

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 *Providing 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

1. Use *Collected Genetic Resources* in a manner consistent with the terms and conditions specified in an applicable *Bioprospecting Agreement*.
2. 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*.
3. 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.
4. 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*.
5. 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*.
6. 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.
7. 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*.