed to the AHTEG on Compliance that were contained in COP IX/12 Annex IIB. The workshop participants reviewed all five questions and concluded that only questions (b) and (e) touched upon issues for which they could provide well-informed and relevant input. The following responses reflect a compilation of the ideas expressed during the workshop.

(b) What kind of voluntary measures are available to enhance compliance of users of foreign genetic resources?

[1] The workshop was sponsored by: The Consortium for the Barcode of Life (CBOL); the Deutsche Forschungsgemeinschaft (DFG, German Research Foundation); Zoological Research Museum Alexander Koenig, Bonn; the Swiss Federal Office for the Environment (FOEN); the International Barcode of Life Project (iBOL); the European Distributed Institute of Taxonomy (EDIT); the Moorea Biocode Project of French Polynesia; Muséum National d'Histoire Naturelle (MNHN, Paris); DIVERSITAS/bioGENESIS; and UNESCO's Natural Sciences Sector.

Voluntary measures can be powerful complements to legally binding measures. Voluntary measures can contribute to transparency which helps in monitoring compliance and can help to build relationships of trust between provider countries and users of their genetic resources. To reach these goals of compliance and trust the measures must be truly voluntary, in the sense of being proactive. "Voluntary" measures may have less impact if they are treated as "optional". Parties could interpret optional measures as efforts to forestall mandatory measures, transfer risk and liability to other parties, and exonerate misappropriation of genetic resources.

On one side, there are several possible measures that could be implemented on a voluntary basis by individual non-commercial researchers, research institutions, and/or entire scientific disciplines. Deciding which measures, or combination thereof, would be most efficient and appropriate will require further discussion and development by the scientific research community. Some of the possible voluntary measures that the research community could consider adopting are:

- Adopting scientific standards of ethical behavior and codes of research conduct that are consistent with ABS principles. Examples of existing Codes of Conduct that could be used as models include MOSAICC (http://www.belspo.be/bccm/mosaicc) and the Principles on Access to Genetic Resources and Benefit Sharing (http://www.kew.org/conservation/principles.html);
- Creating compilations of best practices that reflect CBD objectives (e.g., Access and Benefit Sharing: Good practice for academic research on genetic resources; http://abs.scnat.ch/);
- Developing and adopting institutional policies and codes of conduct that acknowledge and align with CBD principles and ABS provisions (e.g., Kew Botanic Gardens policy; www.kew.org/conservation);
- Making adherence to ABS principles a requirement for research funding from government sources or private foundations (e.g., German Research Foundation Guidelines, http://www.dfg.de/forschungsfoerderung/formulare/download/1_021e.pdf;
- Monitoring compliance with ABS agreements as part of the peer review system of scientific journals and the professional standard for scientific publication. This could create new burdens on publishers who would be asked to install additional monitoring mechanisms;
- Creating more transparent systems of tracking the loan, exchange, and/or utilization of genetic resources that are transferred to *ex situ* collections in museums, herbaria, culture collections and other biological repositories as part of ABS agreements for non-commercial research. Modern information technology is available to implement internet-based systems for tracking these transactions; and
- Implementing systems of certifying and labeling specimens that have been transferred out of provider countries under the terms of ABS agreements for non-commercial research. This approach could be implemented as a membership-based system of organizations that use standard operating procedures, data standards, and/or Charters or Codes of Conduct aligned with CBD and ABS provisions. Museums, herbaria, botanical gardens that are members would be able to track and monitor the transfer and use of genetic resources amongst themselves. This could work on the lines of the CITES registered institute scheme or the IPEN network of institutions that exchange botanical specimens (see http://www.bgci.org/resources/ipen/).

On the other side, national authorities in provider countries could consider implementing the following voluntary measures:

- In negotiating ABS agreements, differentiating between projects proposed by researchers affiliated with institutions with CBD-compliant policies and practices and demonstrated records of compliance, as opposed to researchers affiliated with institutions without such policies, or without institutional affiliations;

- Creating positive incentives for research organizations, professional societies, and publishers to adopt institutional policies, procedures, and compliance monitoring systems that are consistent with CBD principles and ABS provisions; and
- Creating and using standard ABS agreements and approval procedures (essentially a streamlined "fast track") when negotiating ABS agreements with institutions in ways that lower transaction costs, reduce bureaucracy, and accelerate the process of reviewing and making decisions on proposed PICs, MATs and MTAs;

(e) Analyse whether particular compliance measures are needed for research with non-commercial intent, and if so, how these measures could address challenges arising from changes in intent and/or users, particularly considering the challenge arising from a lack of compliance with relevant access and benefit-sharing legislation and/or mutually agreed terms.

The response to question (b) presented above suggests the potential value of a 'fast track' approach to negotiating ABS agreements for non-commercial biodiversity research. It would be appropriate to couple these standard, streamlined agreements with particular compliance measures designed to monitor the following characteristics of non-commercial research:

- ***Open sharing of benefits arising from the utilization of genetic resources.*** In general, the standard PICs and MATs associated with non-commercial research would probably include assurances that users of genetic resources would not seek proprietary ownership of intellectual property rights arising from the research. Results of non-commercial research are placed in the public domain through publication, presentations, and other distribution systems for the benefit of future research. It would therefore be appropriate to consider special compliance measures that monitor unauthorized patents, product development and registration, licensing activities, and other actions that indicate private benefit and/or commercial intent that involve restrictions on the distribution and ownership of research results.
- ***Disposition of reference specimens and samples in research biorepositories that make them available to qualified investigators for non-commercial research.*** Non-commercial biodiversity research relies on access to specimens and samples stored in museums, herbaria, culture collections, and other secure repositories[2].Codes of nomenclature generally do not allow for restriction of access by third parties and consideration should be given to this openness in negotiating ABS agreements[3]. MATs and MTAs for non-commercial research should make clear to all parties the future uses of the genetic resources that are and are not permitted. For example, ABS agreements for non-commercial research could stipulate:
  - In which repository or repositories the genetic resources will be stored;
  - Who will have ownership rights and stewardship responsibilities over the resources;

[2] For example, the taxonomy of bacteria & viruses is governed by the International Code of Nomenclature of Bacteria (now the International Code of Nomenclature of Prokaryotes, ICNP) and the International Code of Virus Classification and Nomenclature, respectively. These Codes are overseen by International Committees of the International Union of Microbiological Societies (IUMS). The ICNP states that reference samples that support the classification must be viable and maintained alive as cultures in two repositories that are not controlled by IUMS. Botany and zoology taxonomies have similar rules but they do not disallow restriction of commercial uses by third parties since the specimen is usually dead and cannot be cultivated.

[3] CBD Article 7 states "Each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention" and Bonn Guidelines 11.l states "Taxonomic research, as specified in the Global Taxonomy Initiative, should not be prevented, and providers should facilitate acquisition of material for systematic use and users should make available all information associated with the specimens thus obtained".

- What subsequent transfers of the resources are permitted, including restrictions against transfer of the resources by third parties that are given access to the resources by a repository;
- What uses of the resources, either non-commercial or commercial, are permitted;
- Requirements to inform third parties of restrictions on allowable use and subsequent access at the time that access to the resources is granted by the repository;
- Requirements to negotiate a new ABS agreement directly with the provider country for any access to or use of the resources not permitted under the terms of the original agreement;
- Access by the provider country to information on access to and use of the resources provided to third parties by the repository; and
- Consequences of violations of the terms of the ABS agreement.

The special compliance measures described above would enable provider countries to identify instances where a non-commercial research project has evolved into a commercial research project or led to activities with commercial intent. In the case of the first compliance measure, the research partner could discover unanticipated commercial potential in the research results. If he or she seeks protection of intellectual property or restricts the distribution of research results in ways prohibited in MAT, this would indicate a change of intent. Similarly, unwillingness to deposit reference specimens in a mutually agreed repository that would provide researchers access to them could represent a change of use of genetic resources that was not authorized in the original ABS agreement.

In each case, the measure would signal a change from the non-commercial intent or non-commercial use of genetic resources that was agreed to in a standard ABS agreement for non-commercial research. Researchers who change the intent of their project and/or change the use of genetic resources originally agreed to should be required to negotiate a new PIC and MAT for the revised project, and should abide by the terms of the original MTAs unless a replacement is negotiated.

There is a third characteristic of non-commercial research for which a particular compliance measure could be useful.

- ***Release of research results into the public domain.*** Non-commercial researchers are motivated primarily to create new knowledge that can be shared with and used by researchers and other sectors of society. In doing so, researchers are expected to document the sources of the genetic resources they have accessed during their studies and to acknowledge the national authorities that have provided this access. Scientific research is based on the open sharing of research results through publications, public presentations, and publicly accessible databases such as those containing gene sequences. Once entered into the public domain, information cannot be patented but it can be used by others as the basis for innovation, invention, and further research and development leading to patentable discoveries. In such cases, it is possible for the original researcher to fully respect the terms of a non-commercial ABS agreement while a third party utilizes the results in the public domain for commercial purposes. Developing provider countries have less ability to capitalize on published results than industrialized countries due to their lower technological capacity. The opportunity to share in the economic benefits stemming from the utilization of a genetic resource may be lost by the provider country, even though it was not gained by the non-commercial researcher. This disadvantage can be countered if provider countries have access to the results of non-commercial research on their biodiversity prior to their publication. Researchers with only non-commercial intent should be willing to share their unpublished results with provider countries so that the provider country has an opportunity to protect the commercial potential of its genetic resources before they enter the public domain. Researchers could reasonably expect appropriate assurances that their work would not be released by provider country authorities to third parties prior to publication, except for the purpose of securing intellectual property rights. This would preserve the ability of researchers to publish their work and gain credit for their contributions.

Some participants in the workshop argued that ABS agreements should include benefit sharing arrangements for any commercial use of research results that have been entered into the public domain. Other participants argued that it would be difficult to establish clear cause-and-effect relationships between published results and subsequent innovations and patents based on those results. This issue raised fundamental issues of public policy concerning patents, copyrights, and the ownership and use of information placed in the public domain. These issues were considered too complicated for in-depth treatment during the workshop.

Pre-publication access to research results is a compliance measure that relies on mutual trust to a great degree. Researchers will be very hesitant to engage in projects if they are not confident of their freedom to publish their findings. ABS agreements for non-commercial research that give provider countries the right to refuse or delay publication will inhibit, not promote, research activity in those countries. In contrast, standard, streamlined ABS agreements with mutually beneficial terms for sharing pre-publication results will contribute to trusting relationships and equitable sharing of benefits.

INTERNATIONAL CHAMBER OF COMMERCE

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Access and Benefit Sharing: Priority Issues for the Compliance TEG

Submission to the Technical Experts Group on Compliance

Introduction

Business has consistently sought to support development of an Access and Benefit Sharing (ABS) International Regime (IR) that is practical, and provides transparent, predictable and non-discriminatory (i.e. between domestic and foreign actors) processes and outcomes. As reflected by record levels of attendance at the Ninth Conference of the Parties, the business community remains engaged and focused on substantive discussions in the ABS negotiations, including on the objectives, scope and main components of an ABS IR. The ABS IR should include compliance measures with proven effectiveness in the real world, that do not inhibit activities needed to generate benefits from commercial use of Genetic Resources (GR) with or without Traditional Knowledge (TK). This submission to the Technical Experts Group (TEG) on Compliance therefore seeks to identify effective compliance measures, consistent with the encouragement of sustainable, commercial use of GR and related TK in the ABS IR.

The business community has been an active participant in negotiations concerning access to and the sharing of benefits from genetic resources even before the entry into force of the Convention on Biological Diversity (CBD) in 1993. The business delegation, coordinated by the International Chamber of Commerce (ICC), today represents various business sectors with diverse interests in genetic resources and related traditional knowledge and their sustainable commercial uses. These include, in alphabetical order: agricultural biotechnology, animal breeding, cosmetics, farming, flavors and fragrances, forestry, herbal medicines and supplements, industrial biotechnology, pets, pharmaceutical and bio-pharmaceutical products, and plant breeding.

ICC Members remain committed to the voluntary Bonn Guidelines, which also represent the broad consensus of CBD Members, and include the principles of prior informed consent (PIC) and mutually agreed terms (MAT); in fact the vast majority of business players always try to adhere to laws and regulations. As the ABS IR will affect and regulate the behavior of legitimate players, emphasis overall should be put on creating an enabling environment that will help generate benefits from the sustainable use of GR with or without TK. Based on careful analysis and consideration of real-world experience, an ABS IR which enables and eases legal compliance would have a much greater likelihood of generating sustainable long-term benefits for all ABS

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stakeholders. It will also be crucial to educate all ABS stakeholders and to provide them with the necessary information on ABS laws to further facilitate compliance.

If the IR is to be effective in promoting economic activity, it should maintain and foster the diversity of uses of GR as well as of the commercial arrangements through which they are acquired. ICC believes that it is of key importance that the IR should be a facilitative structure that promotes national ABS regimes that are transparent, non-discriminatory, and predictable. It should not, business believes, become a heavy regulatory framework that would stifle the creation of value from genetic resources, trade and sustainable uses. A highly-targeted and efficient ABS IR will promote the generation of social and economic benefits, and will also support the two other pillars of the CBD: conservation and sustainable use.

Some of the international instruments currently under discussion should be considered with caution to avoid overly bureaucratic approaches to ABS that preclude benefit generation. Burdensome measures introduce significant costs for governments, traditional and local communities, research institutions, and business alike. Heavy regulatory burdens may deter larger companies from generating benefits and may price innovative small and medium-sized enterprises out of the market entirely. Most significantly, many of these proposed measures have not been "reality-tested" or subject to a benefit-cost analysis, i.e. proven to create benefits in the real world.

With these thoughts in mind, ICC Members offer the following in response to the Terms of Reference for the Technical Experts Group on Compliance:

(a) What kind of measures are available, or could be developed, in public and private international law to:

(i) Facilitate, with particular consideration to fairness and equity, and taking into account cost and effectiveness:

a) Access to justice, including alternative dispute resolution;
b) Access to courts by foreign plaintiffs;

(ii) Support mutual recognition and enforcement of judgments across jurisdictions; and

(iii) Provide remedies and sanctions in civil, commercial and criminal matters;

in order to ensure compliance with national access and benefit-sharing legislation and requirements, including prior informed consent, and mutually agreed terms;

(i) An ABS IR should seek to ensure transparency, predictability, certainty, and non-discriminatory treatment with respect to compliance measures, including clear definitions consistent with the terms and jurisdictional limitations of the CBD itself. Business, like other stakeholders in the ABS process, seeks transparent, predictable, cost-effective and timely remedies in case of difficulties that may arise in the ABS process.

(ii) If the ABS IR meets these conditions, business is convinced that the great majority of participants in ABS activities will comply with the ABS IR. Nevertheless business does recognize that serious concerns remain relating to misuse and/or misappropriation of GR, with or without related TK. Therefore business supports a fact-based approach, with agreed parameters and definitions of misuse/misappropriation, to clearly identify the

magnitude of the problem within the agreed scope of the International Regime. This would greatly assist in identification, where applicable, of any appropriate and proportionate measures, and contribute to the likelihood of success of the ABS IR overall.

(iii) Business proposes that the ABS IR encourage the systematic use of MTAs, contracts, or other mutual agreements to the greatest extent possible. These written agreements may include, in addition to the terms and conditions for access and benefit sharing, clauses addressing agreed dispute settlement mechanisms, choice of law, and/or future termination of the agreement, as appropriate.

(iv) Established forms of alternative dispute resolution, including mediation and arbitration, based on previously agreed written agreements, may provide a cost-effective alternative to cross-border civil litigation given the international scope of arbitral decisions. An example of such an arbitration clause, which cites the Rules of Arbitration of ICC, can be found in Article 8(4)(C) of the sMTA established under the Food and Agriculture Organization (FAO) International Treaty for Plant and Genetic Resources for Food and Agriculture (ITPGRFA). In addition, the New York Convention on the Recognition and Enforcement of Foreign Arbitral Awards ("New York Convention") is an internationally recognized mechanism for foreign enforcement of arbitral decisions - to which most CBD countries adhere - that can provide effective enforcement in cross-border disputes.

(v) Business also supports voluntary capacity building for resource poor stakeholders in respect of compliance related matters and is active in these efforts. In particular, ABS stakeholders may find more information and background relating to ICC arbitration services, through educational resources either provided by the ICC International Secretariat or at a national level through local ICC committees, or by other trade associations in collaboration with NGOs and CBD Members.

(vi) Business understands the priority that a number of CBD Members place on mutual recognition of and enforcement of judgments across borders to enforce domestic national ABS regimes in cases involving allegations of misuse or misappropriation of GR with or without related TK. At the same time, business notes the historic reluctance of states to enter into multilateral obligations requiring mutual recognition. Business looks forward to a deliberative discussion of this difficult issue so that it can learn more about possible approaches to address legitimate concerns while providing access to justice and due process for all ABS stakeholders.

(vii) Finally, all compliance measures should also be "reality-tested" and subject to a benefit-cost analysis, i.e. shown in real-world circumstances not to have, on balance, negative implications for the generation and sharing of benefits from sustainable utilization of GR with or without TK.

(b) What kind of voluntary measures are available to enhance compliance of users of foreign genetic resources;

(i) Best practices: Business believes that discussion of existing voluntary guidelines and "best practices" may help to address a broad range of circumstances that arise in the course of ABS agreements between users and providers, including obligations of the parties, mechanisms for sharing results, causes for termination and ways of dispute settlement.

ICC Members look forward to providing additional information about such existing guidelines and best practices.

(ii) Guidelines and Codes of Conduct already in place include: the Biotechology Industry Organization (BIO) Guidelines for BIO Members Engaging in Bioprospecting, EuropaBio Principles for Accessing Genetic Resources, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Guidelines for IFPMA Members on ABS, the BIO Model Material Transfer Agreement (MMTA), and the International Standard for Wild Collection of Medicinal and Aromatic Plants.

(iii) Business also looks forward to discussion of best practices for prior informed consent (PIC), including guidelines for identification of relevant stakeholders in the negotiation process. Without greater clarity on predictable standards for PIC, business is unable to invest the considerable financial and other resources needed for sustainable commercialization of GR with or without TK. Best practices for PIC, based on a number of existing models and statutes, may provide greater certainty for business while at the same time representing a practical approach to provide guidance for all ABS Stakeholders. (*See "Prior Informed Consent and Access and Benefit Sharing: Recognition and Implementation," DRAFT PAPER, Anne Perrault, Center for International Environmental Law (March 2006) (pp. 16 – 24 providing PIC-related Procedures, Legislation, Guidelines and Agreements*).

(c) Consider how internationally agreed definitions of misappropriation and misuse of GR and associated TK could support compliance where genetic resources have been accessed or used in circumvention of national legislation or without setting up of mutually agreed terms;

ICC members' views on an appropriate definition of "misappropriation" will be influenced in large part by the decisions taken by CBD member states on the nature and scope of the ABS IR, decisions which will be taken only after the discussions of the upcoming Compliance TEG. Accordingly, the following is offered as a possible working definition, for discussion purposes, to further greater understanding among delegations in the Working Group process, based to the greatest extent possible on terms, definitions and standards of the CBD:

"Misappropriation of Genetic Resources with or without associated Traditional Knowledge:

Acquiring non-human "Genetic Resources" found in "in situ conditions" - each as defined in Art. 2 of the CBD - in contravention of ABS provisions of a national law pursuant to the International Regime and in force at the time of this acquisition."

(d) How could compliance measures take account of the customary law of indigenous and local communities?

(i) Business has sympathy with the view that the issue of customary law of indigenous and local communities should be addressed by technical and legal experts with expertise in TK issues, ie the TEG on TK. This would minimize the risk that two expert groups would reach different recommendations on the same or similar issues. As noted above, this is

an important area where greater clarity from the TK TEG is needed in order for business to give a fuller opinion on possible definitions of "misappropriation" within the ABS IR.

(ii) Taking the foregoing into account, as a general principle business considers that such matters should be addressed at the national level in light of the vast differences in customary law approaches of different communities in CBD Parties. In this context, the ABS IR should include related provisions only to the extent needed to ensure that legal certainty, clarity and transparency of national ABS systems, including any provisions relating to customary law, are maintained. The ABS IR also should ensure that compliance-related provisions or principles of local customary law - as they relate to any individual ABS Agreement - are reduced to written form in a language understood by all parties to the contract. This would be necessary in order to determine whether these provisions need to be incorporated by reference into the MTA or whether additional clauses are needed, on a case-by-case basis.

(e) Analyse whether particular compliance measures are needed for research with non-commercial intent, and if so, how these measures could address challenges arising from changes in intent and/or users, particularly considering the challenge arising from a lack of compliance with relevant access and benefit-sharing legislation and/or mutually agreed terms.

(i) At the outset, it is important to recognize that very few collaborative bio-prospecting agreements result in successful products, even in the case of multinational corporations. Successive Merck/INBIO Agreements did not lead to successful commercialization of any of the discoveries found during a complex, multi-year relationship. Nevertheless, the Merck/INBIO agreement, and those that followed, contributed to Costa Rica's science-base through up-front payments, training and laboratory equipment, and collaborative research, providing substantial and continuing social and economic benefits.

(ii) Business as much as non-commercial research institutes may be deterred by increases in expenses or bureaucratic "red tape." Complicated requirements for access and benefit-sharing may have the unintended effect of causing a significant decline in academic and commercial research alike, or, as one commentator noted, may drive scientists underground, resulting in worse documentation of research activities. Declining research may also cause a decline in successful commercialization needed to create social and economic ABS benefits, particularly where outcomes are uncertain and potential commercial benefits lie far in the future.

(iii) This may be especially also true for small and medium enterprises (SMEs), start-up biotechnology or natural products companies, and certain industry sub-sectors like breeders of ornamental and fruit varieties. For SMEs in particular, it would be essential to find simple rules facilitating access and thus the possibilities to generate sharable benefits. At the same time, business in developing countries may have even a greater share of SMEs – these indigenous entrepreneurs would be particularly disadvantaged by a heavily bureaucratic approach in the ABS IR.

(iv) In reality, it may prove extremely difficult if not impossible to differentiate between ABS conditions needed to provide incentives for non-commercial and commercial research.

Scientific research that starts out as non-commercial may ultimately contribute to the commercial development of a product, either by the same party or by others. Similarly, commercial research may be licensed for public research purposes, as in the case of the development of Golden Rice, which relied heavily on commercially funded research. If a country nonetheless chooses to implement a bifurcated commercial/non-commercial use system, then, it is preferable to spell out the steps needed to convert MAT for non-commercial research into terms for commercial development that protects the interests of all parties, whether applying commercial or non-commercial research, in case of eventual successful commercialization. So it might be another consideration to not draw the distinction between commercial/non-commercial uses but rather distinguish according to the specialties of sectors.

(v) CBD Members clearly have the right to structure their domestic ABS regimes to provide incentives and approval only for non-commercial ABS activities. CBD Members choosing this option, however, need to be transparent about limiting access to non-commercial ABS activities and, by extension, explicitly recognize that they also are excluding themselves and their right-holders from potential future commercial benefits available to other CBD Members under the ABS IR.

(vi) Commercial and non-commercial ABS stakeholders have varied concerns and interests as regards publications relating to GR and associated TK. This is an important issue for consideration, particularly given assertions that prohibitions on academic publication rights would have no impact on taxonomic or other non-commercial research. Generally, universities seek open research, with unrestricted publication rights, while business sponsors of research may prefer limited publication rights, at least for an agreed term, in order to protect their proprietary research. This is an area where mutually agreed terms can bridge the gap, meeting individual needs on a case-by-case basis.

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28 November 2008

ANNEX

Background material relating to arbitration

- "Arbitration explained" - Explanatory brief on what arbitration is

- "The Institute for Transnational Arbitration Scoreboard of Adherence to Transnational Arbitration Treaties" - Table of countries adhering to transnational arbitration treaties

- The FAO International Treaty on Plant Genetic Resources for Food and Agriculture Standard Material Transfer Agreement – see Article 8 on Dispute Settlement (http://www.planttreaty.org/smta_en.htm)

Industry sector guidelines

- The Biotechology Industry Organization (BIO) Guidelines for BIO Members Engaging in Bioprospecting (http://www.bio.org/ip/international/200507guide.asp)

- The BIO Model Material Transfer Agreement (MMTA) (http://www.bio.org/ip/international/BIO_Model_MTA.pdf)

- EuropaBio Principles for Accessing Genetic Resources – (http://www.europabio.org/positions/Bioprospecting%20Principles_Final.pdf)

- The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Guidelines for IFPMA Members on ABS (http://www.ifpma.org/Issues/CBD)

- The International Standard for Wild Collection of Medicinal and Aromatic Plants (http://www.floraweb.de/proxy/floraweb/MAP-pro/Standard_Version1_0pdf)

Please note that the International Standard for Wild Collection of Medicinal and Aromatic Plants is available as information document UNEP/CBD/ABS/GTLE/2/INF/1

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Arbitration explained

I/ What is arbitration

Arbitration is a legal technique for the resolution of disputes outside national courts, where the parties to a dispute refer it to one or more persons (the "arbitrators", "arbiters" or "arbitral tribunal"), by whose decision (the "award") they agree to be bound.

It has four fundamental features: (i) it is a private mechanism for dispute resolution; (ii) it is an alternative to national courts; (iii) it is selected and controlled by the parties and the arbitral institution if any; and (iv) it is the final and binding determination by an impartial tribunal of the parties' rights and obligations.

Arbitration is a consensual process; parties have to agree to arbitrate a dispute. Most commonly, this agreement is contained in a contract which provides that, if a dispute should arise, it will be resolved by arbitration. In the absence of a pre-existing agreement containing an arbitration clause, arbitration normally is not possible unless the parties agree, after a dispute has arisen, to submit the dispute to arbitration.

Arbitration is, today, most commonly used for the resolution of commercial disputes, particularly in the context of international commercial transactions.

Parties choose to go to arbitration rather than to a national court for various reasons.

First, due to its international nature, arbitration provides the parties with the possibility of choosing a neutral forum as well as the rules of procedure and the language to be applied by the tribunal. Second, as the arbitration award is final and binding, there should be no appeals and the award will be directly enforceable in over 140 countries under the 1958 New York Convention on Recognition and Enforcement of Foreign Arbitral Awards. Third, the autonomous nature of the arbitration process allows the parties and arbitrators the flexibility to freely determine the procedure best suited for the particular case, without being bound to detailed and rigid national court procedures. Fourth, the parties may select arbitrators with expert knowledge and from certain legal backgrounds.

Another advantage of arbitration is the private and often confidential nature of arbitration and the award.

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II/ Enforcement of arbitration awards

One of the reasons that arbitration is so popular in international trade as a means of dispute resolution, is that it is often easier to enforce an arbitration award in a foreign country than it is to enforce a judgment of a state court.

Under the 1958 New York Convention on Recognition and Enforcement of Foreign Arbitral Awards ("the New York Convention"), an award issued in a contracting state can generally be freely enforced in any other contracting state, only subject to certain limited defences.

Only foreign arbitration awards can be subject to recognition and enforcement pursuant to the New York Convention. An arbitral decision is foreign where the award was made in a state other than the state of recognition or where foreign procedural law was used.

Virtually every significant commercial country in the world is a party to the Convention, but relatively few countries have a comprehensive network for cross-border enforcement of state court judgments.

III/ ICC arbitration

Disputes conducted under the ICC Rules of Arbitration are supervised by the ICC International Court of Arbitration ("the Court") assisted by the Court's Secretariat. The Court— which numbers business specialists as well as international lawyers — was created in 1923. The Court monitors the progress of each case and reviews the awards in order to control their quality thus facilitating their enforcement.

Since its creation, the Court has administered almost 16 000 arbitration cases under the ICC Rules of Arbitration.

Under the ICC Rules, the parties can choose the arbitrators, the place of arbitration, the language of the arbitration proceedings and which rules of law should apply.

ICC arbitration is international in scope.

- In the year 2007, ICC arbitration took place in 42 countries and involved arbitrators of 66 different nationalities.
- The Court's membership is drawn from 88 countries.
- The Secretariat has a staff of more than 60 of over 20 different nationalities, speaking all the world's main languages.

More than 10 % of all ICC cases have a State or Parastatal entity as a party.

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The FAO International Treaty on Plant and Food Genetic Resources Standard Model Transfer Agreement has an arbitration clause (Article 8.4(c)) which cites ICC arbitration as the rules by default in the event the parties do not agree on the arbitration rules to be applied.

28 November 2008

The Institute for Transnational Arbitration
A Division of THE CENTER FOR AMERICAN AND INTERNATIONAL LAW
(formerly The Southwestern Legal Foundation) • www.cailaw.org/ita

SCOREBOARD
OF ADHERENCE TO TRANSNATIONAL ARBITRATION TREATIES
(as of May 10, 2008)

Abbreviations:

NY = United Nations Convention on the Recognition and Enforcement of Foreign Arbitral Awards (commonly, 1958 New York Convention)

ICSID = Convention on the Settlement of Investment Disputes (1965)

MIGA= Convention Establishing the Multilateral Investment Guarantee Agency (1985)

IA = Inter-American Convention on International Commercial Arbitration (commonly, Panama Convention of 1975)

USBIT = United States Bilateral Investment Treaty

OPIC = Agreements supporting programs of the Overseas Private Investment Corp.

Changes from previous issue:

NY = None.
ICSID = None.
MIGA = New Zealand joined MIGA on April 29, 2008
IA = None.
USBIT = Rwanda signed on February 19, 2008.
OPIC = None.

Symbols:

S: Signed, but not ratified
R: Ratified, acceded or succeeded
(*): Capital-exporting country under MIGA
A: Subscribed, but not signed, ratified or paid
N/A: Not applicable

NATION	NY[1]	ICSID[2]	MIGA[3]	IA	USBIT[4]	OPIC[5]
Afghanistan	R	R	R			R
Albania	R	R	R		R	R
Algeria	R	R	R			R
Angola			R			R
Antigua and Barbuda	R		R			R
Argentina	R	R	R	R	R	R
Armenia	R	R	R		R	R
Australia	R	R	R*			
Austria	R	R	R*			
Azerbaijan	R	R	R		R	R
Bahamas	R	R	R			R
Bahrain	R	R	R		R	R
Bangladesh	R	R	R		R	R
Barbados	R	R	R			R
Belarus	R	R	R		R	
Belgium	R	R	R*			
Belize		S	R			R
Benin	R	R	R			R
Bhutan						
Bolivia [6]	R		R	R	R	R
Bosnia and Herzegovina [7]	R	R	R			R
Botswana	R	R	R			R
Brazil	R		R	R		R
Brunei Darussalam	R	R				
Bulgaria	R	R	R		R	R
Burkina Faso	R	R	R			R
Burundi		R	R			R
Cambodia	R	R	R			R
Cameroon	R	R	R		R	R
Canada	R	S	R*			
Cape Verde			R			R
Central African Republic	R	R	R			R
Chad		R	R			R
Chile	R	R	R	R		R
China (People's Republic) [8]	R	R	R			
Colombia	R	R	R	R		R
Comoros		R				
Congo		R	R		R	R

NATION	NY[1]	ICSID[2]	MIGA[3]	IA	USBIT[4]	OPIC[5]
Congo (Democratic Republic of)		R	R		R	R
Costa Rica	R	R	R	R		R
Côte d'Ivoire	R	R	R			R
Croatia [7]	R	R	R		R	R
Cuba	R					
Cyprus	R	R	R			R
Czech Republic	R	R	R*		R	R
Denmark [9]	R	R	R*			
Djibouti	R		R			R
Dominica	R		R			R
Dominican Republic	R	S	R	S		R
Ecuador	R	R	R	R	R	R
Egypt	R	R	R		R	R
El Salvador	R	R	R	R	S	R
Equatorial Guinea			R			R
Eritrea			R			R
Estonia	R	R	R		R	R
Ethiopia		S	R			R
Fiji		R	R			R
Finland	R	R	R*			
France [10]	R	R	R*			
Gabon	R	R	R			R
Gambia		R	R			R
Georgia	R	R	R		R	R
Germany	R	R	R*			
Ghana	R	R	R			R
Greece	R	R	R*			R
Grenada		R	R		R	R
Guatemala	R	R	R	R		R
Guinea	R	R	R			R
Guinea-Bissau		S	R			R
Guyana		R	R			R
Haiti	R	S	R		S	R
Holy See (Vatican City)	R					
Honduras	R	R	R	R	R	R
Hungary	R	R	R			R
Iceland	R	R	R*			
India	R		R			R
Indonesia	R	R	R			R
Iran	R		R			
Iraq			R			R
Ireland	R	R	R*			R
Israel	R	R	R			R
Italy	R	R	R*			
Jamaica	R	R	R		R	R
Japan	R	R	R*			
Jordan	R	R	R		R	R
Kazakhstan	R	R	R		R	R
Kenya	R	R	R			R
Kiribati						R
Korea (North)						
Korea (Republic) (South)	R	R	R			R
Kosovo						R
Kuwait	R	R	R			R
Kyrgyzstan	R	S	R		R	R
Lao People's Democratic Republic	R		R			R
Latvia	R	R	R		R	R

NATION	NY[1]	ICSID[2]	MIGA[3]	IA	USBIT[4]	OPIC[5]
Lebanon	R	R	R			R
Lesotho	R	R	R			R
Liberia	R	R	R			R
Libyan Arab Jamahiriya			R			
Liechtenstein						
Lithuania	R	R	R		R	R
Luxembourg	R	R	R*			
Macedonia, Former Yugoslav Republic of[7]	R	R	R			R
Madagascar	R	R	R			R
Malawi		R	R			R
Malaysia	R	R	R			R
Maldives			R			
Mali	R	R	R			R
Malta	R	R	R			R
Marshall Islands	R					R
Mauritania	R	R	R			R
Mauritius	R	R	R			R
Mexico	R			R		R
Micronesia		R	R			R
Moldova	R	S	R		R	R
Monaco	R					
Mongolia	R	R	R		R	R
Montenegro	R		R			R
Morocco	R	R	R		R	R
Mozambique	R	R	R		R	R
Myanmar (Burma)						
Namibia		S	R			R
Nauru						
Nepal	R	R	R			R
Netherlands[11]	R	R	R*			
New Zealand[12]	R	R	R			
Nicaragua	R	R	R	R	S	R
Niger	R	R	S			R
Nigeria	R	R	R			R
Norway	R	R	R*			
Oman	R	R	R			R
Pakistan	R	R	R			R
Palau			R			R
Panama	R	R	R	R	R	R
Papua New Guinea		R	R			R
Paraguay	R	R	R	R		R
Peru	R	R	R	R		R
Philippines	R	R	R			R
Poland	R		R		R	R
Portugal	R	R	R*			R
Qatar	R		R			
Romania	R	R	R		R	R
Russian Federation	R	S	R		S	R
Rwanda		R	R		S	R
Saint Kitts and Nevis		R	R			R
Saint Lucia		R	R			R
St. Vincent and the Grenadines	R	R	R			R
Samoa		R	R			R
San Marino	R					
Sao Tome and Principe		S				R
Saudi Arabia	R	R	R			
Senegal	R	R	R		R	R

NATION	NY[1]	ICSID[2]	MIGA[3]	IA	USBIT[4]	OPIC[5]
Serbia [7]	R	R	R			R
Seychelles		R	R			
Sierra Leone		R	R			R
Singapore	R	R	R			R
Slovakia	R	R	R		R	R
Slovenia [7]	R	R	R *			R
Solomon Islands		R	R			
Somalia		R				R
South Africa	R		R			R
Spain	R	R	R*			
Sri Lanka	R	R	R		R	R
Sudan		R	R			
Suriname			R			R
Swaziland		R	R			R
Sweden	R	R	R*			
Switzerland	R	R	R*			
Syrian Arab Republic	R	R	R			
Taiwan						R
Tajikistan			R			R
Tanzania	R	R	R			R
Thailand	R	S	R			R
Timor Leste		R	R			R
Togo		R	R			R
Tonga		R				R
Trinidad and Tobago	R	R	R		R	R
Tunisia	R	R	R		R	R
Turkey	R	R	R		R	R
Turkmenistan		R	R			R
Tuvalu						
Uganda	R	R	R			R
Ukraine	R	R	R		R	R
United Arab Emirates	R	R	R			
United Kingdom [13]	R	R	R*			
United States of America [14]	R	R	R*	R	N/A	N/A
Uruguay	R	R	R	R	R	R
Uzbekistan	R	R	R		R	R
Vanuatu			R			
Venezuela	R	R	R	R		
Vietnam	R		R			R
West Bank and Gaza [15]						R
Yemen		R	R			R
Zambia	R	R	R			R
Zimbabwe	R	R	R			R

Notes: (1) Extends to metropolitan and overseas constituent territorial subdivisions but not to overseas dependent territories. Consult UN or ITA for definitive status. Under Art. I(3), 60 states have entered a "reciprocity reservation" (including 8 that will apply it to non-contracting states as well) and 37 states have entered a "commercial reservation". (2) Extends to metropolitan and overseas constituent territorial subdivisions and to overseas dependent territories unless specifically excluded. (3) Extends to metropolitan and overseas constituent territorial subdivisions and to overseas dependent territories. (4) Chapter Eleven of the North American Free Trade Agreement (NAFTA) covers U.S. investment in Canada and Mexico. (5) Countries where OPIC programs are generally available will be listed as ratified. At times, statutory and policy constraints, such as Congressionally required certifications on labor practices, may limit the availability of OPIC programs in various countries. Under agreements with certain countries, the host government may be required to approve OPIC assistance for a project. (See also Notes 6, 9, 10, 11 and 12). (6) The Government of the Republic of Bolivia signed the ICSID Convention on May 3, 1991 and deposited its instrument of ratification on June 23, 1995. The Convention entered into force for Bolivia on July 23, 1995. On May 2, 2007, the depositary received a written notice of Bolivia's denunciation of the Convention. In accordance with Article 71 of the Convention, the denunciation took effect six months after the receipt of Bolivia's notice, i.e., on November 3, 2007. (7) As of 4 February 2003, The Federal Republic of Yugoslavia has changed its name to "Serbia and Montenegro." Montenegro declared itself independent from Serbia on June 3, 2006. Bosnia & Herzegovina, Croatia, the Former Yugoslav Republic of Macedonia, and Slovenia are separated successor states to parts of the former Yugoslavia and have succeeded to the NY. MIGA, ratified by the former Yugoslavia, is considered by MIGA as ratified by Serbia & Montenegro and by the aforementioned four separated successor states. OPIC programs are available in the four separated states. (8) NY and MIGA: includes Hong Kong Special Administrative Region. (See Note 12). (9) NY: includes Faeroe Islands and Greenland. (10) NY: includes, inter alia, French Guiana, French Polynesia, Guadeloupe, Martinique, Mayotte, New Caledonia, Réunion, and St. Pierre and Miquelon. OPIC programs available in French Guiana. (11) NY: includes Aruba and Netherlands Antilles. OPIC programs are available in Aruba and Netherlands Antilles. (12) ICSID: excludes Cook Islands, Niue and Tokelau. OPIC programs available in Cook Islands. (13) NY: includes Bermuda, Cayman Islands, Gibraltar, Guernsey, and Isle of Man. ICSID: excludes British Indian Ocean Territory, Pitcairn Islands, British Antarctic Territory and Sovereign Base Areas of Cyprus. ICSID: continues to include Hong Kong Special Administrative Region. OPIC programs available in Northern Ireland, Anguilla and Turks and Caicos. (14) NY: includes, inter alia, American Samoa, Guam, Northern Mariana Islands, Puerto Rico and U.S. Virgin Islands. (15) West Bank and Gaza are not recognized as states by the United States.

SOURCES:

This issue was compiled by Seem Maleh of the Institute for Transnational Arbitration, and Jennifer Lowary (SMU intern) based on the following sources: United Nations; ICSID; MIGA; Organization of American States; OPIC; and U.S. State Department Bureau of Economic and Business Affairs. The Scoreboard is designed to be a convenient reference, but is not intended to be relied on as legal advice. Please consult the sources directly to confirm the status of any particular ratifications, reservations, changes, special conditions or new developments.

STANDARD MATERIAL TRANSFER AGREEMENT

PREAMBLE

WHEREAS

The International Treaty on Plant Genetic Resources for Food and Agriculture (hereinafter referred to as "the **Treaty**")[1] was adopted by the Thirty-first session of the FAO Conference on 3 November 2001 and entered into force on 29 June 2004;

The objectives of the **Treaty** are the conservation and sustainable use of **Plant Genetic Resources for Food and Agriculture** and the fair and equitable sharing of the benefits arising out of their use, in harmony with the Convention on Biological Diversity, for sustainable agriculture and food security;

The Contracting Parties to the **Treaty**, in the exercise of their sovereign rights over their **Plant Genetic Resources for Food and Agriculture**, have established a **Multilateral System** both to facilitate access to **Plant Genetic Resources for Food and Agriculture** and to share, in a fair and equitable way, the benefits arising from the utilization of these resources, on a complementary and mutually reinforcing basis;

Articles 4, 11, 12.4 and 12.5 of the **Treaty** are borne in mind;

The diversity of the legal systems of the Contracting Parties with respect to their national procedural rules governing access to courts and to arbitration, and the obligations arising from international and regional conventions applicable to these procedural rules, are recognized;

Article 12.4 of the **Treaty** provides that facilitated access under the **Multilateral System** shall be provided pursuant to a Standard Material Transfer Agreement, and the **Governing Body** of the **Treaty**, in its Resolution 1/2006 of 16 June 2006, adopted the Standard Material Transfer Agreement.

[1] *Note by the Secretariat*: as suggested by the Legal Working Group during the Contact Group for the Drafting of the Standard Material Transfer Agreement, defined terms have, for clarity, been put in bold throughout.

ARTICLE 1 — PARTIES TO THE AGREEMENT

1.1 The present Material Transfer Agreement (hereinafter referred to as "**this Agreement**") is the Standard Material Transfer Agreement referred to in Article 12.4 of the **Treaty**.

1.2 **This Agreement** is:

BETWEEN: (*name and address of the provider or providing institution, name of authorized official, contact information for authorized official*[*]) (hereinafter referred to as "the **Provider**"),

AND: (*name and address of the recipient or recipient institution, name of authorized official, contact information for authorized official*[*]) (hereinafter referred to as "the **Recipient**").

1.3 The parties to **this Agreement** hereby agree as follows:

ARTICLE 2 — DEFINITIONS

In **this Agreement** the expressions set out below shall have the following meaning:

"***Available without restriction***": a **Product** is considered to be available without restriction to others for further research and breeding when it is available for research and breeding without any legal or contractual obligations, or technological restrictions, that would preclude using it in the manner specified in the **Treaty**.

"***Genetic material***" means any material of plant origin, including reproductive and vegetative propagating material, containing functional units of heredity.

"***Governing Body***" means the **Governing Body** of the **Treaty**.

"***Multilateral System***" means the **Multilateral System** established under Article 10.2 of the **Treaty**.

"***Plant Genetic Resources for Food and Agriculture***" means any **genetic material** of plant origin of actual or potential value for food and agriculture.

"***Plant Genetic Resources for Food and Agriculture under Development***" means material derived from the **Material**, and hence distinct from it, that is not yet ready for **commercialization** and which the developer intends to further develop or to transfer to another person or entity for further development. The period of development for the **Plant Genetic Resources for Food and Agriculture under Development** shall be deemed to have ceased when those resources are **commercialized** as a **Product**.

"***Product***" means **Plant Genetic Resources for Food and Agriculture** that incorporate[2] the **Material** or any of its genetic parts or components that are ready for **commercialization**, excluding commodities and other products used for food, feed and processing.

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[*] *Insert as necessary. Not applicable for shrink-wrap and click-wrap Standard Material Transfer Agreements.*

A "shrink-wrap" Standard Material Transfer Agreement is where a copy of the Standard Material Transfer Agreement is included in the packaging of the **Material**, and the **Recipient**'s acceptance of the **Material** constitutes acceptance of the terms and conditions of the Standard Material Transfer Agreement.

A "click-wrap" Standard Material Transfer Agreement is where the agreement is concluded on the internet and the **Recipient** accepts the terms and conditions of the Standard Material Transfer Agreement by clicking on the appropriate icon on the website or in the electronic version of the Standard Material Transfer Agreement, as appropriate.

[2] As evidenced, for example, by pedigree or notation of gene insertion.

"*Sales*" means the gross income resulting from the **commercialization** of a **Product** or **Products**, by the **Recipient**, its affiliates, contractors, licensees and lessees.

"***To commercialize***" means to sell a **Product** or **Products** for monetary consideration on the open market, and "**commercialization**" has a corresponding meaning. **Commercialization** shall not include any form of transfer of **Plant Genetic Resources for Food and Agriculture under Development**.

ARTICLE 3 — SUBJECT MATTER OF THE MATERIAL TRANSFER AGREEMENT

The **Plant Genetic Resources for Food and Agriculture** specified in *Annex 1* to **this Agreement** (hereinafter referred to as the "**Material**") and the available related information referred to in Article 5b and in *Annex 1* are hereby transferred from the **Provider** to the **Recipient** subject to the terms and conditions set out in **this Agreement**.

ARTICLE 4 — GENERAL PROVISIONS

4.1 **This Agreement** is entered into within the framework of the **Multilateral System** and shall be implemented and interpreted in accordance with the objectives and provisions of the **Treaty**.

4.2 The parties recognize that they are subject to the applicable legal measures and procedures, that have been adopted by the Contracting Parties to the **Treaty**, in conformity with the **Treaty**, in particular those taken in conformity with Articles 4, 12.2 and 12.5 of the **Treaty**.[3]

4.3 The parties to **this Agreement** agree that (*the entity designated by the **Governing Body***),[4] acting on behalf of the **Governing Body** of the **Treaty** and its **Multilateral System**, is the third party beneficiary under **this Agreement**.

4.4 The third party beneficiary has the right to request the appropriate information as required in Articles 5e, 6.5c, 8.3 and *Annex, 2 paragraph 3,* to **this Agreement**.

4.5 The rights granted to the (*the entity designated by the **Governing Body***) above do not prevent the **Provider** and the **Recipient** from exercising their rights under **this Agreement**.

ARTICLE 5 — RIGHTS AND OBLIGATIONS OF THE PROVIDER

The **Provider** undertakes that the **Material** is transferred in accordance with the following provisions of the **Treaty**:

a) Access shall be accorded expeditiously, without the need to track individual accessions and free of charge, or, when a fee is charged, it shall not exceed the minimal cost involved;

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[3] In the case of the International Agricultural Research Centres of the Consultative Group on International Agricultural Research (CGIAR) and other international institutions, the Agreement between the Governing Body and the CGIAR Centres and other relevant institutions will be applicable.

[4] *Note by the Secretariat:* by Resolution 2/2006, the Governing Body "invite[d] the Food and Agriculture Organization of the United Nations, as the Third Party Beneficiary, to carry out the roles and responsibilities as identified and prescribed in the Standard Material Transfer Agreement, under the direction of the Governing Body, in accordance with the procedures to be established by the Governing Body at its next session". Upon acceptance by the FAO of this invitation, the term, "the entity designated by the Governing Body", will be replaced throughout the document by the term, "the Food and Agriculture Organization of the United Nations".

b) All available passport data and, subject to applicable law, any other associated available non-confidential descriptive information, shall be made available with the **Plant Genetic Resources for Food and Agriculture** provided;

c) Access to **Plant Genetic Resources for Food and Agriculture under Development**, including material being developed by farmers, shall be at the discretion of its developer, during the period of its development;

d) Access to **Plant Genetic Resources for Food and Agriculture** protected by intellectual and other property rights shall be consistent with relevant international agreements, and with relevant national laws;

e) The **Provider** shall periodically inform the **Governing Body** about the Material Transfer Agreements entered into, according to a schedule to be established by the **Governing Body**. This information shall be made available by the **Governing Body** to the third party beneficiary.[5]

ARTICLE 6 — RIGHTS AND OBLIGATIONS OF THE RECIPIENT

6.1 The **Recipient** undertakes that the **Material** shall be used or conserved only for the purposes of research, breeding and training for food and agriculture. Such purposes shall not include chemical, pharmaceutical and/or other non-food/feed industrial uses.

6.2 The **Recipient** shall not claim any intellectual property or other rights that limit the facilitated access to the **Material** provided under **this Agreement**, or its genetic parts or components, in the form received from the **Multilateral System**.

6.3 In the case that the **Recipient** conserves the **Material** supplied, the **Recipient** shall make the **Material**, and the related information referred to in Article 5b, available to the **Multilateral System** using the Standard Material Transfer Agreement.

6.4 In the case that the **Recipient** transfers the **Material** supplied under **this Agreement** to another person or entity (hereinafter referred to as "the **subsequent recipient**"), the **Recipient** shall

a) do so under the terms and conditions of the Standard Material Transfer Agreement, through a new material transfer agreement; and

b) notify the **Governing Body**, in accordance with Article 5e.

On compliance with the above, the **Recipient** shall have no further obligations regarding the actions of the **subsequent recipient**.

6.5 In the case that the **Recipient** transfers a **Plant Genetic Resource for Food and Agriculture under Development** to another person or entity, the **Recipient** shall:

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[5] *Note by the Secretraiat:* The Standard Material Transfer Agreement makes provision for information to be provided to the **Governing Body**, in the following Articles: 5e, 6.4b, 6.5c and 6.11h, as well as in *Annex 2*, paragraph 3, *Annex 3*, paragraph 4, and in *Annex 4*. Such informationshould be submitted to:

The Secretary
International Treaty on Plant Genetic Resources for Food and Agriculture
Food and Agriculture Organization of the United Nations
I-00100 Rome, Italy

a) do so under the terms and conditions of the Standard Material Transfer Agreement, through a new material transfer agreement, provided that Article 5a of the Standard Material Transfer Agreement shall not apply;

b) identify, in *Annex 1* to the new material transfer agreement, the **Material** received from the **Multilateral System**, and specify that the **Plant Genetic Resources for Food and Agriculture under Development** being transferred are derived from the **Material**;

c) notify the **Governing Body**, in accordance with Article 5e; and

d) have no further obligations regarding the actions of any **subsequent recipient**.

6.6 Entering into a material transfer agreement under paragraph 6.5 shall be without prejudice to the right of the parties to attach additional conditions, relating to further product development, including, as appropriate, the payment of monetary consideration.

6.7 In the case that the **Recipient commercializes** a **Product** that is a **Plant Genetic Resource for Food and Agriculture** and that incorporates **Material** as referred to in Article 3 of **this Agreement**, and where such **Product** is not **available without restriction** to others for further research and breeding, the **Recipient** shall pay a fixed percentage of the **Sales** of the **commercialized Product** into the mechanism established by the **Governing Body** for this purpose, in accordance with *Annex 2* to **this Agreement**.

6.8 In the case that the **Recipient commercializes** a **Product** that is a **Plant Genetic Resource for Food and Agriculture** and that incorporates **Material** as referred to in Article 3 of **this Agreement** and where that **Product** is **available without restriction** to others for further research and breeding, the **Recipient** is encouraged to make voluntary payments into the mechanism established by the **Governing Body** for this purpose in accordance with *Annex 2* to **this Agreement**.

6.9 The **Recipient** shall make available to the **Multilateral System**, through the information system provided for in Article 17 of the **Treaty**, all non-confidential information that results from research and development carried out on the **Material**, and is encouraged to share through the **Multilateral System** non-monetary benefits expressly identified in Article 13.2 of the **Treaty** that result from such research and development. After the expiry or abandonment of the protection period of an intellectual property right on a **Product** that incorporates the **Material**, the **Recipient** is encouraged to place a sample of this **Product** into a collection that is part of the **Multilateral System**, for research and breeding.

6.10 A **Recipient** who obtains intellectual property rights on any **Products** developed from the **Material** or its components, obtained from the **Multilateral System**, and assigns such intellectual property rights to a third party, shall transfer the benefit-sharing obligations of **this Agreement** to that third party.

6.11 The **Recipient** may opt as per *Annex 4*, as an alternative to payments under Article 6.7, for the following system of payments:

a) The **Recipient** shall make payments at a discounted rate during the period of validity of the option;

b) The period of validity of the option shall be ten years renewable in accordance with *Annex 3* to **this Agreement**;

c) The payments shall be based on the **Sales** of any **Products** and of the sales of any other products that are **Plant Genetic Resources for Food and Agriculture** belonging to the same

crop, as set out in Annex 1 to the **Treaty**, to which the **Material** referred to in *Annex 1* to **this Agreement** belongs;

d) The payments to be made are independent of whether or not the **Product** is **available without restriction**;

e) The rates of payment and other terms and conditions applicable to this option, including the discounted rates are set out in *Annex 3* to **this Agreement**;

f) The **Recipient** shall be relieved of any obligation to make payments under Article 6.7 of **this Agreement** or any previous or subsequent Standard Material Transfer Agreements entered into in respect of the same crop;

g) After the end of the period of validity of this option the **Recipient** shall make payments on any **Products** that incorporate **Material** received during the period in which this Article was in force, and where such **Products** are not **available without restriction**. These payments will be calculated at the same rate as in paragraph (a) above;

h) The **Recipient** shall notify the **Governing Body** that he has opted for this modality of payment. If no notification is provided the alternative modality of payment specified in Article 6.7 will apply.

ARTICLE 7 — APPLICABLE LAW

The applicable law shall be General Principles of Law, including the UNIDROIT Principles of International Commercial Contracts 2004, the objectives and the relevant provisions of the **Treaty**, and, when necessary for interpretation, the decisions of the **Governing Body**.

ARTICLE 8 — DISPUTE SETTLEMENT

8.1 Dispute settlement may be initiated by the **Provider** or the **Recipient** or the (*the entity designated by the **Governing Body***), acting on behalf of the **Governing Body** of the **Treaty** and its **Multilateral System**.

8.2 The parties to **this Agreement** agree that the (*the entity designated by the **Governing Body***), representing the **Governing Body** and the **Multilateral System**, has the right, as a third party beneficiary, to initiate dispute settlement procedures regarding rights and obligations of the **Provider** and the **Recipient** under **this Agreement**.

8.3 The third party beneficiary has the right to request that the appropriate information, including samples as necessary, be made available by the **Provider** and the **Recipient**, regarding their obligations in the context of **this Agreement**. Any information or samples so requested shall be provided by the **Provider** and the **Recipient**, as the case may be.

8.4 Any dispute arising from **this Agreement** shall be resolved in the following manner:

a) Amicable dispute settlement: The parties shall attempt in good faith to resolve the dispute by negotiation.

b) Mediation: If the dispute is not resolved by negotiation, the parties may choose mediation through a neutral third party mediator, to be mutually agreed.

c) Arbitration: If the dispute has not been settled by negotiation or mediation, any party may submit the dispute for arbitration under the Arbitration Rules of an international body as agreed by the parties to the dispute. Failing such agreement, the dispute shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce, by one or more arbitrators appointed in accordance with the said Rules. Either party to the dispute may, if it so chooses, appoint its arbitrator from such list of experts as the Governing Body may establish for this purpose; both parties, or the arbitrators appointed by them, may agree to appoint a sole arbitrator, or presiding arbitrator as the case may be, from such list of experts. The result of such arbitration shall be binding.

ARTICLE 9 — ADDITIONAL ITEMS

Warranty

9.1 The **Provider** makes no warranties as to the safety of or title to the **Material**, nor as to the accuracy or correctness of any passport or other data provided with the **Material**. Neither does it make any warranties as to the quality, viability, or purity (genetic or mechanical) of the **Material** being furnished. The phytosanitary condition of the **Material** is warranted only as described in any attached phytosanitary certificate. The **Recipient** assumes full responsibility for complying with the recipient nation's quarantine and biosafety regulations and rules as to import or release of **genetic material**.

Duration of Agreement

9.2 **This Agreement** shall remain in force so long as the **Treaty** remains in force.

ARTICLE 10 — SIGNATURE/ACCEPTANCE

The **Provider** and the **Recipient** may choose the method of acceptance unless either party requires **this Agreement** to be signed.

Option 1 –Signature[*]

I, (*Full Name of Authorized Official*), represent and warrant that I have the authority to execute **this Agreement** on behalf of the **Provider** and acknowledge my institution's responsibility and obligation to abide by the provisions of **this Agreement**, both by letter and in principle, in order to promote the conservation and sustainable use of **Plant Genetic Resources for Food and Agriculture**.

Signature..... Date.....
Name of the **Provider** .....

I, (*Full Name of Authorized Official*), represent and warrant that I have the authority to execute **this Agreement** on behalf of the **Recipient** and acknowledge my institution's responsibility and obligation to abide by the provisions of **this Agreement**, both by letter and in principle, in order to promote the conservation and sustainable use of **Plant Genetic Resources for Food and Agriculture**.

Signature..... Date.....
Name of the **Recipient**.....

Option 2 – Shrink-wrap Standard Material Transfer Agreements[*]

The **Material** is provided conditional on acceptance of the terms of **this Agreement**. The provision of the **Material** by the **Provider** and the **Recipient's** acceptance and use of the **Material** constitutes acceptance of the terms of **this Agreement**.

Option 3 – Click-wrap Standard Material Transfer Agreement[*]

□ I hereby agree to the above conditions.

[*] Where the **Provider** chooses signature, only the wording in Option 1 will appear in the Standard Material Transfer Agreement. Similarly where the **Provider** chooses either shrink-wrap or click-wrap, only the wording in Option 2 or Option 3, as appropriate, will appear in the Standard Material Transfer Agreement. Where the "click-wrap" form is chosen, the **Material** should also be accompanied by a written copy of the Standard Material Transfer Agreement.

Annex 1

LIST OF MATERIALS PROVIDED

This *Annex* contains a list of the **Material** provided under **this Agreement**, including the associated information referred to in Article 5b.

This information is either provided below or can be obtained at the following website: (*URL*).

The following information is included for each **Material** listed: all available passport data and, subject to applicable law, any other associated, available, non-confidential descriptive information.

(*List*)

Annex 2

RATE AND MODALITIES OF PAYMENT UNDER ARTICLE 6.7 OF THIS AGREEMENT

1. If a **Recipient**, its affiliates, contractors, licensees, and lessees, **commercializes** a **Product** or **Products**, then the **Recipient** shall pay one point-one percent (1.1 %) of the **Sales** of the **Product** or **Products** less thirty percent (30%); except that no payment shall be due on any **Product** or **Products** that:

(a) are **available without restriction** to others for further research and breeding in accordance with Article 2 of **this Agreement**;

(b) have been purchased or otherwise obtained from another person or entity who either has already made payment on the **Product** or **Products** or is exempt from the obligation to make payment pursuant to subparagraph (a) above;

(c) are sold or traded as a commodity.

2. Where a **Product** contains a **Plant Genetic Resource for Food and Agriculture** accessed from the **Multilateral System** under two or more material transfer agreements based on the Standard Material Transfer Agreement only one payment shall be required under paragraph 1 above.

3. The **Recipient** shall submit to the **Governing Body**, within sixty (60) days after each calendar year ending December 31st, an annual report setting forth:

(a) the **Sales** of the **Product** or **Products** by the **Recipient**, its affiliates, contractors, licensees and lessees, for the twelve (12) month period ending on December 31st;

(b) the amount of the payment due; and

(c) information that allows for the identification of any restrictions that have given rise to the benefit-sharing payment.

4. Payment shall be due and payable upon submission of each annual report. All payments due to the **Governing Body** shall be payable in (*specified currency*)[6] for the account of (*the Trust Account or other mechanism established by the **Governing Body** in accordance with Article 19.3f of the **Treaty***).[7]

[6] *Note by the Secretariat:* The Governing Body has not yet considered the question of currency of payment. Until it does so, Standard Material Transfer Agreements should specify United States dollars (US$).

[7] *Note by the Secretariat:* This is the Trust Account provided for in Article 6.3 of the Financial Rules, as approved by the Governing Body (*Appendix E* to this Report). The details of the Trust Account when established, will be intoduced here, and communicated to Contract Parties.

Annex 3

TERMS AND CONDITIONS OF THE ALTERNATIVE PAYMENTS SCHEME UNDER ARTICLE 6.11 OF THIS AGREEMENT

1. The discounted rate for payments made under Article 6.11 shall be zero point five percent (0.5 %) of the **Sales** of any **Products** and of the sales of any other products that are **Plant Genetic Resources for Food and Agriculture** belonging to the same crop, as set out in Annex 1 to the **Treaty**, to which the **Material** referred to in *Annex 1* to **this Agreement** belong.

2. Payment shall be made in accordance with the banking instructions set out in paragraph 4 of *Annex 2* to **this Agreement**.

3. When the **Recipient** transfers **Plant Genetic Resources for Food and Agriculture under Development**, the transfer shall be made on the condition that the **subsequent recipient** shall pay into the mechanism established by the **Governing Body** under Article 19.3f of the **Treaty** zero point five percent (0.5 %) of the **Sales** of any **Product** derived from such **Plant Genetic Resources for Food and Agriculture under Development**, whether the **Product** is **available or not without restriction**.

4. At least six months before the expiry of a period of ten years counted from the date of signature of **this Agreement** and, thereafter, six months before the expiry of subsequent periods of five years, the **Recipient** may notify the **Governing Body** of his decision to opt out from the application of this Article as of the end of any of those periods. In the case the **Recipient** has entered into other Standard Material Transfer Agreements, the ten years period will commence on the date of signature of the first Standard Material Transfer Agreement where an option for this Article has been made.

5. Where the **Recipient** has entered or enters in the future into other Standard Material Transfer Agreements in relation to material belonging to the same crop[s], the **Recipient** shall only pay into the referred mechanism the percentage of sales as determined in accordance with this Article or the same Article of any other Standard Material Transfer Agreement. No cumulative payments will be required.

Annex 4

OPTION FOR CROP-BASED PAYMENTS UNDER THE ALTERNATIVE PAYMENTS SCHEME UNDER ARTICLE 6.11 OF THIS AGREEMENT

I (*full name of* ***Recipient*** *or* ***Recipient's*** *authorised official*) declare to opt for payment in accordance with Article 6.11 of **this Agreement**.

Signature..... Date.....[8]

[8] In accordance with Article 6.11h of the Standard Material Transfer Agreement, the option for this modality of payment will become operative only once notification has been provided by the **Recipient** to the **Governing Body**. The signed declaration opting for this modality of payment must be sent by the **Recipient** to the **Governing Body** at the following address, whichever method of acceptance of **this Agreement** (signature, shrink-wrap or click-wrap) has been chosen by the parties to **this Agreement**, and whether or not the **Recipient** has already indicated his acceptance of this option in accepting **this Agreement** itself:

The Secretary,
International Treaty on Plant Genetic Resources for Food and Agriculture
Food and Agriculture Organization of the United Nations
I-00100 Rome, Italy

The signed declaration must be accompanied by the following:

- The date on which **this Agreement** was entered into;
- The name and address of the **Recipient** and of the **Provider**;
- A copy of Annex 1 to **this Agreement**.

Guidelines for BIO Members Engaging in Bioprospecting

Preamble

The Biotechnology Industry Organization,

- recognizing that the conservation of biological diversity has significant long-term advantages for all and desiring to play a role in achieving those advantages for all;
- recognizing the importance of promoting the sustainable use of biodiversity and of equitably sharing the benefits arising from use of genetic resources with the parties providing access to those resources;
- recognizing the importance of scientific research on genetic resources and the important benefits to society as a whole that arise from such research;
- wishing to promote the adoption of clear and transparent provisions governing use of genetic resources so as to promote the greater use of such resources as well as the flow of more benefits to parties providing such access and society as a whole; and
- desiring to conduct their activities, and those of their agents, in relation to collection of genetic resources, as well as the evaluation and use of those collected genetic resources in a manner that complies with relevant national and international regimes;

hereby establishes the following Guidelines for bioprospecting.

I. **Definitions; Scope of the Guidelines**

A. Definitions: As used in these Guidelines, the following terms shall have the meaning provided below.

1. *"Benefit Sharing"* means the providing of any form of compensation or consideration, monetary or otherwise, by a *BIO Member* to a *Providing Party* in exchange for the *BIO Member* being provided access to and authorization to use *Regulated Genetic Resources*.
2. *"BIO Member"* means a Member of the Biotechnology Industry Organization.
3. *"Bioprospecting"* means the collection by a *BIO Member* of physical samples of *Regulated Genetic Resources* existing *in situ* or in maintained in an *ex situ* collection of such resources.
4. *"Bioprospecting Agreement"* means a written agreement between a *BIO Member* and either a *Contracting Party* or a *Providing Party* that concerns (i) *Prior Informed Consent* and (ii) the terms and conditions governing collection and use of the *Regulated Genetic Resources*, including, *inter alia*, *Benefit Sharing*.
5. *"Collected Genetic Resources"* means physical samples of *Regulated Genetic Resources* that have been acquired by a *BIO Member* through *Bioprospecting*.
6. *"Contracting Party"* means a country that has accepted, ratified or acceded to the Convention on Biological Diversity and thus is a Contracting Party within the meaning of Convention.
7. *"Ex situ collection"* means a collection of physical samples of *genetic resources* that have been previously obtained from an *in situ* location and which are preserved or maintained in a location external to that *in situ* location.
8. *"Focal Point"* means the entity designated or recognized by the government of a country as having the authority to (i) identify the P*roviding Party* or Parties within the *Contracting Party* with authority over the *genetic resources* to be collected, (ii) provide information concerning the requirements and procedures for obtaining *Prior Informed Consent* to collect and use *Regulated Genetic*

Resources within the territory of that country, (iii) provide information regarding *Benefit Sharing* requirements applicable within the *Contracting Party*, and (iv) identify the representative of local and indigenous communities located within the territory of the country.

9. *"Genetic Resource"* means material of non-human animal, plant or microbial origin containing functional units of heredity.
10. *"In-situ"* means the location in which genetic resources exist within ecosystems and natural habitats within a Country;
11. *"Providing Party"* means any entity within a *Contracting Party* that has been given the legal authority to grant *Prior Informed Consent* or authorization to access and use *Regulated Genetic Resources*, and may include, *inter alia*, an authority of the national government, an authority of a local government, or an indigenous or local community or any combination of these entities.
12. *"Prior Informed Consent"* means an agreement between a *BIO Member* and a *Providing Party* establishing that the *BIO Member* has provided to the *Providing Party* information that meets the requirements of Section III of these Guidelines with respect to a *Regulated Genetic Resource* to which the *BIO Member* has been granted access.
13. *"Regulated Genetic Resource"* means a *Genetic Resource* in respect of which a *Providing Party* in a *Contracting Party*, on or after the date that the Convention on Biological Diversity Party took effect in that *Contracting Party*, imposes requirements concerning *Prior Informed Consent*, collection or use.

B. Scope of the Guidelines:

1. These Guidelines establish principles to govern the conduct of *BIO Members* that are engaged in *Bioprospecting* activities, as defined in section A.3.
2. The Guidelines shall not apply to the acquisition or use of:
   a. any materials obtained from humans or are of human origin;
   b. *Genetic Resources* that are not *Regulated Genetic Resources* within the meaning of these Guidelines;
   c. *Genetic Resources* maintained in an *ex situ* collection where such resources were obtained from a *Contracting Party* prior to the date the Convention on Biological Diversity took effect in that *Contracting Party*;
   d. *Genetic Resources* that are made available to the public on an unrestricted basis, either on commercial or non-commercial terms; or
   e. publicly available information, including, in particular, information published in the scientific literature, disclosed in a patent or published patent application, or disseminated in an unrestricted fashion.

II. Conduct of Bioprospecting

A. Steps to take before engaging in Bioprospecting.

1. Identify and contact the *Focal Point* of the *Contracting Party* for the *Regulated Genetic Resources*.
   a. For samples of *Regulated Genetic Resources* to be collected *in situ*, or from an *ex situ* collection located within the territory of or controlled by the *Contracting Party*, contact the *Focal Point* identified by that *Contracting Party*.
   b. For samples of *Regulated Genetic Resources* to be collected from an *ex situ* collection located outside the territory of or not controlled by the *Contracting Party*, identify the *Focal Point* specified by the custodian of the *ex situ* collection or, if the *Focal Point* is not known to that custodian, take reasonable steps to identify the *Focal Point* for the *Regulated Genetic Resources* to be collected.

2. In cooperation with that *Focal Point*, use all reasonable efforts to identify all entities that comprise the *Providing Party*, and ascertain requirements applicable to *Bioprospecting*.
3. Obtain *Prior Informed Consent* from the *Providing Party* to collect and use *Regulated Genetic Resources* lawfully controlled or held by the Providing Party.
4. Reach agreement with the *Providing Party* on the terms and conditions governing collection, handling and use of physical
5. samples of the *Regulated Genetic Resources*, including, *inter alia*, the sharing of benefits arising from the use of such samples, and measures governing the handling or transfer of such samples.
6. Conclude a *Bioprospecting Agreement* with the *Providing Party* that reflects the terms and conditions of *Prior Informed Consent* and concerning the collection, handling and use of the collected physical samples of the *Regulated Genetic Resource(s)* including, *inter alia*, terms and conditions regarding *Benefit Sharing*.
7. Take reasonable steps to confirm that the *Bioprospecting Agreement* will be binding on the Government of the *Contracting Party*, either directly or through the authority conferred by the *Contracting Party* on a *Providing Party*.

B. After Prior Informed Consent has been obtained and a Bioprospecting Agreement concluded regarding collection and use of the Regulated Genetic Resources, conduct Bioprospecting, and use the Collected Genetic Resources, in a manner that complies with the terms and conditions specified in the Bioprospecting Agreement.

III. **Prior Informed Consent**

A. Make reasonable efforts to determine if any specific requirements for *Prior Informed Consent* apply to the collected *Regulated Genetic Resources*. To do so:
1. Determine if a *Contracting Party* has established requirements for *Prior Informed Consent*, or, if that authority has been delegated to a *Providing Party*.
2. Identify the nature of the requirements for *Prior Informed Consent* established by the *Contracting Party* or the *Providing Party*, as the case may be.
3. Meet the identified requirements to comply with Prior Informed Consent obligations of the *Contracting Party* or the *Providing Party* applicable to the collected Regulated Genetic Resources, and incorporate evidence of such compliance into the *Bioprospecting Agreement*.

B. If a *Contracting Party* has not established requirements for *Prior Informed Consent*, make reasonable effort to provide at least the following information to the *Providing Party*:
1. The general nature of the activities to be conducted with the *Collected Genetic Resources* (e.g., screening of samples for biological properties, growth and study of samples of materials, extraction and isolation of chemical compounds from the samples, genomic analysis of the sample).
2. The anticipated field of use of any products or services that may be developed through the use of the *Collected Genetic Resources* (e.g., pharmaceutical, agricultural, industrial processing, environmental remediation).
3. The identity and contact information of the expected lead researcher in the *BIO Member*, or a contact point in the *BIO Member* for such research activities.

IV. **Benefit Sharing and Sharing of Research Results, Intellectual Property Procurement and Related Provisions**

A. *BIO Members* that enter into a *Bioprospecting Agreement* with a *Providing Party* should give good faith consideration to specific terms for the sharing of benefits arising from use of collected *Regulated Genetic Resources*, and should define such commitments in the terms and conditions in the *Bioprospecting Agreement*.

B. Types of benefits to be considered for inclusion in a *Bioprospecting Agreement*:

1. Monetary and non-monetary benefits arising from the use or commercialization of the Collected Genetic Resources, including provision of equipment and materials, up-front payments and royalty payments;
2. The sharing of scientific information generated through the conduct of research upon the *Collected Genetic Resources* in conformity with standard industry practices regarding timing and conditions of public disclosure to preserve options for procurement of patents or preservation of rights in undisclosed information;
3. The granting of rights to use technology resulting directly from the *BIO Member's* use of the *Collected Genetic Resources* where the granting of such rights and the nature of the rights granted, are consistent with the commercial needs and interests of the *BIO Member*;
4. The provision of training for scientists designated by the *Providing Party*;
5. The inclusion of scientists from the Providing Party in research activities of the *BIO Member* on the *Collected Genetic Resources*;
6. The conduct of research on *Collected Genetic Resources* in the territory of the *Contracting Party* from which such resources have been collected.
7. The transfer to a *Providing Party* of scientific knowledge, expertise, and technology in the control of the *BIO Member* that (a) results from the study of the collected genetic resources and (b) pertains to the conservation, preservation or physical handling of the *Collected Genetic Resources*.
8. Commitments to only seek patents on inventions that arise from the use or study of *Collected Genetic Resources* and that are claimed in a manner clearly distinguishable from the form in which the *Collected Genetic Resources* are provided by the *Providing Party*.

V. **Measures to Protect Interests and Rights of Indigenous or Local Communities**

A. Respect the customs, traditions, values and customary practices of indigenous and local communities within a *Contracting Party* and from which *Collected Genetic Resources* have been obtained.

B. Respond to requests from indigenous and local communities for information concerning the handling, storage or transfer of *Collected Genetic Resources* consistent with the terms of an applicable *Bioprospecting Agreement*.

C. Take all reasonable steps to prevent the disclosure of information provided in confidence by a member of an indigenous or local community, and handle such information in accordance with the terms specified by the community that has provided the information. Where feasible, include such terms in the *Bioprospecting Agreement*.

D. Avoid taking actions in the course of use or commercialization of *Collected Genetic Resources* that impede the traditional use of Regulated Genetic Resources provided by a *Providing Party*.

VI. **Conservation and Sustainable Use of Biological Diversity**

1. Take reasonable steps to prevent harm or alteration to the local environment incidental to acts of collecting samples of genetic resources from an *in situ* location in a *Contracting Party*.
2. Avoid taking actions that pose a threat to the conservation or sustainable use of biological diversity incidental to acts of collecting samples of genetic resources from an *in situ* location in a *Contracting Party*.
3. Take all reasonable steps and give good faith consideration to sharing data with the *Contracting Party* and/or the *Providing Party* which was derived from research on the *Collected Genetic Resources* and which may be useful in the support of conservation efforts related to a species, environment, or habitat from which the *Collected Genetic Resources* were collected.

VII. **Compliance with Terms of a Bioprospecting Agreement and the Guidelines**

0. Use *Collected Genetic Resources* in a manner consistent with the terms and conditions specified in an applicable *Bioprospecting Agreement*.
1. Do not use *Collected Genetic Resources*, for purposes other than those specified in the *Prior Informed Consent* provisions of an applicable *Bioprospecting Agreement*, unless first obtaining a separate *Prior Informed Consent* in writing for the other use of the *Collected Genetic Resource*.
2. After acquiring *Collected Genetic Resources* pursuant to these Guidelines, maintain records concerning the handling, storage and physical movement of the *Collected Genetic Resources*, and be prepared to share such records with the *Providing Party* upon the request of the *Providing Party*, within reasonable limitations.
3. Ensure that the terms and conditions specified in a *Bioprospecting Agreement* entered into with a *Contracting Party* or a *Providing Party* apply to (i) any successor in interest to their rights under the agreement, and (ii) to any party that obtains a sample of a *Collected Genetic Resource* from it, unless those parties have independently obtained from the *Contracting Party* or the *Providing Party* the right to obtain such samples of the *Collected Genetic Resources*.
4. Do not transfer samples of *Collected Genetic Resources* to third parties unless such transfer is consistent with the terms and conditions of an applicable *Bioprospecting Agreement*.
5. Do not accept samples of *Collected Genetic Resources* from a third party that is not able to provide evidence that it has obtained such samples in compliance with obligations of *Prior Informed Consent* and conditions governing use that are applicable to the sample.
6. Include provisions in the *Bioprospecting Agreement* that provide for effective and fair resolution of disputes regarding compliance with the terms and conditions in the *Bioprospecting Agreement*, either by commitments to international arbitration consistent with the procedures specified in the Annex to these Guidelines or as otherwise agreeable to the *Contracting Party* or *Providing Party*.

BIOTECHNOLOGY INDUSTRY ORGANIZATION
Suggested Model Material Transfer Agreement

Introduction

The Biotechnology Industry Organization developed *Guidelines for BIO Members Engaging in Bioprospecting* (Guidelines) in 2005 to educate BIO Members about the relevant issues that could arise in the conduct of bioprospecting activities and to provide assistance to those Members seeking guidance. (See www.bio.org/ip/international/200507guide.asp and www.bio.org/ip/international/200507memo.asp)

These Guidelines envisioned that BIO Members would enter into a "Bioprospecting Agreement" before collecting physical samples of "regulated genetic resources" *in situ* or accessing such resources maintained *ex situ*. That Agreement would include the grant of prior informed consent as well as enumerate the terms and conditions governing the collection and use of the regulated genetic resources including benefit-sharing. Depending on the manner of collection, the Agreement could also include provisions that would transfer the collected physical samples of regulated genetic resources from the Providing Party to the BIO Member. Alternatively, a separate agreement to transfer the regulated genetic resources could be concluded after the physical samples were identified or collected.

At present, transfers of regulated genetic resources are not handled in a consistent manner or a comprehensive fashion within countries or at the international level. This leaves uncertainty as to what provisions should be included in a transfer agreement entered into by a BIO Member. This "Model Material Transfer Agreement" (Model) is intended to provide an outline for a transfer agreement that is consistent with the best practices set forth in the Guidelines. This Model may be incorporated into a Bioprospecting Agreement; it may be the basis for an transfer agreement entered into after the completion of collection activities undertaken pursuant to a Bioprospecting Agreement; or, it may take the place of a Bioprospecting Agreement when a BIO Member seeks a specific regulated genetic resource or a group of regulated genetic resources from an *ex situ* holding.[1]

This Model is intended to supplement and be considered in conjunction with those Guidelines. As such, it is designed only for use with "regulated genetic resources" as that term is used in paragraph I.B.2 of the Guidelines – essentially materials of non-human animal, plant or microbial origin that contain functional units of heredity and that are subject to the requirements of prior informed consent, *etc.* under the Convention on Biological Diversity.

It is recognized that in some instances it is beneficial to transfer "traditional knowledge" associated with a regulated genetic resource along with samples of the resource. While this version of the Model does not include provisions for the transfer of traditional knowledge, this Model could be expanded to transfer traditional knowledge. It should be noted that Part V of the

[1] BIO Members note that some use the term "material transfer agreement" to mean any contract to collect genetic resources, to transfer genetic resources, or to transfer traditional knowledge. BIO Members, however, use the term "material transfer agreement" to refer to a contract the primary purpose of which is to transfer possession of genetic resources. The term "bioprospecting agreement" is used for a contract the primary purpose of which is to collect genetic resources. The term "confidentiality agreement" is used for a contract the main purpose of which is to protect undisclosed information, such as traditional knowledge, that is transferred from one entity to another. These types of contracts may be merged into a single contract in appropriate circumstances.

Guidelines entitled "Measures to Protect Interests and Rights of Indigenous and Local Communities" should be applied.

The terms used in the Model, including the commentaries, are intended to have the same meaning as they have in the Guidelines, unless specified otherwise.

As with the Guidelines, there is no legal obligation that attaches from membership in BIO to use the Model.

This Model is not intended to supplant national requirements that regulate the transfer of regulated genetic resources.

This Model is not intended to be a static document. It is envisioned that it will change over time as BIO Members gain more experience in this area. Comments on the contents of the Model are welcome.

Agreement between the [Transferor/s] and the [Transferee]
Concerning the Transfer of [Certain Regulated Genetic Resources]

Preamble

Whereas:

[*Name of "Transferee" BIO Member*] is a [*company description, location,* etc.];

[*Name or names of the "Transferor(s)*] is a [*description of the Transferor(s), location(s),* etc.];

[The [Transferee] identified and/or collected physical samples of regulated genetic resources under the [Bioprospecting Agreement] with the [Transferor(s);]

The [Transferee] desires to take possession of certain [identified and/or collected] regulated genetic resources held by the [Transferor(s)]; and

The [Transferee] has informed the [Transferor(s)] about the intended uses of those regulated genetic resources for which possession is sought and about the identity and contact information of its lead researcher on these regulated genetic resources; and

The [Transferor(s)] consents to the transfer of possession to the [Transferee] for those uses based on the information provided by the [Transferee];

The [Transferor(s)] and the [Transferee] hereby agree as follows.

Commentary: If the Transferee or a Transferor is acting as an agent for another entity (or the Transferee is under an obligation to transfer the regulated genetic resources to another entity), the other entity should also be identified.

Clause three of the Preamble would only be included if there was a pre-existing Bioprospecting Agreement between the Transferor(s) and the Transferee.

The Transferor(s) would normally be a Providing Party that is defined in paragraph I.A.11 of the Guidelines as the entity that has legal authority to grant prior informed consent or authorization to access and use regulated genetic resources, and may include, inter alia, *an authority of the national government, an authority of a local government, an indigenous or local community or any combination of these entities. Also, a Transferor could be an agent of a Providing Party. If a Bioprospecting Agreement exists, it would normally list the Providing Parties. Additional Transferor(s) may be identified during the identification or collection of regulated genetic resources under that Agreement, however.*

The Preamble notes that prior informed consent has been given for the "transfer" of the regulated genetic resources subject to the Agreement. A pre-existing Bioprospecting Agreement would indicate that prior informed consent was given for collection but may not specifically give prior informed consent for the transfer and use of regulated genetic materials. Part III of the Guidelines entitled "Prior Informed Consent" should be applied.

Article 1. Definitions

As used in this Agreement, the following terms shall have the meaning provided below.

[*"Bioprospecting Agreement"* means the written agreement between the [Transferor(s)] and the [Transferee] entitled "_____" and executed on _____, a copy of which is attached to this Agreement.]

***"Genetic Resource(s)"* means material of non-human animal, plant or microbial origin containing functional units of heredity.**

"*The Parties*" means the [Transferor(s)] and the [Transferee].

Commentary: Definitions of terms used in the Commentaries may be found in Section I.A. of the Guidelines.

Article 2. Materials

The Material(s) that are subject to this Agreement are:

[*Identify the physical samples of the regulated genetic resources to be transferred.*]

Commentary: The identification of the Materials, for which physical samples will be transferred, should include as many of the following as possible:

1. The taxonomical identity of the Materials (If the taxonomical identity is not known, a description of the physical attributes of the Materials.);

2. Photographs, drawings, or other written means of describing the Materials;

3. The location from which the samples of the Materials have been obtained and any information provided by the Transferor(s) as to the geographical origin of the samples (e.g., country of origin); and

4. A sample of the specimen may be deposited in a facility that will maintain the integrity of the sample and permit future characterization of it. Such facilities would include "international depositary institutions" designated under the "Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure". Acceptable facilities are not limited to those international depositary institutions, however, and could include other facilities that are deemed suitable by the Transferor and the Transferee.

To the extent possible, identification of the Materials should be provided by the Transferor(s). In the alternative, the Transferee should work with the Transferor to develop an agreed upon means of identifying and describing the Materials. If a large number of Materials are to be transferred, descriptions of the materials may be placed in an annex. Alternatively, several transfer agreements may be used, particularly if Materials have different uses or are subject to different benefit-sharing arrangements.

Article 3. Transfer

3.1. The [Transferor(s)] shall transfer the samples of the Material(s) identified in Article 2 of this Agreement to the [Transferee] under the conditions specified in the following paragraphs.

3.2. [Conditions for the transfer of the samples, including number of samples, packaging, place and date of delivery, *etc.*]

3.3. The [Transferee] may not further transfer the samples of the Materials provided by the [Transferor(s)] and may not transfer genetic resources made using those samples to others except to:

3.3.1. Those for whom the [Transferee] is acting as agent, identified above, and who are bound by this Agreement;

3.3.2. Those who are authorized in writing to receive samples by the [Transferor(s)]; and

3.3.3. Successors in interest of the [Transferee] who are bound by this Agreement.

3.4. The [Transferee] shall maintain records concerning the handling, storage and physical movement of the samples and provide such records to [Transferor(s)].

Commentary: If the samples are to be removed from the country in which the transfer occurs, government permission may be required for export and/or import. If a government agency is the Transferor, it should be made clear whether it is authorized and/or grants permission to export. In any event, responsibility for obtaining authorization for export and import should be assigned. Similarly, government regulations may require specific procedures for handling the Materials. Responsibility for fulfilling these requirements should be assigned and all such requirements should be fulfilled.

Article 4. Use of the Materials

4.1. The [Transferee] [and the entity for which the Transferee is any agent] shall only use the samples of Materials transferred under Article 3 of this Agreement for the purposes

Alternative 1: **enumerated in Article __ of the Bioprospecting Agreement.**

Alternative 2**: enumerated in Article __ of the Bioprospecting Agreement and for the purposes described below.**

Alternative 3: **described below.**

4.2. The [Transferee] [and the entity for whom the Transferee is acting as agent] shall return the samples of the Materials transferred under Article 3 of this Agreement [and genetic resources or other materials made from those samples or will destroy those samples and genetic resources or other materials, as directed by [Transferor(s)] when the [Transferee] completes the uses referred to in paragraph 1 of this Article, except as necessary to fulfill disclosure requirements for applications for patents or patent variety protection.

4.3. The [Transferee] shall not seek patents or plant variety protection rights in the Materials as such as they are listed in Article 2 (*i.e.*, materials in the form they are transferred to the [Transferee]). The [Transferee] may apply for the grant of patents claiming inventions developed using samples of the transferred Materials, including inventions embodied in modified forms of the materials, or for the grant of plant variety protection claiming varieties developed using samples of the transferred Materials.

Commentary: If the Transferee wishes to use the transferred samples for uses other than those enumerated in paragraph 4.1, the Transferee must negotiate an amendment to this Agreement with the Transferor(s) or negotiate *a new agreement.*

Paragraph 4.3 authorizes the Transferee to apply for patents or plant variety protection on inventions made using the samples. Article 5 on the sharing of benefits, however, may provide that the Transferor(s) are licensees of the Transferee(s) or joint owners of such applications as part of the benefit-sharing arrangements. The prohibition against seeking rights in the materials transferred as such is intended to assure Transferor(s) that rights will not be sought that might limit or otherwise affect use of the materials as such by parties other than the patent owner/plant variety right owner

Article 5. Sharing of Benefits

5.1. The [Transferee] [and the entity for which the Transferee is any agent] shall provide, at a mutually agreed time, benefits arising from use of the transferred materials:

***Alternative 1:* as enumerated in Article __ of the Bioprospecting Agreement.**

***Alternative 2:* as enumerated in Article __ of the Bioprospecting Agreement and as described below.**

***Alternative 3:* as described below.**

Commentary: The definition of benefits to be shared will vary widely depending on the needs of the Transferor(s), the needs of designated beneficiaries such as indigenous or local communities, the commercial value of the transferred physical samples, the intended use of the samples, the likelihood of using the samples to create a commercially viable product, and other factors. As a consequence, it is not appropriate to suggest a model formulation for the nature of benefits, or the manner in which benefits should be shared, as no single definition will be appropriate in all circumstances.

The Model envisions that specific benefits, the conditions giving rise to obligations for benefit sharing will be identified, and the date on which such benefits are to be provided will be specified in this section (e.g., immediate payment of a fee, payment of a fixed fee upon use of the material in a research or experimental setting). Alternatively, this section may contain a commitment to negotiate benefit sharing terms and conditions by a point certain in the future. The point certain may be (i) a date certain, (ii) a date when certain types of research activities are performed on the transferred material, or (iii) a date when a commercial product has been identified and is being prepared for commercial production and marketing. It is generally inadvisable to defer negotiation of benefit sharing to later dates, given the potential for a lack of agreement over such benefit sharing terms to disrupt the commencement of commercial marketing, and/or the possibility of distorting the valuation of the materials.

Part IV.B of the Guidelines lists specific types of benefits that should be considered for inclusion in the formulation of benefits to be provided under the Bioprospecting Agreement. It should also be noted that Annex II to the 'Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of their Utilization" lists various types of benefits that can be provided to the Transferor(s) and their beneficiaries. See http://www.biodiv.org/decisions/default.aspx?m=COP-06&id=7198&lg=0.

Article 6. Conservation and Sustainable Use of Biodiversity

The [Transferee] shall take all reasonable steps and give good faith consideration to sharing data with the [Transferor(s)] which is derived from research on the transferred samples of the Materials enumerated in Article 3 and which may be useful in the support of conservation efforts related to a species, environment, or habitat from which the samples were collected.

Commentary: This obligation is drawn from Part VI.3 of the Guidelines (Parts VI.1 and 2 relate only to collection and are not relevant). The Bioprospecting Agreement may contain a similar provision.

Article 7. General Provisions

7.1. This Agreement shall be in effect for a term of ten years from the date of execution of this Agreement unless otherwise agreed to by the Parties. The Agreement shall be terminated if any of the Parties provides notice in writing to the others of its intent to terminate the Agreement on a date no less than six-months from the date of the notice. [*Insert requirements for notice***.]**

7.2. The obligations and rights contained in Article 4.3 and Article 6 shall survive the expiration or other termination of this Agreement.

7.3. Upon the termination or expiration of this Agreement, the [Transferee] [and the entity for whom the Transferee is acting as agent] shall return the samples of the Materials transferred under Article of this Agreement [and genetic resources or other materials made from the transferred samples of the Materials] to the [Transferor(s)] or will destroy those samples and genetic resources or other materials, as directed by [Transferor(s), except as necessary to fulfill disclosure requirements for applications for patents or patent variety protection.

7.4. The provisions of this Agreement constitute the entire Agreement between the Parties relating to the subject matter and the Parties do not make any representations or warranties except those contained in this Agreement. The Agreement shall not be considered extended, cancelled, or amended in any respect unless done so in writing signed on behalf of the Parties.

7.5. None of the rights or obligations under this Agreement are assignable or otherwise transferable without the prior written consent of the other Party(ies).

7.6. Nothing contained in this Agreement shall constitute a partnership or agency between the Parties.

7.7. This Agreement is governed by and shall be construed in accordance with the laws and regulations of [*jurisdiction***], without regard to its conflict of law principles.**

7.8. [*Reserved for indemnity and confidentiality provisions***]**

7.9. [*Reserved for dispute settlement procedures.]***

Signatures

Commentary: Paragraph 7.1 envisions development of appropriate notice provisions, which are likely to vary significantly depending on the Transferor(s). For example, a notice procedure appropriate for a botanical garden may be very different than notice provisions for an indigenous or local community. If there is a Bioprospecting Agreement, the notice provisions should reflect the notice provisions in that Agreement.

In paragraph 7.2, it may be appropriate to specify that some "uses" from Article 4 and some "benefits" from Article 5 survive the Agreement.

With respect to reserved paragraph 7.9, appropriate dispute settlement provisions could vary significantly depending on the Transferor(s). If there is a Bioprospecting Agreement, the provisions in this agreement should be similar to the dispute settlement provisions in the Bioprospecting Agreement. It should be noted that under Part VII.7 of the Guidelines state that the dispute settlement provisions should provide for "fair and effective resolution" and could include international arbitration consistent with the procedures outlined in the Annex to the Guidelines.

EUROPABIO
The European Association for Bioindustries

March 2006

EuropaBio principles for accessing genetic resources

1. EuropaBio members are supportive of the principles embodied in the United Nations Convention on Biological Diversity (CBD)

A basic principle of the CBD is that States (Countries) have sovereign rights over their biological resources consistent with the terms and limitations of the Convention. Access and transfer with regard to such resources can only be made if "Prior Informed Consent" (PIC) has been obtained from the providing entity, as identified by the appropriate governmental authority within the Contracting Party to the Convention. A contract with the providing entity, with a content of mutually agreed terms, should include sharing of the benefits, to reflect the contracting entities' contribution to commercial value under commercially reasonable terms, allowing for the legal export and use of the material.

However the principles of PIC and access and benefit sharing should only apply to biological resources:

- that are not privately owned[1],
- that are already, or become, available to the public on an unrestricted basis, and/or
- that were obtained after the signature date of the CBD.

Moreover, plant genetic resources are already governed by the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) which was set up to be in harmony with the CBD but provides for a multilateral system for access and benefit sharing[2].

We are aware that some Contracting Parties to the CBD do not yet have authorities in place, and we encourage governments to establish these authorities.

2. EuropaBio members work according to the following guiding principles for access and benefit sharing

Members will make appropriate efforts to ensure that:

- no genetic material to be obtained directly from a Contracting Party will be included in screening for beneficial genetic resources without PIC;

- all materials screened and obtained after the CBD came into force in the providing country (Contracting Party) are covered by contracts and/or material transfer agreements before commercialisation;

1 Proprietary biologic or genetic material, such as germplasm owned and used by companies under trade secret, PVP, or patent, is considered to be legally obtained outside the scope of the CBD. Otherwise the CBD would be in conflict with basic intellectual property rights, which was never its intent.

2 The International Treaty takes into account the specificities and the historical development of plant genetic resources in agriculture and horticulture and provides the appropriate framework for these resources (although the International Treaty is certainly subject to improvements, for instance by extending the number of crops to which it applies).

- local capacity building is supported through collaborations, which may include but not be limited to sampling, collection and/or taxonomy as is appropriate and useful to both parties.

Members believe that:

- contracts should be based on mutually agreed terms that define commercial rights in advance and include, where appropriate, intellectual property rights, royalties, technology transfer or other means of benefit sharing;

- contracts should be signed by the appropriate governmental authority of the Contracting Party, where such exists, or the providing entity in the Contracting Party, subject to national law where the resources were collected:

3. EuropaBio members' cooperation with providing entities

In order to create situations of mutual benefit for EuropaBio members and the providing entities within Contracting Parties, members of EuropaBio will consider:

- monetary or other compensation (via technology transfer and capacity building) consistent with commercial value;

- compensation to the providing entity where the resources were collected if later commercialised;

- encouraging scientist to scientist collaboration.

4. EuropaBio members will consider the following in connection with the use of genetic materials:

- Samples of genetic material from *ex situ* collection depositories, acquired by the depository with the permission of the source country after the CBD came into force in that source country (Contracting Party), may be freely included in both scientific and industrial screening and evaluations, subject to existing contracts and intellectual property rights.

- Samples of genetic material, for which a third party is not willing to provide assurance that it has obtained such samples in conformance with the Convention on Biodiversity, if and when applicable, or prior to the Convention coming into force in the source country, should not be accepted.

Guidelines[1] for IFPMA Members on Access to Genetic Resources and Equitable Sharing of Benefits Arising out of their Utilization

Introduction

IFPMA members:

Supporting the objectives of the Convention on Biological Diversity (CBD) and recognizing the national sovereignty of States over biological resources,

Supporting and wishing to participate in the development of a regime on Access and Benefit Sharing (ABS), which would facilitate the sustainable use of genetic resources (GR) and, once clearly defined, associated traditional knowledge (TK) and regulate the rights and responsibilities of users and providers of such resources in a transparent way, taking into account related discussions and outcomes from other relevant international fora,

Aware of the important role the research-based pharmaceutical industry has to play as a stakeholder in informing policy decision-making related to this issue through its unique expertise and practical experience in managing the complex nature of the medical innovation process,

Willing to participate in appropriate technical assistance, in coordination with the CBD Secretariat and CBD parties/observers or other appropriate organizations, to build the legislative, science and negotiating capacity of CBD parties,

Calling on CBD members to ensure continuing education and outreach efforts to facilitate capacity building, either independently or through a body such as WIPO, relating to the development of model and/or national legislation governing prior consent and benefit sharing laws, including model clauses for ABS agreements, keeping in mind that such laws should achieve a satisfactory balance between the conservation of biodiversity and encouragement of access to and use of GR in a way that would promote fair and equitable benefit sharing,

Propose concrete measures to facilitate implementation of CBD provisions relating to access to genetic resources and equitable sharing of the benefits arising out of their utilization and related traditional knowledge.

Objective

International research-based pharmaceutical companies support a positive approach to CBD implementation consistent with other international obligations and agreements. Successful resolution of issues raised in various fora concerning Access and Benefit Sharing will enable industry to facilitate implementation of CBD provisions relating to access to genetic resources[2], and equitable sharing of the benefits arising out of their utilization and reasonably related and clearly defined forms of traditional knowledge[3] in the context of (i) CBD obligations on states to facilitate access and not impose restrictions on access that run counter to CBD objectives and (ii) the CBD recognition that access and benefits sharing should be on mutually agreed terms.

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[1] The Guidelines list certain "best practices" which should be followed by companies which will engage in the acquisition and use of genetic resources.

[2] Under the CBD, Conference of Parties COP Decision II/11, para. 2, human genetic material is excluded from the scope of the CBD. In addition, materials removed from in situ locations prior to 1992 also fall outside the remit of the CBD.

[3] As recognized by the recent European Community and Member States Proposal to WIPO: "there are concerns about the possibly unclear scope of the term 'traditional knowledge'. In order to achieve the necessary legal certainty, a further in-depth discussion of the concept of TK is necessary." Source: http://www.wipo.int/tk/en/genetic/proposals/european_community.pdf

The following provides an outline of industry best practices and steps that CBD members should take in order to provide the legal environment necessary to allow such best practices.

Industry Best Practices

1. To obtain prior informed consent (PIC) to the acquisition and use of genetic resources controlled by a country/indigenous people and provided to the company in accordance with local law.

2. In obtaining PIC, to disclose the intended nature and field of use of the genetic resources.

3. To gain necessary approval to remove materials found *in situ*, and to enter into formal contractual benefit-sharing agreements reflecting the mutually agreed terms (MAT) on the use of the genetic resources obtained through that removal. These agreements may contain conditions on permissible uses of the genetic resources, transfer of the genetic resources to third parties, and appropriate technical assistance and technology transfers.

4. To avoid taking actions, in the course of use or commercialization of genetic resources obtained as specified under these commitments, that impede the traditional use of such genetic resources.

5. To agree that any disputes as to compliance with the clauses contained in formal contractual benefit-sharing agreements are dealt with through arbitration under international procedures or as otherwise agreeable between the parties.

Enabling Steps by Government

1. Actual enactment of national legislation implementing the CBD.

2. Establishment of Focal Points.

Such national focal points should establish clearly which indigenous groups or other stakeholders possess rights to authorize access to particular genetic resource(s) *in situ* within any CBD member.

This would provide transparency and legal certainty to industry and to other interested parties. Such focal points may wish to establish databases recording the existence of genetic resources and its uses.

3. Commitment to enter into good faith negotiations as to the terms of access and benefit sharing contracts with commercial entities.

4. Agreement on dispute resolution as outlined in point 5) above.

Conclusion

IFPMA members strongly believe that implementing this agenda will significantly contribute in achieving to establish a practical access and benefit sharing environment conducive to value creation and equitable sharing of rewards through the clarification of major stakeholders respective rights and responsibilities.

(Published: 26 January 2007)

(Ends)

INTERNATIONAL UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS (UPOV)

CBD

September 27, 2008

Dear Executive Secretary Djoghlaf,

I have the pleasure to refer to notification reference SCBD/SEL/OJ/VN/GD/64856 of September 12, 2008, concerning Access and Benefit-sharing: Group of technical and legal experts on compliance – nomination of experts and submission of views.

Views and proposals of the International Union for the Protection of New Varieties of Plants (UPOV) in relation to the elaboration and negotiation of the international regime on access and benefit-sharing were expressed in the reply of UPOV to the Notification of June 26, 2003, "Access to Genetic Resources and Benefit-Sharing", adopted by the Council of UPOV on October 23, 2003, and sent to the Secretariat of the Convention on Biological Diversity under cover of a letter dated October 27, 2003.

./. I have the pleasure to send you herewith the reply of UPOV as mentioned above, and I would appreciate it if you could arrange for this document to be distributed to the participants of the meeting of legal and technical experts to examine the issue of compliance which will take place in Tokyo, Japan, from January 27 to 30, 2008.

Sincerely yours,

Rolf Jördens

Rolf Jördens
Vice Secretary-General

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ZUM SCHUTZ VON PFLANZENZÜCHTUNGEN
GENF, SCHWEIZ

UNION INTERNATIONALE POUR LA PROTECTION DES OBTENTIONS VÉGÉTALES
GENÈVE, SUISSE

UNIÓN INTERNACIONAL PARA LA PROTECCIÓN DE LAS OBTENCIONES VEGETALES
GINEBRA, SUIZA

OF NEW VARIETIES OF PLANTS
GENEVA, SWITZERLAND

ACCESS TO GENETIC RESOURCES AND BENEFIT-SHARING

Reply of UPOV to the Notification of June 26, 2003, from the Executive Secretary of the Convention on Biological Diversity (CBD)

adopted by the Council of UPOV
at its thirty-seventh ordinary session
on October 23, 2003

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Introduction

1. The International Union for the Protection of New Varieties of Plants (UPOV) is an intergovernmental organization, established by the International Convention for the Protection of New Varieties of Plants (the "UPOV Convention"). The UPOV Convention was adopted on December 2, 1961, and revised in 1972, 1978 and 1991. The Mission of UPOV, based on the UPOV Convention, is: *"To provide and promote an effective system of plant variety protection, with the aim of encouraging the development of new varieties of plants, for the benefit of society."*

2. As of July 31, 2003, UPOV has 53 members[1]. Furthermore, 18 States and two intergovernmental organizations have initiated, with the Council of UPOV, the procedure for becoming members of the Union and 53 other States have been in contact with the Office of the Union for assistance in the development of legislation on plant variety protection. It is therefore anticipated that more than 100 States or intergovernmental organizations may be members of UPOV in the future.

3. UPOV supports the view that the Convention on Biological Diversity (CBD) and relevant international instruments dealing with intellectual property rights, including the UPOV Convention, should be mutually supportive.

4. It should be recalled that the Conference of the Parties to the CBD, in its Decision IV-24, taken at its sixth Meeting (COP-6) held in The Hague, Netherlands, from April 7 to 19, 2002, acknowledged relevant work being carried out by other intergovernmental organizations, such as the World Intellectual Property Organization (WIPO), the World Trade Organization (WTO), the United Nations Conference on Trade and Development (UNCTAD), the Food and Agriculture Organization of the United Nations (FAO) and UPOV, on issues related to access to genetic resources and benefit-sharing.

5. UPOV has developed a reply based on the principles of the UPOV Convention in order to provide some guidance on UPOV's views on the "process, nature, scope, elements and modalities of an international regime on access to genetic resources and benefit-sharing."

Access to Genetic Resources

6. UPOV considers that plant breeding is a fundamental aspect of the sustainable use and development of genetic resources. It is of the opinion that access to genetic resources is a key requirement for sustainable and substantial progress in plant breeding. The concept of the "breeder's exemption" in the UPOV Convention, whereby acts done for the purpose of breeding other varieties are not subject to any restriction, reflects the view of UPOV that the worldwide community of breeders needs access to all forms of breeding material to sustain greatest progress in plant breeding and, thereby, to maximize the use of genetic resources for the benefit of society.

[1] More detailed information concerning UPOV's membership can be found at: http://www.upov.int/en/about/members/index.htm.

Disclosure of Origin

7. The requirement for "distinctness" in the UPOV Convention[2] means that protection shall only be granted after an examination to determine if the variety is clearly distinguishable from all other varieties, whose existence is a matter of common knowledge[3] at the date of filing of the application, regardless of the geographical origin. Furthermore, the UPOV Convention provides that, if it is discovered that a breeder's right has been granted for a variety that was not distinct, that right shall be declared null and void.

8. The breeder is usually required, in a technical questionnaire that accompanies his application for protection, to provide information concerning the breeding history and genetic origin of the variety. UPOV encourages information on the origin of the plant material, used in the breeding of the variety, to be provided where this facilitates the examination mentioned above, but could not accept this as an additional condition of protection since the UPOV Convention provides that protection should be granted to plant varieties fulfilling the conditions of novelty, distinctness, uniformity, stability and a suitable denomination and does not allow any further or different conditions for protection. Indeed, in certain cases, for technical reasons, applicants may find it difficult, or impossible, to identify the exact geographic origin of all the material used for breeding purposes.

9. Thus, if a country decides, in the frame of its overall policy, to introduce a mechanism for the disclosure of countries of origin or geographical origin of genetic resources, such a mechanism should not be introduced in a narrow sense, as a condition for plant variety protection. A separate mechanism from the plant variety protection legislation, such as that used for phytosanitary requirements, could be applied uniformly to all activities concerning the commercialization of varieties, including, for example, seed quality or other marketing-related regulations.

Prior Informed Consent

10. With regard to any requirement for a declaration that the genetic material has been lawfully acquired or proof that prior informed consent concerning the access of the genetic material has been obtained, UPOV encourages the principles of transparency and ethical behavior in the course of conducting breeding activities and, in this regard, the access to the genetic material used for the development of a new variety should be done respecting the legal framework of the country of origin of the genetic material. However, the UPOV Convention requires that the breeder's right should not be subject to any further or different conditions than the ones required to obtain protection. UPOV notes that this is consistent with Article 15 of the CBD, which provides that the determination of the access to genetic resources rests with the national governments and is subject to national legislation. Furthermore, UPOV considers that the competent authority for the grant of the breeder's rights is not in a position to verify whether the access to genetic material has taken place in accordance with the applicable law in this field.

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[2] Reference to the UPOV Convention in this document should be understood as a reference to the latest Act of the UPOV Convention (the 1991 Act). The full text of the UPOV Convention can be found at: http://www.upov.int/en/publications/conventions/1991/content.htm

[3] The matter of common knowledge is considered further in UPOV document "The Notion of Breeder and Common Knowledge" (C(Extr.)/19/2 Rev.). This document can be found at: http://www.upov.int/en/about/key_issues.htm

Summary

11. Since the legislation on access to genetic material and the legislation dealing with the grant of breeders' rights pursue different objectives, have different scopes of application and require a different administrative structure to monitor their implementation, UPOV considers that it is appropriate to include them in different legislation, although such legislation should be compatible and mutually supportive.

Benefit-Sharing

Breeder's Exemption

12. UPOV would be concerned if any mechanism to claim the sharing of revenues were to impose an additional administrative burden on the authority entrusted with the grant of breeders' rights and an additional financial obligation on the breeder when varieties are used for further breeding. Indeed, such an obligation for benefit-sharing would be incompatible with the principle of the breeder's exemption established in the UPOV Convention whereby acts done for the purpose of breeding other varieties are not, under the UPOV Convention, subject to any restriction and the breeders of protected varieties (initial varieties) are not entitled to financial benefit-sharing with breeders of varieties developed from the initial varieties, except in the case of essentially derived varieties (EDV). Furthermore, a benefit-sharing mechanism within the legislation to grant breeder's rights, would seem to tax only "protected" varieties and, instead of creating incentive mechanisms to develop new varieties, may provoke the opposite effect, whereby breeders would not develop new varieties or would not seek protection (favoring a legally insecure environment).

13. The Food and Agriculture Organization of the United Nations (FAO), at its 31st Conference, on November 3, 2001, adopted the International Treaty on Plant Genetic Resources for Food and Agriculture. This Treaty (Article 13.2. (d)(ii)) recognizes the concept of the breeder's exemption, in that breeders are excepted from financial benefit-sharing whenever their products are "available without restriction to others for further research and breeding ...".

Subsistence Farmers

14. In addition to the breeder's exemption and the research exemption, the UPOV Convention contains another compulsory exception to the breeder's right whereby the breeder's right does not extend to acts done privately and for non-commercial purposes. Therefore, activities of subsistence farmers, where these constitute acts done privately and for non-commercial purposes, are excluded from the scope of the breeder's right and such farmers freely benefit from the availability of protected new varieties.

Farm-Saved Seed

15. The provision on "farm-saved seed" (also known as the "farmer's privilege") is an optional benefit-sharing mechanism provided by the UPOV Convention, under which UPOV members may permit farmers, on their own farms, to use part of their harvest of a protected variety for the planting of a further crop. Under this provision, members of UPOV are able to adopt solutions, which are specifically adapted to their agricultural circumstances. However, this provision is subject to reasonable limits and requires that the legitimate interests of the breeder are safeguarded, to ensure there is a continued incentive for the development of new varieties of

plants, for the benefit of society. For example, certain members of UPOV apply the provision on farm-saved seed only to certain species or limit its application using criteria such as the size of the farmer's holding or the level of production.

Summary

16. Mechanisms of benefit-sharing should take into account the need for a relationship of mutual supportiveness in respect of the essential principles of the UPOV system of plant variety protection and, in particular, of the breeder's exemption provision.

Conclusion

17. UPOV considers that plant breeding is a fundamental aspect of the sustainable use and development of genetic resources. It is of the opinion that access to genetic resources is a key requirement for sustainable and substantial progress in plant breeding. The concept of the "breeder's exemption" in the UPOV Convention, whereby acts done for the purpose of breeding other varieties are not subject to any restriction, reflects the view of UPOV that the worldwide community of breeders needs access to all forms of breeding material to sustain greatest progress in plant breeding and, thereby, to maximize the use of genetic resources for the benefit of society. In addition, the UPOV Convention has inherent benefit-sharing principles in the form of the breeder's exemption and other exceptions to the breeder's right and UPOV is concerned about any other measures for benefit-sharing which could introduce unnecessary barriers to progress in breeding and the utilization of genetic resources. UPOV urges the *Ad Hoc* Open-ended Working Group on Access and Benefit-sharing to recognize these principles in its work and to ensure that any measures it develops are supportive of these principles and, therefore, of the UPOV Convention.

[End]
