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## SUBSIDIARY BODY ON IMPLEMENTATION

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Item 12 of the provisional agenda\*

### **SPECIALIZED INTERNATIONAL ACCESS AND BENEFIT-SHARING INSTRUMENTS IN THE CONTEXT OF ARTICLE 4, PARAGRAPH 4, OF THE NAGOYA PROTOCOL**

*Note by the Executive Secretary*

#### **I. INTRODUCTION**

1. At its second meeting, the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol requested the Executive Secretary, in the context of Article 4, paragraph 4, of the Protocol, to conduct a study into criteria that could be used to identify what constitutes a specialized international access and benefit-sharing (ABS) instrument, and what could be a possible process for recognizing such an instrument (decision NP-2/5, para. 3).

2. At its third meeting, in decision [NP-3/14](#), paragraph 1, the meeting of the Parties to the Protocol took note of the study<sup>1</sup> and potential criteria for specialized international ABS instruments in the context of Article 4, paragraph 4, and agreed to reconsider these potential criteria at its fourth meeting. Parties and other Governments were invited, as per paragraph 2 of the decision, to submit: (a) information on how specialized international access and benefit-sharing instruments are addressed in their domestic measures; and (b) views on the potential criteria contained in the study, taking into account Article 4, paragraphs 1 to 3, of the Protocol.

3. The Executive Secretary was requested to continue to follow developments in relevant international forums (paragraph 3 of the decision) and to synthesize the information and views submitted, including the information from developments in relevant international forums, and make it available for consideration by the Subsidiary Body on Implementation at its third meeting, in order to make a recommendation to the Parties to the Protocol at their fourth meeting (para. 4).

4. By notification 2019-25 of 25 February 2019,<sup>2</sup> the Executive Secretary invited the submission of information and views pursuant to paragraph 2 of decision NP-3/14. Submissions were received from four Parties to the Protocol: the European Union and its member States; Japan; Norway; and Switzerland. Submissions were also received from two non-Parties: Canada; and New Zealand. In addition, a submission was received from one international organization: the African Union. The full text of the submissions has been made available online.<sup>3</sup>

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\*CBD/SBI/3/1.

<sup>1</sup> [CBD/SBI/2/INF/17](#).

<sup>2</sup> <https://www.cbd.int/doc/notifications/2019/ntf-2019-025-abs-en.pdf>.

<sup>3</sup> <https://www.cbd.int/abs/specialized-instruments/2019-2020/>.

5. Section II below briefly recalls the criteria identified and scenarios developed in the study referred to in footnote 1 herein. Section III summarizes the information that was submitted on experiences regarding how specialized international access and benefit-sharing instruments are addressed in domestic measures taken by Parties and other Governments. Section IV synthesizes the views submitted on the potential criteria contained in the study, taking into account Article 4, paragraphs 1 to 3, of the Protocol. Section V contains information regarding developments in relevant international forums. Finally, Section VI presents suggested elements of a draft recommendation for consideration by the Subsidiary Body on Implementation.

## II. CRITERIA IDENTIFIED AND SCENARIOS DEVELOPED IN THE STUDY

6. As reflected in the annex to decision NP-3/14, the potential criteria for specialized international ABS instruments in the context of Article 4, paragraph 4, of the Protocol are:

1. *Intergovernmentally agreed* — The instrument would be developed and agreed through an intergovernmental process. The instrument may be binding or non-binding.

2. *Specialized* — The instrument would:

(a) Apply to a specific set of genetic resources and/or traditional knowledge associated with genetic resources which would otherwise fall under the scope of the Nagoya Protocol;

(b) Apply to specific uses of genetic resources and/or traditional knowledge associated with genetic resources which require a differentiated and hence specialized approach.

3. *Mutually supportive* — The instrument would be consistent with and supportive of, and not run counter to the objectives of the Convention on Biological Diversity and the Nagoya Protocol, including with respect to:

(a) Consistency with biodiversity conservation and sustainable use objectives;

(b) Fairness and equity in the sharing of benefits;

(c) Legal certainty with respect to access to genetic resources or traditional knowledge and to benefit-sharing;

(d) Contribution to sustainable development, as reflected in internationally agreed goals;

(e) Other general principles of law, including good faith, effectiveness and legitimate expectations.

7. The full study provides further information on how these criteria may be understood and applied. It also identifies the following scenarios for the recognition of specialized ABS instruments: (a) recognition by the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol; (b) recognition by another international forum; or (c) initiative of a Party or group of Parties to the Nagoya Protocol.

## III. INFORMATION ON HOW SPECIALIZED INTERNATIONAL ACCESS AND BENEFIT-SHARING INSTRUMENTS ARE ADDRESSED IN DOMESTIC MEASURES OF PARTIES AND OTHER GOVERNMENTS

8. This section summarizes the information provided by Parties and other Governments and organizations in response to the invitation in decision NP-3/14, paragraph 2 (a).

9. The *European Union and its member States* referred to Regulation (EU) No 511/2014 on compliance measures for users of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union. This Regulation recognizes two specialized international ABS instruments: (a) the International Treaty on Plant Genetic Resources for Food and Agriculture (International Treaty) (Preamble 12); and (b) the Pandemic Influenza Preparedness

Framework for the sharing of influenza viruses and access to vaccines and other benefits (the PIP Framework) (Preamble 16).

10. Article 2(2) of the Regulation provides that the Regulation does not apply to genetic resources covered by specialized international ABS instruments that are consistent with, and do not run counter the objectives of the Convention and the Nagoya Protocol. Therefore, the Regulation does not apply to genetic resources falling under the International Treaty and the PIP Framework, except when such resources are accessed in a country that is not a Party to those instruments but is a Party to the Nagoya Protocol with enacted access legislation applicable to these genetic resources. The Regulation also applies where genetic resources covered under those instruments are utilized for purposes other than those of the specialized instrument in question (i.e. if an agricultural resource covered by the International Treaty is utilized for pharmaceutical purposes).

11. *Spain* described its national legislation regarding the International Treaty. Spain indicated that access to genetic resources from wild taxa, *in situ* and *ex situ*, for their utilization is regulated by its Bylaw 124/2017, which entered into force on 15 March 2017. Access to plant genetic resources for food and agriculture is regulated by its Law 30/2006 on seeds and plants from garden centres and plant genetic resources. Spain indicated that it was in the last stages of development of a new legislation to regulate access to plant genetic resources for food and agriculture, taking into account the provisions of both the International Treaty and the Nagoya Protocol. This new legislation distinguishes between resources accessible through the Multilateral System of the International Treaty (included in Annex I to the legislation) and resources not included in the Multilateral System or whose access is carried out for a purpose different from those established by the Multilateral System, which would fall within the scope of the Nagoya Protocol as long as the access is carried out for its “utilization” as defined by the Protocol. Finally, resources covered neither by the International Treaty nor by the Nagoya Protocol, would remain under the scope of Law 30/2006.

12. *Sweden* indicated that, pursuant to Swedish regulation (2011:474) on simplified access to plant genetic resources, a governmental authority holding such plant genetic resources as those referred to in Annex I to the International Treaty may enter into an agreement with a natural or legal person on simplified access to the resources in accordance with Article 12 (4) of the Treaty.

13. *Japan* noted that the International Treaty and the PIP Framework are regarded as specialized international ABS instruments. Consequently, the Nagoya Protocol is not applied for the implementation of the Framework or the utilization of plant genetic resources of crop species listed on Annex I of the International Treaty and similar species, as long as this utilization is consistent with, and does not run counter to the objectives of the Convention on Biological Diversity and the Nagoya Protocol. Japan further noted that the 72nd World Health Assembly, held in May 2019, adopted resolution WHA72(13) on “the public health implication of implementation of the Nagoya Protocol”, which should be taken into account as the impact of the Protocol on public health is significant.

14. *Norway* referred to the Nature Diversity Act, section 58, under which the King has the authority to determine that the collection of genetic material collected from the natural environment requires a permit from the Ministry. Removal from public collections and collection for use and further breeding and cultivation in agriculture and forestry are excepted from the requirement to hold a permit. Norway indicated that the implementation of the International Treaty is supported by several specific regulations and policies, including Sections 60 and 61 of the Nature Diversity Act. Norway indicates that there is close collaboration among the Nordic countries regarding the management of genetic resources, including a joint Nordic genebank (NordGen). The basic principles for the Nordic approach to access and benefit-sharing are reflected in the Kalmar Declaration from 2003 and the NordGen genetic bank uses the Standard Material Transfer Agreement established under the International Treaty for all material covered by this Treaty and to facilitate access to other material and for other purposes applying similar conditions.

15. *Switzerland* indicated that domestic measures oblige users to exercise due diligence when using genetic resources of other Parties to the Nagoya Protocol, provided that these resources were accessed after the entry into force of the Nagoya Protocol and that these Parties have access regulations in place. However, in line with Article 4, paragraph 4, of the Protocol, Article 23n, paragraph 2d, of the Federal Act on the Protection of Nature and Cultural Heritage (NCHA) provides that genetic resources are not subject to the due diligence requirement if they are covered for a specific use by a specialized international ABS instrument under Article 4 of the Nagoya Protocol. Switzerland recognizes the Multilateral System (MLS) of the International Treaty and the PIP Framework as specialized international ABS instruments. Switzerland considers that the application of such specialized instruments can ensure a more specialized, efficient and non-duplicative approach to regulating access to genetic resources and the sharing of benefits arising from their utilization. Switzerland implemented the provisions of the Nagoya Protocol as a “default mechanism”, applying to genetic resources and associated traditional knowledge, as long as no other specialized international ABS instruments are applicable. Domestic regulations concerning the International Treaty are provided in a specific Ordinance (ORPGAA, SR 916.181) while regulations concerning the PIP Framework fall under the general provision of Article 23n, paragraph 2d, of the NCHA.

16. *Canada* explained that it is a Party to various specialized international ABS instruments and engages in coordination regarding ABS issues addressed in different international fora. Canada implements the ABS measures of the International Treaty mainly through the activities of Agriculture and Agri-Food Canada (AAFC). AAFC operates the Plant Gene Resources of Canada (PGRC) and participates in the International Treaty Global Information System. Recognizing that existing ABS practices for food and agriculture differ significantly between subsectors, AAFC also participates in the development of other international ABS efforts, such as the “Elements to Facilitate Domestic Implementation of Access and Benefit-sharing for Different Subsectors of Genetic Resources for Food and Agriculture,” of the Commission on Genetic Resources for Food and Agriculture of the Food and Agriculture Organization of the United Nations (FAO) and seeks to incorporate these, as appropriate, domestically. AAFC has also been involved in the development of best practices for implementation of biological control. AAFC contributed to the publication *The Application of Classical Biological Control for the Management of Established Invasive Alien Species Causing Environmental Impacts*<sup>4</sup> and the International Organization for Biological Control’s “Best practices for the use and exchange of invertebrate biological control genetic resources relevant for food and agriculture”.<sup>5</sup> AAFC uses these best practices in its own research to combat invasive alien species in Canada. Finally, Canada also implements the ABS measures of the PIP Framework.

#### **IV. SYNTHESIS OF VIEWS ON THE POTENTIAL CRITERIA CONTAINED IN THE STUDY, TAKING INTO ACCOUNT ARTICLE 4, PARAGRAPHS 1 TO 3, OF THE PROTOCOL**

17. This section synthesizes the views that were submitted on the potential criteria contained in the study ([CBD/SBI/2/INF/17](#)), taking into account Article 4, paragraphs 1 to 3, of the Protocol, pursuant to decision 3/14. A total of six submissions were received from Parties, non-Parties and organizations on this issue.<sup>6</sup> Although there are some differences in the content of the various submissions, there is also some convergence on a number of points raised under decision NP-3/14. In the subsections that follow, an

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<sup>4</sup> Sheppard AW, Paynter Q, Mason P, Murphy S, Stoett P, Cowan P, Brodeur J, Warner K, Villegas C, Shaw R, Hinz H, Hill, M and Genovesi P (2019), IUCN SSC Invasive Species Specialist Group. *The Application of Biological Control for the Management of Established Invasive Alien Species Causing Environmental Impacts*. Secretariat of the Convention on Biological Diversity, *Technical Series No. 91*. Montreal, Canada, 74 pp.

<sup>5</sup> Mason, P.G., Cock, M.J.W., Barratt, B.I.P. *et al.* “Best practices for the use and exchange of invertebrate biological control genetic resources relevant for food and agriculture”. *BioControl* **63**, 149-154 (2018). <https://doi.org/10.1007/s10526-017-9810-3>.

<sup>6</sup> Out of the six submissions received, one submission represents the views of the European Union and its member States and, another, the views of the African Union. Two of these submissions are from non-Parties to the Protocol.

attempt has been made to identify such points. These are indicated in italics. The explanations or elaborations supporting the ideas are summarized subsequently. Footnotes indicating the sources of the views are provided with a view to facilitating reference to the original submission for further information.

#### A. General views on the criteria and their use

18. While some submissions questioned the need and usefulness of the criteria,<sup>7</sup> one submission, on behalf of a number of Parties, recognized that the criteria constitute good reference points of elements to consider when developing or recognizing specialized international ABS instruments.<sup>8</sup>

19. Submissions reiterated that any criteria developed should take into account the following:

(a) *Not be stricter than Article 4, paragraph 4, itself*: A number of submissions seem to agree that any criteria developed should not narrow the scope of the Article 4, paragraph 4, or be more stringent than elements of this provision.<sup>9</sup> All submissions consider that the core criterion set out in Article 4, paragraph 4, is that a specialized international ABS instrument shall be consistent with and not run counter to the objectives of the Convention and the Protocol, in particular the fair and equitable sharing of the benefits arising from the utilization of genetic resources. The requirement that the Protocol and any specialized international ABS instrument should be mutually supportive is specifically developed in three submissions;<sup>10</sup>

(b) *Not create any hierarchy between the Protocol and other specialized international ABS instruments*: Three submissions highlighted the need to ensure that no hierarchy between the Protocol and any other specialized international ABS instrument exists regardless of how other instruments would be identified;<sup>11</sup>

(c) *Allow flexibility*: Five submissions<sup>12</sup> expressed the view that any criteria developed should: (i) encourage flexibility and specialization; (ii) not prevent valuable initiatives by Parties; and (iii) not undermine the rights of Parties to develop appropriately specialized regimes. It was noted, on the other hand, that such criteria should not weaken the legally binding provisions of the Nagoya Protocol.<sup>13</sup> A Party expressed the view that the criteria should be tailored in such a way as to ensure that the PIP Framework of the World Health Organization falls within the criteria;<sup>14</sup>

(d) *Take into account the general principles of law and the concept of *lex specialis**:<sup>15</sup> One submission,<sup>16</sup> on the other hand, cautions against potential fragmentation of international ABS instruments and that the proliferation of international ABS instruments may have deleterious effects on national implementation, coordination and accountability.

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<sup>7</sup> Switzerland, New Zealand, Norway.

<sup>8</sup> The European Union and its member States.

<sup>9</sup> The European Union and its member States, Norway, Switzerland, Canada, New Zealand.

<sup>10</sup> The European Union and its member States, Canada, and the African Union.

<sup>11</sup> Switzerland, New Zealand, the African Union.

<sup>12</sup> The European Union and its member States, Norway, Switzerland, Canada, New Zealand.

<sup>13</sup> The African Union.

<sup>14</sup> Norway.

<sup>15</sup> European Union and its member States.

<sup>16</sup> The African Union.

## **B. Views on the possible process for recognizing a specialized international ABS instruments**

20. Several submissions appear to converge with regard to there being no need for a formal established process to recognize specialized international ABS instruments. Arguments put forward in this regard are as follows:

(a) The recognition of a specialized international ABS instrument is considered to be a sovereign decision of a State;<sup>17</sup>

(b) Article 4, paragraph 4, does not require a formal process of recognition<sup>18</sup> and there is no consensus among Parties that such a process is necessary;<sup>19</sup>

(c) The Convention and Nagoya Protocol do not have the competence to take decisions relating to other international instruments;<sup>20</sup>

(d) The development of criteria, as characteristics of a specialized international ABS instrument, will depend on the genetic resource in question and the purpose of the instrument.<sup>21</sup>

21. Overall, it seems that it could be considered useful to have criteria as reference points or elements to consider as guidance when developing or recognizing specialized international ABS instruments, but that there is no need to create a formal set of rules for the recognition of specialized international ABS instruments.

## **C. Views on the criteria themselves**

### *1. Criteria 1: Specialized international ABS instruments should be intergovernmentally agreed*

22. Two submissions<sup>22</sup> suggested that a specialized international ABS instrument should be intergovernmentally or internationally agreed.

23. One submission<sup>23</sup> stated that it should also be developed through an intergovernmental process, while other submissions<sup>24</sup> were of the view that how an instrument is developed may not be relevant. One submission<sup>25</sup> noted that it was not always relevant that the instrument be developed through an intergovernmental process, but it was indeed important and appropriate that States or Governments endorse such instruments. For example, according to this submission, an international instrument could result from a formal process within a specific international organization and then be adopted in accordance with its rules and procedures. It could also be possible that specialized international instrument would develop as a result of existing practice, and then be endorsed by an international organization, or as a result of informal cooperation, such as a regional cooperation initiative.<sup>26</sup>

24. Two submissions agreed that the instrument need not be legally binding.<sup>27</sup>

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<sup>17</sup> The European Union and its member States, Switzerland, New Zealand, the African Union.

<sup>18</sup> Switzerland, New Zealand.

<sup>19</sup> Norway, Switzerland, New Zealand.

<sup>20</sup> New Zealand.

<sup>21</sup> Norway.

<sup>22</sup> Norway, Switzerland.

<sup>23</sup> New Zealand.

<sup>24</sup> The European Union and its member States, Switzerland.

<sup>25</sup> The European Union and its member States.

<sup>26</sup> The European Union and its member States.

<sup>27</sup> Norway, Switzerland.

*2. Criteria 2: Specialized international ABS instruments should be specialized*

25. One submission noted that the “requirement” for a differentiated approach in sub-criteria (b) — i.e. that the instrument would apply to specific uses of genetic resources and/or traditional knowledge associated with genetic resources which require a differentiated and hence specialized approach — might be difficult to analyse in practice and that there may be specific sets or specific uses of genetic resources, for which a specialized approach may be more practical but may not necessarily be required.<sup>28</sup>

26. Other submissions that did comment on this criterion suggested that sub-criteria (a) — i.e. the instrument would apply to a specific set of genetic resources and/or traditional knowledge associated with genetic resources which would otherwise fall under the scope of the Nagoya Protocol — and (b) should not be cumulative.<sup>29</sup>

*3. Criteria 3: Specialized international ABS instruments should be mutually supportive*

27. No submission questioned the criterion that the Protocol and any specialized international ABS instrument should be mutually supportive.

28. While for one Party the sub-criteria proposed under criterion 3 should all be fulfilled,<sup>30</sup> other submissions found that these sub-criteria<sup>31</sup> are rather general or even insufficiently clear and therefore very difficult to fully meet as well as to apply and assess.<sup>32</sup> It was further indicated that it is not clear whether these sub-criteria are cumulative.<sup>33</sup> One Party noted that sub-criteria (a) on “consistency with biodiversity conservation and sustainable use objectives” is not applicable to pathogens, which are being eradicated.

29. One submission suggested that this criterion should read “the instrument is consistent with”, as written in Article 4, paragraph 4, and not “this instrument would be consistent with”, as in the annex to decision NP-3/14.<sup>34</sup>

30. There seems to be convergence on criteria 1 and 2, noting some have the view that sub-criteria of criterion 2 should not be cumulative. While there seems to be convergence on the view that the Nagoya Protocol and any specialized international ABS instrument should be mutually supportive, there are some slight differences on the extent of clarity and applicability of one or more of the sub-criteria.

## **V. KEY DEVELOPMENTS IN RELEVANT INTERNATIONAL FORUMS**

31. Issues related to access and benefit-sharing and the Nagoya Protocol are addressed in a number of other international forums besides the Convention on Biological Diversity and the Nagoya Protocol. The Secretariat of the Convention collaborates with intergovernmental organizations working in this area with a view to keeping itself abreast of developments in these processes and to provide information on developments related to the Nagoya Protocol, primarily, as specified in the decisions of the Parties to the Protocol or as reported by each Party to the Protocol. Many of these organizations also participate in processes under the Nagoya Protocol. As requested in decision [NP-3/7](#), the Executive Secretary will

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<sup>28</sup> Switzerland.

<sup>29</sup> The European Union and its member States, New Zealand.

<sup>30</sup> The European Union and its member States.

<sup>31</sup> (a) Consistency with biodiversity conservation and sustainable use objectives; (b) fairness and equity in the sharing of benefits; (c) legal certainty with respect to access to genetic resources or traditional knowledge and to benefit-sharing; (d) contribution to sustainable development, as reflected in internationally agreed goals; (e) other general principles of law, including good faith, effectiveness and legitimate expectations.

<sup>32</sup> Switzerland, Canada, New Zealand.

<sup>33</sup> Switzerland.

<sup>34</sup> Norway.

prepare a report on cooperative activities undertaken, including key developments under international agreements and instruments of relevance to the implementation of the Nagoya Protocol for the consideration of the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol at its fourth meeting. An advance version of this report will be issued for the Subsidiary Body as an information document.

32. This section summarizes information on international forums and processes of relevance to the issue of access and benefit-sharing and presents the status of key developments related to access and benefit-sharing in these forums and processes.

#### **A. Commission on Genetic Resources for Food and Agriculture**

33. The Commission on Genetic Resources for Food and Agriculture of the Food and Agriculture Organization of the United Nations was established in 1983. The original mandate of the Commission, to deal with plant genetic resources, was broadened in 1995 to cover all components of biodiversity relevant to food and agriculture.

34. Between 1994 and 2001, the Commission negotiated the International Treaty on Plant Genetic Resources for Food and Agriculture. In 2007, the Commission agreed on the importance of considering access and benefit-sharing in relation to all components of biodiversity for food and agriculture and decided that work in this field should be conducted within its Multi-Year Programme of Work. Since then, the Commission has revisited the issue of access and benefit-sharing for genetic resources for food and agriculture at each of its regular sessions. In 2013, a Team of Technical and Legal Experts on Access and Benefit-sharing established by the Commission, prepared the Elements to Facilitate Domestic Implementation of Access and Benefit-sharing for Different Subsectors of Genetic Resources for Food and Agriculture (ABS Elements).<sup>35</sup> The ABS Elements were welcomed by the Commission in 2015. The Conference of the Parties to the Convention, in 2016, invited its Parties and other Governments to take note of and to apply, as appropriate, the ABS Elements (see [decision XIII/1](#), para. 28).

35. At its seventeenth regular session, in 2019, the Commission welcomed explanatory notes complementing the ABS Elements that had been prepared by the Expert Team in collaboration with the Commission's Working Groups. The explanatory notes describe, within the context of the ABS Elements, the distinctive features and specific practices of different subsectors of genetic resources for food and agriculture.<sup>36</sup> In addition, the Commission initiated a survey of existing legislative, administrative and policy approaches, including best practices, for ABS for the different subsectors of genetic resources for food and agriculture and traditional knowledge associated with genetic resources for food and agriculture held by indigenous peoples and local communities, with the aim of identifying typical approaches and lessons learned.<sup>37</sup>

#### **B. International Treaty on Plant Genetic Resources for Food and Agriculture**

36. The International Treaty on Plant Genetic Resources for Food and Agriculture was adopted in 2001 and entered into force in 2004. Pursuant to Article 1 of the International Treaty, its objectives are “the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use, in harmony with the Convention on Biological Diversity, for sustainable agriculture and food security.”<sup>38</sup>

37. Under its Article 10.2, the International Treaty establishes a Multilateral System of Access and Benefit-sharing, “which is efficient, effective, and transparent, both to facilitate access to plant genetic

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<sup>35</sup> <http://www.fao.org/3/a-i5033e.pdf>.

<sup>36</sup> <http://www.fao.org/3/ca5088en/CA5088EN.pdf>.

<sup>37</sup> Further information on cooperation with FAO and its CGRFA is provided in CBD/SBI/3/INF/6.

<sup>38</sup> <http://www.fao.org/3/i0510e/i0510e.pdf>.



resources for food and agriculture, and to share, in a fair and equitable way, the benefits arising from the utilization of these resources, on a complementary and mutually reinforcing basis.”<sup>39</sup>

38. In 2013, the Governing Body of the International Treaty launched a process to enhance the Multilateral System of Access and Benefit-sharing by establishing an Ad Hoc Open-ended Working Group, which was tasked, among other things, with developing measures for the increase in user-based payments and contributions to the Benefit-Sharing Fund in a sustainable and predictable long-term manner. The Working Group considered, among other matters, revisions to the Standard Material Transfer Agreement as well as possible changes to the coverage of the Multilateral System. As countries’ interdependence in plant genetic resources represents one of the key arguments for the Multilateral System of the Plant Treaty, the basis for considering its enhancement included a fully updated estimation of such interdependence, as provided in a recent study.<sup>40</sup>

39. In the course of the biennium 2018-2019, the Working Group considered, among other things, criteria and options for the possible adaptation of coverage of the Multilateral System and supportive measures to facilitate the implementation of the possible expansion of the coverage of the Multilateral System. The Working Group considered a possible process to review the status of: ratifications to the amended Annex I of the International Treaty (i.e. crops and forages covered by the Multilateral System); the level of user-based income accruing to the Benefit-sharing Fund; availability of and access provided to material within the Multilateral System.

40. In 2019, at its eighth session, the Governing Body of the International Treaty was aiming to reach consensus on measures to enhance the functioning of the Multilateral System of Access and Benefit-sharing, an item which has been under negotiations for six years. Despite intense negotiations, the Governing Body could not reach consensus on the enhancement of the Multilateral System and adopted resolution 2/2019.<sup>41</sup> It encouraged informal consultations among Contracting Parties and especially national consultations among sectors and relevant stakeholders. Some Contracting Parties wanted the Governing Body, at its future ninth Session, planned for December 2021, to consider how to carry out further work on the enhancement of the Multilateral System, noting the need to consider outcomes of relevant debates under the Convention on Biological Diversity.

### **C. United Nations Convention on the Law of the Sea**

41. The United Nations Convention on the Law of the Sea was adopted in December 1982 and entered into force in November 1994, with the objectives, among others, of enabling equitable and efficient utilization of ocean resources and protecting and preserving the marine environment.

42. The General Assembly of the United Nations, in its resolution 72/249 of 24 December 2017, decided to convene an Intergovernmental Conference on the Conservation and Sustainable Use of Marine Biodiversity of Areas Beyond National Jurisdiction (BBNJ), under the auspices of the United Nations, to consider the recommendations of the Preparatory Committee established by resolution 69/292 of 19 June 2015 on the elements and to elaborate the text of an international legally binding instrument under the Convention on the Law of the Sea, with a view to developing the instrument as soon as possible.

43. In accordance with resolution 72/249, the Intergovernmental Conference addresses the following topics: the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction, in particular, together and as a whole, marine genetic resources, including questions on the sharing of benefits, measures such as area-based management tools, including marine protected areas, environmental impact assessments and capacity-building and the transfer of marine technology.

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<sup>39</sup> Ibid.

<sup>40</sup> The study is available at: <http://www.fao.org/3/a-bq533e.pdf>.

<sup>41</sup> Resolution 2/2019 available at: <http://www.fao.org/3/nb779en/nb779en.pdf>.

44. Three sessions of the Intergovernmental Conference on an international legally binding instrument were convened between September 2018 and August 2019. Delegates at the third session of the Conference embarked, for the first time, on textual negotiations on the basis of a “zero draft” containing treaty text developed by the President of the Conference.

45. A revised draft text<sup>42</sup> of an agreement under the Convention on the Law of the Sea has been prepared by the President for consideration at the fourth session. The revised draft text includes a section on access and benefit-sharing for marine genetic resources and addresses traditional knowledge of indigenous peoples and local communities associated with marine genetic resources (Section II of the revised draft text).

#### **D. World Health Organization**

46. In 2011, the Governing Body of the World Health Organization (WHO), the World Health Assembly, adopted the Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits (PIP Framework). The PIP Framework is a public health instrument that seeks to better prepare the world to respond to pandemic influenza. Its key goals include: to improve and strengthen the sharing of influenza viruses with human pandemic potential; and to increase the access of developing countries to vaccines and other pandemic-related supplies.

47. WHO coordinates the sharing of influenza viruses through an international network of public health laboratories called the “Global Influenza Surveillance and Response System” (GISRS). The PIP Framework established terms of reference for the GISRS laboratories related to their work with influenza viruses with human pandemic potential. The laboratories in GISRS exchange viruses using standard material transfer agreements, binding contracts that established the conditions and obligations for benefit-sharing.

48. At its 72nd meeting, in May 2019, the World Health Assembly addressed two items directly related to access and benefit-sharing: the PIP Framework and public health implications of implementation of the Nagoya Protocol.

49. With regard to the PIP Framework, decision WHA72(12)<sup>43</sup> includes paragraphs that request the Director-General: (a) to urgently work with the GISRS and other partners to identify and address the challenges and uncertainties related to the sharing of seasonal influenza viruses that have emerged as countries implement the Nagoya Protocol; and (b) to prepare a report on the treatment of influenza virus sharing and the public health considerations thereof by existing relevant legislation and regulatory measures, including those implementing the Nagoya Protocol, in consultation with the Secretariat of the Convention; and (c) to work collaboratively across WHO to raise awareness among member States of the implications for public health of implementation of the Nagoya Protocol, particularly given the cross-cutting nature of relevant issues.

50. The WHA adopted decision WHA72(13) on public health implications of implementation of the Nagoya Protocol<sup>44</sup> which requests the Director-General to broaden engagement with member States, the Secretariat of the Convention on Biological Diversity, relevant international organizations and relevant stakeholders: (a) to provide information on current pathogen-sharing practices and arrangements, the implementation of access and benefit-sharing measures, as well as the potential public health outcomes and other implications; and (b) to provide a report to the 74th World Health Assembly, through the

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<sup>42</sup> Advanced unedited version available at:

[https://www.un.org/bbnj/sites/www.un.org.bbnj/files/revised\\_draft\\_text\\_a.conf\\_232.2020.11\\_advance\\_unedited\\_version.pdf](https://www.un.org/bbnj/sites/www.un.org.bbnj/files/revised_draft_text_a.conf_232.2020.11_advance_unedited_version.pdf)

<sup>43</sup> Document WHA72(12), available at: [http://apps.who.int/gb/ebwha/pdf\\_files/WHA72/A72\(12\)-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA72/A72(12)-en.pdf).

<sup>44</sup> Document WHA72(13), available at: [http://apps.who.int/gb/ebwha/pdf\\_files/WHA72/A72\(13\)-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA72/A72(13)-en.pdf).

Executive Board at its 148th session, as well as an interim report to the Executive Board at its 146th session.

51. In the context of the implementation of decision WHA72(13), WHO developed, in consultation with the Secretariat of the Convention, a survey to collect information on: (a) current pathogen-sharing practices and arrangements; and (b) implementation of access and benefit-sharing measures. The survey was also intended to gather perspectives on potential public health outcomes and other implications, as requested in the decision. Through a notification,<sup>45</sup> CBD and ABS national focal points were invited to participate in the survey, in addition to WHO member States, international and national agencies, WHO Collaborating Centres, non-State actors in official relations with WHO, private sector and other relevant stakeholders.

52. The WHA held the first part of its 73<sup>rd</sup> session virtually on 18 and 19 May 2020. Under agenda item 3 on the COVID-19 response, WHA recognized, among other things, the need for all countries to have unhindered, timely access to quality, safe, efficacious and affordable diagnostics, therapeutics, medicines and vaccines, and essential health technologies, and their components as well as equipment for COVID-19 response (PP 13). It also recognized the role of extensive immunization against COVID-19 as a global public good for health in preventing, containing and stopping transmission in order to bring the pandemic to an end, once safe, quality, efficacious, effective, accessible, and affordable vaccines are available (OP 6).<sup>46</sup>

### **E. World Intellectual Property Organization**

53. The Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge was established by the General Assembly of the World Intellectual Property Organization (WIPO) in 2000 as a forum for discussions among member States and text-based negotiations with the objective of reaching an agreement on an international legal instrument(s) that would ensure the effective protection of traditional knowledge, traditional cultural expressions/folklore and genetic resources.

54. At the sixth and last session under the current mandate for 2018-2019, the Intergovernmental Committee addressed traditional knowledge and traditional cultural expressions, took stock of the progress made over the biennium 2018-2019 and made recommendations to the WIPO General Assembly. Among other things, the Committee agreed that the draft articles on genetic resources, traditional knowledge and traditional cultural expressions,<sup>47</sup> as well as the Chair's text of a Draft International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources<sup>48</sup> should be transmitted to the 2019 WIPO General Assembly. It also decided to recommend to the 2019 WIPO General Assembly that the mandate of the Committee be renewed for the biennium 2020-2021.

55. The WIPO General Assembly, at its 51<sup>st</sup> session, in 2019, agreed on the renewal of the mandate of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore for the 2020-2021 biennium, as well as the work plan for the biennium. According to the agreed mandate, the Intergovernmental Committee will continue to expedite its work with the objective of finalizing an agreement on an international legal instrument(s), without prejudging the nature of

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<sup>45</sup> Notification 2020-012 issued on 24 January 2020, available at: <https://www.cbd.int/doc/notifications/2020/ntf-2020-012-abs-en.pdf>.

<sup>46</sup> See the text of the resolution at: [https://apps.who.int/gb/ebwha/pdf\\_files/WHA73/A73\\_R1-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/WHA73/A73_R1-en.pdf)

<sup>47</sup> Draft articles are contained in documents WIPO/GRTKF/IC/40/6, WIPO/GRTKF/IC/40/18 and WIPO/GRTKF/IC/40/19 respectively, available at: [https://www.wipo.int/meetings/en/details.jsp?meeting\\_id=50424](https://www.wipo.int/meetings/en/details.jsp?meeting_id=50424).

<sup>48</sup> WIPO/GRTKF/IC/40/CHAIR TEXT available at: [https://www.wipo.int/meetings/en/doc\\_details.jsp?doc\\_id=438199](https://www.wipo.int/meetings/en/doc_details.jsp?doc_id=438199)

outcome(s), relating to intellectual property which will ensure the balanced and effective protection of genetic resources, traditional knowledge and traditional cultural expressions.<sup>49</sup>

## VI. SUGGESTED ELEMENTS OF A DRAFT RECOMMENDATION

56. In the light of the synthesis of views and the various points of consensus identified through the analysis above, the Subsidiary Body on Implementation may wish to consider making recommendation to the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol, to take a decision, at its fourth meeting, along the following lines:

*The Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol on Access and Benefit-sharing,*

*Taking note* of the information and views submitted in accordance with decision NP-3/14, paragraph 2,

*Recalling* Article 4, paragraph 4, of the Protocol,

1. *Welcomes* the indicative criteria for specialized international access and benefit-sharing instruments in the context of Article 4, paragraph 4, of the Nagoya Protocol contained in the annex to the present draft decision, noting that they are intended to contribute to strengthening coordination and mutual supportiveness between the Nagoya Protocol and other international access and benefit-sharing instruments, without creating a hierarchy among them;

2. *Invites* Parties, and other Governments to take into account the indicative criteria in developing and/or applying access and benefit-sharing measures;

3. *Invites* relevant international organizations and intergovernmental processes to take into account the indicative criteria in their efforts to develop international instruments that include provisions on access and benefit-sharing;

4. *Requests* Parties to include information in their national reports, and *invites* other Governments and relevant international organizations to share information, on any steps that they have taken towards the development and/or implementation of specialized international access and benefit-sharing instrument that is consistent with the objectives of the Convention and the Protocol, including information on the specific genetic resource covered by and for the purpose of the specialized instrument;

5. *Decides* to review this decision in the context of the assessment and review process as provided in Article 31 of the Protocol, taking into account relevant developments and with a view to taking any steps necessary to promote coherence in the international regime on access and benefit-sharing.

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<sup>49</sup> Report on the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (document WO/GA/51/12) available at: [https://www.wipo.int/meetings/en/doc\\_details.jsp?doc\\_id=443934](https://www.wipo.int/meetings/en/doc_details.jsp?doc_id=443934).

*Annex*

**INDICATIVE CRITERIA FOR SPECIALIZED INTERNATIONAL ACCESS AND BENEFIT-SHARING INSTRUMENTS IN THE CONTEXT OF ARTICLE 4, PARAGRAPH 4, OF THE NAGOYA PROTOCOL ON ACCESS TO GENETIC RESOURCES AND THE FAIR AND EQUITABLE SHARING OF BENEFITS ARISING FROM THEIR UTILIZATION**

1. These indicative criteria are reference points or elements to consider as guidance when developing or recognizing specialized international access and benefit-sharing instruments. They are intended to contribute to strengthening coordination and mutual supportiveness between the Nagoya Protocol and other international access and benefit-sharing instruments, without creating a hierarchy among them.
  2. *Intergovernmentally or internationally agreed* — The instrument would be developed and agreed through an intergovernmental process and/or be endorsed by States and/or Governments. The instrument may be binding or non-binding.
  3. *Specialized* — The instrument would:
    - (a) Apply to a specific set of genetic resources and/or traditional knowledge associated with genetic resources which would otherwise fall under the scope of the Nagoya Protocol; or
    - (b) Apply to specific uses of genetic resources and/or traditional knowledge associated with genetic resources which require a differentiated and hence specialized approach.
  4. *Mutually supportive* — The instrument is consistent with, supportive of, and does not run counter to the objectives of the Convention on Biological Diversity and the Nagoya Protocol, including with respect to:
    - (a) Consistency with biodiversity conservation and sustainable use objectives;
    - (b) Fairness and equity in the sharing of benefits;
    - (c) Legal certainty with respect to access to genetic resources or traditional knowledge and to benefit-sharing;
    - (d) Contribution to sustainable development, as reflected in internationally agreed goals;
    - (e) Other general principles of law, including good faith, effectiveness and legitimate expectations.
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