BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

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EMAIL: recursosgeneticos@planalto.gov.br

Re: Sugestões ao projeto de lei que dispõe sobre o access tos recursos genéticos e seus derivados

Dear Sir/Madam:

The Biotechnology Industry Organization (BIO) is submitting these comments in response to the public consultation requested by the Office of the President, Subsector for Legal Affairs (*Casa Civil da Presidência da República, Subchefia para Assuntos Jurídicos*), regarding the draft bill of law covering the collection of biological material, access to genetic resources and their derivatives for scientific or technological research, remittance and transport of biological material, access to and protection of the associated traditional knowledge and rights of farmers and the sharing of benefits.

BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations in Brazil and 31 other nations. BIO Members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products and services. As such, the biotechnology industry is uniquely suited to meaningful partnerships in this area. As an illustration of our interest in these matters, BIO has established *Guidelines for Members Engaging in Bioprospecting* and its *Model Material Transfer Agreement*. These instruments, based on real-world experience and a mind-set of "win-win" or mutual success, offer a practical tool which provides the flexibility to optimally structure the given bargain for access and transferring of genetic resources in compliance with requirements for appropriate access and equitable benefit-sharing.

I hope that our comments, which are attached to this letter, will be helpful in further developing this draft bill of law. BIO looks forward to working with the Brazilian government and other interested stakeholders in Brazil to achieve a system that will improve transparency and accountability regarding the collection and use of genetic resources and associated traditional knowledge.

Sincerely,

Lila Feisee
Managing Director for Intellectual Property

Attachment: Comments

Comments of the Biotechnology Industry Organization (BIO) on the Brazilian Draft Bill of Law Covering the Collection of Biological Material, Remittance and Transport of Biological Material, Access to and Protection of the Associated Traditional Knowledge and Rights of Farmers and the Sharing of Benefits

General

At the outset, BIO commends the Brazilian government for its efforts to create national legislation addressing these important matters. BIO believes that comprehensive national systems regulating the collection of, access to, and benefit-sharing from genetic resources and associated traditional knowledge is important to implement the goals of the Convention of Biological Diversity (CBD) in its member countries. Effective, transparent systems for appropriate access to genetic resources and traditional knowledge, as well as equitable benefit-sharing from their use, can help to provide both an enabling environment for entities seeking access to these resources and an enabling environment for the generation of benefits which can then be shared, as appropriate, with holders of these resources.

We are pleased that Brazil is enacting a national regime limited to biological materials from Brazilian territories, territorial waters, exclusive economic zone or continental shelf (Article 1). Further, we are pleased that the draft bill explicitly excludes human biological material. This is consistent with the scope of the Convention on Biological Diversity (CBD) as reaffirmed in Decision II/11 of the Conference of the Parties (COP) to the CBD (Article 3(I)).

Nonetheless, there are a number of general areas of concern for BIO Members in the draft bill:

- Certain provisions of the draft bill of law, notably Articles 121, 132 and 133, would provide new grounds to prevent, nullify or revoke patent and other intellectual property rights on the basis of compliance with access and benefit-sharing (ABS) requirements for genetic resources. This would cause significant uncertainty in valuable intellectual property rights, reduce incentives for innovation and consequent benefit-sharing, and is not necessary to adequately enforce the ABS requirements. In addition, enactment of these provisions would raise questions of consistency with the obligations of Brazil under the TRIPS Agreement and the 1978 Act of the International Convention for the Protection of New Varieties of Plants ("1978 UPOV Act").
- Certain provisions of the draft bill of law are vague and would be very difficult to comply with due to lack of clear, objective criteria. In light of the significant penalties included in the bill for potential violations, it is imperative that the law clarify these provisions and do so in a manner preserving the ability for innovative biotechnology companies to partner with local institutions and indigenous and other traditional communities in a way that will be beneficial for all parties.
- Terms of collection, access, transport and benefit-sharing are made in terms of "genetic resources, their derivatives, and associated traditional knowledge." The reference to derivatives, in particular, but also traditional knowledge, could be interpreted quite broadly and perhaps trigger requirements for activities that would not be clear to good-faith researchers even years after an initial access has taken place, or for acts performed

by another entity. This may lead to unnecessary disputes and provide disincentives for good-faith researchers to do bioprospecting in Brazil.

- Stringent requirements on foreign entities, such as requirements to work through Brazilian research institutions, appear to be highly restrictive and discriminatory and would appear to limit ability to engage in meaningful research and development partnerships and activities in Brazil.
- Beyond the intellectual property matters mentioned above, the relationship of the draft bill to existing international agreements should be clear. For example, germplasm accessed pursuant to the terms of the International Treaty International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) of the Food and Agriculture Organization (FAO) of the United Nations and the standard Material Transfer Agreement (SMTA) thereunder should be exempted from this legislation and should be governed exlusively by the terms of the FAO ITPGRFA-SMTA.

Specific Comments

Definitions

Article 7(II) defines "access to genetic resources or their derivatives" as "isolation, analysis or processing of functional units of heredity or derivatives of genetic resources to procure or select a specific property." This appears to include scientific research and development work that goes well beyond typical meaning of "access" to these resources. This raises significant uncertainties about when particular ABS requirements in the law would be triggered, when licenses would be required, etc., even with respect to acts taking place years after the initial access and procurement of the resources is made.

BIO is also concerned about the expansive definition of "derivatives of genetic resources" in Article 7(XXIII). This is defined as "the biochemical elements, organic molecules, metabolic substances, description of chemical structures or functional units of heredity, or samples or a whole or part of a living or dead organism." This could be construed in a very broad manner to potentially include down-stream inventions that may be subject to patent or other intellectual property rights protection due to the inventive activity of a third party.

The Article 7(XVIII) definition of "associated traditional knowledge" also raises some concerns. The definition purports to include "all knowledge, innovation or practice, either individual or collective, of indigenous communities, *quilombos*, or other traditional communities associated with properties, uses and characteristics of biological diversity, within cultural contexts than can be identified as belonging to the respective community, even if made available outside these contexts, such as databases, cultural collections, publications and in commerce." The phrase "all knowledge, innovation or practice" encompasses a wide range of information and activities. Further, it is not clear what standards would be used to determine how closely associated with biological diversity such information or activities would have to be or what criteria would be used to judge when something would be within a particular cultural context or when it would be able to be "identified" as belong to a particular community.

Access and Benefit-Sharing Regimes

The draft bill creates a new body, the Council for Managing Genetic Resources (*Conselho de Gestão dos Recursos Genéticos* or CGEN), to manage genetic resources. The terms of reference for CGEN envision that representatives of "civil society, including the scientific community and the public sector" may be invited to assist the work of the CGEN. We would like clarification that private sector representatives from industry will also be able to assist in this work. The biotechnology industry is a major stakeholder in the conservation and sustainable use of biological resources and has significant expertise and experience that would assist CGEN in its mission.

The bill sets forth detailed regulations for the collection of biological materials, access to genetic resources, access to genetic resources related to alimentation or agriculture ("agrobiodiversity"), remittance and transport of biological materials, sharing of benefits and administrative penalties for violating these provisions. BIO supports the development of highly transparent and structured access and benefit-sharing regimes. However, any system should facilitate, rather than impede, access to genetic resources for environmentally sound uses in line with Article 15 of the CBD and the relevant terms of the FAO-ITPGRFA. The following are examples of matters that raise concerns:

- In addition to generally applicable requirements, foreign legal entities interested in collecting or accessing genetic resources in Brazil would have to conduct any work together with a Brazilian national research institution, which must coordinate the activities. The foreign entity must also obtain the authorization of the Ministry of Science and Technology (see, e.g., Articles 28 and 37). While BIO understands the value of partnering with local institutions, this type of mandatory requirement may unduly restrict bioprospecting and related research and development activities.

- The bill requires prior informed consent from the relevant community for activities relating to genetic resources or traditional knowledge originating from an indigenous community, *quilombo* or other traditional community. As noted above, it is not always clear what would constitute "traditional knowledge" or a "traditional community" for this purpose. Further, it may be difficult, even in recognized "communities" to determine the recognized authority for providing prior informed consent for these purposes. As the bill envisions significant penalties for violation of these laws, clarity is of paramount importance on these matters.

- In Article 70, the remittance or transport abroad of biological material originating from "native agrobiodiversity" is limited solely to Brazilian teaching or research institutions under a material transfer agreement and ABS contract. The relevant foreign institution must have signed a contract with the Brazilian institution pursuant to Section 2 of Article 70.

The Protection of Associated Traditional Knowledge ("TK") and Farmers Rights.

Articles 38-44 recognize and confer rights of indigenous communities, *quilombos*, and other traditional communities to their traditional knowledge. Articles 55-57 recognize and confer the rights of farmers. In light of definitional issues mentioned previously, the language regarding application of these rights is vague and raises a number of concerns for entities engaged in

research with respect to biological resources. In addition, these provisions raise a number of questions, as follows:

- Article 40 refers to the protection of "moral" rights of the relevant holders of TK. However, it is not clear whether the term "moral rights" is intended to be used in the sense that "moral rights" is used in certain copyright systems around the world, whether these are rights that are incorporated in the rights enumerated later in Article 42, or something different.

- Article 42 delineates the "rights" of owners of traditional knowledge. This includes the right to "deny access" without prejudice to the consent that may be given by others that share the same knowledge. This should be clarified to reflect the ability of an entity to gain access from one community without having to confirm access from any other community that may claim ownership rights in that same knowledge. If disputes arise among different communities as to ownership of TK, that should not affect a good faith entity that relies on legitimate consent from a recognized entity that grants access.

- Similar concerns arise with respect to Articles 55-57, relating to Farmers' rights, which also protects "moral rights," confers rights of protection of traditional knowledge, and provides for multiple farmers to have rights to the same traditional knowledge.

- Section 2 of Article 43 establishes a procedural right to reversal of the burden of proof in civil procedures if (i) at the discretion of the judge, the allegation is "likely", or (ii) the community is deemed the "weaker party." By providing these two broad conditions, this raises concerns as to the ability of a judge or party to a suit to change the burden of proof even when the equities would dictate otherwise.

- Article 45 states that in cases of "disseminated TK", the requirement for a license for access to that TK is waived. However, there is no such reference to "disseminated TK" in Article 38-44. This raises concerns that information that is widely disseminated and not recognized as being associated directly with the culture of identified indigenous or traditional communities may nonetheless be entitled to protection as "traditional knowledge" under Articles 38-44.

- It should also be noted that the World Intellectual Property Organization (WIPO) has tasked its Intergovernmental Committee (IGC) on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore to look into issues relating to TK more broadly. The IGC has done extensive work on definitions and exchanges of national experiences with respect to TK and genetic resources. Brazil may want to consider deferring more comprehensive definitional elements of TK pending an international consensus on those matters.

Benefit-Sharing

Article 72 sets out that sharing of benefits from the use of genetic resources, their derivatives or the associated TK will be done by: (i) a contribution for intervention in the economic domain (CIDE); (ii) a contract for access and sharing benefits executed directly by the Brazilian government with a foreign institution; and (iii) a contract for access and benefit-sharing executed directly by the community providing the associated TK.

Article 76 provides that, in the case of "agrobiodiversity," sharing obligations may apply to genetic resources, their derivatives, or associated traditional knowledge even if these are

accessed prior to the effective date of the law. This retroactive application of new obligations under the law may result in unsettling existing arrangements and other uncertainties with the potential for significant negative consequences for those entities that engaged in good faith activities under existing laws. BIO urges that any such retroactive aspects of the law be removed in future drafts.

The CIDE is created in Article 90 *et seq.* and appears to be a levy similar to a tax that is calculated at a rate of either (i) one percent of the operations for commercialization in the Brazilian market; or (ii) two percent of the royalties received for licensing the patent or protected cultivar (plant variety protection). This would constitute an additional "tax" on innovation, in addition to any other regulatory fees in Brazil. This may reduce incentives to innovate in this area and would be contrary to the general principle of facilitating appropriate access to that end.

Article 84 provides that ABS contracts that are in "disaccord" with the provisions of Article 83 "shall be null and void." This seemingly rigid provision may add uncertainty as to activities undertaken pursuant to this law if a dispute arises over a particular term in an ABS agreement that is later judged to be incompatible with the law. This could put significant investment at risk for those entities engaged in these activities as the ABS contract is necessary for valid licenses and for compliance with other parts of the draft bill.

Administrative Provisions and Penalties

The bill has detailed provisions on administrative proceedings that would follow administrative infractions described in the bill. BIO has some concerns about the "precautionary measures" that may be used prior to a finding of a violation, which includes suspension of the relevant license or authorization, seizure of the product, suspension of sale of a product, or embargo of the activity. Any of these measures could cause significant harm to the intellectual property rights or greater economic interests of parties engaged in good-faith activities prior to any finding of wrongdoing.

Article 122 sets outs a number of potential penalties that can be applied, including warning, fine, revocation of licenses, forfeiture of goods, etc. In addition, it provides that goods that are forfeited because of these violations of the law would be donated, when possible, to scientific, cultural, philanthropic or educational entities and, if not donated, the seized goods would be "destroyed or sold." This raises significant concerns about unwarranted risks to proprietary information and rights of good faith researchers that may become involved in a regulatory dispute, particularly if the goods are sold into the stream of commerce.

Provisions on Intellectual Property and Patent Rights

BIO is very concerned about the patent-related provisions contained in Articles 132 and 133. These provisions provide for declaratory requirements to be made in each and every patent application that is filed with the Brazilian INPI. In addition, Article 133 requires that where a patent "has been obtained as a result of access to a genetic resources, its derivatives or associated traditional knowledge" without observing the provisions of the law, the patent "shall be declared null and void," or, in the alternative, will be subject to transfer of the ownership right in the patent to either a government entity or an indigenous community.

As a fundamental matter, patent laws are designed to promote innovation, not to regulate misconduct. It should be recalled that a patent right does not permit an inventor to engage in particular conduct. Restrictions can be placed on activities related to certain inventions to ensure compliance with other goals. For example, it is common to have regulations governing safety and efficacy of products. These restrictions, however, are generally enforced outside the patent system by separate regulatory mechanisms. While BIO supports the view that the holders of genetic resources and traditional knowledge have the ability to impose conditions on access, the rules to enforce these conditions should not put intellectual property rights at risk.

These policies subject valuable patent rights to great uncertainty which will reduce incentives for innovation and create a strong disincentive to utilization of any resources or processes that may relate to biological materials that have a connection to Brazil. This would also have the effect of reducing the generation of potential benefits to be shared with holders of genetic resources and TK in Brazil. Also, the provision is written broadly and may be read to include down-stream inventions that have resulted from some resources or knowledge that may have been accessed by third parties to introduce these resources into streams of commerce. The down-stream inventors may have no knowledge or control of these acts. Such a system would create unacceptable risks for innovative companies in developing new technologies.

In addition, these provisions raise questions of consistency with Brazil's obligations under the TRIPs Agreement, which requires that patents be made available for "any inventions … provided that they are new, involve and inventive step and are capable of industrial application." Providing that availability of patent rights depends on compliance with laws relating to procurement of genetic or biological resources and associated traditional knowledge, which may be starting materials for innovation, appears to be adding a new requirement of patentability which is not permitted by the TRIPS Agreement.

While Articles 132-133 are specific to patents, Article 121 also expressly envisions "nullifying" plant variety protection. This would create uncertainties in valuable plant variety protection rights. Further, similarly as with TRIPS, the draft bill would also raise issues of consistency with Brazil's obligations as a member of the 1978 Act of the International Convention for the Protection of New Varieties of Plants ("1978 UPOV Act"). The 1978 UPOV Act, Article 6, clearly requires that plant variety protection be granted where the plant variety complies with the four substantive requirements of Article 6(1), which are comparable to the more commonly used terms contained in the 1991 Act of novelty, uniformity, distinctness, and stability, as well as an appropriate variety denomination. Article 6(2) also clearly states that "the grant of protection may not be made subject to conditions other than those set forth above" in Article 6(1). Further, Article 10(4) of the 1978 UPOV Act clarifies that no plant variety protection right can be nullified on grounds other than the four substantive criteria, inability to provide the competent authority with reproductive or propagating material, or failure to pay fees as set forth in Article 10. The grounds for nullification set forth in the draft bill appear to fall outside these permissible grounds.

Final Provision Relating to Foreign Genetic Resources

Article 138 states that access to genetic resources originating from other countries and their derivatives must respect the rules of the corresponding countries of origin. While this is stated categorically, it is unclear what the effect of this provision is, other than to show respect for foreign laws. The provision does not indicate any means of enforcement of this provision. Further clarity would be helpful to understand what, if any, requirements may be envisioned as applying in Brazil with respect to this Article.