Third World Network

131 Jalan Macalister, 10400 Penang, MALAYSIA

Tel: 60-4-2266728/2266159
Telefax: 60-4-2264505
E-mail: twn@twnetwork.org
Website: www.twn.my

30 September 2015

Ref: SCBD/ABS/VN/jh/84620

Executive Secretary
Secretariat
Convention on Biological Diversity

Dear Sir,

Third World Network is pleased to submit the attached in response to the call for views related to Article 10 of the Nagoya Protocol.

With best wishes,

Chee Yoke Ling
Director of Programmes

Submission by Third World Network

Ref: SCBD/ABS/VN/jh/84620
Item A – Decision NP-1/10 the need for and modalities of a global multilateral benefit-sharing mechanism

A. Situations in which a bilateral approach may not be applicable:

1. Use of genetic resources and derivatives from *ex situ* biodiversity collections, wherein the origin of genetic resources cannot be determined. This may be due to inadequate or lost records, undeclared or uncertain origin upon deposit in the collection, or other factors. It must also not be possible to determine origin based on other factors, such as biology (e.g. use of a species or subtype known to be endemic in a particular country) or records kept elsewhere (e.g. scientific literature or records of collection in the country of origin indicating the source of the *ex situ* sample).

An important note: As a general rule, it should be incumbent upon *ex situ* collections to diligently attempt to determine, and maintain a record of the origin of genetic resources they hold. This includes that *ex situ* collections require depositors to provide origin information. Presently many do not. For example, it is problematic that there is no obligation to record such information in the Budapest Treaty, depositaries under which hold *ex situ* collections particularly relevant to questions of access and benefit sharing.

A GMBSM should only be potentially applicable after a verified, diligent search to identify the origin of a resource ends without success. (Requirements for the scope of such a search might be elaborated in future work.)

An indicative list of cases in which a GMBSM might be applicable include use of genetic resources from the following types of collections in cases where the origin cannot be determined:

a. Culture collections with research, industrial, veterinary, biomedical, and other purposes, including collections of microbes and higher organisms (e.g. cell cultures, preserved DNA, gametes, embryos, etc.), for holdings where country of origin information has not been maintained an cannot be determined.

b. Botanical garden collections, for example, where the original collection site of a species is inadequately described (e.g. “Amazonia” or “Indochina”), and the species is not endemic to a country.

c. Zoological collections, including aquaria, where the original collection location of a genetic resource or its ancestors cannot be determined, or where the parentage of a relevant individual or population is sufficiently complex or unknown, so that origin cannot be meaningfully ascribed.

d. Herbaria or other biodiversity reference collections that yield genetic resources (e.g. genes) in cases where the origin of the deposit cannot be determined.

e. Seed banks, i.e. collections of agricultural seeds and other propagation materials, for genetic materials not covered by the Multilateral System of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), where the origin cannot be ascertained.

2. Resources outside national jurisdictions, such as those from the international waters and seabeds, should be covered under a GMBSM. Patents and other intellectual property (IP) claims cover marine and Antarctic genetic resources, their derivatives, and use thereof. For example, claims related to some strains of the grass *Deschampsia antarctica* or the yeast *Candida antarctica.*

Much IP, for example claims on genetic materials and derivatives from marine sources (e.g. candidate pharmaceuticals from coral ecosystems) do not disclose a precise geographic origin of resources. These may or may not originate in an area outside national jurisdiction. Aside from indicating the importance of disclosure of origin when genetic resources are used and claimed in intellectual property applications, these cases indicate the need for a multilateral benefit sharing system for resources originating outside national jurisdiction.

3. Gene synthesis technology enables the recreation of increasingly complex genetic resources through the transfer and use of sequence data. Many repositories of genetic sequence data (GSD) may record the depositor's name and species of origin, but do not systematically request and record information on the geographic origin of sequences. Some of these repositories, public and private, large and small, continue to accept GSD without an identified geographic origin, and/or have large amounts of older GSD for which an origin was not recorded. This indicates an already large, and growing, amount of GSD from which genetic resources may be generated and used but which exists in the absence of sufficient information to determine the country of origin.

As is the case with *ex situ* collections, it is possible that diligent research on these sequences may yield a country of origin, and in that case, the bilateral approach may be used. In other cases, however, firm identification of the country of origin may not be possible and a GMBSM approach may be helpful to ensure equitable sharing of benefits.

The question of how to ensure fulfillment of access and benefit sharing obligations in the context of synthesis of GSD is a question that has also been raised in the Convention's Ad Hoc Technical Expert Group on Synthetic Biology as well as the World Health Organization Pandemic Influenza Preparedness Framework, and in discussions regarding the ITPGRFA Multilateral System.

4. A specific issue related to gene sequencing and synthesis that may be considered in the context of a possible GMBSM is the use of homologous genes from different accessions than those in which a salient beneficial / commercial characteristic(s) is (are) identified. That is, when a genetic resource of a particular origin provides the key insight or discovery for a commercial application, but the user instead sources the genetic resource as a homolog of a different origin. In such cases, the benefit might be discovered through use of one genetic resource, but another, homologous, genetic resource might be the one used in a commercial application.

For example, if a disease resistance gene is found in a wild tomato accession from one country, it may be possible to find and use a homologous gene in an accession from another country. In choosing to use the second genetic resource, a claimant might assert that no benefit sharing is due to the first country, even though the genetic resource from the first country was the source of the key insight.

While in this scenario the bilateral approach may frequently prove to be sufficient, in complex cases or those where disagreements exist, a GMBSM may possibly be a useful approach.

B. The areas for further examination as identified in Paragraph 23 of the report of the Expert Meeting on Article 10 of the Nagoya Protocol:

(a) Whether or not there is a need for a GMBSM

Over 20 years experience with the Convention on Biological Diversity indicates there are resources not well covered by existing approaches. While the Protocol is on a path to addressing many cases where application of the bilateral model may be improved, the GMBSM can address other cases where the bilateral model has not proven effective.

(b) Whether there is sufficient experience with implementation of the Protocol to determine whether such a need exists;

There is sufficient experience with implementation of the bilateral model to know that there are genetic resources and situations that it does not adequately cover, hence the need for a multilateral approach for those resources and situations, and possibly others as agreed by Parties and indigenous peoples and local communities.

(c) Whether the utilization of genetic resources without PIC would entail benefit-sharing obligations that could be met through a GMBSM;

Of course PIC must be obtained whenever possible. A GMBSM could be used to address benefit sharing obligations in some, but not all, cases where genetic resources are utilized without PIC.

(d) Whether a Party's decision not to require PIC (e.g. under Art. 6(1)) or to waive PIC (e.g. under Art. 8) can constitute situations for which it is not possible to grant or obtain PIC in the context of Article 10;

Since benefit sharing is triggered by utilization these situations under Article 6(1) and Article 8 could fall under Article 10.

(e) Whether benefit-sharing requirements are waived when a Party has decided not to require PIC or has waived PIC;

A GMBSM could be the default benefit sharing mechanism for cases where a Party has not required / waived PIC, except where the Party expressly disavows use of the GMBSM for those particular resources.

(f) Whether there is no requirement for benefit-sharing when mutually agreed terms are not required or have not been established;

There should not be an automatic exclusion of benefit sharing unless there is express waiver of benefit sharing.

(g) Whether the absence of ABS legislation or regulatory requirements in a Party due to lack of capacity or lack of governance means that PIC for access to genetic resources is not required and there is no obligation to share benefits. In the context of Article 10, whether such instances would constitute situations for which it is not possible to grant or obtain PIC;

In principle, in the absence of legislation it should still be incumbent on the user to comply with the CBD/Nagoya Protocol obligations.

For traditional knowledge, the obligation is absolute. If (a) holder(s) of the TK exists, PIC is necessary.

On genetic resources without TK, if the user makes a really good faith effort and just cannot get a response from the provider, perhaps there should be a way for the user to share benefits through a GMBSM. Operationalizing this notion, however, appears difficult, because it would be necessary to document and evaluate the user's effort to obtain PIC and independently determine that it was earnest and sufficiently serious to justify going to the GMBSM rather than continuing efforts to obtain PIC from the provider. On the other hand, to not make the effort would frustrate the CBD/Nagoya Protocol objectives.

(h) Whether the absence of measures in a Party to implement Article 7 means that PIC for access to traditional knowledge associated with genetic resources is not required and there is no obligation to share benefits. In the context of Article 10, whether such instances would constitute situations for which it is not possible to grant or obtain PIC;

As observed in response to (g), the obligation to obtain PIC for TK and share benefits for use of TK should be absolute, so long as holders of the TK exist (which is essentially in every case).

(i) Whether a genetic resource that is found in more than one Party constitutes a transboundary situation in the language of Article 10 (even if it is possible to identify the source of the genetic resource) or whether the bilateral approach should be applied if a genetic resource is found in more than one Party and it is possible to identify the source of the genetic resource. In the latter case, whether the bilateral approach or a GMBSM could be fair and equitable;

(j) Whether traditional knowledge associated with a genetic resource that is found in more than one Party constitutes a transboundary situation in the language of Article 10 (even if it is possible to identify the source of the genetic resource) or whether the bilateral approach should be applied if traditional knowledge associated with a genetic resource is found in more than one Party and it is possible to identify the source of the genetic resource. In the latter case, whether the bilateral approach or a GMBSM could be fair and equitable;

In line with the position that obtaining PIC and MAT for use of TK is obligatory in every case, a transboundary TK situation does not obviate the need to obtain PIC and MAT. However, if the relevant ILCs are agreeable to the proposition, it is possible that the GMBSM could be an appropriate benefit sharing mechanism. There is need for greater elaboration and more detailed consideration.

(k) Whether Article 11 is sufficient to respond to transboundary situations;

Article 11 can and should be applied to cases of transboundary TK, but alone is not sufficient. Further, the existence of a GMBSM might be useful for indigenous peoples and local communities and Parties in addressing transboundary situations successfully.

(l) Whether a GMBSM should address the sharing of benefits arising from the utilization of:

(i) Genetic resources in *ex situ* collections in relation to transboundary situations or for which it is not possible to grant or obtain PIC;

Yes, emphatically. This is discussed in detail at the outset of this submission.

(ii) Genetic resources in *ex situ* collections used for purposes for which PIC was not granted and for which it is not possible to grant or obtain PIC;

Yes, bearing in mind that there must be a diligent effort by the user – perhaps meeting an international standard to be developed – to ensure that it is, in fact, not possible to grant or obtain PIC.

(iii) Genetic resources in areas beyond national jurisdiction or whether this issue falls within the competence of the United Nations General Assembly;

A GMBSM would have principles, standards and modalities that are not available at the UNGA. Coordination with processes under the UNGA would be needed and jurisdictional issues will need to be examined. At

this stage there should be no automatic exclusion of genetic resources in areas beyond national jurisdiction from a GMBSM.

(iv) Genetic resources in the Antarctic Treaty area;

As in (iii) coordination efforts should be undertaken to explore synergies rather than exclude at this stage.

(v) Traditional knowledge associated with genetic resources that is publicly available and where the holders of such traditional knowledge cannot be identified or for which it is not possible to grant or obtain PIC.

Possibly, but these cases should be few and far between. In general the topic deserves more discussion, particularly with indigenous peoples and local communities, but it should be understood from the outset that a very high standard of effort to obtain PIC must be met before any TK would be considered "orphaned".

There are also situations where the holders of such traditional knowledge cannot be identified but the body of TK is a national heritage and even codified, as raised by CBD Parties including China, India and Thailand during the Nagoya Protocol negotiations. In these situations the country of origin is identifiable and so would not fall within a GMBSM.