



**COMMENTS OF THE BIOTECHNOLOGY INDUSTRY ORGANIZATION (BIO) ON
ISSUES TO BE ADDRESSED BY THE TECHNICAL EXPERTS GROUP ON
TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES**

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 submit comments on matters to be addressed by the Technical and Legal Experts Group on Traditional Knowledge Associated with Genetic Resources (“Traditional Knowledge TEG”) at its meeting in June 2009 at Hyderabad, India. BIO respectfully requests that the experts selected for the Traditional Knowledge TEG take these comments into consideration during their deliberations.

General Comments:

BIO supports further consideration of provisions intended for the International Regime relating to the use of “traditional knowledge” in accordance with the appropriate access and equitable benefit-sharing principles articulated in the CBD, including under Article 8(j). As noted in our previous comments, BIO members firmly believe that the proposed international regime on access and benefit-sharing should be within the scope of the CBD. In that light, the scope of what is envisioned by the term “traditional knowledge” is of paramount importance. CBD Article 8(j) specifically recites that this concept 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.” Therefore, any definition of traditional knowledge must be within the parameters set by this provision.

As discussed in relation to the particular questions below, any provisions in the International Regime relating to access and benefit-sharing (ABS) in the context of traditional knowledge should be based on the fundamental concept of mutually agreed terms between provider and recipient. This will help to establish clarity and transparency and, consequently, facilitate compliance and avoid disputes.

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.

Specific Comments:

The terms of reference of the Traditional Knowledge TEG provide that the experts group will consider and address the following questions. The questions are reproduced below and are followed with comments from BIO.

(a) What is the relationship between access and use of genetic resources and associated traditional knowledge?

As an initial matter, it should be noted that the term “associated traditional knowledge” does not appear in the CBD. As such, this question emphasizes the importance of providing a clear understanding of this concept, if it is to be addressed in the provisions of the International Regime. CBD Article 8(j), which addresses “in-situ conservation,” provides certain obligations on Parties in respect of “knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity.” For the purposes of this paper, we will treat the term “associated traditional knowledge” as synonymous with this language from Article 8(j).

When addressing “genetic resources” in Article 15, the CBD states that national governments have the authority to determine access to genetic resources. This is based on the recognition of the sovereign rights of States over their “natural resources.” There is no parallel to this provision in respect of “associated traditional knowledge.”

CBD Article 8(j) provides that, subject to its national legislation, each Party has the obligation to “respect, preserve and maintain” associated traditional knowledge “with the approval of the holders of such knowledge, innovations and practices and encourage the equitable sharing of benefits arising from the utilization of such knowledge, innovation and practices.” Thus, there is some parallel between the concepts of prior informed consent and equitable benefit-sharing, provided in CBD Article 15 in respect of genetic resources with CBD Article 8(j) provisions relating to associated traditional knowledge. However, Article 8(j) is further limited to the objectives of respecting, preserving and maintaining this traditional knowledge.

Notwithstanding these differences that derive from the CBD itself, BIO believes that any provisions relating to associated traditional knowledge in the International Regime should be based on mutually agreed terms between providers and recipients, similarly as with respect to genetic resources, and should be clear and transparent to ensure legal certainty regarding the access of traditional knowledge and benefit-sharing arising therefrom.

(b) What practical impacts should the negotiations of the international regime take into account based on the range of community level procedures and customary systems of indigenous and local communities for regulating access to traditional knowledge associated with genetic resources at the community level?

BIO members consider transparency and clarity to be of the utmost importance for the International Regime to operate successfully. Following this reasoning, it is imperative that measures are developed at the national level to address customary law approaches that may exist within the political structure of the relevant Party. These measures must be easy to navigate for potential bioprospectors.

When domestic measures are implemented, the approval of appropriate traditional knowledge holders should be part of the “prior informed consent” process established at the national level. National governments must act in accordance with their national legal framework to obtain appropriate input from

traditional knowledge holders in their jurisdiction. This will help ensure that disputes will not arise once the system is implemented.

The International Regime should provide legal certainty for those who enter into ABS agreements in respect of associated traditional knowledge within a particular jurisdiction. This would include provisions relating to the identification of clear points-of-contact (e.g., national focal points or competent national authorities) and clear regulations regarding the appropriate legal hierarchy so that those seeking access to traditional knowledge are on notice of appropriate actions to be taken and so that good-faith actors will not be subject to later claims by third parties that could interrupt a legitimate benefit-sharing arrangement.

(c) Identify the range of community level procedures and determine to what extent customary laws of indigenous and local communities regulate access to genetic resources and associated traditional knowledge at the community level and its relevance to the international regime;

BIO defers comment on the range of community level procedures that are implemented by the various CBD Parties to others with greater expertise in this area. We look forward to the findings of the Traditional Knowledge TEG in this regard and consider greater fact-finding in this area to be important for further informed deliberations of the ABS Working Group.

It is evident that there are a wide range of community level procedures, including existing customary laws of indigenous and local communities, that may be relevant for consideration in developing the International Regime. In this light, it is clear that a “one size fits all” approach in the International Regime will be unworkable. Instead, the International Regime should ensure, whatever regime is established at the national level, that there is certainty, clarity and transparency. This will facilitate compliance by bioprospecting entities and reduce the potential for disputes.

(d) To what extent do measures to ensure compliance with prior informed consent and mutually agreed terms under Article 15 also support the prior informed consent of indigenous and local communities for the use of their associated traditional knowledge?

BIO supports effective compliance measures in respect of genetic resources to ensure that the objectives of the CBD can be implemented in a fair and equitable manner that facilitates access. In this 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. These can be 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.

These tools appear to apply equally in respect of access and benefit-sharing of associated traditional knowledge. Additional tools beyond these private law mechanisms may also help to facilitate compliance. For example, tools such as awareness-raising activities aimed at potential bioprospecting entities as well as mechanisms for information exchange between Parties should be more fully considered. Each of these tools are useful to facilitate compliance more broadly, but also may be applied to support prior informed consent of indigenous and local communities in respect of their associated traditional knowledge

However, certain other proposals have been made in respect of genetic resources that raise concerns. These proposals raise similar concerns in the context of associated traditional knowledge. For example, proposals regarding international certificates, discussed further in the response to question (g), continue to

raise a number of questions, some particular to traditional knowledge, that need to be resolved before serious consideration to include a certificate mechanism in the International Regime should be pursued.

In addition, some Parties have proposed that new requirements be placed on patent applicants with the goal of promoting CBD objectives. BIO opposes proposals made regarding new patent disclosure requirements (e.g., regarding source/origin of genetic resources) in respect of both genetic resources and/or associated traditional knowledge. 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 thereby decrease potential benefit-sharing from such efforts.

Detailed and lengthy discussions in the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO) have confirmed this view and have not led to any consensus on such proposals in respect of either genetic resources or traditional knowledge. These proposed requirements are highly controversial and should not be included in the International Regime. Instead, promoting access and benefit-sharing through “mutually agreed terms” is the best approach. To the extent further discussions are necessary in respect of patent systems, such discussions should be left to the intellectual property experts at the WIPO.

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

If the national ABS regime that is developed by a particular country does not fully comply with customary law principles, it is the State that should be held accountable and the laws changed.

(e) Identify elements and procedural aspects for the prior informed consent of holders of associated traditional knowledge when traditional knowledge associated with genetic resources is accessed also taking into account potential transboundary contexts of such associated traditional knowledge and identifying best practice examples;

The CBD and the Bonn Guidelines are based on the fundamental principle that access and equitable benefit-sharing will be based on mutually agreed terms that would normally be embodied in a contract or other type of agreement that represents a meeting of the minds of the provider and the recipient. This principle appear to apply equally to associated traditional knowledge, and BIO members have consistently supported its application to the transfer of traditional knowledge.

The fact that certain genetic resources or associated traditional knowledge may have “transboundary contexts” should not impede the application of this principle. Mutually agreed terms should bind the provider and the recipient. There should be no mechanism for “claims” by third countries or other third parties not party to a particular contract or agreement that may have some interest in the traditional knowledge at issue. This would greatly add uncertainty into the system and subject good-faith actors to potential liabilities they would not have been able to anticipate at the time of access.

Instead, where multiple jurisdictions hold traditional knowledge in common, agreement between such countries or jurisdiction could be arranged so that one member in a group of countries or indigenous communities that hold a resource in common would share the benefits received with others from that group. This would maintain certainty among the parties to a particular ABS agreement, yet would also

provide a mechanism to more equitably share benefits in transboundary situations – at least where a particular “group” of countries is identifiable.

(f) Is there a basis for prior informed consent for indigenous and local communities relative to traditional knowledge associated to genetic resources in international law? If so, how can it be reflected in the international regime?

As noted, the CBD and the Bonn Guidelines start with the fundamental principle that access and equitable benefit-sharing will be based on mutually agreed terms. This agreement, reached at the point of access, also embodies prior informed consent. In that light, BIO members have consistently supported contract-based approaches to ensuring appropriate access and equitable benefit-sharing from the use of genetic resources and associated traditional knowledge. Well-established principles of private international law can be applied in this context.

The International Regime can draw on these principles. The agreement between the provider and the recipient of the traditional knowledge at issue will be usually manifested in a contract. The provider, in this case, the indigenous or local community at issue, should have some type of authority to enter into such agreements that is recognized as the appropriate authority for the purposes of the national ABS regime. The International Regime can provide guidelines or specific requirements for national governments to adhere to when developing national ABS regimes to establish a legal framework that will require prior informed consent of the relevant communities in the national system while still preserving certainty and transparency for those parties seeking appropriate access to that knowledge.

Reference can be made to elements identified in the Bonn Guidelines relating to the provision of prior informed consent.¹ However, the International Regime should not attempt to mandate specific terms of agreement. Instead, providers and recipients will obtain optimum economic and social benefits through negotiation of mutually agreed terms for ABS in particular cases at the point of access.

(g) Assess options, considering the practical difficulties and distinct implementation challenges, for including traditional knowledge associated with genetic resources in a potential internationally recognized certificate issued by the competent domestic authority also by considering the possibility of a declaration on such certificate as to whether there is any associated traditional knowledge and who the relevant holders of traditional knowledge are;

There are still many concerns regarding the feasibility of establishing an international certificate system that require further study,² including the nature of what is to be certified, the information that should be provided in the certification, and the need for possible compliance measures (e.g., check-points or other measures). Until these concerns are resolved, it is doubtful that a certificate system represents a workable option.

These concerns are magnified in the context of traditional knowledge, in light of the intangible nature of associated traditional knowledge and how it would be accessed. The Technical Experts Group on an Internationally Recognized Certificate of Origin/Source/Legal Provenance specifically noted “distinct

¹ SECRETARIAT OF THE CONVENTION ON BIOLOGICAL DIVERSITY, BONN GUIDELINES ON ACCESS TO GENETIC RESOURCES AND FAIR AND EQUITABLE SHARING OF THE BENEFITS ARISING OUT OF THEIR UTILIZATION (2002), *see* paras. 24-37.

² *See, e.g., Report of the Technical Experts Group on an Internationally Recognized Certificate of Origin/Source/Legal Provenance*, UNEP/CBD/WG-ABS/5/7 (Feb. 20, 2007), paras. 40-48.

implementation challenges hence requiring special consideration” in the context of traditional knowledge.³

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 and underlying rationale of such certificates. Further, these types of certificates, if pursued, should not be tied to other laws, e.g., intellectual property laws, and should strive to avoid any unintended consequences, e.g., impeding global trade in goods.

(h) How to define traditional knowledge associated to genetic resources in the context of access and benefit-sharing?

As a starting point, we reiterate that any definition or notion of “associated traditional knowledge” must be consistent with the terms of the CBD.

A workable definition of traditional knowledge associated to genetic resources remains elusive. The Traditional Knowledge TEG should consider that the experts at the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) have dealt with this issue for many years and have yet to come to a consensus. However, the Traditional Knowledge TEG could consider some of the more fundamental items identified in the “List of Issues” developed by the WIPO IGC. A greater common understanding of these items is needed to provide more certainty. These items include the following questions:

- definition of traditional knowledge that should be protected;
- who should benefit from any such protection or who hold the rights to protectable traditional knowledge;
- what forms of behavior in relation to the protectable traditional knowledge should be considered unacceptable/illegal; and
- which issues should be dealt with internationally and which nationally, or what division should be made between international regulation and national regulation.⁴

The WIPO IGC is also considering a number of other items, but these relate more directly to the relationship between intellectual property rights and traditional knowledge and, therefore, are more appropriate for consideration in that body. It should also be noted that the WIPO IGC considers “traditional knowledge” to be a distinct subject broader than the CBD notion of traditional knowledge associated with genetic resources.

Nonetheless, a clear understanding of these fundamental questions is necessary to ensure that both traditional knowledge holders and those seeking to access that knowledge can communicate in a manner that avoids confusion and dispute, and contributes to the CBD objectives of facilitating access and ensuring equitable benefit-sharing.

³ *Id.* at para. 19.

⁴ Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, *Revised Draft Report: Document Prepared by the Secretariat*, WIPO/GTRKF/IC/10/7 Prov. 2 (April 25, 2007) at Annex I.