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ACCESS AND BENEFIT-SHARING
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COLLATION OF ANY OTHER VIEWS AND INFORMATION SUBMITTED BY PARTIES, GOVERNMENTS, INTERNATIONAL ORGANIZATIONS, INDIGENOUS AND LOCAL COMMUNITIES AND RELEVANT STAKEHOLDERS IN RESPECT OF THE MAIN COMPONENTS OF THE INTERNATIONAL REGIME ON ACCESS AND BENEFIT-SHARING LISTED IN DECISION IX/12, ANNEX I

Note by the Executive Secretary

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INTRODUCTION

In decision IX/12, paragraph 9, the Conference of the Parties invited Parties, other Governments, international organizations, indigenous and local communities, and relevant stakeholders to submit, for further elaboration and negotiation of the international regime on access and benefit-sharing, views and proposals including operational text, where relevant, in respect of the main components listed in the annex I to decision IX/12, preferably with supporting rationale.

In paragraph 10 of the same decision, the Executive Secretary is requested to "compile the submissions received and to collate in three separate documents:

(a) Any operative text submitted;
(b) Operative text including related explanations and rationale;
(c) Any other views and information;

by subject matter, in accordance with the annex I to decision IX/12 and as indicated in the submissions, and to identify in the collation the respective sources." It further requested the Executive Secretary to make the compilation and these documents available to Parties sixty days prior to the seventh meeting of the Working Group on Access and Benefit-sharing.

In accordance with the above, notification 2008-120 of 19 September 2008 was sent to Parties, Governments, international organizations, indigenous and local communities and relevant stakeholders inviting them to provide their submissions by 15 December 2008.

As requested by the Conference of the Parties, the present document provides a collation of any other views and information submitted by Parties, Governments, international organizations, indigenous and local communities and relevant stakeholders following the structure of annex I to decision IX/12.

ANY OTHER VIEWS AND INFORMATION RELATED TO THE INTERNATIONAL REGIME FOLLOWING THE STRUCTURE OF ANNEX I TO DECISION IX/12 1

I. OBJECTIVE

Access and Benefit-Sharing Alliance (ABSA)

The objectives of the ABS IR should harken back to the words of the CBD Treaty itself, and accordingly should encompass the following:

1. Protect "the sovereign rights of States" 2/ over the *in situ* "genetic resources being provided by a Contracting Party" 3/ and "only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance wit this Convention." 4/

2. Identify mechanisms for ABS stakeholders to ensure "[a]ccess, where granted, shall be on mutually agreed terms," 5/ and "shall be subject to prior informed consent of the Party providing such resources, unless otherwise determined by that Party,"6 and, finally, to establish terms of benefit sharing "upon mutually agreed terms." 7/

3. "Encourage the equitable sharing of the benefits arising from the utilization of" traditional "knowledge, innovations and practices." 8/

4. Endeavor "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." 9/

Biotechnology Industry Organization (BIO)

General Comment on Objectives: The mandate of the ABS WG is "to elaborate and negotiate an international regime on access to genetic resources and benefit-sharing with the aim of adopting an instrument\instruments to effectively implement the provisions in Article 15 and Article 8(j) of the Convention and the three objectives of the Convention" (COP Decision VII/19D, para. 1). As a general matter, the objectives of the International Regime (IR) must track the terms of reference of the ABS Working Group, which were dictated by the COP in Decision VII/19D and must also be consistent with the terms of the CBD itself. Efforts to further broaden or otherwise modify these governing principles are outside the scope of the ABS WG exercise and should be avoided.

The mandate of the ABS WG refers to the implementation of Article 15 and Article 8(j) of the CBD and "the three objectives of the Convention" (Decision VII/19D). The text of this paragraph should therefore be limited to CBD Articles 15 and 8(j). References that have been proposed to other articles, e.g., Articles

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1/ For ease of reference, the text of annex I reproduced in this paper has been shaded.

2/ Convention on Biological Diversity, Article 15.1.

3/ Convention on Biological Diversity, Article 15.3.

4/ Ibid.

5/ Convention on Biological Diversity, Article 15.4.

6/ Convention on Biological Diversity, Article 15.5.

7/ Convention on Biological Diversity, Article 15.7.

8/ Convention on Biological Diversity, Article 8(j) (order of phrasing reversed).

9/ Convention on Biological Diversity, Article 15.2.

16 (transfer of technology) and 19.2 (access to benefits from "biotechnologies based on genetic resources") address different issues and should not be included.

The provisions of Article 15 regarding access and benefit-sharing are limited to "genetic resources." The IR should be limited as such and therefore should not include "derivatives" or "products." In addition, including such concepts may be inconsistent with the notion of obligations arising through "mutually agreed terms" in an ABS arrangement and would have potential to subject downstream actors to further uncertainties.

The ABS WG should proceed with care when addressing the topic of "traditional knowledge." For example, the term "associated traditional knowledge," which is presented as a textual option for the objectives, is not used in the CBD. Article 8(j) specifically recites that its scope is limited to such "knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity." In order to avoid confusion, a specific reference to Article 8(j) is warranted when addressing "traditional knowledge" issues. In addition, the terms "misappropriation" and "misuse" are not used or defined in the CBD. While these terms may be a useful tool for dialog, they should not be included as a potential definitional element relating to the objectives of the international regime.

Intellectual Property Owners Association (IPO)

According to Decision IX/12 of the Conference of the Parties to the CBD, the Working Group's mandate is to elaborate and negotiate an International Regime with the purpose of implementing Articles 15 and 8(j), and the three objectives, of the Convention. This should occur in accordance with Decisions VII/19D and XIII/4A.

Therefore, IPO interprets these Decisions as limiting the objectives of the International Regime to the following: (1) to protect the sovereignty of states over their natural resources; (2) to facilitate access to Genetic Resources on the basis of mutually agreed terms and with the prior informed consent of the providing Party; and (3) to ensure sharing of the results of research and other benefits arising from the use of Genetic Resources on the basis of mutually agreed terms. Furthermore, the International Regime must do so in a manner that is consistent with the other two defined objectives of the CBD – namely, conservation and sustainable use.

IPO believes that the focus of the International Regime should be on facilitating mutually agreed terms between users and providers, which are best agreed at the time of acquisition. Focusing specifically on the point of acquisition will ensure not only that there is agreement between user and provider on the terms and conditions of access, but will also serve to guarantee prior informed consent, and in a manner that preserves the sovereign right of states over their *in situ* Genetic Resources.

International Chamber of Commerce (ICC)

The objectives of the IR should be consistent with the terms of reference of the AHOEWG detailed by the Ninth Conference of the Parties (COP-9), Decision VII/19D, and with the terms of the CBD itself. The mandate of the AHOEWG is clear: "to elaborate and negotiate an international regime on access to genetic resources and benefit-sharing with the aim of adopting an instrument\instruments to effectively implement the provisions in Article 15 and Article 8(j) of the Convention and the three objectives of the Convention."

The **objectives** of the International Regime should therefore be **limited to the said mandate**, namely:

(1) to protect the sovereignty of states over their natural resources;

(2) to facilitate access to Genetic Resources on the basis of mutually agreed terms and with the prior informed consent of the providing Party; and
(3) to ensure sharing of the results of research and other benefits arising from the use of genetic resources on the basis of mutually agreed terms.

Furthermore, the IR must be consistent with the other defined objectives of the CBD – namely, conservation and sustainable use. Efforts to further broaden or otherwise modify these governing principles are **outside the scope** of the working group and should be rejected.

In the view of business, the most effective way of achieving these objectives would be for the IR to establish international benchmarks and guidelines that would assist CBD Members in developing **consistent, predictable, non-discriminatory, transparent and effective national ABS systems which provide legal certainty**.

The IR should develop Article 15(7) of the Convention, by identifying those "legislative, administrative or policy measures" which can, through implementation by the contracting parties, facilitate the activities of interested parties in the identification of sustainable uses, the agreement of mutually-agreed terms and the sharing of benefits.

II. SCOPE

Access and Benefit-Sharing Alliance (ABSA)

Consistent with the **Objectives** proposed above and with the terms of its mandate from Decision VII/19 D, the ABS IR should be limited to effective implementation of the relevant provisions in Article 15, Article 8(j) and the three objectives of the Convention. 10/

Based on the clear language of the CBD Treaty, CBD members should limit the scope of the ABS IR to "genetic resources being provided by a Contracting Party" 11/ and "only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention.", 12/ based on "mutually agreed terms" (MAT's) between the acquirer and the provider, and Prior Informed Consent, "unless otherwise determined by that Party," 13/

In this context, CBD Parties should agree to exclude "biological resources" as defined in Article 2 of the CBD that would otherwise would bring under the IR all natural resources and other commodities currently traded by countries all over the world, such as ornamental and garden plants, timber, agricultural produce (like apples or rice), and even household pets.

In addition, the IR should exclude human genetic resources consistent with Article 2 of the CBD, subsequent decisions taken by CBD Ministers, and the *Bonn Guidelines*. Article 2 of the Convention, for example, first defines "Genetic Material" as "any material of plant, animal, microbial or other origin containing functional units of heredity", and subsequently defines "genetic resources" as "any material of plant, animal, microbial or other origin containing functional units of heredity." Further, as adopted by

10/ Ideas such as "derivatives" or "products" have no mention in the CBD. Nonetheless, they should be addressed under the ABS IR via individual ABS agreements. For more discussion of derivatives and other downstream products in the ABS IR, see **Fair and Equitable Benefit Sharing**, pp.5 - 6.

11/ Convention on Biological Diversity, Article 15.3.

12/ Ibid.

13/ Convention on Biological Diversity, Article 15.5.

CBD Ministers at the 2nd Conference of the Parties, Decision II/11: Access to Genetic Resources, "Reaffirms that human genetic resources are not included within the framework of the Convention" 14/ The intention to exclude human genetic resources is confirmed explicitly in defined scope of the *Bonn Guidelines:* "All genetic resources and associated traditional knowledge, innovations and practices covered by the Convention on Biological Diversity and benefits arising from the commercial and other utilization of such resources should be covered by the guidelines, *with the exclusion of human genetic resources*." (emphasis added) 15/

The IR should recognize existing international instruments and also exclude resources that are already the subject of agreements or negotiations in other fora such as the FAO International Treaty on Plant and Genetic Resources for Food and Agriculture (ITPGRFA), the International Technical Conference on Animal Genetic Resources for Food and Agriculture under FAO, and human, plant and animal pathogens currently the subject of unrelated benefit sharing negotiations in the World Health Organization (WHO).

The IR should apply to *in situ* GR with or without TK acquired after entry into force of the ABS IR in the provider country, and should form a prospective system with no retroactive effect. 16/

Biotechnology Industry Organization (BIO)

The IR should be within the scope of the CBD. In respect of access and benefit-sharing, the terms of the CBD are limited to "genetic resources." Thus, the IR should not apply to the broader term "biological resources" and should also not apply to "derivatives," "products" or other items, however defined, unless those items would also meet the definition of a genetic resource under the Convention, i.e., "genetic material of actual or potential value," where genetic material is defined as "any material of plant, animal, microbial or other origin containing functional units of heredity" (CBD Article 2). Thus, proposed references to "derivatives" and "products," should be deleted to be consistent with the scope of the CBD. In addition, reference to Article 8(j) is warranted when discussing "traditional knowledge" to link the concept of traditional knowledge to the context in which it is used in the CBD.

The Options: In respect of the three options presented, Option 1 is more comprehensive and would make the most appropriate basis for discussions. However, option 3 could be amended to be consistent with the views of BIO set forth herein. Option 2, however, appears to suggest an overly broad scope for the IR. For example, it contains no exception for genetic resources made freely available (e.g., "commodities"), resources found beyond national jurisdictions or other excluded categories of genetic resources.

Excluded Subject Matter

The following subject matter should be excluded from the scope of the IR:

i. *Human genetic resources* – human genetic resources must be excluded consistent with COP Decision II/11, reaffirming that "human genetic resources are not included within the framework of the Convention;"

14/ Decision II/11: Access to Genetic Resources, UNEP/CBD/COP/2/19, p. 22.

15/ See *Bonn Guidelines*, "C. Scope 9, p.7.

16/ The CBD does not apply to genetic resources beyond those "that are provided by Contracting Parties that are countries of origin of such resources." CBD Article 15.3. In that light, these resources should be excluded from the scope of the IR.

ii. *Genetic resources acquired prior to the entry into force of the IR* (i.e., no retroactive effect) - any effect should arise only after obligations are accepted by a particular Contracting Party;

iii. *Genetic material made freely available or that otherwise enters the public domain* (i.e., commodities or other genetic resources made available without restriction) - If the genetic resources are made freely available without restriction, they should not be covered by the IR;

iv. *Species listed in Annex I of the ITPGRFA*, unless the use is beyond the scope of that agreement;

v. *Genetic resources found in areas beyond national jurisdiction* - The CBD recognizes "the sovereign rights of States over their natural resources" (CBD Article 15.1). In that light, resources accessed beyond national jurisdictions should be excluded from the scope of the IR to avoid any doubt.

vi. *Genetic resources located in the Antarctic Treaty Area* - To the extent that such an exclusion would avoid competing "sovereignty" claims to resources located in the Antarctic Treaty Area, it would seem positive, so we suggested keeping this exclusion.

vii. *Human, plant and animal pathogens, including viruses* - Pathogens should be excluded from the IR. Inclusion of such resources does not appear consistent with the scope of the Convention and its objective of conservation of biological resources.

Effective Date

The effective date should be the date of the international regime and not the CBD in order to establish a prospective system that has no retroactive effect. The IR will likely add additional guidance or requirements relating to ABS regimes. Any acquisitions of genetic resources made prior to the IR will have been accessed pursuant to national laws and access and benefit-sharing terms that were agreed at that time. The IR should not contemplate the possibility of changing obligations relating to such acquisitions after the fact. In addition, applying the IR in a purely prospective manner will enhance enforcement by providing greater certainty to providers and recipients of the relevant genetic resources.

The proposed language referring to applying the IR to "continuing benefits" arising from utilization prior to the CBD or the IR itself as proposed in current paragraph II(2)(b) of the Annex is not appropriate as it would retroactively apply the IR to acts done prior to the entry into force of the CBD and the IR. This type of approach, attempting to regulate acts already agreed or to re-negotiate terms of access already granted under access and benefit-sharing laws in effect at that time, would be unworkable.

Relationship to Other International Organizations and Agreements

The scope section proposes negotiating instructions that provide for "flexibility" in respect of "specialized" ABS systems such as the Multilateral System established under the ITPGRFA, and for "special" consideration of particular matters. These provisions appear to be negotiating instructions, that may be helpful for the negotiation, but should not be incorporated into a final agreement.

This section also addresses relationship to UPOV, which deals with the protection of plant varieties, and discussions in the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (GRTKF). The IR should not interfere with protection of plant varieties under UPOV. To that extent, it is appropriate for the CBD to give special consideration to the

relationship with that agreement. Similarly, the WIPO IGC is the appropriate body in WIPO for the consideration of matters relating to the relationship of intellectual property and CBD related issues. The work in the WIPO IGC should be given "special consideration" in the sense that the CBD should defer to WIPO on all intellectual property-related issues.

Genetic resources within the remit of the FAO Commission on Genetic Resources for Food and Agriculture may deserve special consideration, and at least some of these resources (e.g., species listed in Annex I of the Multilateral System of the ITPGRFA) should be excluded entirely. For example, animal genetic resources may justify special consideration in light the ongoing work of the Intergovernmental Technical Working Group on Animal Genetic Resources for Food and Agriculture in the FAO context.

As noted previously, genetic resources found in areas beyond national jurisdiction as well as resources located within the Antarctic Treaty Area should be excluded from the IR.

European Seed Association (ESA)

Downstream products

The IR should only regulate the relationship between the provider and party gaining access to genetic resources and not seek to regulate downstream activities and/or derivatives or products being developed from them. An IR which tries to regulate downstream activities and products will be unworkable, unenforceable and extremely costly to implement by governments and users alike. Broadening the scope of the IR to downstream products would bring under the IR common household items such as wine, bread and wood products. Benefit-sharing arrangements in relation to derivatives and downstream products should instead be determined through MAT in the ABS contract between the providing and accessing parties, as provided for in Article 15(7).

Intellectual Property Owners Association (IPO)

If the International Regime is to be successfully negotiated and implemented, one of the most important aspects that will provide certainty to users and providers of Genetic Resources is a clear delineation of the scope of the Regime. IPO lists below certain elements for further consideration by the Parties:

- The International Regime should apply only to Genetic Resources, as defined in Article 2 of the CBD, so as not to extend beyond the objectives of Article 15. According to the definition of Genetic Resources, the Regime should apply only to "Genetic Material" (that is, material containing functional units of heredity) of actual or potential value. This necessarily requires that the Regime exclude those Biological Resources that do not contain functional units of heredity. This distinction can be seen in the following examples: (1) plant materials (such as sugar beets or sugarcane) contain functional units of heredity, but products developed from these plants (such as sucrose or bagasse) do not; (2) the opium poppy plant contains functional units of heredity, but morphine (an extract used as an analgesic) does not; (3) Fungi such as *Penicillium* contain functional units of heredity, but penicillin (an anti-bacterial compound produced from the fungus) does not.

- Human Genetic Resources are exempt from the scope of the International Regime. This has already been decided by the Parties (Decision II/11, and Bonn Guidelines). Recent negotiations have appeared to contradict this earlier decision; therefore, in order to provide clarity, the Regime should specifically reiterate the exclusion of human Genetic Resources from its scope.

- To be most effective, the International Regime should apply only at the time of acquisition of a Genetic Resource, and as a result, should not encompass so-called "Derivatives" or derived

"Products" that are downstream of the actual acquisition. Using the example of morphine described above, research on chemical analogs of morphine may be undertaken by scientists in an effort to create new compounds that may be useful as analgesics. Such research may involve pure synthetic chemistry and can easily take place without the need for access to a single opium poppy plant. Such research should not be encompassed under the access and benefit-sharing obligations of the Regime, which are specifically related to "bioprospecting" activities. If a particular situation exists in which benefit-sharing is appropriate and valid for downstream research activities, these decisions are best made through mutually agreed terms between the user and the provider, consistent with Articles 15(4) and 15(7).

- The above example also illustrates that many "Derivatives" may enter the public domain, for example, through publication in research literature or through availability of the "Derivative" in the open market. In those instances where "derivatives," including information about the genetic resource from which they are derived, enter the public domain, they should be excluded from the International Regime. This is necessary in order to promote clarity and to maintain a workable system.

- The International Regime should be prospective; therefore, it should apply only to the *in-situ* acquisition of Genetic Resources after entry into force of the Regime in the provider country, consistent with the provisions of Article 36 of the CBD.

- The International Regime should not apply to items readily available in trade. The CBD specifically addresses issues of access and benefit-sharing as related to "bioprospecting." The ready sale and availability of items in trade (also referred to as "biotrade") is not intended to be encompassed under the more limited category of "bioprospecting." To apply the International Regime to items in trade would also contradict the principle of sovereignty found in Article 3 of the CBD, which gives member states the freedom to exploit their own resources (but with the obligation of doing so in an environmentally sustainable manner).

- The International Regime should not apply to pathogens. The purpose and objective of the CBD is to ensure conservation and sustainable use of biological diversity, and to minimize adverse effects on biological diversity. To broaden the scope of the Regime to include pathogens would contradict these goals.

- The International Regime should not apply to those Genetic Resources that are subject to other international agreements, such as plant genetic resources subject to the International Treaty on Plant Genetic Resources for Food and Agriculture, or animal genetic resources subject to the International Technical Conference on Animal Genetic Resources for Food and Agriculture, both under the Food and Agriculture Organization of the United Nations.

International Chamber of Commerce (ICC)

The scope of the IR will be key in determining the approach to other issues under discussion, such as compliance measures. It is therefore essential that the scope of the IR be clearly defined.

Business suggests that the IR's scope be determined along the following lines:

- In order to ensure legal certainty, the IR should only apply to **acquisitions of genetic resources** which take place **after entry into force of the IR in the provider country**, and be without prejudice to prior acquisitions carried out in good faith. The IR will likely add additional requirements relating to ABS regimes. Any acquisitions prior to the entry into force of the IR in

the provider country will have been made pursuant to national laws in force at that time, and access and benefit-sharing terms agreed accordingly. The IR should not provide the possibility of changing obligations relating to such acquisitions after they have been made.

- The IR should only regulate the relationship between the provider and party gaining access to genetic resources and not seek to regulate downstream activities. An IR which tries to regulate downstream activities and products will be unworkable, unenforceable and extremely costly to implement by governments and users alike. Broadening the scope of the IR to downstream products would bring under the IR common household items such as wine, bread and wood products. Benefit-sharing arrangements in relation to derivatives and downstream products should instead be determined through MAT in the ABS contract between the providing and accessing parties, as provided for in Article 15(7). Concepts such as "derivatives" or "products", should not be part of the IR itself, but instead should be determined in the **MAT** between parties to the individual ABS agreement. ABS stakeholders already rely heavily on mechanisms based on written agreements which are proven and feasible methods to address ABS concerns.

- The scope of the IR should be **limited to only genetic resources** as defined in the CBD. Consistent with the terms of its mandate from Decision VII/19 D, the IR should be limited to effective implementation of Article 15, Article 8(j) and the three objectives of the Convention. As such, it should seek only to elaborate matters relating to access and benefit-sharing with respect to genetic resources, as defined in the Convention, based on MAT's between the acquirer and the provider (Article 15(4) and 15(7)).

  The inclusion **of biological resources** as defined in Article 2 of the CBD would bring under the IR biological resources that are currently traded by countries all over the world as commodities, such as ornamental and garden plants, timber, agricultural produce (like apples or rice), and even household pets. There are good reasons to draw clear lines between commodity trade in biological resources and the sustainable use of genetic resources. The IR will have to draw clear boundaries between what is included and what is excluded or it will risk inadvertently **stifling trade** in several areas.

- **Certain genetic resources should be excluded**. When defining which genetic resources should be covered by the IR, Parties should consider the following points:

  - The IR should exclude human genetic resources, consistent with COP Decision II/11 and the Bonn Guidelines.
  - The IR should recognize existing international instruments and also exclude resources that are already the subject of agreements or negotiations in **other fora** such as the FAO International Treaty on Plant and Genetic Resources for Food and Agriculture (ITPGRFA) and the International Technical Conference on Animal Genetic Resources for Food and Agriculture under FAO.
  - The IR should not include genetic resources that enter the **public domain** without any restriction by the provider country.
  - Genetic resources **not subject to the jurisdiction of any particular country** should be excluded from the scope of the IR. The CBD does not apply to such resources and only recognizes "the sovereign rights of States over their natural resources" (CBD Article 15.1).
  - The IR should not seek to regulate transactions involving **human, plant and animal pathogens**. Pathogens are arguably not included within the scope of the CBD itself. For example, such "resources" do not appear to fit within the CBD objectives of "conservation" and "sustainable use" in the sense used in the CBD. Since the objective of

the IR refers to these CBD objectives, it is best to exclude pathogens from this framework.

- **Traditional knowledge** (TK) is a very difficult concept to define and is subject to different interpretations by different communities and peoples. To ensure legal certainty, it is essential that if TK associated with genetic resources is to be governed by the IR, it should be clearly defined based on a common understanding, and limited to "knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity." As with other ABS measures, measures regarding traditional knowledge associated with genetic resources must be transparent.

International Union for Protection of New Varieties of Plants (UPOV)

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The reply of UPOV to the Notification of June 26, 2003, from the Executive Secretary of the CBD on UPOV's views on the process, nature, scope, elements and modalities of an international regime on access to genetic resources and benefit-sharing"[1] supported the view that the CBD and the UPOV Convention should be mutually supportive.

On that basis, the Council of UPOV, at its twenty-fifth extraordinary session, held in Geneva on April 11, 2008, decided to:

"request the Conference of the Parties of the Convention on Biological Diversity (CBD), at its Ninth Meeting, to consider the inclusion of the following elements in a decision relating to the 'Recommendation of

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[1] UPOV's reply of 2003 is included in document UNEP/CBD/WG-ABS/3/INF/1 and can be found at: *http://www.upov.int/en/news/2003/intro_cbd.html*

the Working Group on Access and Benefit-Sharing at its Sixth Meeting on Possible Elements of a Decision on Access and Benefit-Sharing for the Consideration of the Conference of the Parties at its Ninth Meeting':

"1. In the first page (considerations):

Recognizing that UPOV supports the view that the Convention on Biological Diversity (CBD) and the UPOV Convention should be mutually supportive.[2]

"2. In the guidance for further negotiation of an international regime on access to genetic resources and benefit-sharing:

Further instructs the *Ad Hoc* Open-ended Working Group on Access and Benefit-Sharing that any provisions which it develops for an international regime on access to genetic resources and benefit-sharing should ensure mutual supportiveness with the UPOV Convention.[3]"

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2 See paragraph 3 of UPOV's reply of 2003.

3 See paragraph 16 of UPOV's reply of 2003.

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III. MAIN COMPONENTS

A. Fair and equitable benefit-sharing

Access and Benefit-Sharing Alliance (ABSA)

ABSA members understand the economic value and importance of derivatives and/or downstream products relating to GR with or without TK, and the concern of many developing country CBD members of their importance to **Fair and Equitable Benefit- Sharing**. However, to date it has proven impossible for the ABS WG to agree even upon workable definitions, and/or their inclusion in the ABS IR. Again, the *Bonn Guidelines* provide valuable guidance, and specifies that the parties should address this important issue through negotiation of Mutually Agreed Terms (MAT) in ABS agreements. 17/ ABSA supports this approach for use in the ABS IR so that the parties to individual ABS agreements can address the issue of derivatives and/or downstream products on a case by case basis, as appropriate given the specific issues raised by research that may differ from sector to sector.

Overall, ABSA members believe that Fair and Equitable Benefit Sharing can best be ensured through an ABS IR that stresses transparency, predictability, legal certainty, equity and provides national treatment to all ABS stakeholders. As noted in the ABSA ABS Principles, ABSA members remain committed to "respect the sovereign rights of CBD members over their *in situ* genetic resources (GR) and to the

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17/ "(b) In the implementation of mutually agreed terms, users should . . . (v) Ensure that uses of genetic resources other than those for which they were acquired, only take place after new prior informed consent and mutually agreed terms are given;" and, further, "2. Indicative list of mutually agreed terms 44. (i) Provisions regarding the sharing of benefits arising from the commercial and other utilization of genetic resources and their derivatives and products." *Bonn Guidelines,* p. 6 and p.13.

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." 18/

Biotechnology Industry Organization (BIO)

BIO supports fair and equitable benefit-sharing under the terms of the CBD. The CBD is clear that the benefit-sharing envisioned "shall be on mutually agreed terms" (see, e.g., Article 15.7). It should be understood that any of the potential components listed for further consideration are to be subject to reaching "mutually agreed terms" consistent with the CBD. Such terms will normally be embodied in a contract or other type of agreement that represents a meeting of the minds of the provider and the recipient of the genetic resources at issue. In addition, there needs to be transparency and typical contracting principles must apply. Therefore, attempting to establish a "multilateral benefit-sharing option" through the treaty mechanism or to otherwise mandate particular ABS terms would appear to be both inconsistent with CBD principles and unworkable. In order to maintain legal certainty for both the provider and the recipient, the mutually agreed terms must govern the transaction and ensure compliance.

European Seed Association (ESA)

Benefit-sharing: the breeder's exemption
For the plant breeding sector the Standard Material Transfer Agreement of the International Treaty on Plant Genetic resources for Food and Agriculture (ITPGRFA) is a workable system. Access and Benefit Sharing of genetic resources in this way can be done quick and efficient. The use of the contract could be extended for those crops that are not yet in Annex 1 of the ITPGRFA.

The UPOV convention has inherent benefit sharing principle in the form of the breeder's exemption and other exceptions, which authorise the free use of improved varieties and the genetic diversity for further breeding activities. The FAO ITPGRFA (Article 13(d)(ii)) recognises the concept of breeders' exemption, in that breeders, who commercialise a variety, that incorporates material accessed from the Treaty's Multilateral System (MLS), are exempted from mandatory financial benefit sharing whenever these products are available without restriction to others for further research and breeding.

Intellectual Property Owners Association (IPO)

- Benefit-sharing can take many forms – direct payments (up front, at various development milestones, or at the time of commercialization), technology transfer, and indirect benefits (employment opportunities, infrastructure development). Users and providers require flexibility in reaching mutually agreed terms in order to fully realize the proper type of benefit-sharing for a particular situation.

- Examples of successful access and benefit-sharing arrangements have been described in Cabrera Medaglia J., Bioprospecting Partnerships In Practice: A Decade of Experiences at INBio in Costa Rica. *IP Strategy Today* (2004) No. 11-2004,1 p. 27-40. As noted in this publication, INBio has entered into numerous agreements in diverse fields, and many patent applications have been filed by the parties to the agreement as a result. However, the actual development and commercialization of products from these research efforts is minimal. Nonetheless, because INBio entered into mutually agreed terms with its collaboration partners, many benefits were still realized. As noted in the publication, these benefits were both monetary (direct payment of

18/ ABSA ABS Negotiating Principles, attached at Annex 1, and available online at: http://www.absalliance.org/version02/html/issue.html.

research budgets, payments for conservation, technology transfer) and non-monetary (improved negotiations expertise, improved legal infrastructure for conservation, training).

International Chamber of Commerce (ICC)

Business supports fair and equitable benefit-sharing which, under the terms of the CBD, should be on "**mutually agreed terms**" (Article 15(7)). Such terms will normally be embodied in an agreement between the provider and the recipient of the genetic resource. Transparency and internationally accepted contracting principles must apply to such agreements in order to maintain legal certainty for the provider and the recipient of genetic resources.

The development of **model clauses** or menus of clauses may be helpful to guide ABS negotiations. Alternatives, such as a database of sample clauses from successful ABS agreements or capacity building programs relating to "best practices" are preferable. If established, any such clauses should not be binding as the IR should permit flexibility in achieving MAT for material transfers. However, the Standard Material Transfer Agreement of the International Treaty on Plant Genetic Resources for Food and Agriculture is a good workable system for the plant breeding sector where many transfers of genetic resources are constantly being made.

There is a long history of benefit-sharing in many sectors using genetic resources. The manner in which benefits are currently shared should be considered in the development of the IR. **Existing systems** should not be unnecessarily disturbed and should, on the contrary, be recognized and carefully considered for the development of the IR.

Benefits from ABS transactions are not necessarily monetary in nature, (such as payments upfront or during the development process; funding for research or joint ventures), but can also include: the exchange of knowledge, skills, and technology; the sharing of research data, the free access to the use of protected varieties for further research and breeding, and networks; and the collection and conservation of genetic resources through financing or specific support activities.

ABS transactions also indirectly benefit society as a whole as they can lead to improved productivity of agricultural crops, the development of new health, food and other products, and the creation of new employment opportunities resulting from the economic stimulus of new innovative products. The **full range of benefit-sharing** should be taken into account on the negotiations on the IR.

The wide-spread availability of genetic resources has led to demands for **horizontal benefit-sharing among in-situ repository countries**. The resolution of such questions and any disputes that arise from them should lie outside the IR and above all should not prevent acquirers of genetic resources from holding clear title to acquired resources. Claims of third countries not party to an ABS agreement would add great uncertainties to the process and should not be permitted. However, in cases where multiple countries hold resources in common, agreements between such countries could be arranged so that benefits received by one member in a group of countries or indigenous communities that holds a particular resource in common would share the benefits received with others from that group. Any such agreement would be between potential providers of the genetic resource in question, and therefore should not have any effect on the liabilities or obligations of the user under an ABS agreement. It should be noted, however, that attempting to negotiate such an agreement would likely be highly complex and resource intensive.

CBD Parties should address with caution certain IR instruments currently under discussion, such as **certificates**, which could engender bureaucratic approaches to ABS that preclude benefit generation. Burdensome measures introduce significant costs for governments, users and local communities, and may deter larger companies and price innovative small and medium-sized enterprises, and research institutions out of the market entirely.

International Union for Protection of New Varieties of Plants (UPOV)

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.

1. Components to be further elaborated with the aim of incorporating them in the international regime

1) Linkage of access to the fair and equitable sharing of benefits

Biotechnology Industry Organization (BIO)

BIO supports linking fair and equitable sharing of benefits to access to the genetic resources. In fact, benefit-sharing issues should be handled at the point of access through the mutually agreed terms embodied in an appropriate ABS agreement in order to reduce any uncertainties as to the status of genetic resources and benefits arising from their use.

BIO also supports further elaboration of different types of benefits, including monetary and non-monetary benefits, when included in mutually agreed terms. This work could draw on the elements articulated in respect of monetary and non-monetary benefits in Appendix II of the Bonn Guidelines. However, BIO does not support any "mandatory" benefits or a "fixed-basket of" benefits under the IR. To be consistent with the CBD, benefit-sharing must be based on mutually agreed terms. Access to and transfer of technology could be addressed as an issue of benefit-sharing arising from the use of genetic resources, if included in mutually agreed terms, consistent with CBD Articles 15 and 16.

2) Benefits to be shared on mutually agreed terms

3) Monetary and/or non-monetary benefits

4) Access to and transfer of technology

5) Sharing of results of research and development on mutually agreed terms

6) Effective participation in research activities, and/or joint development in research activities

7) Mechanisms to promote equality in negotiations

8) Awareness-raising

Biotechnology Industry Organization (BIO)

Exercises in capacity building for developing countries, as well as awareness raising activities for bio-prospectors may be helpful in ensuring better compliance with ABS systems. For example, BIO has voluntarily established detailed guidelines for bio-prospecting for its members with the

goal of educating BIO members regarding relevant issues that may arise in the conduct of these activities. These guidelines are publicly available and are attached to the comments that BIO submitted to the Technical Expert Group on Concepts, Terms and Working Definitions (those comments are attached to this document for consideration by the ABS Working Group).

9) Measures to ensure participation and involvement of indigenous and local communities in mutually agreed terms and sharing of benefits with traditional knowledge holders

European Union and its Member States

Measures to ensure participation and involvement of indigenous and local communities holding traditional knowledge associated with genetic resources must be an important component of the international regime. However, this "brick" is closely linked to Sections D and E of the International Regime Annex. These sections will only be discussed at the Eighth Meeting of the ABS Working Group, in light of the deliberations of the Technical Expert Group on Traditional Knowledge. The EU welcomes the opportunity to further discuss this issue and intends to submit an example of operational text and underlying rationale prior to ABS WG8. The EU will continue to discuss its views with representatives of indigenous and local communities prior to this submission.

Biotechnology Industry Organization (BIO)

It is important that both the participation of indigenous and local communities, as well as any sharing of the benefits with traditional knowledge holders be based on mutually agreed terms. In addition, any such measures must be part of a transparent national ABS regime and provide clear points of contact/approval for obtaining prior informed consent and agreement relating to mutually agreed terms.

10) Mechanisms to encourage benefits to be directed toward conservation and sustainable use of biodiversity and socio-economic development, in particular the Millennium Development Goals (MDGs) in accordance with national legislation

Biotechnology Industry Organization (BIO)

It is not clear what mechanisms are envisaged to encourage benefits to be "directed toward biodiversity and socio-economic development." The IR should not regulate specific terms of ABS relating to how the benefits should be "directed." However, internal to national systems, countries may choose to allocate benefits, once received. The recipient, however, should have no obligation other than to transfer benefits according to the ABS agreement.

2. Components for further consideration

1) Development of international minimum conditions and standards

Biotechnology Industry Organization (BIO)

This element should not be further elaborated. For example, it is not clear what "conditions" and "standards" are being referred to in the draft language of paragraph (1). To the extent that this is an attempt to regulate particular terms in ABS agreements, this should be avoided.

2) Benefit-sharing for every use

Mexico

Benefit-sharing for every use has created confusion, seeing as various countries propose that use for scientific purposes be treated differently. However, by referring exclusively to "benefits", there should be no doubt that if the scientific activity generates benefits, said benefits should be covered by the IR. Said benefits may be non-monetary, such as technology transfer and capacity building.

We propose and hope that benefits ultimately be used for the conservation and sustainable use of biodiversity, in accordance with the Convention. However, some have rightfully pointed out that benefits will be used according to the providers' priorities, mainly in accordance with the PIC and MAT.

Biotechnology Industry Organization (BIO)

This concept appears to indicate mandatory benefit-sharing for "every use" of a genetic resource, even including uses that are not subject to mutually agreed terms (e.g., uses of a genetic resource made freely available). This is outside the scope of the CBD and should not be included in the International Regime.

3) Multilateral benefit-sharing options when origin is not clear or in transboundary situations

Mexico

The content of this option must be clarified. We assume that it refers to the fact that there will be cases in which it is not known exactly where the material came from, when a single ecosystem is shared by various Parties. Multilateral benefit sharing can give rise to disputes, even when efforts are made to avoid them. The reason for including this is clear, seeing as biological and genetic resources are oblivious of political boundaries, giving rise to a number of cases in this situation. This uncertainty should not be used as a pretext not to share benefits. The establishment of a multilateral fund or account might help complement the above point.

Biotechnology Industry Organization (BIO)

This introduces uncertainties and may not be consistent with the concept of "mutually agreed terms" to the extent that this may envision rights of third countries to "claim" benefits even if they are not party to an ABS agreement. Permitting claims of third countries not party to an ABS agreement would add great uncertainties to the process. However, in cases where multiple countries hold resources in common, agreements between such countries could be arranged so that benefits received by one member in a group of countries or indigenous communities that holds a particular resource in common would share the benefits received with others from that group. Such agreement should be separate from the ABS agreement between provider and recipient and should not have any effect on the liabilities or obligations of a recipient of genetic resources that is not party to that agreement. It should be noted, however, that attempting to negotiate such an agreement would likely be highly complex and resource intensive. In addition, the wide diffusion of many resources would likely make such an exercise impracticable in at least a number of cases.

4) Establishment of trust funds to address transboundary situations

Mexico

The Parties must clarify their points of view, seeing as this element is not covered by the regime.

Biotechnology Industry Organization (BIO)

It is not clear what such a "trust fund" would entail. If it is a fund for capacity building to address certain biodiversity sustainability issues, this may be further considered. However, the fund should not envision any type of international "claim" or "tribunal" under the CBD that would make findings as to potential wrongdoing or "rights" to share in benefits. Disputes should be handled pursuant to mutually agreed terms and appropriate dispute settlement mechanisms. In addition, if such a fund were to be established, funding sources would need to be identified. BIO does not support "taxing" transfers made under an ABS agreement pursuant to obligations of the IR.

5) Development of menus of model clauses for potential inclusion in material transfer agreements

Mexico

We agree.

Biotechnology Industry Organization (BIO)

The development of model clauses also may be helpful to guide ABS negotiations in certain cases. However, if established, any such clauses should not be binding as the IR should permit flexibility in achieving mutually agreed terms for material transfers. In addition, alternatives, such as a database of sample clauses from successful ABS agreements or capacity building programs relating to "best practices," may be preferable.

6) Enhanced utilization of Bonn Guidelines

Biotechnology Industry Organization (BIO)

BIO supports, in principle, enhanced utilization of the Bonn Guidelines. The Bonn Guidelines are particularly useful in respect of presenting options for Material Transfer Agreements, including monetary and non-monetary benefit options, etc. However, the Bonn Guidelines also discuss certain matters (e.g., consideration of patent disclosure requirements (see para. 16(d)(ii) of the Bonn Guidelines) that have been shown to have negative consequences. As such, enhanced utilization of the Guidelines must not be construed as an endorsement of all concepts presented therein, but rather as guidelines to assist in developing national ABS regimes.

B. Access to genetic resources 19/

Access and Benefit-Sharing Alliance (ABSA)

As noted by the Indian Minister for Environment and Forestry at the High-level Segment of the 9th Conference of the Parties (COP 9) at Bonn in May 2008: "So far, even after 16 years of adoption of CBD,

19/ The title is without prejudice to the eventual scope of the international regime.

only 18 countries have come up with legislation on Access and Benefit Sharing. A benefit sharing arrangement needs to be put in place with utmost speed to prevent provider countries from losing interest and diverting the scarce resources for their development needs." 20/ Industry agrees with India's assessment that the issue of national regimes is an area in urgent need of assistance. It is a truism that without effective ABS regimes at the national level to facilitate access to GR and provide clean title to GR, businesses will remain reluctant to engage in high-risk commercial activities in developing countries.

An ABS IR should encourage adoption of national access provisions flexible enough to provide for the timely decision-making on ABS applications made by scientific and commercial researchers in different sectors. Procedures established to regulate bioprospecting in a number of CBD members, including in Brazil and in India, have failed to provide for timely decisions, thus frustrating commercial and scientific activities. In addition, there should not be any discrimination between domestic and foreign bioprospecting applications. There is evidence that the promulgation of restrictive laws in the Philippines and in a number of Latin American countries has chilled bio-prospecting and has not advanced CBD goals.

It is well understood that complicated requirements may drive academic scientists underground or result in worse documentation of research activities; in fact this could affect commercial bio-prospecting even more negatively. Few bio-prospecting agreements lead to commercialized discoveries, but nonetheless contribute to the goals of the Convention and the science-base of CBD members. 21/ Non-commercial research ultimately may contribute to the commercial development of a product and commercial research may be licensed for public research purposes. The development of Golden Rice, for example, relied heavily on private-sector research. Given the need for research to move back and forth between non-commercial and commercial purposes, ABSA members fail to understand how different rules or standards for commercial versus noncommercial uses of GR, with or without TK, would be workable in real world conditions.

Fortunately, the clear text of the CBD Treaty recognizes the need for creation of "conditions to facilitate access to genetic resources for environmentally sounds uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of the Convention." 22/ The ABS IR should encourage the further development and harmonization of national regimes in the spirit of the *Bonn Guidelines*, including establishment of national focal points and possible model provisions for access and benefit sharing critical to its successful implementation at the national level.

Biotechnology Industry Organization (BIO)

BIO supports the concept of access to genetic resources being linked to fair and equitable sharing of benefits on the basis of mutually agreed terms, as envisioned in the CBD. However, national laws governing the terms of access, e.g., in national ABS regimes, should be non-discriminatory and should thereby treat domestic and foreign researchers on similar terms. In addition, access terms should be "facilitative" in nature and should not be overly regulatory or punitive in nature.

20/ Statement by Honorable Minister of State (Environment), India for the High-level Segment of the Ninth Conference of the Parties (COP-9) to the Convention on Biological Diversity (CBD), 28-30th May 2008, Bonn, Germany.

21/ Merck, a founding member of the ABSA, did not successfully commercialize any of the discoveries found during its multiyear collaborative bio-prospecting agreement with INBIO.

22/ Convention on Biological Diversity, Article 15.2.

European Seed Organization (ESA)

ESA recognizes the sovereign rights and the authority of Parties to determine access. However, it is important that legal certainty is provided through access rules. In addition those access rules should be non-discriminatory over nationalities. In providing access, it is important that the administration and transaction costs are minimized to stimulate sustainable use of genetic resources.

Intellectual Property Owners Association (IPO)

- States should have sovereign control over their *in-situ* Genetic Resources, and an International Regime can assist states with creating access regulations based on model legislation that is consistent and accepted among member countries.

- States must determine how best to ensure that access, when granted, has the consent of all involved parties – indigenous groups, local community and local government. Parties that wish to acquire Genetic Resources should be able to approach a single entity and be assured access is consented to by all interested parties. Overly long, burdensome processes could simply result in lost interest in the research, or drive potential users to another provider country. In this respect, some members of IPO have attempted to use the focal point contacts established under the Convention on Biological Diversity, but encountered bureaucracy and non-responsiveness that ultimately discouraged access.

International Chamber of Commerce (ICC)

Business supports the concepts of access to genetic resources being linked to fair and equitable sharing of benefits on the basis of mutually agreed terms, as envisioned in the CBD. The IR should **facilitate responsible access** and **prevent illegal access** to genetic resources. Business therefore supports **access standards** consistent with the CBD requirement to "facilitate" access in Article 15(2), such as those that would help ensure transparency and clarity, including the identification of clear authorities and points of contact to improve reliability in agreed terms of access. All concerns should be handled at the point of access through ABS agreements in order to reduce any uncertainties as to the status of genetic resources and benefits arising from their use.

Certainty, clarity and transparency of access rules depend fundamentally on the identification of **national focal points.** Business strongly supports the identification of a national focal point – one single authority that is authorized to grant access and grant prior informed consent. This is an essential part of developing an access regime that is consistent with the principles of legal certainty and transparency and is thereby a crucial element of a workable IR.

Any national laws governing the terms of access, e.g. in national ABS regimes, should be **non-discriminatory** and should thereby treat domestic and foreign researchers on similar terms. It should be realized that all countries are interdependent in terms of genetic resources and that most countries, including developing countries with extensive biodiversity, depend heavily on genetic resources accessed from other countries. Non-discriminatory treatment would therefore be beneficial for all CBD parties.

All researchers, regardless of their national origin or their countries' standing in the CBD, should be permitted to access resources under the facilitative mechanisms of the ABS regime, but also be subject to the benefit-sharing requirements implemented by national laws in provider countries; this will help maximize potential benefits consistent with the goals of the CBD.

Negotiations on the IR also need to move toward a much more informed discussion of the **realities of access to genetic resources today**, and specifically a better understanding of access to genetic resources

through **ex-situ** collections. The model upon which CBD obligations were based was one of a linear flow of genetic resources beginning with "bioprospecting" of genetic resources from their in-situ state, negotiation of mutually agreed terms with the sovereign state, and consultation with the concerned indigenous and local communities. This model is not an accurate reflection of how genetic resources are accessed, utilized, or shared today. Many genetic resources have long since been extracted from their original natural environment. Many have become commodities or staple commercial products in the trading system. Ex-situ collections exist in many countries for different types of genetic resources and range from zoos and aquariums to herbaria, such as the various botanical gardens and the Consultative Group on International Agricultural Research (CGIAR) system. Although the in-situ case is more conceptually clear and manageable than ex-situ cases, access of genetic resources through ex-situ collections is considerably more common in today's context.

International Union for Protection of New Varieties of Plants (UPOV)

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.

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.

1. Components to be further elaborated with the aim of incorporating them in the international regime

1) Recognition of the sovereign rights and the authority of Parties to determine access

Biotechnology Industry Organization (BIO)

This language must be consistent with the language used in CBD Article 15.1. In that light, it should refer to the recognition of "the sovereign rights of States over their natural resources," and "the authority to determine access to genetic resources rests with national governments and is subject to national legislation." The language used should not be susceptible of interpretation that may extend the "sovereignty" principle beyond that contained in the CBD.

2) Linkage of access to fair and equitable sharing of benefits

3) Legal certainty, clarity and transparency of access rules

Biotechnology Industry Organization (BIO)

BIO strongly supports the legal certainty, clarity and transparency of access rules. Specific and detailed guidance should be incorporated into the IR with respect to access rules that, e.g., require identification of clear points of contact and give legal security to bioprospectors that access genetic resources in a particular CBD Member.

2. Components for further consideration

1) Non-discrimination of access rules

Mexico

Non-discrimination of access rules has been requested by potential user countries that foresee some protectionist behaviour. This request is consistent with most international trade and investment commitments among countries.

Biotechnology Industry Organization (BIO)

BIO supports non-discrimination of access rules. All researchers, regardless of their status within the CBD or their national origin, should be permitted to access resources under the facilitative mechanisms of the ABS regime. These researchers should also be subject to the benefit-sharing requirements implemented by national laws in provider countries, in order to provide benefits that may flow thereby consistent with the goals of the CBD.

2) International access standards (that do not require harmonization of domestic access legislation) to support compliance across jurisdictions

Mexico

This has not yet been properly defined. We think this proposal involves properly defining which element of access should be complied with across jurisdictions, and according to which criteria. The purpose is to know what legal procedure should be carried out and deemed worthy of legal protection.

Biotechnology Industry Organization (BIO)

International access standards and internationally developed model legislation or guidance

BIO can support detailed guidance in the IR as to certain access principles consistent with the CBD requirement to "facilitate" access in Article 15.2, including, e.g., standards that would help ensure transparency and clarity, including identification of clear authorities and points of contact to improve reliability in agreed terms of access.
However, while model legislation may be useful to standardize approaches between nations and thereby facilitate access by eliminating differences of law between jurisdictions, such an approach would be resource-intensive. It would be difficult for Parties to negotiate appropriate model legislation in light of different national circumstances and the general recognition that a "one-size fits all" approach will not be workable. It may also be inconsistent with the principle contained in CBD Article 15.5 that Parties may, e.g., forego requirements for prior informed consent if they so choose. Resources would be better spent on developing specific guidance on certain access and other principles consistent with the CBD and providing needs-based capacity building for countries when implementing their national ABS regimes.

3) Internationally developed model domestic legislation

Mexico

Internationally developed model domestic legislation should be a voluntary element.

4) Minimization of administration and transaction costs

Mexico

Cost minimization is a general aspiration, and this aspect becomes inevitable in combating biopiracy, or illegal activity. However, the wording is unfortunate, and it would seem to indicate that regulation must be sacrificed to efficiency. This element must therefore be drafted more clearly.

5) Simplified access rules for non-commercial research

Mexico

The issue of simplified access rules for non-commercial research must undergo in-depth examination. In principle, there seems to be no reason to differentiate between commercial and scientific access within a regime for fair benefit-sharing; if there are benefits, they must be

shared. While it is true that current scientific research means that a sample may cross various borders over a short period, which creates monitoring headaches for a regime like the one being designed, it is also true that the IR deals with the sharing of benefits – be they monetary or non-monetary – which is why the regime must comply with the PIC and MAT, which are the pillars and most complex elements of the regime. In any event, the simplified rules have to do with responsibility for the samples, irrespective of the exchanges of genetic material carried out by laboratories.

Biotechnology Industry Organization (BIO)

It will be very difficult to define "non-commercial research" for purposes of providing a separate set of access rules. Generally speaking, a unitary system in which 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 would be an better approach. To the extent that work on a split system is pursued, any system that envisions a differentiation between "non-commercial" and "commercial" research should provide for the ability to "convert" from non-commercial to commercial research. While not optimal, this approach may be workable if a clear definition for what is intended by "non-commercial" research and for how this may transition to "commercial" applications is developed.

C. Compliance

Mexico

The establishment of monitoring and reporting systems is key in an area where the products at the outcome of the production chain spend a number of years within the production process. Without a doubt, the best and most up-to-date information technology is required for monitoring, to ensure optimum functioning of said systems.

Norway

We need to develop an understanding of what constitutes "misappropriation" of genetic resources and a related international obligation to prohibit the use of misappropriated genetic resources (see text on this at the end of this document).

Under Section A we have already identified some measures to monitor compliance. In addition, we support the introduction of an internationally recognized format for certificates of compliance which should serve 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. The certificate could contain, *inter alia*, the following information: codified unique identifier (for example code certificate NO 2008 A XXXX); issuing national authority, details of the provider, details of the right holders of associated traditional knowledge, as appropriate; details of the user; links to mutually agreed terms; conditions for transfer to third parties etc.

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.

These criteria and rules should not be open to arbitrary interpretation. Commercial users should be met with a clear and stable set of rules that they can trust in.

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.

Access and Benefit-Sharing Alliance (ABSA)

ABSA members joins CBD Parties, research institutes, indigenous groups and local communities in seeking the development of an enforcement system in the ABS IR that provides effective and proportionate redress for all parties in cases of illegal or inappropriate activities related to the IR. While there is currently no agreement on the appropriate mechanism to enforce the ABS IR, ABSA members believe that an existing mechanism or, more likely, a combination of mechanisms, can be identified to serve as a deterrent to illegal or inappropriate activities and to address the question of enforcement across borders that would ensure durable and meaningful benefits for CBD members and indigenous peoples without undermining the incentives that industry needs to undertake bio-prospecting.

ABSA members have long believed that mechanisms considered for inclusion in the ABS IR be measured against real world experience. In this context, all compliance mechanisms under consideration for inclusion in the ABS IR should be subject to two key tests:

1. Examination of real-world experience at the national level to see if they have been effective in domestic ABS regimes;
   And,
2. Benefit-cost analysis to ensure that their potential value to ABS stakeholders would not be outweighed by the cost either at the national level (particularly the cost to developing countries) and/or at the international level.

ABSA members also seek the legal certainty, consistency and equity, which would benefit all CBD stakeholders, through the inclusion of a requirement to provide Mutually Agreed Terms (MAT) in each ABS Agreement – the detailed, written terms and conditions required for legitimate bio-prospecting in those agreements governed by the ABS IR.

Japan's highly-regarded ABS regime does just that. Japan's domestic ABS regime is currently the single most effective national ABS system with proven benefit-generation, and operates through written agreements, i.e., contracts. One way to promote greater inclusion of MATs in written ABS agreements would be through development of model Material Transfer Agreements (MTAs) as in the International Treaty on Plant Genetic Resources (ITPGR). 23/ Development of model MTAs also could help to avoid later disputes by promoting transparency and greater understanding on both sides.

There is also increasing awareness that the ABS IR should balance compliance mechanisms with incentives. CBD members understand the need to encourage responsible *in situ* bio-prospecting and to contribute to the increased conservation of *in situ* GR. Development of an ABS IR that encourages environmentally sustainable levels of *in situ* bio-prospecting, is needed both to identify promising areas of research for scientific and commercial development that will generate benefits for CBD members, as well as to provide a greater awareness of the resources found in CBD members. These incentives should encourage the continued cataloguing of the genetic inventory of the planet – a process that has not even approached a fifth of the genetic resources remaining *in situ* in CBD members. These goals are related, in that increased taxonomy and related bio-prospecting activities may provide greater incentives for conservation.

23/ "UNU-IAS Report, Certificates of Clarity or Confusion: The search for a practical, feasible, and cost effective system for certifying compliance with PIC and MAT" (2008), where authors Brendan Tobin, Geoff Burton and Jose Carlos Fernandez-Ugalde note that MTAs may be helpful to address the absence of national ABS regimes. p. 8.

Compliance mechanisms that would create only a right to litigate in the national judicial system should be avoided. The current situation facing CBD members and indigenous peoples will not improve through the adoption of enforcement mechanisms that rely on far-flung civil litigation. Established forms of alternative dispute resolution include negotiation, mediation and arbitration based on previously agreed written agreements. Alternative dispute resolution may provide a cost-effective alternative to cross-border civil litigation given the international scope of arbitral decisions. For example, Article 8(4)(C) of the Food and Agriculture Organization (FAO) International Treaty for Plant and Genetic Resources for Food and Agriculture (ITPFGRA) Standard MTA provides for recourse to negotiation, mediation and binding arbitration under the auspices of the International Chamber of Commerce' International court of Arbitration.

Some of the international instruments currently under discussion in the area of compliance, such as certificates of origin, still lack clarity in their basic terms and concepts. While ABSA members conceptually understand the potential value of an international certificate as formal documentation of PIC and/or MAT, we have seen very little documentation relating to successful real-world experience with international certificates, 24/ and so are not able to make informed decisions on the merits of various certificates proposals. Further, there has been little discussion at the expert level of the actual need for the various certificate systems, as balanced against their cost at the national and international level. As noted, this benefit-cost analysis is essential to the development of a successful ABS IR.

Finally, the ABS IR providing legally binding provisions requiring CBD member governments to provide focal points and transparency in decision-making regarding penalties, to avoid any adverse impact that subsequent changes in government policy may have on companies that had sought and received the appropriate permits in the ordinary course of business.

Biotechnology Industry Organization (BIO)

BIO supports effective compliance to ensure that the objectives of the CBD can be implemented in a fair and equitable manner that facilitates access. In that light, a contract-based approach envisions tools that are currently used effectively in many international business transactions, such as private international law mechanisms including voluntary international mediation, arbitration and civil law regarding enforcement of foreign judgments, used in manner that can provide effective enforcement. In respect of foreign enforcement of judgments, however, it should be noted that CBD Members in the past have been reluctant to recognize judgments from other jurisdictions. The delegation of Canada has explained the utility of private international law measures in their submission to the sixth session of the ABS Working Group (UNEP/CBD/WG-ABS/6/INF/3/Add.2).

European Seed Organization (ESA)

On this issue, ESA would like to recall that the business delegation, coordinated by the International Chamber of Commerce (ICC) has developed and submitted a position to the CBD Secretariat on "Access and Benefit Sharing; Priority issues for the Compliance TEG" from 28 November 2008 (Document n° 450/1042).

Intellectual Property Owners Association (IPO)

- Compliance measures occurring within the context of the patent system are not effective means to ensure proper access and benefit-sharing. Most uses of Genetic Resources for scientific research will not result in a patent filing, and the mere act of a patent filing may not result in a commercial

24/ ABSA members would appreciate an opportunity to review information on national experiences by commercial and noncommercial researchers certification systems implemented at the national level.

product or financial benefit to any party. Furthermore, compliance measures that involve refusal to examine a patent application, or invalidation or revocation of a patent should not be part of the International Regime. Although there have been several often-cited examples of alleged "misappropriation" of Genetic Resources in patents, a more careful examination of these patents shows that patent disclosure mechanisms will fail to achieve the intended compliance goals. In some instances, the source and origin of the Genetic Resource was already clearly indicated in the patent, but with no effect on the examination of the application or the ultimate status of the patent. See, for example, U.S. patent no. 5,401,504 (turmeric) and EP patent no. 0973534 (hoodia). In other instances, the Genetic Resource is claimed by one country of origin, though the patent indicates that the Genetic Resource was readily obtained from another country of origin. For example, U.S. patent no. 6,136,316 makes use of a "winter weed [found] throughout the hotter parts of India," but that patent was claimed by Peru to be a potential example of "biopiracy" (see, WIPO/GRTKF/IC/8/12). Finally, some claims of "biopiracy" involve patents that merely list a Genetic Resource in the description of the patent, but which make no use of the actual Genetic Resource in the invention. See, for example, U.S. patent no. 6,569,488, which is claimed by Peru to be a potential case of "biopiracy." The Genetic Resource in question is listed in the description of the patent; however, there is no evidence that the Genetic Resource was accessed or used in the development of the invention (WIPO/GRTKF/IC/8/12). As these examples show, patents are too often improperly characterized as the source of and the solution for "biopiracy."

- The use of certificates is burdensome and will likely result in an unworkable bureaucracy.

- The preferred option is for the International Regime to provide a framework to enable users and providers to come to mutually agreed terms subject to the dispute resolution system of their choosing or as provided in an International Treaty. For example, the sMTA established under the Food and Agriculture Organization (FAO) International Treaty for Plant Genetic Resources for Food and Agriculture (ITPGRFA) refers to the ICC Rules of Arbitration as a means of dispute resolution.

International Chamber of Commerce (ICC)

When discussing compliance issues, it is helpful to distinguish between regulatory compliance (i.e. compliance with laws and regulations set by governments relating to ABS); and compliance with contractual provisions (i.e. compliance with terms in an agreement mutually agreed between two parties such as Material Transfer Agreements).

Mechanisms for enforcing compliance will differ according to the type of compliance that is being addressed. In both cases, business submits that any compliance system set up by the IR should build on **existing enforcement systems**.

Regulatory Compliance

- Business believes that that the great majority of users of genetic resources make their best efforts to comply with ABS requirements. Nevertheless business does recognize that many CBD Parties have serious concerns relating to **misuse and/or misappropriation of GR**, with or without related TK. As there is currently little empirical data on the scope or the significance of such misuse and/or misappropriation, business supports more research on this topic to provide a solid factual basis for the AHOEWG's efforts to address this issue. This would greatly assist in identification, where applicable, of any appropriate and proportionate measures, and contribute to the likelihood of success of the IR overall.

- Business recognizes the importance that a number of CBD Members place on mutual recognition of and enforcement of **judgments across borders** to enforce domestic national ABS laws 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 discussion of possible approaches to address this difficult issue.

- Any further consideration of "**disclosure requirements**" 25/ should be made dependent on the outcome of discussions in the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) in WIPO which, because of its collective intellectual property (IP) expertise, as illustrated by its discussions and detailed documentation, is the appropriate body for the consideration of matters relating to the relationship between IP and CBD related issues.

- Business remains greatly concerned about the possible **introduction of new instruments** without proven effectiveness in real life. 26/ It therefore strongly recommends that the further elaboration of an "internationally recognized certificate" should not begin before a feasibility study is first undertaken and carefully analysed. Business firmly believes that if many of the issues still outstanding are not addressed in detail, the feasibility of establishing such a certificate system will be called into question (see report of the Technical Experts Group in UNEP/CBD/WG-ABS/5/7 (Feb. 20, 2007)). To date, discussions in the negotiations concerning certificates have failed so far to clarify fundamental concepts.

- Key matters that remain unresolved are:
    - what would the system certify (compliance with the CBD or national laws)?
    - who would certify?
    - who would use the certification and why?
    - what would be the impact of not having a certificate?
    - when does a certificate have to be produced?
    - what would be the cost and benefit of such a system?

- Business believes that **raising awareness** among stakeholders about ABS requirements will play a key role in improving compliance with ABS regimes. CBD Parties should make positive efforts to educate stakeholders about ABS laws and to make these more transparent. Business is willing to support governments in these efforts with respect to its own constituency.

In this respect, several sectors have put into place **voluntary guidelines** and "**best practices**" to help companies in those industries to understand and comply with ABS requirements. Among those are Biotechnology Industry Organization (BIO) Guidelines for BIO Members Engaging in Bioprospecting, 27/ the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Guidelines for IFPMA Members on ABS, and the BIO Model Material Transfer Agreement (MMTA), 28/ EuropaBio Principles for Accessing Genetic Resources, 29/ International Standard for Wild Collection of Medicinal and Aromatic Plants. 30/

25/ See ICC paper on "Access and benefit-sharing: special disclosure requirements in patent applications" - 25 May 2005 : http://www.iccwbo.org/uploadedFiles/ICC/policy/intellectual_property/Statements/ABS_%20Special%20Disclosure.pdf

26/ See ICC paper on "Issues for consideration by the CBD Group of Technical Experts concerning a Certificate relating to genetic resources" 15 September 2006 at http://www.iccwbo.org/uploadedFiles/ICC/policy/intellectual_property/Statements/CertificationSubmission_to_CBD.pdf

27/ http://www.bio.org/ip/international/200507guide.asp

28/ http://www.ifpma.org/Issues/CBD and http://www.bio.org/ip/international/BIO_Model_MTA.pdf

Business believes that such voluntary guidelines contribute significantly to promoting awareness of, and compliance with, ABS regimes among the users of genetic resources, and should be taken into account by CBD Parties when considering a sectoral approach to the IR.

Contractual Compliance

- Private international law offers many opportunities that are currently used to enforce agreements relating to international business transactions around the world (see for example the paper by the delegation of Canada submitted to the sixth ABS WG meeting (UNEP/CBD/WG-ABS/6/INF/3/Add. 2 (Jan. 15, 2008)). No special "measures to ensure access to justice" need to be developed that are peculiar to the CBD context. Instead, **existing tools** such as negotiation, mediation, arbitration and legal instruments for the enforcement of foreign judgments should be further explored.

- Negotiation, mediation, arbitration and conciliation mechanisms are common in business and provide a concrete basis for discussions on **the resolution of disputes arising from ABS contracts**. An example of a dispute resolution process referenced in an international instrument is found in Article 8(4)(C) of the Food and Agriculture Organization (FAO) International Treaty for Plant and Genetic Resources for Food and Agriculture (ITPFGRA) Standard MTA. This article provides that if the dispute has not been settled by negotiation or mediation, any party to the sMTA can submit the dispute to arbitration using the rules of an international body agreed by the parties or, failing such agreement, the Rules of Arbitration of the International Chamber of Commerce's International Court of Arbitration. Although arbitration procedures are unlikely always to be appropriate for all relationships or sectors, a potential advantage of them is that they allow ABS stakeholders to gain cost effective legally-binding judgments that are enforceable across borders in countries that adhere to the New York Convention on Recognition and Enforcement of Foreign Arbitral Awards.

1. Components to be further elaborated with the aim of incorporating them in the international regime

1) Development of tools to encourage compliance:

(a) Awareness-raising activities

Biotechnology Industry Organization (BIO)

BIO supports the use of tools to encourage compliance, including awareness-raising activities to assist potential commercial and non-commercial bioprospectors in understanding the objectives of the CBD and elements of national ABS laws.

29/ http://www.europabio.org/positions/Bioprospecting%20Principles_Final.pdf

30/ http://www.floraweb.de/proxy/floraweb/MAP-pro/Standard_Version1_0pdf

2) Development of tools to monitor compliance:

(a) Mechanisms for information exchange

Biotechnology Industry Organization (BIO)

BIO supports, in principle, mechanisms for information exchange relating to monitoring compliance with CBD requirements. However, more information is needed on specific proposals for information exchange for BIO to articulate a view. For example, recipient country officials should not be tasked with interpreting or enforcing foreign laws, whether or not in the context of alleged "infringements." Further, any such mechanisms must respect agreements regarding confidentiality of the relevant parties.

(b) Internationally recognized certificate issued by a domestic competent authority

European Union and its Member States

The EU suggests focussing further elaborations on an internationally recognised certificate of compliance. Such certificate could provide legal credibility across different jurisdictions that a specific genetic resource has been obtained in accordance with national access rules in the country issuing the certificate. It could thereby add to legal certainty for users and providers of genetic resources.

The EU considers that an internationally recognised certificate of compliance could essentially be the written decision of a national competent authority granting prior informed consent that is registered in the CBD's clearing-house mechanism. Registration should be required for Parties implementing the international access standards set out in Operational Text III.B.2.2).

An internationally recognised certificate of compliance could provide legal credibility across jurisdictions that a specific genetic resource has been obtained in accordance with national access rules in the country issuing the certificate. The EU considers that it would raise legal certainty for users of genetic resources if internationally recognised certificates of compliance were to be available and reliable. Such certificates could potentially be a reliable tool to demonstrate that genetic resources have been acquired in accordance with national rules. More detailed considerations on the scope, nature, content and governance of an internationally recognised certificate of compliance are needed, including its interaction with potential further elements of the international ABS regime.

Biotechnology Industry Organization (BIO)

There are still many outstanding issues regarding the feasibility of establishing such an international certificate system (see, e.g., the Report of the Technical Experts Group in UNEP/CBD/WG-ABS/5/7 (Feb. 20, 2007)). In that light, such certificates should not be considered for the International Regime until a much more thorough discussion has taken place as to the actual use of such certificates. Further, these types certificates, if pursued, should not be tied to other laws, e.g., intellectual property laws.

3) Development of tools to enforce compliance

Biotechnology Industry Organization (BIO)

Any enforcement system should build on existing systems. In cases involving violations of national access laws, appropriate, effective and proportionate measures (including civil and/or criminal measures) should be considered. However, extraterritorial "enforcement" mechanisms under the CBD itself, e.g., CBD tribunals, would be unworkable and should be avoided.

In the case of enforcing ABS systems, private international law offers many dispute settlement mechanisms that are currently used to enforce contracts relating to international business transactions around the world; see, e.g., paper by the delegation of Canada submitted to the sixth ABS WG meeting (UNEP/CBD/WG-ABS/6/INF/3/Add. 2 (Jan. 15, 2008)). Measures such as negotiation, mediation, arbitration and consideration of enforcement of foreign judgments should be further elaborated.

Further consideration of existing frameworks established under private international law to improve cross-border enforcement of ABS agreements may be further studied, however, CBD Members in the past have been reluctant to recognize judgments from other jurisdictions. The voluntary use of existing mechanisms, such as the New York Convention on the Recognition and Enforcement of Foreign Arbitral Awards, in mutually agreed terms, could provide a good starting point for discussion.

2. Components for further consideration

1) Development of tools to encourage compliance:

(a) International understanding of misappropriation/misuse

European Union and its Member States

The EU recalls its expressed willingness to engage in a substantive discussion on further measures to support compliance with prior informed consent and mutually agreed terms not excluding legally binding ones and that this discussion could also include work on an international definition of misappropriation and a related international obligation to prohibit the use of misappropriated genetic resources.

The EU continues to see merit in further discussing the issue of misappropriation. An international understanding of "misappropriation" of genetic resources must focus on (1) acquisition of a genetic resource in circumvention of national PIC requirements that meet international access standards (purposeful or negligent); (2) the acquisition of a genetic resource without setting up MAT (purposeful or negligent). Breaches of contract must be left outside the scope of any international understanding of "misappropriation", since breaches of contracts can be pursued through a well established set of national and international level rules.

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 countries measures to pursue instances of misappropriation so that fundamental legal principles of clarity, predictability, proportionality and reciprocity are respected and 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. The

development of international access standards that are linked to the application of any provisions on misappropriation is central in this regard.

Mexico

We agree, this is essential for the IR

Biotechnology Industry Organization (BIO)

A further understanding of the concept of "misappropriation" or "misuse" may be helpful to the dialog among Members of the ABS Working Group. However, providing a definition in the IR of "misappropriation" or "misuse" may not be appropriate in that this would add a term that is not found in the CBD. A common understanding of these terms should include the notion of a link to compliance with national ABS laws. In other words, if there is no violation of national law, there is no misappropriation. Further, in order to reach a common understanding of the term, it will be necessary to better understand the intended context, e.g., the purpose for which the term will be used and any consequences of acts that may be deemed "misappropriation" or "misuse."

(b) Sectoral menus of model clauses for material transfer agreements

Mexico

We agree, however, we think that it would be more appropriate for said clauses to be developed according to use of the genetic resources, rather than according to sector.

Biotechnology Industry Organization (BIO)

Sectoral MTA model clauses and access standards

A sectoral approach in the IR is needed as a general matter because a "one size fits all" approach would be unworkable given the vast differences in how genetic resources are utilized by different industries. Further, the development of model clauses may be helpful to guide ABS negotiations in certain cases. However, if established, any such clauses should not be binding as the IR should permit flexibility in achieving mutually agreed terms for material transfers. In addition, alternatives, such as a database of sample clauses from successful ABS agreements or capacity building programs relating to "best practices" may be preferable. BIO also supports providing guidance with respect to certain access principles consistent with the CBD requirement to "facilitate" access in Article 15.2. For example, guidelines that would help ensure transparency and clarity, including identification of clear authorities and points of contact to improve reliability in agreed terms of access.

(c) Codes of conduct for important groups of users

Biotechnology Industry Organization (BIO)

Codes of conduct and identification of "best practices"

Voluntary "Codes of Conduct" for industry may be helpful. One current example in the biotechnology sector is the BIO Guidelines on Bioprospecting. Any such code should be established on a voluntary basis by an industry association with participation from industry actors. The industry group itself may monitor compliance. Mandatory "codes of conduct" would be counterproductive and would not be appropriate. In addition, to the extent that this language

envisions a "mandated" code to be enforced through a CBD compliance-type mechanism, this would be very problematic and should be avoided. Identification of "best practices," however, could also take the form of guidelines or other instruments that would not be binding and would provide significant benefits in this area.

(d) Identification of best-practice codes of conduct

Mexico

We agree, this is essential for the IR

(e) Research funding agencies to oblige users receiving research funds to comply with specific access and benefitsharing requirements

European Union and its Member States

The EU welcomes the opportunity to further discuss this issue with a view to submitting an example of operational text and underlying rationale prior to ABS WG8.

(f) Unilateral declaration by users

European Union and its Member States

The EU welcomes the opportunity to further discuss the potential role of unilateral declarations by users in supporting compliance (particularly with PIC) by demonstrating that genetic resources have been legally obtained, with a view to submitting an example of operational text and underlying rationale prior to ABS WG8.

Biotechnology Industry Organization (BIO)

It is not clear what is envisioned to be a "unilateral declaration" in this context. More information is needed on the nature of the declarations intended. If it is a voluntary, "good faith" declaration that, to the knowledge of the user, no resources were obtained in contravention of any national laws, it could be studied further. However, any declaration should be kept out of particular areas of law, such as intellectual property law. Further study of unilateral, voluntary declarations may be envisioned, e.g., on customs forms when bringing resources into recipient countries. A voluntary declaration may be feasible, depending on how it is designed. However, the potential for unintended consequences such as interruption of trade flows must be fully considered.

(g) International access standards (that do not require harmonization of domestic access legislation) to support compliance across jurisdictions

2) Development of tools to monitor compliance:

(a) Tracking and reporting systems

Biotechnology Industry Organization (BIO)

Attempting to develop a centralized tracking and reporting system relating to any and all transfers of genetic resources would be a highly resource intensive exercise. In addition, the potential for

unintended consequences, such as interruption of voluminous trade in goods, must be fully considered. However, further study of tracking mechanisms may be appropriate.

(b) Information technology for tracking

European Union and its Member States

The EU welcomes the opportunity to further discuss steps that allow tracking of genetic resources in cases of doubt on the fulfilment of ABS requirements by users, with a view to submitting an example of operational text and underlying rationale prior to ABS WG8. The EU also stresses the need to ensure that the international regime is crafted in a way that maximises the utility of modern IT tools to ABS governance. The EU envisages an international regime that is practical, and minimises costs and administrative burden for both providers and users.

(c) Disclosure requirements

European Union and its Member States

The EU recalls its proposal to the World Intellectual Property Organization (WIPO) of December 2004 that sets out a balanced and effective way to include in international patent law a binding requirement to disclose the origin or source of genetic resources and associated traditional knowledge in patent applications. The disclosure requirement as proposed by the EU would, if adopted, allow States to keep track, at global level, of all patent applications with regard to genetic resources and thereby enhance transparency about uses of genetic resources that have left the providing country.

In the context of the ongoing WTO negotiations of the Doha Development Agenda the EU has agreed to amend the WTO Agreement on Trade-Related Aspects of Intellectual Property rights (TRIPS) to include a mandatory requirement for the disclosure of the country providing/source of genetic resources, and/or associated traditional knowledge for which a definition would be agreed, in patent applications. Patent applications would not be processed without completion of the disclosure requirement. On substance the EU would not go beyond its above-mentioned proposal in WIPO.

Biotechnology Industry Organization (BIO)

BIO opposes proposals made regarding new patent disclosure requirements (e.g., regarding source/origin of genetic resources). BIO members are 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 WIPO and WTO have confirmed this view and further, have not led to any consensus on such proposals. These proposed requirements should not be included in the IR. 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.

(d) Identification of check points

Mexico

Further work is required to search for and identify check points. This work does not entail any commitment. We therefore do not understand why it has not been included as an agreed element for discussion, unless there are negotiation-strategy reasons for this. The same applies to the proposal to use information technology.

Biotechnology Industry Organization (BIO)

The concept of identification of "check points" envisions a user-country approach to enforcement of foreign ABS laws. The IR should instead focus on implementation of effective national ABS regimes in provider countries. Nonetheless, certain check points in user countries, such as agencies responsible for border entry points, may be feasible. However, agencies involved in functions generally unrelated to transport or acquisition of materials, such as intellectual property offices, are not appropriate "check points." In addition, potential for unintended consequences, such as interruption of voluminous trade in goods, must be fully considered.

3) Development of tools to enforce compliance:

European Union and its Member States

The EU looks forward to the deliberations of the Group of Legal and Technical Experts on ABS compliance issues that will take place in Tokyo, 27-30 January 2009. The EU expects to benefit from the advice of this group and intends to submit examples of operational text and underlying rationale prior to ABS WG8.

(a) Measures to ensure access to justice with the aim of enforcing ABS arrangements

(b) Dispute settlement mechanisms:

Norway

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 in the regime be encouraged to accept these dispute settlement 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.

In cases where the access and benefit-sharing agreements consistent with the Convention on Biological Diversity and national legal instruments of the country of origin of genetic resources have not been complied with, the use of sanctions could be considered, such as penalty fees set out in contractual agreements.

(i) Inter-State

(ii) Private international law

(iii) Alternative dispute resolution

(c) Enforcement of judgments and arbitral awards across jurisdictions

(d) Information exchange procedures between national focal points for access and benefitsharing to help providers obtain relevant information in specific cases of alleged infringements of prior-informed-consent requirements

(e) Remedies and sanctions

Biotechnology Industry Organization (BIO)

This topic should be understood in the sense of exploring remedies and sanctions available through the dispute settlement mechanisms mentioned above and should not attempt to impose a type of international regulation with respect to bioprospecting or related activities.

4) Measures to ensure compliance with customary law and local systems of protection

Mexico

Once behaviour that seems to violate a bioprospecting contract has been detected, the IR must swing into action, which is why measures to ensure compliance must be developed. These include measures to ensure access to justice, in order to apply agreements on access and benefit sharing. There is seemingly some confusion, seeing as this element appears twice, and was accepted in the section on fair and equitable sharing of benefits.

The proposed measures include elements that are par-for-the-course in legally binding regimes, and a decision on those measures will have to await consensus on the nature of the regime. The dispute resolution mechanism could prevent long and costly trials that might take place under international private law, and must, without a doubt, play an important role in the regime's implementation, simply upon presentation of evidence of non-compliance with a given contract.

The meaning of "alternative dispute resolution" must be defined more clearly. Any instrument for this purpose would seem acceptable in principle.

The enforcement of judgments and arbitral awards across jurisdictions must be considered more closely. If this is considered a mandatory element, it should be pointed out that it would be very difficult to do so without particular or specific protocols established bilaterally between Parties, making the IR subject to subsequent arrangements and, to a certain extent, invalid.

Another essential element for a good IR is the generation of "information exchange procedures between national focal points for access and benefit sharing to help providers obtain relevant information in specific cases of alleged infringements of prior-informed-consent requirements." This is, in fact, an element that supports monitoring.

Biotechnology Industry Organization (BIO)

Any measures to ensure compliance with customary law and local systems of protection should be developed at the national level, in light of the vast differences in customary law approaches. However, the IR should include provisions, such as the identification of clear points-of-contact, to ensure that legal certainty, clarity and transparency of the ABS regime are maintained as to the appropriate hierarchy and so the terms of ABS agreements will be respected.

D. Traditional knowledge associated with genetic resources 31/

Biotechnology Industry Organization (BIO)

BIO supports use of traditional knowledge in accordance with the appropriate access and equitable benefit-sharing principles articulated in the Convention, including under Article 8(j). However, any such measures must be transparent in nature. In addition, the scope of what is envisioned by the term "traditional knowledge" is paramount. The scope in the IR should be limited to "knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity" consistent with CBD Article 8(j). In addition, any provision relating to traditional knowledge should not attempt to regulate or repatriate information that has entered, or may enter, the public domain. This could have significant ramifications beyond the CBD context and would provide great uncertainty.

1. Components to be further elaborated with the aim of incorporating them in the international regime

1) Measures to ensure the fair and equitable sharing with traditional knowledge holders of benefits arising out of the utilization of traditional knowledge in accordance with Article 8(j) of the Convention on Biological Diversity

Biotechnology Industry Organization (BIO)

Measures regarding use of TK in ABS context

BIO supports further consideration of measures to ensure the fair and equitable sharing of benefits with traditional knowledge holders. However, any such measures should be clear and transparent in order to ensure legal certainty regarding the access of traditional knowledge and benefit-sharing arising therefrom.

Similarly, any measures to ensure that access to TK takes place in accordance with community level procedures should be developed at the national level, in light of the vast differences in customary law approaches. However, the IR should include provisions, such as the identification of clear points-of- contact to ensure that legal certainty, clarity and transparency of the ABS regime are maintained. Along these lines, BIO supports the identification of an individual or authority to grant access. This is an essential part of developing an access regime that is

31/ The title is without prejudice to the eventual scope of the international regime.

consistent with the principles of legal certainty and transparency and is thereby a crucial element of a workable regime.

In order to facilitate this work, further consideration of measures, such as the "identification of best practices" or establishment of model clauses for MTAs could be further elaborated as a non-binding set of guidelines with respect to those entities that may access traditional knowledge. As noted previously, BIO can support detailed guidance as to certain access principles consistent with the CBD requirement to "facilitate" access in Article 15.2. Similar principles may also be appropriate in the context of TK. However, it should be noted that CBD Article 15.2 only applies to genetic resources.

2) Measures to ensure that access to traditional knowledge takes place in accordance with community level procedures

3) Measures to address the use of traditional knowledge in the context of benefit-sharing arrangements

4) Identification of best practices to ensure respect for traditional knowledge in ABS related research

5) Incorporation of traditional knowledge in development of model clauses for material transfer agreements

6) Identification of individual or authority to grant access in accordance with community level procedures

7) Access with approval of traditionalknowledge holders

8) No engineered or coerced access to traditional knowledge

2. Components for further consideration

1) Prior informed consent of, and mutually agreed terms with, holders of traditional knowledge, including indigenous and local communities, when traditional knowledge is accessed

Biotechnology Industry Organization (BIO)

Access with approval of TK holders

When domestic procedures are implemented, the approval of TK holders should be part of "prior informed consent" process established at national level with appropriate input from TK holders in the relevant jurisdiction. Recipients should not be drawn into potential disputes between provider countries and TK holders.

Engineered or coerced access to TK without consent of the relevant TK holders would not be consistent with notions of prior informed consent. Appropriate legal authority to address this concern should be established at the national level. For example, many countries provide for protection against "contracts of adhesion" or other manifestly unfair arrangements. Similarly, contracts may be voided if entered into under duress. However, if there is a grievance that the access has been "coerced" because of dissatisfaction with the national ABS law, and the recipient

has acted in good faith, this should be considered a domestic matter regarding the ABS regime and should not affect the researchers and the terms agreed by that party.

2) Internationally developed guidelines to assist Parties in the development of their domestic legislation and policies

3) Declaration to be made on the internationally recognized certificate as to whether there is any associated traditional knowledge and who owners of traditional knowledge are

4) Community-level distribution of benefits arising out of traditional knowledge

E. Capacity

India

The international regime shall provide for capacity building of developing country Parties, for development of national legislation, participation in negotiations, information and communication technology, development and use of valuation methods, monitoring and enforcing compliance, technology transfer and cooperation, etc.

Biotechnology Industry Organization (BIO)

BIO members support capacity building measures as developed by CBD Parties under the terms of that agreement. This includes capacity building at levels for the various acts listed in item E(1) of the Annex. However, industry actors should not bear any mandatory obligation to provide resources for such activities. Instead, participation should be done on a voluntary, case-by-case basis involving mutually agreed terms.

1. Components to be further elaborated with the aim of incorporating them in the international regime

1) Capacity-building measures at all relevant levels for:

(a) Development of national legislation

(b) Participation in negotiations, including contract negotiations

(c) Information and communication technology

(d) Development and use of valuation methods

(e) Bioprospecting, associated research and taxonomic studies

(f) Monitoring and enforcing compliance

(g) Use of access and benefit-sharing for sustainable development

2) National capacity self-assessments to be used as a guideline for minimum capacity-building requirements

3) Measures for technology transfer and cooperation

4) Special capacity-building measures for indigenous and local communities

5) Development of menus of model clauses for potential inclusion in material transfer agreements

2. Components for further consideration

1) Establishment of a financial mechanism

IV. NATURE

Text of decision IX/12, annex I

Compilation of proposals on nature 32/

1. Recommendation of Co-Chairs of the Working Group

Options
1. One legally binding instrument
2. A combination of legally binding and non-binding instruments
3. A non-binding instrument

2. Submissions

Option 1
The international regime should be legally binding. In addition, it should stress more cooperative enforcement between parties and not refer conflicts primarily to private international law, which is not only expensive, but also a strain on resource poor countries.

Option 2
1. One legally binding instrument
2. A combination of legally binding and/or non-binding instruments
3. A non-binding instrument

Option 3
The international regime shall be composed of a single legally binding instrument containing a set of principles, norms, rules and compliance and enforcement measures.

Option 4
The nature should be discussed after deliberations of the substance of an international regime are completed. For the time being, Japan suggests the following: the international regime could be composed of one or more non-binding instruments within a set of principles, norms, rules and decision-making procedures.

Option 5
The international regime should be composed of one or more legally binding and/or non-binding instruments within a set of principles, norms, rules and procedures, legally binding and non-binding.

32/ These proposals were neither discussed, negotiated nor agreed.

India

The international regime shall be composed of a single legally binding instrument containing a set of principles, norms, rules and compliance and enforcement measures.

Norway

The regime should be composed of, but not limited to, a single legally binding international agreement, namely a Protocol under the CBD. It should *inter alia* build upon and further develop the Bonn Guidelines.

Mexico

We recommend option 2, seeing as non-binding elements will appear as annexes to the International Regime

Biotechnology Industry Organization (BIO)

BIO supports the view that the international regime should be non-binding. This is based on a number of factors, including: (i) many countries have only recently implemented or have not yet implemented national ABS systems; (ii) until further experience is gained, maximum flexibility should be afforded under the CBD while still documenting best-practices and norms to enhance operability of the agreement; and (iii) further consideration of utility of existing mechanisms, i.e., ABS agreements, arbitration and other dispute settlement mechanisms, etc., need to be pursued prior to entering into a binding regime.

Options

BIO favors Options 2 and 4 as presented in Decision IX/12. As noted above, BIO members continue to support the concept of a non-binding instrument. Therefore, to maintain all options without prejudice to the outcome of the negotiations, the recitation of a combination of "legally binding and/or non-binding instruments" (emphasis added, from Option 2) should be maintained. BIO can also agree with Option 4. The work should at least commence on the basis of creating one or more non-binding instruments and delineating best practices. Once the substantive provisions are worked out, then a more informed discussion may take place regarding the nature of the agreement. It is very difficult to reach agreement on the binding nature of any such agreement if the content is unknown.

Options 1 and 3 are not appropriate as both mandate an entirely legally binding instrument and should be deleted. Further, with respect to Option 1, any successful IR must include a heavy reliance on private international law mechanisms, particularly with respect to cross-border disputes that may arise with respect to mutually agreed terms of access and benefit-sharing.

ADDITIONAL VIEWS RELATED TO THE INTERNATIONAL REGIME ON ISSUES NOT COVERED BY ANNEX I TO DECISION IX/12

Namibia on behalf of the African Group

Definitions

Derivatives and Products:

The use of a dynamic definition of GR based on its utilization solves the problem of trying to define derivatives and products since every use, whether direct or through another interim product, would be separately evaluated as a possible "utilization of genetic resources". This is also the approach that is taken by the ITPGRFA.

Norway

Definitions

Genetic resources

The definitions of the terms *biological resources/genetic resources* in the international ABS regime should be the same as the definitions in the CBD. It is important to notice that the term *genetic resource* is to be defined from its utilisation. What is deemed to be a 'genetic resource' may therefore depend on the intended or actual use of the genetic material. It can only be characterized as a genetic resource when the intended or actual use is based on the genetic information in the biological material.

The same biological material may have a function both as a biological resource and as a genetic resource. The actual or potential utilisation of the biological material should decide which of these two categories the biological material is subsumed under. When the biological material, e.g. a variety of soya bean, is to be used as a commodity and to be sold in bulk on an international market, it should be seen as a 'biological resource'. However, the same biological material may be treated as a 'genetic resource' when used in a plant breeding programme.

The definition on what is a genetic resource could however vary from sector to sector. In the cosmetic industry, a flower petal may represent a genetic resource, in food production it may be the seed. It may be important to address separately the utilisation of GRs in each of the industrial sectors that make use of genetic resources.

Derivatives and products
The terms of reference for the ABS negotiations require parties "to address the issue of derivatives". The concern with regard to derivatives is addressed by the CBD through the Bonn Guidelines.

Derivates and products from a genetic resource will also differ between the different utilisations of the material. The use of a dynamic understanding of what constitutes a genetic resource based on its utilization would seem to solve the derivatives problem.

First a comment with regard to the perceived limitation of the existing definition of genetic resources. In order to be covered by the CBD definition of genetic material, the material of plant, animal, microbial or other origin needs to contain *functional units of heredity*. No definition exists on "functional units of heredity". However, our understanding is that it refers to all the elements that are necessary to establish functional units of heredity. Functionality is expanding all the time in light of technological development.

A functional unit of heredity is the sum of a number of interacting physical factors – not simply a piece of DNA. This is also the understanding with regard to the definition of genetic material in the preparatory works on new Norwegian legislation on access to genetic resources and benefit-sharing.

As a working definition, we prefer using the term derivatives and products the way they are used in the context of Mutually Agreed Terms in the Bonn Guidelines (paras. 36 and 44(f) and (i). It is then up to *providers and users* of genetic resources *to decide* to what extent derivatives or products should be covered by mutually agreed terms on benefit-sharing. As such, they should be considered as falling within the scope of the regime, taking also into account that benefits arising from the commercial and other utilization of genetic resources are covered by the scope of the Bonn Guidelines.

In the International Treaty on Plant Genetic Resources it is the commercializing of a product which is a genetic resource that may trigger benefit sharing.

Misappropriation of genetic resources/traditional knowledge

Norway believes that a working understanding on what we mean with 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 national legislation
- Any acquisition or utilisation of genetic resources by illegal means
- Use of a genetic resource for purposes substantially different from those for which it was 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 traditional knowledge, 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 10bis 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 concept 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 indigenous peoples 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 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."

International Chamber of Commerce (ICC)

Introduction

The business delegation – coordinated under the umbrella of ICC - remains committed to contributing constructively on substantive discussions in the access and benefit sharing (ABS) negotiations. It has made submissions to and participated in the Technical Expert Groups on Concepts, Terms, Working Definitions and Sectoral Approaches, 33/ and on Compliance, 34/ and intends to do so with respect to the Technical Expert Group on Traditional Knowledge. Business looks forward to continuing to play an active and helpful role in the negotiations on an ABS International Regime (IR).

A diverse range of industries 35/ utilize genetic resources in their everyday business, and access, use and create value from these resources in different ways. These industries - many of which consist in large part of small and medium-sized enterprises (SMEs) - play an essential role in creating social and economic benefits from genetic resources. As the Convention on Biological Diversity (CBD) negotiations struggle with the challenge of increasingly complex issues and a call to move toward a more practical discussion based on established common terms and definitions, business can assist in clarifying exactly how genetic resources are accessed, developed and commercialised and methods to best ensure the sharing of benefits.

All businesses are engaged in a continuous evaluation of risk and return on investment. A high risk environment will discourage investment and reduce opportunities for creating benefits.

33/ "Access and Benefit Sharing: Sectoral Approaches, Concepts, Terms and Working Definitions" - 17 October 2008, http://www.iccwbo.org/uploadedFiles/ICC/policy/intellectual_property/Statements/Sectoral%20approaches%20final.pdf

34/ "Priority Issues for the CBD/ABS Compliance TEG" - 28 November 2008, http://www.iccwbo.org/uploadedFiles/ICC/policy/intellectual_property/Statements/ICC%20Compliance%20TEG%20Paper%20final%2028%20Nov%2008.pdf

35/ Including, in alphabetical order: agricultural biotechnology, animal breeding, cosmetics, farming, flavours and fragrances, foods and drinks, forestry, herbal medicines and supplements, industrial biotechnology, pets, pharmaceutical and biopharmaceutical products, and plant breeding.

Given the long time period and heavy investments required to commercialize inventions using genetic resources, businesses need national laws or guidelines which are transparent, practical, science-based, non-discriminatory, and provide legal certainty to justify their investments.

Business therefore supports the creation of a practical and workable IR which will facilitate the activities of the different sectors working with genetic resources today and take into account the future evolution of those activities.

This paper outlines general principles business believes to be important to the success of an IR and specifically provides input to the issues which the Ad Hoc Open-ended Working Group on Access and Benefit Sharing (AHOEWG) is mandated to negotiate at its 7th meeting: objective, scope, fair and equitable benefit-sharing, access and compliance.

General Principles

It is of critical importance that the IR should be **a precisely targeted, facilitative structure that promotes national ABS regimes that are transparent, non-discriminatory, predictable and coherent across borders**; national ABS regimes that are difficult to reconcile with each other should be avoided. The IR should not be a heavy regulatory framework that will stifle the creation of value from genetic resources, and their trade and sustainable uses. This approach will promote not only the efficient organization of access and benefit sharing, but also the other two pillars of the CBD: conservation and sustainable use of genetic resources. Lessons should be learnt from the experiences of national regimes which show that highly regulated and bureaucratic ABS systems have failed to generate social and economic benefits.

In order to ensure that the CBD's objectives are attained, business submits **that the IR should be based on the following principles:**

- An IR should include **clear definitions** consistent with the terms and jurisdictional limitations of the CBD itself.

- **Research, economic activity and freedom to innovate** using genetic resources should be encouraged rather than constrained. This will help promote the generation of benefits and will be the single most important basis for assessing the success of the Regime. Access conditions should respect the Article 15(2) directive to "facilitate access" to genetic resources. Benefit-sharing arrangements in relation to derivatives and downstream products should be determined through mutually agreed terms in the ABS contract between the providing and accessing parties, as provided for in Article 15(7). 36/ Concepts such as "derivatives" or "products", however they may be defined or understood, should be determined between contracting parties.

- The IR should **not seek to restrict what can be mutually agreed** and should encourage the systematic use of contracts, in the form of Material Transfer Agreements (MTAs) or other forms of agreements, to the greatest extent possible. These agreements may include, as appropriate, in addition to the terms and conditions for access and benefit sharing, clauses addressing conditions for the use of the GR, commercial rights, transfer of the GR with or without traditional knowledge to third parties, short-term and long term non-commercial and commercial benefits, the agreed dispute settlement mechanism, choice of law, and/or conditions regulating the future termination of the agreement. **Contractual agreements**, common in the normal course of ethical international business, enforceable under the judicial systems of sovereign CBD member states,

36/ Article 15(7) "….Such sharing shall be on mutually agreed terms."

and respecting CBD standards (if implemented by the applicable national law), remain the best methods to manage ABS of genetic resources.

- The CBD specifies that national governments have sovereign rights over the regulation of genetic resources found in their territories. The IR should therefore leverage national law, enforcement, and regulatory structures rather than attempt to create new mechanisms and obligations that are yet to be proven effective in real world experience. The IR should therefore focus on the **further development and harmonization of national regimes** in the spirit of the **Bonn Guidelines**.

- Such national ABS regimes should identify a **national focal point** which is authorized to grant access and prior informed consent, and to facilitate the negotiation of mutually agreed terms – this is essential to provide legal certainty and transparency for all stakeholders. Any measures to ensure the participation and involvement of indigenous and local communities in mutually agreed terms, and the sharing of benefits with traditional knowledge holders, must be part of a transparent ABS regime.

- The IR should take a **sectoral approach** to address the unique aspects of how genetic resources are accessed and managed in the many business and science sectors using genetic resources. If the IR is to be effective in promoting business activities which support biodiversity, it should maintain and foster the diversity of uses of these resources as well as of the commercial arrangements through which they are acquired.

- The IR should draw a distinction according to the specialties of sectors rather than between **commercial/non-commercial uses**. In reality, it may prove extremely difficult if not impossible to differentiate between 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). It is important to recognize that very few collaborative bio-prospecting agreements result in successful products, even in the case of multinational corporations. Business, especially SMEs, 37/ may be deterred by increases in expenses or bureaucratic red-tape as much as non-commercial research institutes. Complicated requirements for access and benefit-sharing may have the unintended effect of causing a significant decline in academic and commercial research alike.

- The IR should not promote ABS regimes characterized by the **stacking of multiple payments** for a single product. This should apply in cases where multiple countries have particular GRs in common as indigenous resources, but also in cases where a particular GR has multiple beneficial properties and/or becomes the subject of multiple research projects. The IR should provide for **mutual recognition** between countries of ABS agreements so that once a user has entered into an ABS agreement in good faith, no further demands will be made.

37/ Many sectors working with genetic resources, such as biotechnology, plant and animal breeders, traditional medicines, etc - and businesses working in this area in developing countries - consist mainly of SMEs.

- When negotiating the IR, CBD Parties should consider the **implementation costs** of proposed elements for both countries providing genetic resources and users, as well as the bureaucratic challenges that could have significant negative impacts on SMEs and research, and on the generation of potential benefits. In particular, any lengthy processes or negotiations before the start of a research program should be avoided. Cost-benefit and regulatory impact assessments should be undertaken before introducing new untested mechanisms.

- The IR should be a **prospective** system with no retroactive effect. Provisions of the IR should only take effect after the entry into force of the IR and its ratification in the provider country consistent with the provisions of Article 36 of the CBD.

International Union for Protection of New Varieties of Plants (UPOV)

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.
