October 17, 2008

COMMENTS OF THE BIOTECHNOLOGY INDUSTRY ORGANIZATION (BIO) ON ISSUES TO BE ADDRESSED BY THE TECHNICAL EXPERTS GROUP ON CONCEPTS, TERMS, WORKING DEFINITIONS AND SECTORAL APPROACHES

Introduction:

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

The Biotechnology Industry Organization (BIO) appreciates this opportunity to set forth its views on matters to be addressed by the Technical Expert Group on Concepts, Terms, Working Definitions and Sectoral Approaches ("Concepts TEG"). BIO respectfully requests that the experts selected for the Technical Experts Group take these comments into consideration during their deliberations.

General Comments:

Scope of the International Regime:
BIO members firmly believe that the proposed international regime on access and benefit-sharing should be within the scope of the CBD. For example, under the CBD, the access and benefit-sharing provisions only apply to access of "genetic resources." Therefore, the rules in the international regime imposed with respect to genetic resources should be applied consistently with the definition of genetic resources in CBD Article 2 and should not cover the broader concept of biological materials or categories such as derivatives or products, however defined. Suppliers and recipients of genetic resources, however, may elect to assess benefits on biological materials or derivatives arising from the use of those resources through mutually agreed terms.

The international regime should provide for appropriate exclusions, including those areas already explicitly excluded from the CBD, such as human genetic resources.[1] In addition, pathogens and commodities (genetic resources already made freely available) should be excluded from the international regime. The paradigm underlying the CBD access and benefit-sharing rules is "bio-prospecting" for genetic resources. That is, a research entity seeks to access a genetic resource *in situ* or in an *ex situ* collection and to develop a commercially viable product therefrom. Access to pathogens and to genetic resources that are made freely available do not fit this paradigm. Thus, applying the access and benefit-

[1] *See* COP Decision II/11.

sharing obligations in the CBD to pathogens and commodities does not appear to be socially beneficial, and it would be inappropriate to apply these rules in the international regime based on the paradigm to pathogens and commodities.

No "One Size Fits All" Approach for Access and Benefit-sharing:
It is also our strong belief that suppliers and recipients of genetic resources will obtain optimum economic and social benefits through the negotiation of "mutually agreed terms" for access and benefit-sharing at the "point of access", rather than applying a fixed access scheme and a fixed "basket" of benefits mandated by a treaty. Negotiations at the point of access would allow suppliers and recipients to determine the appropriate balance between "up-front" and "back-end" benefits for the relevant transaction as well as to determine an appropriate level of benefits arising from the contemplated arrangement.

Specific Comments:

The terms of reference of the Concepts TEG provide that the experts group will consider the following questions, labeled as (a) – (d). The questions are reproduced below, along with BIO's comments.

(a) What are the different ways of understanding biological resources, genetic resources, derivatives and products and what are the implications of each understanding for the development of the main components of the international regime on access and benefit-sharing, including in relation to sectoral and subsectoral activities and in relation to commercial and non-commercial research?

CBD Article 2 provides the following definitions:

> "Biological resources" includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity.
>
> "Genetic resources" means genetic material of actual or potential value.
>
> "Genetic material" means any material of plant, animal, microbial or other origin containing functional units of heredity.

Consequently, genetic resources are a subset of biological resources that have "functional units of heredity." An example of a genetic resource is a seed of a tree or young tree plant. An example of a biological resource that is not a genetic resource is a chemical extract from that seed or plant. Some genetic resources may be commercial commodities. Many biological resources would be commercial commodities. The "benefit-sharing" objective in CBD Article 1 is limited to "genetic resources" – it does not encompass "biological resources." CBD Article 15, which sets forth the obligations on access and benefit-sharing, is also limited to genetic resources.

The concept of "derivatives" is not contained in the CBD provisions on benefit-sharing. This concept is further not defined in the agreement, although the term is used in the definition of "biotechnology" in CBD Article 2.[2] We firmly believe that the proposed international regime on access and benefit-sharing should be within the scope of the CBD. The access obligations in the CBD only apply to genetic resources and the benefit-sharing obligations only apply to use arising from the accessed genetic resources. Therefore, the rules in the international regime imposed with respect to genetic resources should not be applied to "derivatives" (regardless of the definition of the term) of acquired genetic resources. Providers and recipients of genetic resources should define "derivatives" for the purposes of their individual endeavors and determine what benefits, if any, should be based on such derivatives on an endeavor-by-endeavor basis.

Similarly, the term "product" is not used in CBD Article 15 or in any other provision relevant to benefit-sharing. BIO reiterates that the international regime should be commensurate in scope with the CBD. Similarly as above, any definition of "product" should be left to providers and recipients in the development of material transfer agreements (MTAs) that will reflect the specific terms of access and benefit-sharing that will apply to the particular transaction at issue. Consistent with this notion, the Food and Agriculture Organization (FAO) International Treaty for Plant Genetic Resources for Food and Agriculture (ITPGRFA) also does not contain the term "product" or seek to define it. Nonetheless, it is

[2] CBD Article 2 defines "biotechnology" as "any technological application that uses biological systems, living organisms, or *derivatives* thereof, to make or modify products or processes for specific use(*emphasis added*)."

defined as part of the Standard Material Transfer Agreement (SMTA) under that treaty.[3] BIO does not believe that an SMTA is workable in respect of the International Regime. The FAO ITPGRFA context is much narrower and therefore more amenable to a standard agreement. Nonetheless, the FAO system is instructive in that the SMTA is where the term is defined. Similarly, the "mutually agreed terms" (usually envisioned to be an MTA) between the recipient and provider are the appropriate mechanism to define such terms if needed with respect to the broader range of transactions envisioned under the International Regime.

(b) Identify different forms of utilization of genetic resources in relation to sectoral and subsectoral activities in the context of Article 15, paragraph 7, of the Convention;

Genetic resources are used in a wide variety of ways in the biotechnology sector. For example, when used in the research-intensive biopharmaceutical industry, genetic resources are generally used as instruments to create an "end" product either as a research tool or as a component in the process of making the product. Although with respect to certain products, such as vaccines, the genetic resource itself may be in the end product.

(c) Identify and describe sector specific characteristics of access and benefit-sharing arrangements and to identify the differences, if any, between approaches in sectors;

Benefit-sharing arrangements in the research-intensive pharmaceutical and agricultural biotechnology sectors vary widely and may involve sharing benefits before and/or after the marketing of a product arising from use of accessed genetic resources. There is some sentiment among commentators that suggests that emphasis on benefits that accrue after marketing may be misplaced, particularly given that many genetic resources are investigated for pharmaceutical potential but few give rise to a marketable product.

Agreements involving the research-intensive biopharmaceutical sector are nearly always individually negotiated, albeit negotiators may start with a familiar, model agreement as a starting point.[4] IFPMA and BIO have published guidelines to educate and assist their members on access and benefit-sharing practices. BIO has also published a model material transfer agreement (MMTA). While not intended to be standard agreements or codes of conduct, these guidelines help identify "best practices" in the industry and also are intended to be updated as practices change. A copy of the BIO guidelines and the BIO MMTA are attached as an Annex to this document.

(d) What are the range of options and approaches for taking these different characteristics into account and that may bring coherence to access and benefit-sharing related practices in different sectors?

BIO supports a flexible approach for the International Regime that takes into account different needs of different industry sectors and other stakeholders. The International Regime should facilitate the implementation of clear and transparent national ABS systems. This includes providing for clear points-of-contact for national authorities that can be easily identified by those who seek access.

[3] Under the FAO SMTA, "product" is defined as "plant genetic resources for Food and Agriculture that incorporate the Material or any of its genetic parts or components that are ready for commercialization, excluding commodities and other products used for food, feed and processing."

[4] *See* "Access and Benefit-sharing in Practice: Trends in Partnerships across Sectors" (hereinafter "ABS in Practice"), part 4.4, p. 27, *available at* http://www.cbd.int/doc/publications/cbd-ts-38-en.pdf).

In addition, flexibility with respect to "mutually agreed terms" should be employed. The International Regime should not attempt to regulate specific terms applicable to all agreements or to otherwise attempt to impose strict conditions that go beyond the ABS principles enshrined in the CBD. This would not only be counterproductive, but would not be consistent with the notion of "mutually agreed terms used in the CBD itself. A system that permits the provider and recipient to come to agreement based on the specific circumstances surrounding the proposed access will help to provide a workable framework that will facilitate implementation of the ABS objectives of the CBD at the national level, while, at the same time, be able to provide necessary flexibility to meet the goals of both parties.

A number of options can be employed to meet these goals and thereby bring coherence to ABS-related practices that may apply to different sectors under the International Regime. Broad measures to build capacity in developing countries will help in establishing clear, transparent national ABS regimes that are more easily understood by others. Efforts to increase awareness of national ABS laws among those seeking access to genetic resources will assist in compliance. In addition, detailed guidance could be incorporated into the International Regime with respect to access rules in order to facilitate implementation of systems with clear points of contact that give legal security and certainty to those who seek access in good faith. Further, aspects to be dealt with in the area of compliance, e.g., use of mediation and arbitration dispute settlement mechanisms, may help to build greater confidence in the implementation of appropriate mechanisms to reach mutually agreed terms.

ANNEX I

Guidelines for BIO Members Engaging in Bioprospecting

Preamble

The Biotechnology Industry Organization,

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

hereby establishes the following Guidelines for bioprospecting.

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

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

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

Resources within the territory of that country, (iii) provide information regarding *Benefit Sharing* requirements applicable within the *Contracting Party*, and (iv) identify the representative of local and indigenous communities located within the territory of the country.

9. *"Genetic Resource"* means material of non-human animal, plant or microbial origin containing functional units of heredity.
10. *"In-situ"* means the location in which genetic resources exist within ecosystems and natural habitats within a Country;
11. *"Providing Party"* means any entity within a *Contracting Party* that has been given the legal authority to grant *Prior Informed Consent* or authorization to access and use *Regulated Genetic Resources*, and may include, *inter alia*, an authority of the national government, an authority of a local government, or an indigenous or local community or any combination of these entities.
12. *"Prior Informed Consent"* means an agreement between a *BIO Member* and a *Providing Party* establishing that the *BIO Member* has provided to the *Providing Party* information that meets the requirements of Section III of these Guidelines with respect to a *Regulated Genetic Resource* to which the *BIO Member* has been granted access.
13. *"Regulated Genetic Resource"* means a *Genetic Resource* in respect of which a *Providing Party* in a *Contracting Party*, on or after the date that the Convention on Biological Diversity Party took effect in that *Contracting Party*, imposes requirements concerning *Prior Informed Consent*, collection or use.

B. Scope of the Guidelines:

1. These Guidelines establish principles to govern the conduct of *BIO Members* that are engaged in *Bioprospecting* activities, as defined in section A.3.
2. The Guidelines shall not apply to the acquisition or use of:
   a. any materials obtained from humans or are of human origin;
   b. *Genetic Resources* that are not *Regulated Genetic Resources* within the meaning of these Guidelines;
   c. *Genetic Resources* maintained in an *ex situ* collection where such resources were obtained from a *Contracting Party* prior to the date the Convention on Biological Diversity took effect in that *Contracting Party*;
   d. *Genetic Resources* that are made available to the public on an unrestricted basis, either on commercial or non-commercial terms; or
   e. publicly available information, including, in particular, information published in the scientific literature, disclosed in a patent or published patent application, or disseminated in an unrestricted fashion.

II. Conduct of Bioprospecting

A. Steps to take before engaging in Bioprospecting.

1. Identify and contact the *Focal Point* of the *Contracting Party* for the *Regulated Genetic Resources*.
   a. For samples of *Regulated Genetic Resources* to be collected *in situ*, or from an *ex situ* collection located within the territory of or controlled by the *Contracting Party*, contact the *Focal Point* identified by that *Contracting Party*.
   b. For samples of *Regulated Genetic Resources* to be collected from an *ex situ* collection located outside the territory of or not controlled by the *Contracting Party*, identify the *Focal Point* specified by the custodian of the *ex situ* collection or, if the *Focal Point* is not known to that custodian, take reasonable steps to identify the *Focal Point* for the *Regulated Genetic Resources* to be collected.
2. In cooperation with that *Focal Point*, use all reasonable efforts to identify all entities that comprise the *Providing Party*, and ascertain requirements applicable to *Bioprospecting*.
3. Obtain *Prior Informed Consent* from the *Providing Party* to collect and use *Regulated Genetic Resources* lawfully controlled or held by the Providing Party.
4. Reach agreement with the *Providing Party* on the terms and conditions governing collection, handling and use of physical samples of the *Regulated*

Genetic Resources, including, *inter alia*, the sharing of benefits arising from the use of such samples, and measures governing the handling or transfer of such samples.

5. Conclude a *Bioprospecting Agreement* with the *Providing Party* that reflects the terms and conditions of *Prior Informed Consent* and concerning the collection, handling and use of the collected physical samples of the *Regulated Genetic Resource(s)* including, *inter alia*, terms and conditions regarding *Benefit Sharing*.
6. Take reasonable steps to confirm that the *Bioprospecting Agreement* will be binding on the Government of the *Contracting Party*, either directly or through the authority conferred by the *Contracting Party* on a *Providing Party*.

B. After Prior Informed Consent has been obtained and a Bioprospecting Agreement concluded regarding collection and use of the Regulated Genetic Resources, conduct Bioprospecting, and use the Collected Genetic Resources, in a manner that complies with the terms and conditions specified in the Bioprospecting Agreement.

III. **Prior Informed Consent**

A. Make reasonable efforts to determine if any specific requirements for *Prior Informed Consent* apply to the collected *Regulated Genetic Resources*. To do so:
1. Determine if a *Contracting Party* has established requirements for *Prior Informed Consent*, or, if that authority has been delegated to a *Providing Party*.
2. Identify the nature of the requirements for *Prior Informed Consent* established by the *Contracting Party* or the *Providing Party*, as the case may be.
3. Meet the identified requirements to comply with Prior Informed Consent obligations of the *Contracting Party* or the *Providing Party* applicable to the collected Regulated Genetic Resources, and incorporate evidence of such compliance into the *Bioprospecting Agreement*.

B. If a *Contracting Party* has not established requirements for *Prior Informed Consent*, make reasonable effort to provide at least the following information to the *Providing Party*:
1. The general nature of the activities to be conducted with the *Collected Genetic Resources* (e.g., screening of samples for biological properties, growth and study of samples of materials, extraction and isolation of chemical compounds from the samples, genomic analysis of the sample).
2. The anticipated field of use of any products or services that may be developed through the use of the *Collected Genetic Resources* (e.g., pharmaceutical, agricultural, industrial processing, environmental remediation).
3. The identity and contact information of the expected lead researcher in the *BIO Member*, or a contact point in the *BIO Member* for such research activities.

IV. **Benefit Sharing and Sharing of Research Results, Intellectual Property Procurement and Related Provisions**

A. *BIO Members* that enter into a *Bioprospecting Agreement* with a *Providing Party* should give good faith consideration to specific terms for the sharing of benefits arising from use of collected *Regulated Genetic Resources*, and should define such commitments in the terms and conditions in the *Bioprospecting Agreement*.

B. Types of benefits to be considered for inclusion in a *Bioprospecting Agreement*:
1. Monetary and non-monetary benefits arising from the use or commercialization of the Collected Genetic Resources, including provision of equipment and materials, up-front payments and royalty payments;
2. The sharing of scientific information generated through the conduct of research upon the *Collected Genetic Resources* in conformity with standard industry practices regarding timing and conditions of public disclosure to preserve options for procurement of patents or preservation of rights in undisclosed information;
3. The granting of rights to use technology resulting directly from the *BIO Member's* use of the *Collected Genetic Resources* where the granting of such rights and the nature of the rights granted, are consistent with the commercial needs and interests of the *BIO Member*;

4. The provision of training for scientists designated by the *Providing Party*;
5. The inclusion of scientists from the Providing Party in research activities of the *BIO Member* on the *Collected Genetic Resources*;
6. The conduct of research on *Collected Genetic Resources* in the territory of the *Contracting Party* from which such resources have been collected.
7. The transfer to a *Providing Party* of scientific knowledge, expertise, and technology in the control of the *BIO Member* that (a) results from the study of the collected genetic resources and (b) pertains to the conservation, preservation or physical handling of the *Collected Genetic Resources*.
8. Commitments to only seek patents on inventions that arise from the use or study of *Collected Genetic Resources* and that are claimed in a manner clearly distinguishable from the form in which the *Collected Genetic Resources* are provided by the *Providing Party*.

V. **Measures to Protect Interests and Rights of Indigenous or Local Communities**

A. Respect the customs, traditions, values and customary practices of indigenous and local communities within a *Contracting Party* and from which *Collected Genetic Resources* have been obtained.

B. Respond to requests from indigenous and local communities for information concerning the handling, storage or transfer of *Collected Genetic Resources* consistent with the terms of an applicable *Bioprospecting Agreement*.

C. Take all reasonable steps to prevent the disclosure of information provided in confidence by a member of an indigenous or local community, and handle such information in accordance with the terms specified by the community that has provided the information. Where feasible, include such terms in the *Bioprospecting Agreement*.

D. Avoid taking actions in the course of use or commercialization of *Collected Genetic Resources* that impede the traditional use of Regulated Genetic Resources provided by a *Providing Party*.

VI. **Conservation and Sustainable Use of Biological Diversity**

1. Take reasonable steps to prevent harm or alteration to the local environment incidental to acts of collecting samples of genetic resources from an *in situ* location in a *Contracting Party*.

2. Avoid taking actions that pose a threat to the conservation or sustainable use of biological diversity incidental to acts of collecting samples of genetic resources from an *in situ* location in a *Contracting Party*.

3. Take all reasonable steps and give good faith consideration to sharing data with the *Contracting Party* and/or the *Providing Party* which was derived from research on the *Collected Genetic Resources* and which may be useful in the support of conservation efforts related to a species, environment, or habitat from which the *Collected Genetic Resources* were collected.

VII. **Compliance with Terms of a Bioprospecting Agreement and the Guidelines**

0. Use *Collected Genetic Resources* in a manner consistent with the terms and conditions specified in an applicable *Bioprospecting Agreement*.

1. Do not use *Collected Genetic Resources*, for purposes other than those specified in the *Prior Informed Consent* provisions of an applicable *Bioprospecting Agreement*, unless first obtaining a separate *Prior Informed Consent* in writing for the other use of the *Collected Genetic Resource*.

2. After acquiring *Collected Genetic Resources* pursuant to these Guidelines, maintain records concerning the handling, storage and physical movement of the *Collected Genetic Resources*, and be prepared to share such records with the *Providing Party* upon the request of the *Providing Party*, within reasonable limitations.

3. Ensure that the terms and conditions specified in a *Bioprospecting Agreement* entered into with a *Contracting Party* or a *Providing Party* apply to (i) any successor in interest to their rights under the agreement, and (ii) to any party that obtains a sample of a *Collected Genetic Resource* from it, unless those parties have independently obtained from the *Contracting Party* or the *Providing Party* the right to obtain such samples of the *Collected Genetic Resources*.

4. Do not transfer samples of *Collected Genetic Resources* to third parties unless such transfer is consistent with the terms and conditions of an applicable *Bioprospecting Agreement*.

5. Do not accept samples of *Collected Genetic Resources* from a third party that is not able to provide evidence that it has obtained such samples in compliance with obligations of *Prior Informed Consent* and conditions governing use that are applicable to the sample.

6. Include provisions in the *Bioprospecting Agreement* that provide for effective and fair resolution of disputes regarding compliance with the terms and conditions in the *Bioprospecting Agreement*, either by commitments to international arbitration consistent with the procedures specified in the Annex to these Guidelines or as otherwise agreeable to the *Contracting Party* or *Providing Party*.

ANNEX II

BIOTECHNOLOGY INDUSTRY ORGANIZATION
Suggested Model Material Transfer Agreement

Introduction

The Biotechnology Industry Organization developed *Guidelines for BIO Members Engaging in Bioprospecting* (Guidelines) in 2005 to educate BIO Members about the relevant issues that could arise in the conduct of bioprospecting activities and to provide assistance to those Members seeking guidance. (See www.bio.org/ip/international/200507guide.asp and www.bio.org/ip/international/200507memo.asp).

These Guidelines envisioned that BIO Members would enter into a "Bioprospecting Agreement" before collecting physical samples of "regulated genetic resources" *in situ* or accessing such resources maintained *ex situ*. That Agreement would include the grant of prior informed consent as well as enumerate the terms and conditions governing the collection and use of the regulated genetic resources including benefit-sharing. Depending on the manner of collection, the Agreement could also include provisions that would transfer the collected physical samples of regulated genetic resources from the Providing Party to the BIO Member. Alternatively, a separate agreement to transfer the regulated genetic resources could be concluded after the physical samples were identified or collected.

At present, transfers of regulated genetic resources are not handled in a consistent manner or a comprehensive fashion within countries or at the international level. This leaves uncertainty as to what provisions should be included in a transfer agreement entered into by a BIO Member. This "Model Material Transfer Agreement" (Model) is intended to provide an outline for a transfer agreement that is consistent with the best practices set forth in the Guidelines. This Model may be incorporated into a Bioprospecting Agreement; it may be the basis for an transfer agreement entered into after the completion of collection activities undertaken pursuant to a Bioprospecting Agreement; or, it may take the place of a Bioprospecting Agreement when a BIO Member seeks a specific regulated genetic resource or a group of regulated genetic resources from an *ex situ* holding.[5]

This Model is intended to supplement and be considered in conjunction with those Guidelines. As such, it is designed only for use with "regulated genetic resources" as that term is used in paragraph I.B.2 of the Guidelines – essentially materials of non-human animal, plant or microbial origin that contain functional units of heredity and that are subject to the requirements of prior informed consent, *etc.* under the Convention on Biological Diversity.

It is recognized that in some instances it is beneficial to transfer "traditional knowledge" associated with a regulated genetic resource along with samples of the resource. While this version of the Model does not include provisions for the transfer of traditional knowledge, this Model

[5] BIO Members note that some use the term "material transfer agreement" to mean any contract to collect genetic resources, to transfer genetic resources, or to transfer traditional knowledge. BIO Members, however, use the term "material transfer agreement" to refer to a contract the primary purpose of which is to transfer possession of genetic resources. The term "bioprospecting agreement" is used for a contract the primary purpose of which is to collect genetic resources. The term "confidentiality agreement" is used for a contract the main purpose of which is to protect undisclosed information, such as traditional knowledge, that is transferred from one entity to another. These types of contracts may be merged into a single contract in appropriate circumstances.

could be expanded to transfer traditional knowledge. It should be noted that Part V of the Guidelines entitled "Measures to Protect Interests and Rights of Indigenous and Local Communities" should be applied.

The terms used in the Model, including the commentaries, are intended to have the same meaning as they have in the Guidelines, unless specified otherwise.

As with the Guidelines, there is no legal obligation that attaches from membership in BIO to use the Model.

This Model is not intended to supplant national requirements that regulate the transfer of regulated genetic resources.

This Model is not intended to be a static document. It is envisioned that it will change over time as BIO Members gain more experience in this area. Comments on the contents of the Model are welcome.

Agreement between the [Transferor/s] and the [Transferee]
Concerning the Transfer of [Certain Regulated Genetic Resources]

Preamble

Whereas:

[*Name of "Transferee" BIO Member*] is a [*company description, location,* etc.];

[*Name or names of the "Transferor(s)*] is a [*description of the Transferor(s), location(s),* etc.];

[The [Transferee] identified and/or collected physical samples of regulated genetic resources under the [Bioprospecting Agreement] with the [Transferor(s);]

The [Transferee] desires to take possession of certain [identified and/or collected] regulated genetic resources held by the [Transferor(s)]; and

The [Transferee] has informed the [Transferor(s)] about the intended uses of those regulated genetic resources for which possession is sought and about the identity and contact information of its lead researcher on these regulated genetic resources; and

The [Transferor(s)] consents to the transfer of possession to the [Transferee] for those uses based on the information provided by the [Transferee];
The [Transferor(s)] and the [Transferee] hereby agree as follows.

Commentary: *If the Transferee or a Transferor is acting as an agent for another entity (or the Transferee is under an obligation to transfer the regulated genetic resources to another entity), the other entity should also be identified.*

Clause three of the Preamble would only be included if there was a pre-existing Bioprospecting Agreement between the Transferor(s) and the Transferee.

The Transferor(s) would normally be a Providing Party that is defined in paragraph I.A.11 of the Guidelines as the entity that has legal authority to grant prior informed consent or authorization to access and use regulated genetic resources, and may include, inter alia*, an authority of the national government, an authority of a local government, an indigenous or local community or any combination of these entities. Also, a Transferor could be an agent of a Providing Party. If a Bioprospecting Agreement exists, it would normally list the Providing Parties. Additional Transferor(s) may be identified during the identification or collection of regulated genetic resources under that Agreement, however.*

The Preamble notes that prior informed consent has been given for the "transfer" of the regulated genetic resources subject to the Agreement. A pre-existing Bioprospecting Agreement would indicate that prior informed consent was given for collection but may not specifically give prior informed consent for the transfer and use of regulated genetic materials. Part III of the Guidelines entitled "Prior Informed Consent" should be applied.

Article 1. Definitions

As used in this Agreement, the following terms shall have the meaning provided below.

[*"Bioprospecting Agreement"* means the written agreement between the [Transferor(s)] and the [Transferee] entitled "_____" and executed on _____, a copy of which is attached to this Agreement.]

***"Genetic Resource(s)"* means material of non-human animal, plant or microbial origin containing functional units of heredity.**

"*The Parties"* means the [Transferor(s)] and the [Transferee].

Commentary: Definitions of terms used in the Commentaries may be found in Section I.A. of the Guidelines.

Article 2. Materials

The Material(s) that are subject to this Agreement are:

[*Identify the physical samples of the regulated genetic resources to be transferred*.]

Commentary: The identification of the Materials, for which physical samples will be transferred, should include as many of the following as possible:

1. The taxonomical identity of the Materials (If the taxonomical identity is not known, a description of the physical attributes of the Materials.);

2. Photographs, drawings, or other written means of describing the Materials;

*3. The location from which the samples of the Materials have been obtained and any information provided by the Transferor(s) as to the geographical origin of the samples (*e.g., *country of origin); and*

4. A sample of the specimen may be deposited in a facility that will maintain the integrity of the sample and permit future characterization of it. Such facilities would include "international depositary institutions" designated under the "Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure". Acceptable facilities are not limited to those international depositary institutions, however, and could include other facilities that are deemed suitable by the Transferor and the Transferee.

To the extent possible, identification of the Materials should be provided by the Transferor(s). In the alternative, the Transferee should work with the Transferor to develop an agreed upon means of identifying and describing the Materials. If a large number of Materials are to be transferred, descriptions of the materials may be placed in an annex. Alternatively, several transfer agreements may be used, particularly if Materials have different uses or are subject to different benefit-sharing arrangements.

Article 3. Transfer

3.1. The [Transferor(s)] shall transfer the samples of the Material(s) identified in Article 2 of this Agreement to the [Transferee] under the conditions specified in the following paragraphs.

3.2. [Conditions for the transfer of the samples, including number of samples, packaging, place and date of delivery, *etc.*]

3.3. The [Transferee] may not further transfer the samples of the Materials provided by the [Transferor(s)] and may not transfer genetic resources made using those samples to others except to:

3.3.1. Those for whom the [Transferee] is acting as agent, identified above, and who are bound by this Agreement;

3.3.2. Those who are authorized in writing to receive samples by the [Transferor(s)]; and

3.3.3. Successors in interest of the [Transferee] who are bound by this Agreement.

3.4. The [Transferee] shall maintain records concerning the handling, storage and physical movement of the samples and provide such records to [Transferor(s)].

Commentary: *If the samples are to be removed from the country in which the transfer occurs, government permission may be required for export and/or import. If a government agency is the Transferor, it should be made clear whether it is authorized and/or grants permission to export. In any event, responsibility for obtaining authorization for export and import should be assigned. Similarly, government regulations may require specific procedures for handling the Materials. Responsibility for fulfilling these requirements should be assigned and all such requirements should be fulfilled.*

Article 4. Use of the Materials

4.1. The [Transferee] [and the entity for which the Transferee is any agent] shall only use the samples of Materials transferred under Article 3 of this Agreement for the purposes

> ***Alternative 1:*** **enumerated in Article __ of the Bioprospecting Agreement.**
>
> ***Alternative 2*****: enumerated in Article __ of the Bioprospecting Agreement and for the purposes described below.**
>
> ***Alternative 3:*** **described below.**

4.2. The [Transferee] [and the entity for whom the Transferee is acting as agent] shall return the samples of the Materials transferred under Article 3 of this Agreement [and genetic resources or other materials made from those samples or will destroy those samples and genetic resources or other materials, as directed by [Transferor(s)] when the [Transferee] completes the uses referred to in paragraph 1 of this Article, except as necessary to fulfill disclosure requirements for applications for patents or patent variety protection.

4.3. The [Transferee] shall not seek patents or plant variety protection rights in the Materials as such as they are listed in Article 2 (*i.e.*, materials in the form they are transferred to the [Transferee]). The [Transferee] may apply for the grant of patents claiming inventions developed using samples of the transferred Materials, including inventions embodied in modified forms of the materials, or for the grant of plant variety protection claiming varieties developed using samples of the transferred Materials.

Commentary: If the Transferee wishes to use the transferred samples for uses other than those enumerated in paragraph 4.1, the Transferee must negotiate an amendment to this Agreement with the Transferor(s) or negotiate *a new agreement.*

Paragraph 4.3 authorizes the Transferee to apply for patents or plant variety protection on inventions made using the samples. Article 5 on the sharing of benefits, however, may provide that the Transferor(s) are licensees of the Transferee(s) or joint owners of such applications as part of the benefit-sharing arrangements. The prohibition against seeking rights in the materials transferred as such is intended to assure Transferor(s) that rights will not be sought that might limit or otherwise affect use of the materials as such by parties other than the patent owner/plant variety right owner

Article 5. Sharing of Benefits

5.1. The [Transferee] [and the entity for which the Transferee is any agent] shall provide, at a mutually agreed time, benefits arising from use of the transferred materials:

Alternative 1: **as enumerated in Article __ of the Bioprospecting Agreement.**

Alternative 2: **as enumerated in Article __ of the Bioprospecting Agreement and as described below.**

Alternative 3: **as described below.**

Commentary: The definition of benefits to be shared will vary widely depending on the needs of the Transferor(s), the needs of designated beneficiaries such as indigenous or local communities, the commercial value of the transferred physical samples, the intended use of the samples, the likelihood of using the samples to create a commercially viable product, and other factors. As a consequence, it is not appropriate to suggest a model formulation for the nature of benefits, or the manner in which benefits should be shared, as no single definition will be appropriate in all circumstances.

The Model envisions that specific benefits, the conditions giving rise to obligations for benefit sharing will be identified, and the date on which such benefits are to be provided will be specified in this section (e.g., immediate payment of a fee, payment of a fixed fee upon use of the material in a research or experimental setting). Alternatively, this section may contain a commitment to negotiate benefit sharing terms and conditions by a point certain in the future.

The point certain may be (i) a date certain, (ii) a date when certain types of research activities are performed on the transferred material, or (iii) a date when a commercial product has been identified and is being prepared for commercial production and marketing. It is generally inadvisable to defer negotiation of benefit sharing to later dates, given the potential for a lack of agreement over such benefit sharing terms to disrupt the commencement of commercial marketing, and/or the possibility of distorting the valuation of the materials.

Part IV.B of the Guidelines lists specific types of benefits that should be considered for inclusion in the formulation of benefits to be provided under the Bioprospecting Agreement. It should also be noted that Annex II to the 'Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of their Utilization" lists various types of benefits that can be provided to the Transferor(s) and their beneficiaries. See http://www.biodiv.org/decisions/default.aspx?m=COP-06&id=7198&lg=0.

Article 6. Conservation and Sustainable Use of Biodiversity

The [Transferee] shall take all reasonable steps and give good faith consideration to sharing data with the [Transferor(s)] which is derived from research on the transferred samples of the Materials enumerated in Article 3 and which may be useful in the support of conservation efforts related to a species, environment, or habitat from which the samples were collected.

Commentary: This obligation is drawn from Part VI.3 of the Guidelines (Parts VI.1 and 2 relate only to collection and are not relevant). The Bioprospecting Agreement may contain a similar provision.

Article 7. General Provisions

7.1. This Agreement shall be in effect for a term of ten years from the date of execution of this Agreement unless otherwise agreed to by the Parties. The Agreement shall be terminated if any of the Parties provides notice in writing to the others of its intent to terminate the Agreement on a date no less than six-months from the date of the notice. [*Insert requirements for notice.***]**

7.2. The obligations and rights contained in Article 4.3 and Article 6 shall survive the expiration or other termination of this Agreement.

7.3. Upon the termination or expiration of this Agreement, the [Transferee] [and the entity for whom the Transferee is acting as agent] shall return the samples of the Materials transferred under Article of this Agreement [and genetic resources or other materials made from the transferred samples of the Materials] to the [Transferor(s)] or will destroy those samples and genetic resources or other materials, as directed by [Transferor(s), except as necessary to fulfill disclosure requirements for applications for patents or patent variety protection.

7.4. The provisions of this Agreement constitute the entire Agreement between the Parties relating to the subject matter and the Parties do not make any representations or warranties except those contained in this Agreement. The Agreement shall not be considered extended, cancelled, or amended in any respect unless done so in writing signed on behalf of the Parties.

7.5. None of the rights or obligations under this Agreement are assignable or otherwise transferable without the prior written consent of the other Party(ies).

7.6. Nothing contained in this Agreement shall constitute a partnership or agency between the Parties.

7.7. This Agreement is governed by and shall be construed in accordance with the laws and regulations of [*jurisdiction***], without regard to its conflict of law principles**.

7.8. [*Reserved for indemnity and confidentiality provisions***]**

7.9. [*Reserved for dispute settlement procedures.]*

Signatures

Commentary: Paragraph 7.1 envisions development of appropriate notice provisions, which are likely to vary significantly depending on the Transferor(s). For example, a notice procedure appropriate for a botanical garden may be very different than notice provisions for an indigenous or local community. If there is a Bioprospecting Agreement, the notice provisions should reflect the notice provisions in that Agreement.

In paragraph 7.2, it may be appropriate to specify that some "uses" from Article 4 and some "benefits" from Article 5 survive the Agreement.

With respect to reserved paragraph 7.9, appropriate dispute settlement provisions could vary significantly depending on the Transferor(s). If there is a Bioprospecting Agreement, the provisions in this agreement should be similar to the dispute settlement provisions in the Bioprospecting Agreement. It should be noted that under Part VII.7 of the Guidelines state that the dispute settlement provisions should provide for "fair and effective resolution" and could include international arbitration consistent with the procedures outlined in the Annex to the Guidelines.