December 15, 2008

VIEWS AND PROPOSALS OF THE BIOTECHNOLOGY INDUSTRY ORGANIZATION (BIO) IN RESPECT OF THE MAIN COMPONENTS IN ANNEX I OF DECISION IX/12 OF THE CONFERENCE OF THE PARTIES (COP) OF THE CONVENTION ON BIOLOGICAL DIVERSITY (CBD)

General Comments:

The decisions of the Conference of the Parties (COP) of the Convention on Biological Diversity (CBD) define the work program for the Ad-hoc Working Group on Access and Benefit-Sharing (ABS Working Group). The Working Group has been tasked by the COP to "elaborate and negotiate an international regime on access to genetic resources and benefit-sharing" (Decision VII/19) at the earliest possible time before the tenth meeting of the COP in October 2010(Decision VIII/4).

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 submit, for further elaboration and negotiation of the international regime on access and benefit-sharing, views and proposals including operational text, where relevant, in respect of the main components listed in Annex I to the present decision, preferably with supporting rationale."

As requested by the COP, set forth below are the views and proposals of BIO regarding the components listed in Annex I to Decision IX/12 along with accompanying rationale in the form of comments.

The Biotechnology Industry Organization (BIO) is pleased to take this opportunity to submit such views and proposals on matters to be addressed by the ABS Working Group. BIO respectfully requests that the ABS Working Group Members take these comments into consideration during their deliberations.

Annex I [Annex to COP 9 Decision IX/12]

THE INTERNATIONAL REGIME

I. OBJECTIVE

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

The mandate of the ABS WG refers to the implementation of Article 15 and Article 8(j) of the CBD and "the three objectives of the Convention" (Decision VII/19D). The text of this paragraph should therefore be limited to CBD Articles 15 and 8(j). References that have been proposed to other articles, e.g., Articles 16 (transfer of technology) and 19.2 (access to benefits from "biotechnologies based on genetic resources") address different issues and should not be included.

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

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

II. SCOPE

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

The Options: In respect of the three options presented, Option 1 is more comprehensive and would make the most appropriate basis for discussions. However, option 3 could be amended to be consistent with the views of BIO set forth herein. Option 2, however, appears to suggest an overly broad scope for the IR.

For example, it contains no exception for genetic resources made freely available (e.g., "commodities"), resources found beyond national jurisdictions or other excluded categories of genetic resources.

Excluded Subject Matter

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

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

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

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

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

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

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

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

Effective Date

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

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

Relationship to Other International Organizations and Agreements

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

This section also addresses relationship to UPOV, which deals with the protection of plant varieties, and discussions in the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (GRTKF). The IR should not interfere with protection of plant varieties under UPOV. To that extent, it is appropriate for the CBD to give special consideration to the relationship with that agreement. Similarly, the WIPO IGC is the appropriate body in WIPO for the consideration of matters relating to the relationship of intellectual property and CBD related issues. The work in the WIPO IGC should be given "special consideration" in the sense that the CBD should defer to WIPO on all intellectual property-related issues.

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

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

III. MAIN COMPONENTS

A. Fair and equitable benefit-sharing

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

Linkage of Access and Benefit-Sharing

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

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

Capacity Building and Awareness Raising

Exercises in capacity building for developing countries, as well as awareness raising activities for bio-prospectors may be helpful in ensuring better compliance with ABS systems. For example, BIO has voluntarily established detailed guidelines for bio-prospecting for its members with the goal of educating BIO members regarding relevant issues that may arise in the conduct of these activities. These guidelines

are publicly available and are attached to the comments that BIO submitted to the Technical Expert Group on Concepts, Terms and Working Definitions (those comments are attached to this document for consideration by the ABS Working Group).

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

Mechanisms to Encourage Benefits be Directed to Conservation and Sustainable Use

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

Development of international minimum conditions and standards

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

Benefit Sharing for Every Use

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

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

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

Establishment of trust funds to address transboundary situations.

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

Enhanced utilization of Bonn Guidelines and Development of Model Clauses for MTAs

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

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

B. **Access to genetic resources**

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

Recognition of the sovereign rights and the authority to determine access

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

Legal certainty, clarity and transparency of access rules

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

Non-discrimination of access rules

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

International access standards and internationally developed model legislation or guidance

BIO can support detailed guidance in the IR as to certain access principles consistent with the CBD requirement to "facilitate" access in Article 15.2, including, e.g., standards that would help ensure transparency and clarity, including identification of clear authorities and points of contact to improve reliability in agreed terms of access.

However, while model legislation may be useful to standardize approaches between nations and thereby facilitate access by eliminating differences of law between jurisdictions, such an approach would be resource-intensive. It would be difficult for Parties to negotiate appropriate model legislation in light of different national circumstances and the general recognition that a "one-size fits all" approach will not be workable. It may also be inconsistent with the principle contained in CBD Article 15.5 that Parties may,

e.g., forego requirements for prior informed consent if they so choose. Resources would be better spent on developing specific guidance on certain access and other principles consistent with the CBD and providing needs-based capacity building for countries when implementing their national ABS regimes.

Simplified access rules for non-commercial research

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

C. **Compliance**

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

Awareness-raising activities

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

Mechanisms for information exchange

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

Internationally recognized certificate issued by a domestic competent authority

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

Development of tools, including private international law mechanisms, to enforce compliance

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

In the case of enforcing ABS systems, private international law offers many dispute settlement mechanisms that are currently used to enforce contracts relating to international business transactions around the world; see, e.g., paper by the delegation of Canada submitted to the sixth ABS WG meeting

(UNEP/CBD/WG-ABS/6/INF/3/Add. 2 (Jan. 15, 2008)). Measures such as negotiation, mediation, arbitration and consideration of enforcement of foreign judgments should be further elaborated.

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

International understanding of misappropriation/misuse

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

Sectoral MTA model clauses and access standards

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

Codes of conduct and identification of "best practices"

Voluntary "Codes of Conduct" for industry may be helpful. One current example in the biotechnology sector is the BIO Guidelines on Bioprospecting. Any such code should be established on a voluntary basis by an industry association with participation from industry actors. The industry group itself may monitor compliance. Mandatory "codes of conduct" would be counterproductive and would not be appropriate. In addition, to the extent that this language envisions a "mandated" code to be enforced through a CBD compliance-type mechanism, this would be very problematic and should be avoided. Identification of "best practices," however, could also take the form of guidelines or other instruments that would not be binding and would provide significant benefits in this area.

Unilateral declaration by users

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

Tracking and reporting systems and identification of check-points.

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

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

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

Disclosure requirements

BIO opposes proposals made regarding new patent disclosure requirements (e.g., regarding source/origin of genetic resources). BIO members are of the view that such requirements will be (a) ineffective in promoting the objectives sought (e.g., compliance with CBD principles) and (b) will introduce uncertainties into the patent system that will inhibit innovation in relevant technologies and will thereby decrease potential benefit-sharing from such efforts. Detailed and lengthy discussions in WIPO and WTO, have confirmed this view and further, have not led to any consensus on such proposals. These proposed requirements should not be included in the IR. Instead, promoting access and benefit-sharing through "mutually agreed terms" is the best approach. To the extent further discussion is necessary on these proposals, it should be done at WIPO.

Remedies and sanctions

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

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

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

D. Traditional knowledge associated with genetic resources

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

Measures regarding use of TK in ABS context

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

Similarly, any measures to ensure that access to TK takes place in accordance with community level procedures should be developed at the national level, in light of the vast differences in customary law approaches. However, the IR should include provisions, such as the identification of clear points-of-

contact to ensure that legal certainty, clarity and transparency of the ABS regime are maintained. Along these lines, BIO supports the identification of an individual or authority to grant access. This is an essential part of developing an access regime that is consistent with the principles of legal certainty and transparency and is thereby a crucial element of a workable regime.

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

Access with approval of TK holders

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

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

E. Capacity

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

IV. NATURE

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

Options:

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

discussion may take place regarding the nature of the agreement. It is very difficult to reach agreement on the binding nature of any such agreement if the content is unknown.

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