

## 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](http://www.bio.org/ip/international/200507guide.asp) and [www.bio.org/ip/international/200507memo.asp](http://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 a 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.<sup>1</sup>

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

It is recognized that in some instances it is beneficial to transfer “traditional knowledge” associated with a regulated genetic resource along with samples of the resource. While this version of the Model does not include provisions for the transfer of traditional knowledge, this Model could be expanded to transfer traditional knowledge. It should be noted that Part V of the

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<sup>1</sup> BIO Members note that some use the term “material transfer agreement” to mean any contract to collect genetic resources, to transfer genetic resources, or to transfer traditional knowledge. BIO Members, however, use the term “material transfer agreement” to refer to a contract the primary purpose of which is to transfer possession of genetic resources. The term “bioprospecting agreement” is used for a contract the primary purpose of which is to collect genetic resources. The term “confidentiality agreement” is used for a contract the main purpose of which is to protect undisclosed information, such as traditional knowledge, that is transferred from one entity to another. These types of contracts may be merged into a single contract in appropriate circumstances.

Guidelines entitled “Measures to Protect Interests and Rights of Indigenous and Local Communities” should be applied.

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

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

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

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

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

**Preamble**

**Whereas:**

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

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

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

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

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

**The [Transferor(s)] consents to the transfer of possession to the [Transferee] for those uses based on the information provided by the [Transferee];**

**The [Transferor(s)] and the [Transferee] hereby agree as follows.**

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

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

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

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

## **Article 1. Definitions**

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

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

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

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

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

## **Article 2. Materials**

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

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

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

- 1. The taxonomical identity of the Materials (If the taxonomical identity is not known, a description of the physical attributes of the Materials.);*
- 2. Photographs, drawings, or other written means of describing the Materials;*
- 3. The location from which the samples of the Materials have been obtained and any information provided by the Transferor(s) as to the geographical origin of the samples (e.g., country of origin); and*
- 4. A sample of the specimen may be deposited in a facility that will maintain the integrity of the sample and permit future characterization of it. Such facilities would include “international depositary institutions” designated under the “Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure”. Acceptable facilities are not limited to those international depositary institutions, however, and could include other facilities that are deemed suitable by the Transferor and the Transferee.*

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

### **Article 3. Transfer**

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

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

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

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

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

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

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

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

#### **Article 4. Use of the Materials**

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

*Alternative 1: enumerated in Article \_\_\_ of the Bioprospecting Agreement.*

*Alternative 2: enumerated in Article \_\_\_ of the Bioprospecting Agreement and for the purposes described below.*

*Alternative 3: described below.*

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

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

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

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

## **Article 5. Sharing of Benefits**

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

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

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

***Alternative 3: as described below.***

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

*The Model envisions that specific benefits, the conditions giving rise to obligations for benefit sharing will be identified, and the date on which such benefits are to be provided will be specified in this section (e.g., immediate payment of a fee, payment of a fixed fee upon use of the material in a research or experimental setting). Alternatively, this section may contain a commitment to negotiate benefit sharing terms and conditions by a point certain in the future. The point certain may be (i) a date certain, (ii) a date when certain types of research activities are performed on the transferred material, or (iii) a date when a commercial product has been identified and is being prepared for commercial production and marketing. It is generally inadvisable to defer negotiation of benefit sharing to later dates, given the potential for a lack of agreement over such benefit sharing terms to disrupt the commencement of commercial marketing, and/or the possibility of distorting the valuation of the materials.*

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

## **Article 6. Conservation and Sustainable Use of Biodiversity**

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

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

## **Article 7. General Provisions**

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

*[Insert requirements for notice.]*

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

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

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

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

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

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

7.8. [Reserved for indemnity and confidentiality provisions]

7.9. [Reserved for dispute settlement procedures.]

### **Signatures**

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

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

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