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EXPERT GROUP MEETING ON ARTICLE 10 OF THE NAGOYA PROTOCOL ON ACCESS AND BENEFIT-SHARING Montreal, Canada, 1-3 February 2016 Item 3 of the provisional agenda\*

#### SYNTHESIS OF VIEWS PURSUANT TO DECISION NP-1/10

Note by the Executive Secretary

#### I. INTRODUCTION

1. Article 10 of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization reads as follows:

Parties shall consider the need for and modalities of a global multilateral benefit-sharing mechanism to address the fair and equitable sharing of benefits derived from the utilization of genetic resources and traditional knowledge associated with genetic resources that occur in transboundary situations or for which it is not possible to grant or obtain prior informed consent. The benefits shared by users of genetic resources and traditional knowledge associated with genetic resources through this mechanism shall be used to support the conservation of biological diversity and the sustainable use of its components globally.

- 2. An expert meeting on Article 10 was held in September 2013. Among other things, the 2013 Expert Meeting identified a number of areas of common understanding as well as areas for further examination. These are reflected in, respectively, paragraphs 21 and 23 of the report of the meeting (UNEP/CBD/ABSEM-A10/1/3) which has also been made available as an information document for the present meeting.
- 3. With the entry into force of the Nagoya Protocol on 12 October 2014, the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol (COP-MOP) was held in Pyeongchang, Republic of Korea from 13 to 17 October 2014. The meeting adopted decision NP-1/10 on the need for and modalities of a global multilateral benefit-sharing mechanism.
- 4. In paragraph 1 of the decision, Parties, other Governments, international organizations, indigenous and local communities and relevant stakeholders were invited to submit to the Executive Secretary views on: (a) situations which might support the need for a global multilateral benefit-sharing mechanism (GMBSM) that were not covered under the bilateral approach; (b) possible modalities for a global multilateral benefit-sharing mechanism as well as information regarding the implications of different scenarios for these modalities; and (c) the areas requiring further consideration as identified in paragraph 23 of the report of the 2013 expert meeting on this matter. The paragraph also provided that such views could include, where available, reflections on any experiences gained working towards the implementation of the Nagoya Protocol.

<sup>\*</sup> UNEP/CBD/ABS/A10-EM/2016/1/1.

- 5. In paragraph 2 of the decision, the Executive Secretary was requested:
- (a) To prepare a synthesis of the views submitted in accordance with paragraph 1 of the decision;
- (b) To commission a study on: (i) the experiences gained with the development and implementation of the Nagoya Protocol and other multilateral mechanisms; and (ii) the potential relevance of ongoing work undertaken by other processes, including case studies in relation to *ex situ* and *in situ* genetic resources, traditional knowledge associated with genetic resources, and transboundary situations;
- (c) To convene a meeting of a regionally balanced expert group to review the synthesis of views and the study referred to in subparagraphs (a) and (b) above, with a view to reaching a common understanding on the areas requiring further examination, as identified in paragraph 23 of the report of the 2013 Expert Meeting, and submit the outcomes of its work for consideration by COP-MOP at its second meeting.
- 6. By notification 2015-049 of 5 May 2015,<sup>1</sup> the Executive Secretary invited the submission of views pursuant to paragraph 1 of decision NP-1/10. Views were received from five Parties to the Protocol: the European Union; India; Mexico; Norway; and South Africa; views were also received from seven non-Parties: Australia; Brazil; Costa Rica; Japan; New Zealand; Nigeria; and the United States of America. In addition, submissions were received from five organizations: the Centre for Cellular and Molecular Biology (India); the International Chamber of Commerce (ICC); the IUCN Specialist Group on ABS and Related Issues;<sup>2</sup> the Japan Bioindustry Association (JBA); and Third World Network (TWN). The full text of the submissions has been made available online.<sup>3</sup>
- 7. The Executive Secretary also commissioned the study requested in paragraph 2(b) of decision NP-1/10. That study has been issued as UNEP/CBD/ABS/A10/EM/2016/1/2.
- 8. Section II of the present document summarizes the information that was submitted on experiences gained working towards implementation of the Nagoya Protocol. Section III synthesizes the views submitted on the three different areas identified in paragraph 1 of decision NP-1/10. Section IV identifies some cross-cutting elements that were raised across different parts of the submissions which may be a basis for discussion by the Expert Meeting.

### II. EXPERIENCES GAINED WORKING TOWARDS IMPLEMENTATION OF THE NAGOYA PROTOCOL

- 9. One element on which views were invited was "reflections on any experiences gained working towards the implementation of the Nagoya Protocol". This section summarizes the information that was provided in response.
- 10. Australia submitted information on its measures for regulating access to genetic resources and benefit-sharing (ABS). They described how its system was introduced in 2005 under Part 8A of the country's Environment Protection and Biodiversity Conservation Regulation 2000. They indicated that the system was explicitly designed to facilitate access and encourage research, which is done through a simple, legally binding declaration that includes an obligation to renegotiate terms should the user seek to commercialize the resource or the results of the research. They described how the country's approach establishes and maintains a beneficial relationship between user and provider. They also described how, in implementing their measures, they had found that users had increasingly insisted on documented evidence of both prior informed consent (PIC) and mutually agreed terms (MAT) to legally underpin their work. Australia indicated that having this legal certainty leads to improved practices and operating standards of

<sup>&</sup>lt;sup>1</sup> https://www.cbd.int/doc/notifications/2015/ntf-2015-049-abs-en.pdf.

<sup>&</sup>lt;sup>2</sup> The IUCN submission included the collective submission of the Global Specialist Group on ABS and Related Issues as well as an annex containing the views of three members of the Group.

<sup>&</sup>lt;sup>3</sup> See https://www.cbd.int/abs/submissions.shtml.

users of genetic resources and expressed the view that the Protocol provides the necessary framework for establishing such standards and change.

- 11. Brazil shared its experience regarding responsibility for monetary benefit-sharing. They explained that they had found it detrimental to place benefit-sharing obligations on the whole production chain as it created a heavy and ineffective system that might harm the development of scientific knowledge and production, reducing benefits. In this light, the country's new ABS system will focus on the collection of benefits in the final link in the chain of production: Law 13.123/2015 establishes that benefits will be collected from the profits gained with the commercialization of a final product. In the case of genetic resources for food and agriculture, benefits will be collected from the commercialization of reproductive materials.
- 12. *Mexico* provided information on its national discussions on measures to implement the Protocol. They indicated that they intend to establish a National Fund for the Conservation and Sustainable Use of Genetic Resources. The Fund will cover genetic resources and associated traditional knowledge that are widely distributed and diffuse in nature as well as those in which the original supplier of the resource cannot be identified. In these cases, access agreements will be entered into by the State (through the relevant competent authority) and the user. Benefits arising from the utilization of these resources and traditional knowledge will be deposited in the Fund and used for the purposes of conservation of biodiversity and sustainable use of its components. They noted that the main point of discussion is the mechanism for benefit-sharing and the allocation of resources towards the conservation of biodiversity and the sustainable use of its components.
- 13. *Norway* provided information on the Norwegian Nature Diversity Act 61 A, which states that:

Authorities shall facilitate respect and safeguarding of the interests of indigenous peoples and local communities when traditional knowledge associated with genetic material that is developed and preserved by indigenous and local communities is accessed and utilized.

The King may issue a regulation stipulating that access to and utilization of traditional knowledge associated with genetic material requires prior informed consent from the indigenous peoples or local community, including rules on sanctions and remedies against misappropriation of such traditional knowledge associated with genetic resources. This could also be applied to traditional knowledge associated with genetic material that is developed, transferred and preserved by indigenous peoples and local communities in another state, provided that the national legislation of that state requires prior informed consent for access to or utilization of traditional knowledge associated with genetic material (courtesy translation).

- 14. They explained that, in their national context, a request for PIC will only have relevance for actions in the country and not in neighbouring countries even if the same traditional knowledge should exist there.
- 15. Norway also referred to a reflection meeting on Article 10 of the Protocol that was held in the country in March 2011.<sup>4</sup>
- 16. South Africa noted that many of its medicinal plants also occur in the northern part of Africa, and are used traditionally by other cultural groups or the same cultural groups across borders (e.g. San and Hoodia). They expressed the view that bioprospecting of the country's plants, animals and microbes and associated traditional knowledge will likely often lead to the need for a multilateral benefit-sharing mechanism, whether they are accessed, for example, in Namibia, Kenya or South Africa. They noted that other key species, such as Aloe ferox and Pelargonium sidoides, also occur in Lesotho, a country neighbouring South Africa. Although a bilateral approach may be adopted for Lesotho, a multilateral scenario will often arise on other species (e.g. baobab). The country feels that a GMBSM will be essential for it as the mechanism is one of the most promising routes through which benefits will be returned by

<sup>&</sup>lt;sup>4</sup> The report of the meeting is available at http://www.fni.no/doc&pdf/FNI-R1011.pdf.

international businesses. South Africa views ongoing engagement on a GMBSM as being beneficial to its current plans to amend its ABS legislation.

#### III. SYNTHESIS OF VIEWS

17. This section synthesizes the views that were submitted in line with the three areas identified in paragraph 1 of decision NP-1/10. In many instances, the submissions took different approaches to expressing views on the areas. In the subsections that follow, an attempt has been made to identify common ideas or conclusions that were expressed in the submissions. These are indicated in italics. The explanations or elaborations supporting the ideas are summarized in bulleted lists beneath each idea. Footnotes indicating the sources of the ideas and views are provided so that the reader may refer to the original submissions for further information.

### A. Situations which may support the need for a global multilateral benefit-sharing mechanism that are not covered under the bilateral approach

- 18. This first area on which views were invited in paragraph 1 of decision NP-1/10 is very similar to the first area for further examination as identified in paragraph 23 of the 2013 expert meeting, i.e. whether or not there is a need for a GMBSM. Accordingly, the synthesis that follows incorporates the information submitted under both points. Furthermore, many of the views on whether or not there is a need for a GMBSM were similar to or the same as some of the others areas for further consideration as identified in the report of the 2013 expert meeting. Accordingly, rather than repeating these views in different parts of the document, views have been synthesized according to the area for further consideration to which they correspond. The views on whether or not there is a need for a GMBSM largely correspond to situations not addressed elsewhere in the document.
- 19. A GMBSM may be needed where the origin of the genetic resource or associated traditional knowledge is unknown or unidentifiable:
- (a) A GMBSM may be needed to address instances where the country of origin of the genetic resource or associated traditional knowledge is unknown or unidentifiable even after reasonable efforts have been made.<sup>5</sup> Different submissions suggested specific examples of when this might occur:
  - Where it is impossible to identify an original supplier and where the genetic resource or associated traditional knowledge have potential commercial use;<sup>6</sup>
  - For genetic resources in the public domain for which the source cannot be traced to individuals, organizations or countries;<sup>7</sup>
  - For databases or repositories of gene sequence data;<sup>8</sup>
  - For migratory species;<sup>9</sup>
    - Benefits collected in such a scenario could be directed to transboundary cooperation under Article 11 of the Protocol, particularly in circumstances where there are competent regional organizations;<sup>10</sup>
  - For microorganisms and other compounds;<sup>11</sup>
- (b) From this perspective, a GMBSM would have limited application<sup>12</sup> and would only cover cases that cannot be addressed by the bilateral approach to ABS that is the focus of the Nagoya Protocol;<sup>13</sup>

<sup>&</sup>lt;sup>5</sup> India, Brazil.

<sup>&</sup>lt;sup>6</sup> Mexico, South Africa.

<sup>&</sup>lt;sup>7</sup> Nigeria.

<sup>&</sup>lt;sup>8</sup> Costa Rica, IUCN, TWN.

<sup>&</sup>lt;sup>9</sup> Brazil.

<sup>&</sup>lt;sup>10</sup> Brazil.

<sup>&</sup>lt;sup>11</sup> IUCN.

- (c) The question whether it is possible to identify the origin of a genetic resource or associated traditional knowledge points to the need for the development of data management systems and traceability arrangements as these are essential for the effective functioning of ABS systems;
  - There is existing experience with the development of traceability tools and catalogues of organisms, including microorganisms. The use of such tools in the context of the ABS Clearing-House might be of great help in the implementation of the Protocol.<sup>14</sup>
- 20. Other situations that may support the need for a GMBSM:
  - Genetic resources for which it is difficult to determine who has the right to grant PIC due to the natural distribution or diversification of these species as a result of being naturalized for many years;
    - O Questions related to (i) the origin of a resource versus its domestication in different countries, and (ii) where the centre of diversity is different from the centre of origin of the resource may need further consideration;<sup>15</sup>
  - A GMBSM is needed to address traditional knowledge associated with genetic resources that is shared between neighbouring or nearby countries or communities; 16
    - O Indigenous peoples are not aware of political borders, which poses a challenge to protecting their traditional knowledge and ensuring fair and equitable benefit-sharing. In these cases, collaboration among the countries involved should be strengthened, and regional mechanisms could be established and share experiences with a GMBSM.<sup>17</sup>
    - Genetic resources of species of common interest for their key role from an environmental and food perspective; 18
    - For benefit-sharing from material in the Multilateral System of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) where access to that material is being provided to a non-Party to the Treaty; 19
    - The use of homologous genes from accessions different from those in which the salient beneficial or commercial characteristics are identified;
      - O This may occur when a genetic resource of a particular origin provides the key insight for a commercial application but the user sources another homologous genetic resource from a different origin for use in a commercial application. The bilateral approach may frequently be sufficient in such a scenario, but, in complex cases or where disagreements arise, a GMBSM may be useful;<sup>20</sup>
    - A GMBSM would be a way to eliminate rather than exacerbate conflicts. If there is no GMBSM, then direct legal action will be the only way for providers to determine their rights. In this light, a GMBSM would be a way to avoid the cost and acrimony of such an approach.<sup>21</sup>

<sup>13</sup> Costa Rica.

<sup>&</sup>lt;sup>12</sup> India.

<sup>&</sup>lt;sup>14</sup> Brazil.

<sup>&</sup>lt;sup>15</sup> Mexico.

<sup>&</sup>lt;sup>16</sup> Mexico, Costa Rica, Nigeria, IUCN.

<sup>&</sup>lt;sup>17</sup> Costa Rica.

<sup>&</sup>lt;sup>18</sup> Mexico.

<sup>&</sup>lt;sup>19</sup> Mexico.

<sup>&</sup>lt;sup>20</sup> TWN.

<sup>&</sup>lt;sup>21</sup> IUCN.

- 21. There is no need for a GMBSM:<sup>22</sup>
  - The circumstances contemplated in Article 10 can be adequately addressed through the implementation of other provisions of the Nagoya Protocol and other existing instruments;<sup>23</sup>
  - Many of the areas for further consideration identified in paragraph 23 of the 2013 Expert
    Meeting do not fit the situations in Article 10 of the Protocol (i.e. transboundary
    situations and where it is not possible to grant or obtain prior informed consent) and so
    would not warrant the development of a GMBSM.<sup>24</sup>
- 22. Situations in which a GMBSM would apply remain unclear:
  - The vast majority of ABS situations would be subject to national measures, particularly in the light of Articles 3 and 15 of the Protocol. If a GMBSM is established, it should only be applicable where appropriate national legislation or agreed bilateral/multilateral approaches (e.g. agreements in place across countries) do not exist;<sup>25</sup>
  - More clarity is needed on the gaps that should be regulated, practices that should be promoted and needs that must be met and could be applied in exceptional cases that are not covered by the bilateral approach;<sup>26</sup>
  - Identifying gaps that are not covered under existing mechanisms would build a discussion based on shared understanding among stakeholders regarding the need for a GMBSM.<sup>27</sup>

- Article 10 is a procedural obligation that requires consideration of the need for such a
  mechanism. The mere existence of the Article does not presuppose the need for a
  mechanism.<sup>28</sup>
- B. Possible modalities for a global multilateral benefit-sharing mechanism as well as information regarding the implications of different scenarios for these modalities
- 24. Both monetary and non-monetary benefits should be shared through a GMBSM:
  - Article 10 refers to a "mechanism" for benefit-sharing, a term which indicates an intent to acquire and distribute monetary and non-monetary benefits;<sup>29</sup>
  - The Annex to the Nagoya Protocol includes examples of both monetary and non-monetary benefits, so a GMBSM would also need to include both types of benefits.<sup>30</sup>
- 25. Purpose to which benefits shared through a GMBSM should be put:
  - Benefits shared through a GMBSM should support the conservation of biodiversity and the sustainable use of its components;<sup>31</sup>
    - o Priority for benefit-sharing through a GMBSM should be given to support *in situ* conservation measures in the biomes and ecosystems where the genetic resource

<sup>&</sup>lt;sup>22</sup> United States, ICC, JBA.

<sup>&</sup>lt;sup>23</sup> United States.

<sup>&</sup>lt;sup>24</sup> United States.

<sup>&</sup>lt;sup>25</sup> Australia.

<sup>&</sup>lt;sup>26</sup> Costa Rica.

<sup>&</sup>lt;sup>27</sup> Japan.

<sup>&</sup>lt;sup>28</sup> JBA.

<sup>&</sup>lt;sup>29</sup> Mexico.

<sup>&</sup>lt;sup>30</sup> Brazil.

<sup>&</sup>lt;sup>31</sup> Mexico, Costa Rica, Japan, Nigeria.

- might be found even though it is not possible to determine the country of origin of that resource as this would support the link between ABS and the conservation of biodiversity on the ground;<sup>32</sup>
- o Benefits to be shared through a GMBSM should be primarily accessible to megadiverse countries, developing countries and small island countries that are part of the multilateral mechanism.<sup>33</sup>
- 26. *A GMBSM and the bilateral approach.* Many submissions raised interrelated points regarding how a GMBSM (and consideration thereof) should complement, support and be in line with the Convention on Biological Diversity and the Nagoya Protocol, including the principle of State sovereignty over genetic resources;<sup>34</sup> that it must respect the bilateral nature of the Protocol and would need to be an additional tool, complementary to bilateral ABS;<sup>35</sup> and that a GMBSM should only be used in exceptional cases that cannot be addressed by the bilateral approach.<sup>36</sup>
  - This is in line with one of the areas of common understanding that was identified by the 2013 Expert Meeting, namely that a "GMBSM is not intended to replace the bilateral nature of the Nagoya Protocol but to supplement it";<sup>37</sup>
  - The spirit of the Protocol favours bilateral and regional approaches to ABS over multilateral approaches. This is a way to ensure that measures related to the conservation and sustainable use of biodiversity are taken as close as possible to implementation on the ground. A GMBSM should not create disincentives to the establishment of national frameworks by Parties;<sup>38</sup>
  - A GMBSM would need to be consistent with other aspects of the Convention on Biological Diversity and Nagoya Protocol including the ABS Clearing-House;<sup>39</sup>
  - Consideration is required of how a GMBSM could apply without changing existing national ABS requirements for PIC and MAT.<sup>40</sup>
- 27. Experiences from other multilateral benefit-sharing mechanisms. The importance of experiences from other multilateral benefit-sharing mechanisms, such as the ITPGRFA and its Funding Strategy, was highlighted. However, it was also pointed out that:
  - Not all countries have sufficient experience in the implementation of other multilateral benefit-sharing mechanisms; 42
  - Results to date with the Multilateral System of the ITPGRFA are insufficient to assess its effectiveness;<sup>43</sup>
  - Resources in the Benefit-sharing Fund of the Treaty have been provided through voluntary contributions rather than as a result of benefit-sharing under the terms of the Standard Material Transfer Agreement. 44

<sup>33</sup> Costa Rica.

<sup>&</sup>lt;sup>32</sup> Brazil.

<sup>34</sup> Mexico, Brazil, Japan, Nigeria.

<sup>&</sup>lt;sup>35</sup> Norway.

<sup>&</sup>lt;sup>36</sup> Costa Rica.

<sup>&</sup>lt;sup>37</sup> Japan.

<sup>&</sup>lt;sup>38</sup> Brazil.

<sup>&</sup>lt;sup>39</sup> Mexico, Costa Rica.

<sup>&</sup>lt;sup>40</sup> Australia.

<sup>&</sup>lt;sup>41</sup> India, Mexico, Norway, Costa Rica.

<sup>&</sup>lt;sup>42</sup> Costa Rica.

<sup>&</sup>lt;sup>43</sup> Costa Rica.

<sup>44</sup> Mexico

- 28. Other possible roles for a GMBSM. Some submissions identified other possible roles for a GMBSM:
- (a) It could play a role in tracking and monitoring utilization of genetic resources, including new uses of genetic resources; 45
  - (b) It could encourage the exchange of experiences and lessons learned; 46
- (c) It could include a match-making facility between non-monetary benefits provided to the mechanism and projects seeking use of such benefits;<sup>47</sup>
- (d) It could be oriented to work in collaboration with existing bilateral arrangements and regional organizations to foster cooperation on ABS.
  - Suggestions of regional organizations with which there could be collaboration were the Amazon Cooperation Treaty Organization, Mercosur, the Union of South American Nations (UNASUR) and the Caribbean Biodiversity Fund;<sup>48</sup>
  - For non-monetary benefits, a GMBSM could serve to foster bilateral, regional and multilateral cooperation, including capacity-building and technology transfer;<sup>49</sup>
  - There could be a multi-level modality including regional or subregional mechanisms, which should apply primarily to resources from areas outside national ABS systems determined on the basis of the resource's regional distribution;<sup>50</sup>
  - The possibility should be offered for nearby countries to establish smaller regional mechanisms, for example between those who share traditional knowledge, so that the benefits are not diluted and go to countries that are trying to conserve genetic resources of biodiversity and associated knowledge.<sup>51</sup>
- 29. Other elements to be considered in a GMBSM. A number of submissions raised other elements that would need to be considered regarding the modality of a GMBSM:
  - (a) Objectives would need to be analysed in the context of the Protocol:<sup>52</sup>
- (b) The scope of a mechanism i.e. the situations that would be covered by a GMBSM would need to be analysed in the context of the Protocol; $^{53}$ 
  - The importance of legal certainty and transparency for implementation and application of the Nagoya Protocol was noted;<sup>54</sup>
  - (c) The nature of a GMBSM;<sup>55</sup>
    - Parties have not yet reached any conclusion on whether a GMBSM would be compulsory or voluntary;<sup>56</sup>

<sup>46</sup> Mexico, Costa Rica, Nigeria.

<sup>48</sup> Brazil, IUCN.

<sup>&</sup>lt;sup>45</sup> Mexico, Nigeria.

<sup>&</sup>lt;sup>47</sup> Brazil.

<sup>&</sup>lt;sup>49</sup> Brazil.

<sup>&</sup>lt;sup>50</sup> IUCN.

<sup>&</sup>lt;sup>51</sup> Costa Rica.

<sup>&</sup>lt;sup>52</sup> Mexico, Nigeria.

<sup>&</sup>lt;sup>53</sup> Mexico, Nigeria.

<sup>&</sup>lt;sup>54</sup> Mexico.

<sup>&</sup>lt;sup>55</sup> India, Nigeria.

<sup>&</sup>lt;sup>56</sup> Japan.

- Where a GMBSM applies, participation (including reporting and benefit-sharing) should be mandatory;<sup>57</sup>
- How to have fair and equitable benefit-sharing through a GMBSM;<sup>58</sup> (d)
- Monitoring the utilization of genetic resources covered by Article 10:<sup>59</sup> (e)
- Funding source;<sup>60</sup> (f)
- Administrative issues such as institutional arrangements; administration and (g) administrative costs; decision-making; and monitoring of utilization of funds;<sup>61</sup>
- The promotion of clear rules and procedures and flexibility for Article 10 situations would be important.6
- 30. Discussion of modalities is premature:
  - The need for a GMBSM needs to be determined first before possible modalities can be discussed:63
    - The dimensions of the situations that could be covered by a GMBSM need to be agreed upon before it is possible to discuss and design a mechanism.<sup>64</sup>

- A GMBSM should not impose a burden only on users of genetic resources and associated traditional knowledge. Rather, the mechanism should bring "win-win" effects to both users and providers, and support the conservation of biological diversity and the sustainable use of its components in the most cost-effective manner. 65
- If no modality can be designed that will operate legally in all countries, then it is not meaningful to discuss the need for such a mechanism or the fact that the transboundary loophole may be preventing functional ABS implementation.<sup>66</sup>
- A GMBSM needs to create incentives for users to comply with national requirements and for all countries to adopt ABS measures.<sup>67</sup>
- 32. Proposal for a global modality through the economic concept of "bounded openness". Some contributors to an organization's submission proposed a modality based on an understanding of genetic resources as "natural information". The modality consists of 10 steps:
- A negotiation of royalty rates between user and provider countries based on a matrix of relevant characteristics of utilization:
  - Establishment of a global fund to hold royalties in escrow; (b)
  - (c) Disclosure of utilization in the transmittal of applications for intellectual property;

<sup>&</sup>lt;sup>57</sup> IUCN.

<sup>&</sup>lt;sup>58</sup> Mexico, Costa Rica.

<sup>&</sup>lt;sup>59</sup> Mexico.

<sup>&</sup>lt;sup>60</sup> India.

<sup>&</sup>lt;sup>61</sup> India.

<sup>&</sup>lt;sup>62</sup> Japan.

<sup>&</sup>lt;sup>63</sup> India, ICC, JBA.

<sup>&</sup>lt;sup>64</sup> Mexico, IUCN.

<sup>65</sup> Japan.

<sup>66</sup> IUCN.

<sup>&</sup>lt;sup>67</sup> IUCN.

- Recognition of need to address the redundancy of natural information at different taxa as (d) an empirical question;
- Determination of the diffusion of natural information across taxa, and recognition of the costs of that determination as a transaction cost that is subject to change and that will decrease as the technology and information resources involved develop;
- Determination of the geographic distribution of the information dispersed across taxa and recognition of the costs of that determination as a transaction cost that is subject to change and that will decrease as the technology and information resources involved develop;
- Monitoring and tracking of patents which have disclosed natural information and their (g) commercialization;
  - (h) Collection of revenues by the global fund;
- Allocation to appropriate accounts, reimbursement of the infrastructure costs required in (i) order to perform steps (e) through (h), to be distributed when the patents involved have expired;
- Dispersal of royalties to the identified countries of origin, proportional to their relative holdings of the natural information, when the revenues collected under step (h) exceed the costs allocated under step (i).
- The submission also included elaboration on the proposed modality as well as challenges and 33. criticisms of it.68

#### C. Areas requiring further consideration as identified in paragraph 23 of the report of the Expert Meeting on Article 10 of the Nagoya Protocol

- Whether or not there is a need for a GMBSM
- 34. This area is addressed under section (a) above.
  - Whether there is sufficient experience with implementation of the Protocol to determine whether such a need exists
- 35. Experience with the Protocol is insufficient to determine whether there is a need for a GMBSM:
  - More experience on how the Protocol will work in practice needs to be gained to allow a realistic assessment of the need for, and potential modalities of, establishing such a tool in addition to the bilateral system on which the Nagova Protocol is based:69
  - No specific instance has been convincingly put forward that demonstrates an urgent requirement for a GMBSM;<sup>70</sup>
  - The lack of information in the ABS Clearing-House since the entry into force of the Protocol makes it difficult to conclude that there is sufficient experience;<sup>71</sup>
  - Considerable efforts are currently being made by Parties and stakeholders to implement the Protocol and national implementation should be prioritized rather than considering additional mechanisms. Efforts to consider adding another layer of complexity, such as a GMBSM, to the international ABS framework are likely to disperse the energy and resources available for the implementation of the Protocol at the national level.<sup>72</sup>

<sup>&</sup>lt;sup>68</sup> IUCN.

<sup>&</sup>lt;sup>69</sup> European Union, New Zealand, United States.

<sup>&</sup>lt;sup>70</sup> New Zealand, ICC.

<sup>&</sup>lt;sup>71</sup> Japan, ICC.

<sup>&</sup>lt;sup>72</sup> ICC.

- 36. The question is not determinative, and work on a GMBSM could begin while more information is being gathered:
  - Implementation of the Nagoya Protocol and learning from this experience is an ongoing process which may go hand-in-hand with discussions on potential situations that may support the creation of a GMBSM and the possible modalities of such a mechanism;<sup>73</sup>
  - Due to the complexities of access and PIC relating to genetic resources and associated traditional knowledge, a GMBSM would be used extensively. The issue of whether or not there is sufficient experience should not be a focus of discussion until the mechanism is piloted.<sup>74</sup>
  - What is central is whether the bilateral nature of the Protocol will be effective across borders or where it is not possible to grant or obtain PIC.<sup>75</sup>
  - As experience with the implementation of the Protocol is still in its early stages, it would be wise to start the work on a GMBSM in a pilot phase, allowing Parties to gather the knowledge needed for its future enhancement.<sup>76</sup>
- 37. *More information is needed to inform further discussions:* 
  - Areas where more information is needed are:
    - Experience regarding implementation of the Nagoya Protocol, particularly in terms of the number current ABS cases and those that have generated benefits;
    - o National experience on the issues of widely distributed genetic resources and associated traditional knowledge and lessons learned on the resolution of these situations;
    - An analysis of internationally recognized certificates of compliance to verify:
      - Whether the resources they address have a wide distribution or are transboundary;
      - Whether the genetic resources were accessed from in situ or ex situ conditions;
      - Whether they include associated traditional knowledge obtained in situ conditions or from the public domain.<sup>77</sup>
  - Consideration of relevant case studies would be helpful.<sup>78</sup>
- 38. There has been extensive experience with ABS systems to date and it shows that a GMBSM would be limited to exceptional cases that cannot be addressed by the bilateral approach:
  - Some countries have strong track records in implementing ABS systems and successfully granting access through PIC and the establishment of MAT through bilateral agreements.
    - The bilateral approach could be monitored to identify recommendations and comparative studies and provide lessons learned for its strengthening. The existence of formal mechanisms about the use of genetic resources contributes to a better distribution of the benefits derived from their use.
    - The non-Party pointed to its own experience since 1998 in regulating ABS regarding genetic and biochemical resources *in situ* and *ex situ* through which it has granted more

<sup>74</sup> South Africa.

<sup>&</sup>lt;sup>73</sup> India.

<sup>&</sup>lt;sup>75</sup> Norway.

<sup>&</sup>lt;sup>76</sup> Brazil.

<sup>77</sup> Mexico.

<sup>&</sup>lt;sup>78</sup> New Zealand.

than 420 access licenses using the bilateral approach including the signing of PIC and  ${\rm MAT}^{79}$ 

- 39. Experience with ABS systems to date shows that the bilateral approach is insufficient
  - With over 20 years of experience with the implementation of the bilateral model under the CBD, there is sufficient experience to know that there are genetic resources and situations that are not well covered by existing approaches and that could be addressed by a GMBSM. 80
    - The disparity in implementation of the Protocol between countries that are primarily access providers and those that have mostly users under their jurisdiction suggests that it is unlikely that the loophole of transboundary resources can be resolved by relying on comprehensive implementation.<sup>81</sup>
- (iii) Whether the utilization of genetic resources without PIC would entail benefit-sharing obligations that could be met through a GMBSM
- 40. This is a situation to be addressed by measures for non-compliance, not through a GMBSM:<sup>82</sup>
  - Where genetic resources are utilized without obtaining PIC from a legal regime that mandates the same, the activity is a violation of the legal requirement of the country from which the genetic resource is accessed and should be addressed by measures for non-compliance with the ABS law of the State concerned.<sup>83</sup>
  - A non-Party explained that under its ABS measures, PIC is always necessary for access to genetic resources so the absence of PIC would make the whole procedure invalid.<sup>84</sup>
- 41. New uses of genetic resources may support the need for a GMBSM:
  - While access requirements do not apply retroactively, new uses of genetic resources in the public domain could support the need for a GMBSM;<sup>85</sup>
  - Historic abuses of the ABS regime whereby genetic resources or associated traditional knowledge may have been removed from their country of origin without PIC and without an ABS agreement but the resources have not yet been utilized or are only utilized until after the "relevant date" for application of ABS principles would appear to trigger a need for a GMBSM.
    - O More clarity is needed on the "relevant date" for determining whether a particular action related to a genetic resource or associated traditional knowledge is governed by the Nagoya Protocol and how to address genetic resources and associated traditional knowledge accessed before that date.<sup>87</sup>
- 42. *The Protocol should not be applied retroactively:* 
  - It would not be appropriate for a GMBSM to address access to genetic resources or associated traditional knowledge that occurred prior to the Protocol. This would constitute retroactive application of the Protocol, which is not foreseen in the Protocol or CBD in the light of Article 28 of the Vienna Convention on the Law of Treaties<sup>88</sup> and would create uncertainty.

<sup>&</sup>lt;sup>79</sup> Costa Rica.

<sup>&</sup>lt;sup>80</sup> TWN, IUCN.

<sup>&</sup>lt;sup>81</sup> IUCN.

<sup>82</sup> India, United States.

<sup>&</sup>lt;sup>83</sup> India.

<sup>84</sup> Costa Rica.

<sup>85</sup> Nigeria.

<sup>&</sup>lt;sup>86</sup> IUCN.

<sup>&</sup>lt;sup>87</sup> IUCN.

<sup>88</sup> ICC, JBA.

- In multilateral situations, a user country may be faced with the complexity of dealing with different ABS regulations in different countries. In such a case, it would be easier to transfer funds to a GMBSM and leave the provider countries to sort who gets what and how they get it. 90
- It is inappropriate to pre-judge that the utilization of genetic resources without PIC should always fall under the scope of a GMBSM. The situations that would be addressed by a GMBSM should be limited to the situations where it is essentially required. 91
- 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. 92
- (iv) 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
- 44. It is the sovereign right of a State to decide not to require PIC or to waive PIC. While different submissions supported this idea, some of them drew different conclusions on whether decisions not to require PIC or to waive PIC constitute situations where it is not possible to grant or obtain PIC:
  - This is a situation in which PIC must indeed be granted or obtained but the Party has chosen not to exercise the requirement so this would constitute a situation in which it is not possible to grant or obtain PIC in the context of Article 10;<sup>93</sup>
  - Such a situation cannot be considered a situation where it is not possible to grant or obtain PIC in the context of Article 10 as this would violate the sovereign decision of the State concerned;<sup>94</sup>
    - o Parties that have decided not to require PIC should be encouraged to affirmatively and publicly note this so as to provide certainty to prospective users;<sup>95</sup>
  - In this situation, there could be voluntary contributions to a GMBSM, <sup>96</sup> which would respect the sovereign right of States not to require PIC or to waive PIC; <sup>97</sup>
  - Benefit-sharing is triggered by utilization so situations under Article 6(1) and Article 8 could fall under Article 10. 98
  - (v) Whether benefit-sharing requirements are waived when a Party has decided not to require PIC or has waived PIC
- 45. The views expressed in response to this issue approached the matter from very different perspectives, as may be seen from the points below.
- 46. PIC and benefit-sharing are two different requirements so a waiver of PIC does not necessarily entail a waiver of benefit-sharing:

<sup>90</sup> South Africa.

<sup>89</sup> Japan.

<sup>&</sup>lt;sup>91</sup> Japan.

<sup>&</sup>lt;sup>92</sup> TWN.

<sup>&</sup>lt;sup>93</sup> India.

<sup>94</sup> Norway, Japan, United States, ICC, JBA.

<sup>&</sup>lt;sup>95</sup> ICC, JBA.

<sup>&</sup>lt;sup>96</sup> South Africa.

<sup>&</sup>lt;sup>97</sup> Norway.

<sup>&</sup>lt;sup>98</sup> TWN.

- A waiver of PIC does not automatically mean that benefit-sharing requirements are also waived unless this is expressly provided for through MAT. A GMBSM could enable users to discharge their benefit-sharing obligation in situations following utilization of genetic resources obtained from a country that has decided not to establish access requirements.
- Benefit-sharing requirements are not waived in these circumstances and a GMBSM could be used to receive benefits.<sup>100</sup>
- Benefit-sharing requirements are imposed by providers, which may or may not be national authorities. Accordingly, for States without a general national PIC requirement, providers of genetic resources may transfer genetic resources on mutually agreed terms that require benefit-sharing. Such requirements would not be waived just because there is not also a national PIC requirement.<sup>101</sup>
- A GMBSM could be the default benefit-sharing mechanism for cases where a Party has not required or has waived PIC except where the Party expressly disavows use of a GMBSM for the particular resources concerned.<sup>102</sup>

- It is not possible to answer this question in general terms as it would depend on the legal system of the Party in question. 103
- Without prejudice to the existence of PIC, benefits should be shared upon mutually agreed terms in accordance with Article 15 of the Convention and Article 5 of the Protocol. 104
- In situations where the benefit-sharing requirement is imposed at the national level, can national law ever require benefit-sharing upon utilization without a PIC requirement?
  - Ensuring adequate notice and fairness for people who access genetic resources are important considerations as is the need to ensure that benefit-sharing requirements are on mutually agreed terms. Full efforts should be made to ensure that a predictable environment is created that serves to encourage and foster discovery and innovation. <sup>105</sup>
- Where a sovereign right is involved, it is not permissible to assume that any aspect of that right is waived by a particular State unless that State has specifically waived the right in writing. 106
- Decisions to waive PIC and benefit-sharing are the prerogative of a Party so this question is not relevant for discussions of a GMBSM.<sup>107</sup> If this question were acknowledged as relevant, it would mean that a Party could not waive benefit-sharing requirements related to a genetic resource over which it has sovereign rights, which would be counter to the bilateral nature of the Protocol.
  - The question becomes more difficult when Parties are unclear about their intention to require PIC, MAT or benefit-sharing and so Parties are urged to implement the Protocol in a way that is clear and provides certainty to potential users. 108

100

<sup>99</sup> India.

<sup>100</sup> South Africa.

<sup>&</sup>lt;sup>101</sup> United States.

<sup>&</sup>lt;sup>102</sup> TWN.

<sup>&</sup>lt;sup>103</sup> Norway.

<sup>&</sup>lt;sup>104</sup> Japan.

<sup>&</sup>lt;sup>105</sup> United States.

<sup>106</sup> IUCN.

<sup>&</sup>lt;sup>107</sup> ICC, JBA.

<sup>&</sup>lt;sup>108</sup> ICC.

- (vi) Whether there is no requirement for benefit-sharing when mutually agreed terms are not required or have not been established
- 48. The views expressed in response to this issue approached the matter from very different perspectives, as may be seen from the points below.
- 49. Respecting State sovereignty over genetic resources and the bilateral nature of the Protocol:
  - An obligation to share benefits through a GMBSM in the absence of MAT could undermine the bilateral nature of the Protocol. There is a need to understand why there are no MAT.
    - Where, for example, it has been impossible to reach the authority with the right to grant access or where a State has not yet determined whether access should be subject to PIC then benefit-sharing via a GMBSM could be more relevant.
  - It would be inappropriate for others (through a GMBSM or otherwise) to undermine a sovereign decision not to require PIC or, in the case of genetic resources provided by the Party itself, MAT.
    - A provider can choose not to require benefit-sharing and in some sectors, it is routine to transfer genetic resources with no conditions attached.
    - O In a case where national law requires PIC and MAT, and MAT does not exist (for example because one government agency indicated that no MAT is required and a court subsequently finds that they were the wrong authority), it would be inconsistent with the treaty to retrospectively require benefit-sharing on unilaterally imposed terms.
- 50. The Convention and the Protocol require benefit-sharing to be on mutually agreed terms: 111
  - Article 5(1) of the Protocol makes benefit-sharing with the country of origin or country providing a genetic resource on mutually agreed terms a legal obligation in respect of utilization. There cannot be a situation where no MAT are required as not establishing MAT would be a violation of this provision. The only situation where there may not be a benefit-sharing requirement is where this is provided for in the MAT.<sup>112</sup>
  - This is without prejudice to the existence of PIC. 113
- 51. *Other views:* 
  - The response to this question will depend on the specific circumstances of the situation and the decision to determine whether to require MAT and benefit-sharing should be left to the individual Parties. 114
  - Benefit-sharing cannot be waived unless this is expressly done.
    - o Failure to establish MAT may arise from many factors that bear no relation to a national intention to waive benefit-sharing.
  - The interpretation that there is no requirement for benefit-sharing when MAT are not required or have not been established would create an incentive for users to never agree to MAT. 116

<sup>110</sup> United States.

<sup>109</sup> Norway.

<sup>&</sup>lt;sup>111</sup> India, Japan, United States.

<sup>&</sup>lt;sup>112</sup> India.

<sup>113</sup> Japan.

<sup>&</sup>lt;sup>114</sup> ICC, JBA.

<sup>115</sup> IUCN, TWN.

<sup>116</sup> IUCN.

(vii) 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

and

- (viii) 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
- 52. Many of the submissions expressed similar views on these two areas for further consideration so they are considered here together. At the same time, however, the views expressed in response to these issues approached the matter from very different perspectives, as reflected in the points below.
- 53. These situations point to a need for capacity-building: 117
  - These situations point to a need for capacity-building and should not be considered situations where it is not possible to grant or obtain PIC in the context of Article 10;<sup>118</sup>
  - Should access in a situation where there is an absence of ABS measures for access to genetic resources be postponed until conditions for the establishment of PIC and MAT are improved?<sup>119</sup>
  - Capacity-building would be important in these situations and a GMBSM is not as a sole solution in this regard. 120
- 54. A GMBSM could be necessary in these situations: 121
  - A GMBSM could enable users to comply with the spirit of the Convention on Biological Diversity and the Nagoya Protocol where they find there are no ABS measures in the country from which they are seeking access.
    - Such an approach would require the consent of the Party involved and not all Parties would see this as an acceptable approach.<sup>122</sup>
- 55. There may still be ABS obligations even in the absence of national measures:
  - In the absence of national ABS measures, there would still be an obligation to share benefits on the basis of mutually agreed terms in accordance with Article 5(1) of the Protocol<sup>123</sup> and Article 15 of Convention on Biological Diversity would apply, including its requirements for access to be on mutually agreed terms and to be subject to prior informed consent of the Party providing the resources, unless otherwise determined by that Party.<sup>124</sup>
    - O In such a situation, benefits arising from the utilization of a genetic resource should still be shared in accordance with terms agreed upon by the Parties bilaterally and not through a GMBSM. Use of a GMBSM in such a situation could be an affront to the rights of the country of origin and could bring additional difficulties for developing countries that still need to put national frameworks in place.

<sup>&</sup>lt;sup>117</sup> Mexico, Japan, the Centre for Cellular and Molecular Biology.

<sup>&</sup>lt;sup>118</sup> India, Brazil, JBA.

<sup>119</sup> Norway.

<sup>&</sup>lt;sup>120</sup> Japan.

<sup>&</sup>lt;sup>121</sup> Nigeria.

<sup>122</sup> South Africa.

<sup>123</sup> India.

<sup>&</sup>lt;sup>124</sup> Brazil.

<sup>125</sup> Brazil.

- The absence of measures does not necessarily mean that PIC and benefit-sharing for traditional knowledge are not obligatory; this will depend on the legal system of each Party.
  - It is not clear how measures under Article 10 could serve the same function as national rules that protect indigenous and local communities. Further work is needed to explore how these situations can be solved in order to protect the rights and traditional knowledge of indigenous and local communities.
  - o If benefits are to be shared via a GMBSM in this situation, it needs to be clear that it has been impossible to determine the question of PIC.
  - o Some Parties may wish to establish a link to a GMBSM in their national legislation. 126
- In principle, in the absence of legislation, it should still be incumbent on a user to comply with the obligations of the Convention on Biological Diversity and the Nagoya Protocol:
  - o If a user makes a good faith effort but is unable to secure a response from a provider, it may be an option for the user to share benefits through a GMBSM; however, it would be necessary to assess the user's efforts to obtain PIC and to determine whether they were sufficient to warrant resorting to a GMBSM rather than continuing efforts to obtain PIC. Not making the effort to obtain PIC would frustrate the objectives of Convention on Biological Diversity and the Protocol. 127
- The obligation to obtain PIC for access to associated traditional knowledge and to share benefits from the utilization of such knowledge is absolute so long as holders of the traditional knowledge exist, which would be the vast majority of cases. 128
- It is legally inappropriate to assume that a country has decided to give up its rights solely on the basis of the fact that it has not been able or felt it necessary to adopt legislation saying that it 'accepts' that particular sovereign right.
  - Many countries have experienced difficulties in trying to establish ABS systems so any delays they may face in adopting their measures should not put them in danger of losing their rights to genetic resources and associated traditional knowledge and should not become a justification for legitimizing biopiracy.
  - Allowing this type of reasoning might set an unfortunate precedent that could also apply to other sovereign rights and resources. 129
- Allowing a user to obtain and utilize associated traditional knowledge without PIC because the user has unilaterally decided that it was impossible to grant or obtain PIC in a particular country would be a means of giving users permission to engage in biopiracy. 130
- 56. There would not be ABS obligations in the absence of national measures:
  - Where a Party does not have an established national legal framework on ABS, a potential user will not have any specific ABS obligations, PIC is not required and there is no obligation to share benefits.<sup>131</sup>
    - O This may be a situation where it is not possible to grant or obtain PIC but it does not justify a GMBSM as it is up to Parties to make ABS a national priority in order to implement measures in a manner that meets their national needs and interests.<sup>132</sup>

<sup>126</sup> Norway.

<sup>&</sup>lt;sup>127</sup> TWN.

<sup>&</sup>lt;sup>128</sup> TWN.

<sup>120 ----</sup>

<sup>&</sup>lt;sup>129</sup> IUCN.

<sup>&</sup>lt;sup>130</sup> IUCN.

<sup>&</sup>lt;sup>131</sup> ICC.

 Establishing appropriate ABS measures is a responsibility of a Party and is for a Party to determine in accordance with its domestic law. It would not be appropriate for outside Governments to decide the intent of a sovereign country through a GMBSM.<sup>133</sup>

#### 57. *Other views:*

and

- Without prejudice to the existence of PIC, benefits should be shared upon mutually agreed terms in accordance with Article 15 of the Convention and Article 5 of the Protocol. 134
- Where a sovereign right is involved, it should not be permissible for anyone to assume that any aspect of that right is waived by a particular State unless that State has specifically waived the right in writing. It should be a priority for all countries to eliminate any doubt by promptly adopting an initial ABS measure that specifically states that the country, in the exercise of its sovereign rights over its genetic resources, declares that PIC and MAT are or are not required. 135
- (ix) 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
- (x) 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
- 58. Many of the submissions expressed similar views on these two areas for further consideration so they are considered here together. At the same time, however, the views expressed in response to these issues approached the matter from very different perspectives, as reflected in the points below.
- 59. Where it is possible to identify the source of a <u>genetic resource</u> that is found in more than one Party, this would not constitute a transboundary situation in the language of Article 10 and access should be done through the bilateral approach, <sup>136</sup> with the following elaborations:
  - Where a country has decided that access is free with no rules on benefit-sharing, benefit-sharing through a GMBSM could be done on a voluntary basis;<sup>137</sup>
  - PIC is not required with each and every Party having the genetic resource: 138
- 60. Where it is possible to identify the source of <u>associated traditional knowledge</u> that is found in more than one Party, this would not constitute a transboundary situation in the language of Article 10 and access should be done through the bilateral approach, <sup>139</sup> with the following elaborations:

<sup>133</sup> United States.

<sup>&</sup>lt;sup>132</sup> ICC.

<sup>&</sup>lt;sup>134</sup> Japan.

<sup>135</sup> IUCN.

<sup>&</sup>lt;sup>136</sup> India, Norway, Australia, Brazil, ICC, IUCN, JBA.

<sup>&</sup>lt;sup>137</sup> Norway.

<sup>&</sup>lt;sup>138</sup> United States.

<sup>&</sup>lt;sup>139</sup> India, ICC, JBA.

- The decisive factor for benefit-sharing for traditional knowledge that is found in more than one Party is whether the indigenous and local communities have consented to the utilization of their traditional knowledge. In such cases, it would not be appropriate to use a GMBSM.<sup>140</sup>
- Traditional knowledge in a transboundary situation does not obviate the need to obtain PIC and MAT but a GMBSM could be an appropriate benefit-sharing mechanism if the relevant indigenous and local communities agree.<sup>141</sup>
- 61. Where it is possible to identify the source of a <u>genetic resource or associated traditional knowledge</u> that is found in more than one Party, this would not constitute a transboundary situation in the language of Article 10 and access should be done through the bilateral approach:
  - Widely available genetic resources and associated traditional knowledge should provide
    an incentive for providers to implement the Protocol in a way that provides certainty to
    users and to negotiate reasonable MAT with such users.<sup>142</sup>
  - For genetic resources and associated traditional knowledge found in more than one Party, these Parties may cooperate pursuant to Article 11 of the Protocol (discussed further below).<sup>143</sup>

- Situations where *in situ* access to a genetic resource is denied but the user may access the genetic resource from another Party or under *ex situ* conditions require further discussion;<sup>144</sup>
- The response to these situations would depend on the level of complexity of the regulatory requirements of the Parties involved; 145
- These situations require further discussion; 146
- The meaning of a "transboundary situation" needs to be clarified. The view that widely distributed species cannot be sourced from a single location and that they are "natural information" seems inconsistent with the definition of a genetic resource under the Protocol.
  - Genetic resources are a taxonomic entity, such as a plant species sourced from a specific location. The user of the sample for research purposes would be subject to the ABS requirement for access in that location.<sup>147</sup>
- A clear definition of "traditional knowledge associated with genetic resources" is needed. 148
- It is necessary to clarify how and by what taxonomy the identity of a certain genetic resource is determined. 149
- The understanding of "genetic resource" needs to be clarified and whether the term refers only to the physical material or the informational content of that material or a combination of the two; 150

<sup>141</sup> TWN.

<sup>140</sup> Norway.

<sup>142</sup> 

<sup>&</sup>lt;sup>142</sup> ICC.

<sup>&</sup>lt;sup>143</sup> United States, ICC, IUCN, JBA.

<sup>&</sup>lt;sup>144</sup> Mexico.

<sup>&</sup>lt;sup>145</sup> South Africa.

<sup>&</sup>lt;sup>146</sup> Mexico, TWN, IUCN.

<sup>&</sup>lt;sup>147</sup> Australia.

<sup>&</sup>lt;sup>148</sup> Japan, IUCN.

<sup>&</sup>lt;sup>149</sup> Japan.

<sup>150</sup> IUCN.

- Would the efforts of a Party that contributes more to the conservation of biodiversity and the sustainable use of its components be acknowledged through a greater share of benefits?<sup>151</sup>
- It would not be reasonable for the mere existence of the same traditional knowledge in more than one country to result in a greater burden for benefit-sharing. 153
- (xi) Whether Article 11 is sufficient to respond to transboundary situations
- Article 11 is sufficient to respond to transboundary situations. 153 63.
  - Article 11 is sufficient to respond to transboundary situations where the countries of origin are identifiable; 154
  - The design and implementation of mechanisms for cooperation in the scenarios described in Article 11 should be emphasized and promoted; 15:
  - Article 11 acknowledges the need for cooperation between Parties in transboundary situations without undermining the sovereign rights of Parties over their genetic resources; 156
  - The specific place of collection or access should govern all ABS activities except in situations where the collection happened near an international boundary or outside national jurisdiction; 157
  - Most transboundary genetic resources or associated traditional knowledge could be addressed through regional coordination; 158
  - Article 11 provides a more expeditious result for addressing transboundary situations than does Article 10.<sup>159</sup>
- Article 11 may not be sufficient to respond to transboundary situations. 64.
  - A GMBSM may be needed for transboundary situations in which the countries of origin cannot be identified after making reasonable efforts: 160
  - Article 11 is a voluntary provision that encourages Parties to collaborate. It will only work in certain straightforward situations but will be difficult to implement in more complex cases; 161
  - Article 11 can and should be applied to cases of transboundary traditional knowledge but is not sufficient. A GMBSM might be useful for indigenous and local communities and Parties to address transboundary situations successfully. 162
  - Article 11 would be insufficient as it does not include ex situ genetic resources and genetic resources of unknown origin;<sup>163</sup>

<sup>&</sup>lt;sup>151</sup> Japan.

<sup>&</sup>lt;sup>152</sup> Japan.

<sup>&</sup>lt;sup>153</sup> India, Mexico, United States, ICC, JBA.

<sup>154</sup> India.

<sup>155</sup> Mexico.

<sup>&</sup>lt;sup>156</sup> ICC.

<sup>157</sup> IUCN.

<sup>158</sup> IUCN.

<sup>159</sup> IUCN.

 $<sup>^{160}</sup>$  India.

<sup>&</sup>lt;sup>161</sup> South Africa.

<sup>&</sup>lt;sup>162</sup> TWN.

<sup>163</sup> IUCN.

- Article 10 is asking the Parties to consider whether a mechanism is needed to address transboundary situations in the event that the Parties involved have been unable to achieve a solution through their endeavours to cooperate in Article 11. 164
- 65. Experience with the implementation of Article 11 is needed: 165
  - A GMBSM should not preclude the efforts of Parties to cooperate on genetic resources in transboundary situations pursuant to Article 11 of the Protocol, and, so, experience with transboundary cooperation should be respected. 166
  - Examples of two successful cases of transboundary cooperation: (1) the 1996 Andean Community regime on genetic resources, which created a committee to address the management, monitoring and control of access authorizations related to genetic resources existing in two or more member countries; and (2) traditional knowledge related to the hoodia cactus for which San tribes living in South Africa, Namibia, Angola and Botswana formed a council to negotiate benefit-sharing agreements among themselves.<sup>167</sup>
  - Article 11 is silent on how transboundary cooperation should be carried out. How should the duty to cooperate be applied, particularly where states have different ABS frameworks?<sup>168</sup>

- There could be bilateral or regional agreements in the context of Article 11. <sup>169</sup> These could also result in specialized ABS agreements as envisaged by Article 4 of the Protocol which would avoid the need to apply Article 10. <sup>171</sup>
- (xii) Whether a GMBSM should address the sharing of benefits arising from the utilization of:
  - a. Genetic resources in ex situ collections in relation to transboundary situations or for which it is not possible to grant or obtain PIC

and

- b. 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
- 67. Many of the submissions expressed similar views on these two areas for further consideration so they are considered here together.
- 68. A GMBSM could or should apply in these cases: 172
- (a) A GMBSM could address the sharing of benefits arising from the utilization of genetic resources in situations where it is not possible to identify countries of origin even after reasonable efforts are made.
  - The important consideration in applying a GMBSM needs to be when it is not possible to identify the country of origin; 173

<sup>164</sup> IUCN.

<sup>&</sup>lt;sup>165</sup> ICC.

<sup>166</sup> Japan.

<sup>&</sup>lt;sup>167</sup> ICC.

<sup>&</sup>lt;sup>168</sup> Mexico, Norway.

<sup>169</sup> Norway.

<sup>&</sup>lt;sup>170</sup> ICC.

<sup>&</sup>lt;sup>171</sup> IUCN.

<sup>&</sup>lt;sup>172</sup> South Africa.

<sup>&</sup>lt;sup>173</sup> India, Nigeria.

- A GMBSM should only be potentially applicable after a verified, diligent search to identify the origin of a resource ends without success; 174
  - o It should be incumbent on *ex situ* collections to diligently attempt to determine and maintain a record of the origin of the genetic resources that they hold, including by requiring depositors to provide origin information.<sup>175</sup>
- 69. This is a situation to be addressed by measures for non-compliance, not through a GMBSM: 176
  - Such a situation should be solved by the bilateral approach and if there is any possibility that the bilateral approach does not work, this should be identified through experience with implementation. 177
- 70. A GMBSM is not necessary in these situations. Many of these submissions emphasized the question of the temporal scope of the Protocol:
- (a) It is not possible to obtain PIC for genetic resources that have already been accessed or utilized and this matter is beyond the scope of the Nagoya Protocol;
  - For example, for a long time, records were not required regarding where genetic resources came from, so there is no way to know the source, conditions under which the genetic resources were accessed; or if there was even a foreign source at all; and existing contracts regarding the use of already transferred genetic resources cannot generally be modified;<sup>178</sup>
- (b) If the resources were accessed and put in a collection prior to the entry into force of the Protocol in accordance with applicable laws, the national ABS laws of the country where the collection is based will govern the potential need for and modalities of PIC concerning access to resources in the collection. Requiring users who access these genetic resources to obtain PIC from the country from which the genetic resources were originally collected would create retroactivity which is not contemplated by either the Convention on Biological Diversity or the Nagoya Protocol;<sup>179</sup>
- (c) Following the entry into force of the Protocol, accessing genetic resources or associated traditional knowledge to place them in *ex situ* collections would need to follow the bilateral approach; <sup>180</sup>
- (d) If a GMBSM requires benefit-sharing from genetic resources or associated traditional knowledge accessed before its establishment, this will create legal uncertainty for those who have accessed such genetic resources or traditional knowledge. 181

• How *ex situ* collections should be regarded in terms of benefit-sharing should depend on the ABS framework of the Party in question. Some national frameworks have provisions for genetic material in public collections. The Party expressing this view provided the example of their own national framework, which includes a provision stating that: "Genetic material from public collections shall be managed or utilized to the greatest possible benefit of the environment and human beings in both a national and an international context, also attaching importance to appropriate measures for sharing the benefits arising out of the utilization of genetic material and in such a way as to safeguard the interests of indigenous peoples and local communities". 182

<sup>&</sup>lt;sup>174</sup> TWN.

<sup>&</sup>lt;sup>175</sup> TWN.

<sup>&</sup>lt;sup>176</sup> Mexico, Norway.

<sup>&</sup>lt;sup>177</sup> Japan.

<sup>&</sup>lt;sup>178</sup> United States.

<sup>&</sup>lt;sup>179</sup> ICC.

<sup>&</sup>lt;sup>180</sup> United States, ICC, JBA.

<sup>&</sup>lt;sup>181</sup> Japan.

<sup>&</sup>lt;sup>182</sup> Norway.

- Further consideration is needed regarding the rules that will guide access to genetic resources and associated traditional knowledge that are found in *ex situ* collections. Nothing in the Protocol implies that it applies retroactively. At the same time, though, it is not clear how to address situations of new access to a genetic resource deposited in an *ex situ* collection following the entry into force of the Protocol. National experience with the implementation of ABS rules shows this to be a complex issue that should be thoroughly analysed. 184
- If a GMBSM were to be used in situations where it is not possible to grant or obtain PIC, such impossibility would need to be clearly documented. Otherwise, a GMBSM could be misused as a way to avoid national ABS measures, which would create legal uncertainty for both providers and users of genetic resources, damaging the whole ABS system. 185
  - c. Genetic resources in areas beyond national jurisdiction or whether this issue falls within the competence of the United Nations General Assembly and
  - d. Genetic resources in the Antarctic Treaty area
- 72. The issues raised on these two areas were, in many cases, very similar so they are considered together here.
- 73. A GMBSM could or should apply to genetic resources from these areas: 186
  - (a) Genetic resources in these areas are within the scope of the Protocol;
    - Articles 4 and 5 of the Convention on Biological Diversity allow for scope under the Nagoya Protocol to address benefit-sharing issues from genetic resources in areas beyond national jurisdiction. Current discussions under the aegis of United Nations General Assembly relate to conservation and sustainable use of marine biodiversity beyond areas of national jurisdiction and do not seem to cover benefit sharing arising from the utilisation of resources from such areas.
- (b) There should not be an automatic exclusion of genetic resources in areas beyond national jurisdiction or genetic resources in the Antarctic Treaty area from a GMBSM;<sup>188</sup>
  - A GMBSM would have principles, standards and modalities not available at the United Nations General Assembly. 189
- 74. A GMBSM should not apply to genetic resources from these areas:
- (a) Genetic resources in areas beyond national jurisdiction and genetic resources in the Antarctic Treaty area are beyond the scope of the Protocol, so it would not be possible for a GMBSM to apply to them; <sup>190</sup>
  - The Protocol applies to genetic resources and associated traditional knowledge in areas within national jurisdiction and does not affect rights and obligations deriving from preexisting international agreements or apply retroactively.

<sup>185</sup> Brazil.

<sup>&</sup>lt;sup>183</sup> Mexico, Brazil.

<sup>&</sup>lt;sup>184</sup> Brazil.

<sup>&</sup>lt;sup>186</sup> India, South Africa.

<sup>&</sup>lt;sup>187</sup> India.

<sup>&</sup>lt;sup>188</sup> TWN.

<sup>189</sup> TWN.

<sup>&</sup>lt;sup>190</sup> New Zealand, United States, ICC, JBA.

<sup>&</sup>lt;sup>191</sup> New Zealand.

- Article 3 of the Protocol and Articles 15 and 4(a) of the Convention support the view that the Convention on Biological Diversity applies to States in areas within the limits of their national jurisdiction; 192
- (b) Other organizations and ongoing processes are addressing genetic resources in these areas:
  - Marine genetic resources are under consideration in the context of the United Nations Convention on the Law of the Sea (UNCLOS) and Antarctic genetic resources are considered in the context of the Antarctic Treaty so it would not be appropriate or productive for discussions under the Nagoya Protocol to engage on these issues and duplicate or prejudge the work being undertaken elsewhere;<sup>193</sup>
    - O The Antarctic Treaty is the appropriate framework for managing the collecting of biological material in the Antarctic Treaty area and for considering its use. In resolutions 9(2009) and 6(2013) of the Antarctic Treaty Consultative Meetings, Parties to the Antarctic Treaty agreed that questions on access and utilization of genetic resources in the Antarctic Treaty area should be handled within the Antarctic Treaty System;<sup>194</sup>
    - O Under Article 4 of the Nagoya Protocol and its provisions for specialized ABS instruments, negotiations of a legally binding instrument on the conservation and sustainable use of marine biodiversity in areas beyond national jurisdiction under UNCLOS, including the topic of marine genetic resources and benefit-sharing, would constitute a specialized ABS agreement provided that the agreement is consistent with and does not run counter to the objectives of the Convention on Biological Diversity and the Nagoya Protocol. In this light, the Nagoya Protocol and its Article 10 would not apply to the new agreement; <sup>195</sup>
  - There is a need to respect other agreements and organizations. Decisions on genetic resources in areas beyond national jurisdiction or genetic resources in the Antarctic Treaty area should by made by the Parties to the competent and appropriate forums; 196
  - Article 4 of the Protocol demonstrates that the Protocol is compatible with other international agreements and instruments and that there is no hierarchy among them. 197
- 75. There should be cooperation with other organizations and processes working on these issues. Both submissions that were in favour of including such genetic resources in a GMBSM as well as those that were opposed suggested cooperation with other organizations and processes active on these issues:
- (a) Coordination with processes under the United Nations General Assembly and the Antarctic Treaty would be needed:
  - Links and synergies should be established with other international instruments such as UNCLOS and the Antarctic Treaty so that ABS principles are consistent; 198
  - Jurisdictional issues would need to be examined: 199

<sup>193</sup> Australia, Japan, United States, JBA.

<sup>&</sup>lt;sup>192</sup> ICC, JBA.

<sup>&</sup>lt;sup>194</sup> Norway, United States.

<sup>&</sup>lt;sup>195</sup> Norway.

<sup>&</sup>lt;sup>196</sup> Brazil.

<sup>&</sup>lt;sup>197</sup> JBA.

<sup>198</sup> Brazil, Costa Rica.

<sup>&</sup>lt;sup>199</sup> TWN.

- The law of the sea negotiations and Antarctic Treaty discussions could provide useful inputs to the Article 10 process <sup>200</sup> and the Article 10 process may provide useful input into other processes; <sup>201</sup>
- A GMBSM could be structured in a way that would harmonize its operation with the efforts of the United Nations General Assembly to address conservation and sustainable use of marine biodiversity in areas beyond national jurisdiction;<sup>202</sup>
- 76. *Other views:* COP-MOP should take a decision on the inclusion or exclusion of areas beyond national jurisdiction. <sup>203</sup>
  - e. 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
- 77. A GMBSM should not apply to publicly available traditional knowledge:<sup>204</sup>
  - If the knowledge has been publicly available for a reasonable period of time, access should be free;
    - o However, a GMBSM could be open for voluntary contributions from utilization of such traditional knowledge even where it is publicly available;<sup>205</sup>
  - Publicly available traditional knowledge associated with genetic resources should not be included under a GMBSM regardless of whether any holders of the traditional knowledge can be identified;<sup>206</sup>
  - Such traditional knowledge is outside the scope of the Protocol. <sup>207</sup>
- 78. Benefit-sharing should first be sought with the country of origin:
  - Where the holders of publicly available traditional knowledge cannot be identified, in many cases, it would be possible to identify the country of origin of the traditional knowledge and so benefit-sharing should be with this country rather than through a GMBSM:<sup>208</sup>
    - o If, after reasonable efforts, it is not possible to determine the country of origin of publicly available traditional knowledge then a GMBSM could apply;<sup>209</sup>
    - Where associated traditional knowledge is accessed through a public or secondary source but the origin of the knowledge is known then benefits should be shared with the country of origin or the indigenous and local community where the traditional knowledge was developed. In any scenario, PIC for access to traditional knowledge must respect community protocols where these have been established.<sup>210</sup>

<sup>&</sup>lt;sup>200</sup> Norway, Japan.

<sup>&</sup>lt;sup>201</sup> Norway.

<sup>&</sup>lt;sup>202</sup> India.

<sup>&</sup>lt;sup>203</sup> IUCN.

<sup>&</sup>lt;sup>204</sup> Norway, United States, JBA.

<sup>&</sup>lt;sup>205</sup> Norway.

<sup>&</sup>lt;sup>206</sup> United States.

<sup>&</sup>lt;sup>207</sup> JBA.

<sup>&</sup>lt;sup>208</sup> India, Brazil, TWN.

<sup>&</sup>lt;sup>209</sup> India.

<sup>&</sup>lt;sup>210</sup> Brazil.

- Further discussion is needed of traditional knowledge associated with genetic resources found in the public domain (which is understood to mean publications);<sup>211</sup>
- A GMBSM should apply especially in situations where the traditional knowledge was recorded long ago from different groups that can no longer be traced directly to a modern community. The modalities would need to be negotiated with inputs from the holders of traditional knowledge;<sup>212</sup>
- A clear and internationally shared definition of "traditional knowledge associated with genetic resources" would be needed for benefit-sharing arising from the utilization of such knowledge to be addressed by a GMBSM. There would also need to be a threshold for determining publicly available traditional knowledge associated with genetic resources in order to distinguish it from useful information that anyone knows, which would be too broad for the scope of a GMBSM;<sup>213</sup>
- Discussions in other fora on publicly available traditional knowledge are ongoing and so it is premature to address this question;<sup>214</sup>
- This situation could possibly be subject to a GMBSM but there would be few such cases.
   Additional discussion is needed, particularly with indigenous and local communities, but a very high standard of effort to obtain PIC would be needed before any traditional knowledge would be considered "orphaned";<sup>215</sup>
- There is a wide variation in national approaches to traditional knowledge and a GMBSM should include a means of addressing this situation. 216

### IV. CROSS-CUTTING ELEMENTS

80. The synthesis in section III above is organized according to the different areas on which the submission of views was invited. Although conflicting views were expressed on a number of issues, some common views emerged on certain elements that were repeated across different areas and may provide a basis for discussion by the expert group.

### A. The importance of State sovereignty over genetic resources and, as a result, respecting the bilateral approach to ABS that is set out in the Nagoya Protocol

- 81. These points were already identified as areas of common understanding by the 2013 expert meeting. They are summarized in paragraph 22 of the report of that meeting as follows: "A GMBSM should not undermine State sovereignty;" (subparagraph (b)) and "A GMBSM is not intended to replace the bilateral nature of the Nagoya Protocol but to supplement it" (subparagraph (d)).
- 82. Most of the views submitted pursuant to decision NP-1/10 recognized the principle of State sovereignty over genetic resources. For many of the submissions, the effect of this principle was that the bilateral approach to ABS that is elaborated in the Protocol is to be followed wherever possible, and any potential GMBSM would have a narrow application and would only be used in exceptional cases.

## B. The importance of the ability to identify the source of a genetic resource and associated traditional knowledge

83. Also following from the primacy of the bilateral approach was the cross-cutting idea that the most important consideration in determining the need for a GMBSM is whether or not it is possible to identify the country of origin of a genetic resource or the holder of associated traditional knowledge.

<sup>212</sup> South Africa

<sup>&</sup>lt;sup>211</sup> Mexico.

<sup>&</sup>lt;sup>213</sup> Japan.

<sup>&</sup>lt;sup>214</sup> ICC.

<sup>&</sup>lt;sup>215</sup> TWN.

<sup>&</sup>lt;sup>216</sup> IUCN.

84. Where it is not possible to identify the country of origin of a genetic resource or the holder of associated traditional knowledge, there was some agreement that this situation supports the need for a GMBSM.

### C. Potential retroactive application of the Convention and/or the Protocol, ex situ collections and databases of genetic information

- 85. One situation where it may not be possible to identify the country of origin of a genetic resource or the holder of associated traditional knowledge is where these resources or knowledge were accessed prior to the Convention or the Protocol.
- 86. A number of submissions expressed concern that applying a GMBSM to such resources or knowledge would constitute retroactive application of the Convention and/or the Protocol. These views generally considered that the Convention and the Protocol do not foresee retroactive application and so to apply them retroactively is not legally tenable. Furthermore, it was also considered that retroactive application would create legal uncertainty, which would be detrimental to the ABS system.
- 87. A specific situation where it may not be possible to identify the origin of a genetic resource or holder of associated traditional knowledge is where these resources or knowledge are found in *ex situ* collections or in databases of genetic information. Different examples were provided of how a GMBSM could apply in these situations.
- 88. For example, some felt that requiring benefit-sharing for genetic resources in *ex situ* collections prior to the Protocol is beyond the scope of the Protocol and does not support the need for a GMBSM. However, under these circumstances, the suggestion was also made that benefit-sharing through a GMBSM could be voluntary. It was also pointed out that a GMBSM could apply to genetic information contained in a database following the entry into force of the Protocol and it is not possible to identify the source of the information.
- 89. The need for collections and databases to respect the bilateral approach was also expressed. It was suggested that collections and databases should endeavour to identify the origin or source of the material or information they hold or, for new material or information being added to the collections or databases, they should require information on PIC and MAT.
- 90. Questions were also raised about how to address new uses of genetic resources in *ex situ* collections. It was also suggested that further consideration of ABS and *ex situ* collections would be needed. More information on *ex situ* collections and databases of genetic information and how they relate to the Nagoya Protocol may be helpful.

#### D. Transboundary situations

- 91. Emphasizing again the primacy of the bilateral approach, a number of submissions expressed the view that a genetic resource or associated traditional knowledge found in more than one Party does not constitute a transboundary situation in the context of Article 10 so long as it is possible to identify the source of the genetic resource or associated traditional knowledge.
- 92. Many submissions underlined the importance of cooperation in situations where genetic resources or associated traditional knowledge are found in more than one country as foreseen in Article 11 of the Protocol. A few examples of cooperation were provided as well as suggestions of regional organizations that could play a role in this regard.
- 93. More information on experience with cooperation in situations where genetic resources and/or associated traditional knowledge are found in more than one country may be useful.

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