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# COMMISSION ON GENETIC RESOURCES FOR FOOD AND AGRICULTURE

## Item 6 of the Provisional Agenda

### INTERGOVERNMENTAL TECHNICAL WORKING GROUP ON AQUATIC GENETIC RESOURCES FOR FOOD AND AGRICULTURE

#### Fourth Session

Rome, 21–23 February 2023

### ACCESS AND BENEFIT-SHARING FOR GENETIC RESOURCES FOR FOOD AND AGRICULTURE

## TABLE OF CONTENTS

|  | Paragraphs |
|--|------------|
| I. Introduction .....  | 1–6        |
| II. Recent developments under other international agreements and instruments ..... | 7–48       |
| III. Awareness-raising activities.....   | 49–50      |
| IV. Typology of access and benefit-sharing country measures.....                   | 51–55      |
| V. Implementation of access and benefit-sharing country measures.....              | 56–57      |
| VI. Guidance sought.....   | 58         |

## I. INTRODUCTION

1. The Commission on Genetic Resources for Food and Agriculture (Commission), at its last session, reviewed its past work on access and benefit-sharing (ABS) for genetic resources for food and agriculture (GRFA) and associated traditional knowledge (TKGRFA) and identified several areas for further work.
2. The Commission requested the Secretariat to continue monitoring relevant developments under other international agreements and instruments relevant to ABS and report them back to the Commission.<sup>1</sup>
3. The Commission requested that the Secretariat, in close collaboration with other relevant international organizations and instruments, including the International Treaty on Plant Genetic Resources for Food and Agriculture (the Treaty) and the Convention on Biological Diversity (CBD), continue to raise awareness among key stakeholders, including breeders, and provide capacity building and training programmes on ABS for GRFA, in particular for developing countries. It requested the Secretary to bring the *Elements to facilitate domestic implementation of access and benefit-sharing for different subsectors of genetic resources for food and agriculture – with explanatory notes* (ABS Elements)<sup>2</sup> to the attention of the Open-ended Working Group on the Post-2020 Global Biodiversity Framework. It further requested the Secretariat to collaborate with the Secretariats of the Treaty and the CBD, as needed, on “means of assembling relevant information for measuring and monitoring monetary and non-monetary benefit-sharing, within their respective mandates and existing frameworks.”<sup>3</sup>
4. The Commission requested for its next session the preparation of a stand-alone document providing specific examples of existing country legislative, administrative or policy measures that directly or indirectly accommodate distinctive features of GRFA and TKGRFA.<sup>4</sup>
5. In addition, the Commission “supported future work that further deepens the empirical evidence needed to understand the effects of ABS measures.”<sup>5</sup> In this regard, it requested the Secretariat to prepare, based on responses to a pre-tested country questionnaire, a report on the practical application of ABS country measures to the different subsectors of GRFA and TKGRFA, including monitoring of ABS compliance, with a view to identifying the effects of ABS measures on the utilization and conservation of the different GRFA, TKGRFA and the sharing of benefits.<sup>6</sup>
6. This document responds to these requests of the Commission. It provides an overview of relevant developments under other international agreements and instruments since the last session of the Commission (section II) and information on awareness-raising activities (section III). Furthermore, it provides a typology of ABS country measures relevant to GRFA (section IV) and an update on the preparation of a report on the implementation of access and benefit-sharing country measures and their implications for the use and exchange of genetic resources for food and agriculture, associated traditional knowledge and benefit-sharing (section V).

## II. RECENT DEVELOPMENTS UNDER OTHER INTERNATIONAL AGREEMENTS AND INSTRUMENTS

7. Matters related to ABS are addressed under various international instruments and in various fora, including the CBD and its Nagoya Protocol, the International Treaty on Plant Genetic Resources for Food and Agriculture (International Treaty), the United Nations Convention on the Law of the Sea (UNCLOS), the World Intellectual Property Organization (WIPO) and the World Health Organization (WHO).

<sup>1</sup> CGRFA-18/21/Report, paragraph 31.

<sup>2</sup> FAO. 2019. ABS Elements: Elements to facilitate domestic implementation of access and benefit-sharing for different subsectors of genetic resources for food and agriculture – with explanatory notes. FAO, Rome. <https://www.fao.org/documents/card/en/c/CA5088EN/>

<sup>3</sup> CGRFA-18/21/Report, paragraph 29.

<sup>4</sup> CGRFA-18/21/Report, paragraph 26.

<sup>5</sup> CGRFA-18/21/Report, paragraph 27.

<sup>6</sup> CGRFA-18/21/Report, paragraph 27.

**Convention on Biological Diversity and Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity**

8. The CBD requires its Contracting Parties to take legislative, administrative or policy measures, as appropriate, with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Parties providing such resources.<sup>7</sup> Access to genetic resources shall be subject to prior informed consent (PIC)<sup>8</sup> and, where granted, shall be on mutually agreed terms (MAT).<sup>9</sup> Potential benefits to be shared also include: access to and transfer of technology using genetic resources; participation in biotechnological research activities based on the genetic resources; and priority access to the results and benefits arising from biotechnological use of the genetic resources.<sup>10</sup>

9. The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (the Nagoya Protocol) is the instrument for the implementation of the ABS provisions of the CBD.<sup>11</sup> It covers genetic resources, including GRFA, within the scope of Article 15 of the CBD,<sup>12</sup> as well as TKGRFA, and sets out core obligations for its Parties with regard to: (i) regulating access to genetic resources for research and development, and to associated traditional knowledge; (ii) the sharing of benefits derived from such utilization, as well as subsequent applications and commercialization and from the utilization of associated traditional knowledge; and (iii) the compliance of users of genetic resources with the domestic ABS measures of the Contracting Party that provided the genetic resources (“country compliance measures”) and with the contractual obligations providers and users have mutually agreed on.

10. The Nagoya Protocol, in its Preamble, explicitly recognizes the importance of genetic resources to food security, the special nature of agricultural biodiversity, its distinctive features and problems needing distinctive solutions, as well as the interdependence of all countries with regard to GRFA and the special nature and importance of these resources for achieving food security worldwide and for the sustainable development of agriculture in the context of poverty alleviation and climate change. In this regard, the Nagoya Protocol also acknowledges the fundamental role of the International Treaty and the Commission.<sup>13</sup>

11. In its operational provisions, the Nagoya Protocol requires Parties to consider, in the development and implementation of their ABS legislation or regulatory requirements, the importance of GRFA and their special role for food security.<sup>14</sup> Parties shall also create conditions to promote and encourage research that contributes to the conservation and sustainable use of biological diversity, particularly in developing countries, including through simplified measures on access for non-commercial research purposes, taking into account the need to address a change of intent for such research.<sup>15</sup>

*Specialized international access and benefit-sharing instruments*

12. The Nagoya Protocol leaves room for other international agreements in the field of ABS and it does not prevent its Parties from developing and implementing other relevant international agreements, including other specialized ABS instruments.<sup>16</sup> Article 4, paragraph 4 of the Protocol provides that where a specialized international ABS instrument applies that is consistent with, and does not run counter to the objectives of the CBD and the Protocol, the Protocol does not apply for the

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<sup>7</sup> CBD, Article 15.7.

<sup>8</sup> CBD, Article 15.5.

<sup>9</sup> CBD, Article 15.4.

<sup>10</sup> CBD, Articles 15, 16, 19, 20, 21.

<sup>11</sup> Nagoya Protocol, Article 4.4.

<sup>12</sup> Nagoya Protocol, Article 3.

<sup>13</sup> Nagoya Protocol, Preamble.

<sup>14</sup> Nagoya Protocol, Article 8(c).

<sup>15</sup> Nagoya Protocol, Article 8(a).

<sup>16</sup> Nagoya Protocol, Article 4.2.

Party or Parties to the specialized instrument in respect of the specific genetic resource covered by and for the purpose of the specialized instrument. One of the instruments explicitly acknowledged in the Preamble of the Nagoya Protocol is the International Treaty, which has been developed in harmony with the CBD prior to the adoption of the Nagoya Protocol.<sup>17</sup>

13. The fourth meeting of the Conference of the Parties to the CBD serving as the meeting of the Parties to the Nagoya Protocol (COP-MOP NP) (Part II) held from 7 to 19 December 2022, will consider criteria for specialized international ABS instruments in the context of Article 4, paragraph 4 of the Nagoya Protocol. Discussions are expected to be based on a draft text along the lines of which the Subsidiary Body on Implementation recommends that a decision be taken.<sup>18</sup> According to the draft text, specialized international ABS instruments would apply to: (i) specific sets of genetic resources or associated traditional knowledge, (ii) specific uses of genetic resources or of associated traditional knowledge, or (iii) specific purposes, which require a differentiated and hence specialized approach.

14. The draft text also includes criteria that aim to ensure that the specialized international ABS instrument is consistent with, supportive of and does not run counter to, the objectives of the CBD and the Nagoya Protocol. The criteria include: (a) consistency with biodiversity conservation and sustainable use objectives; (b) fairness and equity in the sharing of benefits; (c) legal certainty; (d) full and effective participation of Indigenous Peoples and local communities concerned; (e) contribution to sustainable development, as reflected in internationally agreed goals; (f) other general principles of law, including good faith, effectiveness and legitimate expectations. Whether an instrument would need to be binding or could also be non-binding to qualify as specialized international ABS instrument in the context of Article 4, paragraph 4 of the Nagoya Protocol is still controversial.

15. No agreement has been reached yet on the operationalization of the proposed criteria. While some Parties wish to assign to the meeting of the Parties to the Nagoya Protocol “the authority to assess, determine, review or terminate the status of instruments as specialized international access and benefit-sharing instruments”, others prefer that the development/implementation of specialized international ABS instruments would only have to be reported by the relevant international organizations or intergovernmental processes, and by Parties in their national reports and through the ABS Clearinghouse.

*Post-2020 global biodiversity framework and access and benefit-sharing*

16. As reported to the last session of the Commission, the 15th meeting of the Conference of the Parties to the CBD is expected to adopt the Post-2020 Global Biodiversity Framework that contributes to the 2030 Agenda for Sustainable Development and places the global community on a path towards realizing the 2050 Vision for Biodiversity, “Living in harmony with nature”.<sup>19</sup>

17. At the time of writing, consultations on the post-2020 Global Biodiversity Framework have not been concluded. The Open-ended Working Group on the Post-2020 Global Biodiversity Framework held its first meeting in August 2019,<sup>20</sup> the second in February 2020,<sup>21</sup> the third in August/September 2021<sup>22</sup> and March 2022<sup>23</sup> and the fourth in June 2022.<sup>24</sup> An Informal Group on the Post-2020 Global Biodiversity Framework convened in September 2022 to prepare proposals for a streamlined text of the post-2020 global biodiversity framework for participants in the fifth meeting of the Working Group.<sup>25</sup> A fifth meeting of the Working Group is scheduled for December 2022 prior to the 15th meeting of the Conference of the Parties to the CBD.

18. The first draft of the Post-2020 Global Biodiversity Framework was posted in July 2021. The most recent draft, the “Compiled streamlined text as suggested by the meeting of the Informal Group

<sup>17</sup> International Treaty, Article 1.1.

<sup>18</sup> CBD/SBI/3/21, Recommendation 3/16; see also CBD/SBI/2/INF/17.

<sup>19</sup> CGRFA-18/21/14 Rev.1.

<sup>20</sup> CBD/WG2020/1/5.

<sup>21</sup> CBD/WG2020/2/4.

<sup>22</sup> CBD/WG2020/3/5.

<sup>23</sup> CBD/WG2020/3/7.

<sup>24</sup> CBD/WG2020/4/4.

<sup>25</sup> CBD/WG2020/5/2.

[on the Post-2020 Global Biodiversity Framework]” stresses the importance of access and benefit-sharing in Goal C and Target 13.<sup>26</sup> No agreement could be reached yet as to whether Goal C and Target 13 should aim at a “substantial increase” of (monetary and non-monetary) benefits to be shared.

19. In addition to the Post-2020 Global Biodiversity Framework, the Conference of the Parties is expected to adopt a framework for monitoring the implementation of the post-2020 Global Biodiversity Framework. At the request of the Open-ended Working Group on the Post-2020 Global Biodiversity Framework<sup>27</sup>, the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) prepared a draft approach to monitoring, including indicators relevant to the draft goals and targets of the draft Post-2020 Global Biodiversity Framework.<sup>28</sup> SBSTTA also established a process for further review of the potential indicators, including through an expert workshop. Two headline indicators are proposed for Goal C, “monetary benefits received” and “non-monetary benefits received.” The headline indicator suggested for Target 13 would count countries that have operational legislative, administrative or policy frameworks for ABS in place, collated from binary (yes/no) reporting from countries through national reporting. As noted by the expert workshop, no methodology exists for these indicators, but their development is considered a priority.<sup>29</sup>

20. Once a decision on the indicators for access and benefit-sharing has been taken, the Commission may wish to consider the role it should play, in collaboration with other instruments and organizations, as needed, in assembling relevant information for measuring and monitoring monetary and non-monetary benefit-sharing.

#### *Global multilateral benefit-sharing mechanism*

21. Article 10 of the Nagoya Protocol requires Parties to 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. At the request of the meeting of the Parties to the Protocol,<sup>30</sup> a study to identify specific cases meeting the aforementioned criteria was commissioned.<sup>31</sup> While the study identifies cases for which it is difficult or impossible to grant or obtain prior informed consent (e.g. migratory species, *ex situ* genetic resources with untraceable provenance), Parties to the Protocol seem to hold divergent views as to whether these cases necessitate the establishment of a global benefit-sharing mechanism.<sup>32</sup>

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

22. The International Treaty, negotiated under the aegis of the Commission, is a specialized ABS instrument that applies to plant genetic resources for food and agriculture (PGR).<sup>33</sup> Its Multilateral System of Access and Benefit-sharing (MLS) covers some 35 crops – or in the case of Brassicas, crop complexes – and 29 forages listed in Annex 1 to the Treaty. In the exercise of their sovereignty, Contracting Parties provide access to PGR that are under their management and control and in the public domain.<sup>34</sup> The MLS also comprises CGIAR “in trust” materials, materials held by other international institutions that sign agreements with the Governing Body of the International Treaty and materials that individual holders voluntarily make available. Under the MLS, access is provided for the purpose of utilization and conservation for research, breeding and training for food and agriculture, provided that such purpose does not include chemical, pharmaceutical and/or other non-food/feed industrial uses.<sup>35</sup> Materials are accessed and benefits shared under conditions set out in the Standard

<sup>26</sup> CBD/WG2020/5/2, Annex II

<sup>27</sup> CBD/WG2020/1/5, para. 7(a).

<sup>28</sup> CBD/SBSTTA/24/12, Recommendation 24/2.

<sup>29</sup> CBD/ID/OM/2022/1/2.

<sup>30</sup> NP-3/13.

<sup>31</sup> CBD/SBI/3/15/Add.1.

<sup>32</sup> CBD/SBI/3/21, Recommendation 3/17.

<sup>33</sup> International Treaty, Article 3.

<sup>34</sup> International Treaty, Article 11.2.

<sup>35</sup> International Treaty, Article 12.3 a.

Material Transfer Agreement (SMTA), which binds the initial provider and recipient as well as subsequent users.<sup>36</sup>

23. In 2013, the Governing Body of the International Treaty launched a process to enhance the MLS by establishing the Ad Hoc Open-ended Working Group to Enhance the Functioning of the Multilateral System of Access and Benefit-sharing.<sup>37</sup> The Working Group considered, among other matters, revisions to the SMTA, as well as possible changes to the coverage of the MLS. The Working Group also 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 MLS); the level of user-based income accruing to the Benefit-sharing Fund; and availability of and access provided to material within the MLS. In 2019, at its Eighth Session, the Governing Body of the International Treaty, despite intense negotiations, could neither reach consensus on the enhancement of the MLS, nor on a formal intersessional process to continue negotiations.

24. After informal consultations held in 2021 and 2022,<sup>38</sup> the Governing Body, at its Ninth Session, decided to re-establish the Ad Hoc Open-ended Working Group to Enhance the Functioning of the Multilateral System of Access and Benefit-sharing to finalize the enhancement of the functioning of the MLS by the Eleventh Session of the Governing Body. Contracting Parties committed to working together towards adopting a package of measures to enhance the functioning of the MLS with the aims of: (i) increasing the benefits that arise from the MLS for all Contracting Parties and users, both monetary and non-monetary; (ii) increasing user-based income to the Benefit-sharing Fund in a sustainable and predictable long-term manner; (iii) expanding the crops and plant genetic diversity available through the MLS; (iv) improving the availability of plant genetic resources for food and agriculture in the MLS; (v) making the MLS more dynamic given that there are developments and emerging issues in science, innovation, plant breeding and global policy environment; and (vi) creating legal certainty, administrative simplicity and transparency for everyone participating in the System. The Governing Body also requested the Co-Chairs of the Working Group to “[s]tructure the process so to accord early attention to the key issues such as Digital Sequence Information / Genetic Sequence Data (DSI/GSD), payment rates, and other relevant aspects.”<sup>39</sup>

**Intergovernmental Conference on an international legally binding instrument under the United Nations Convention on the Law of the Sea (UNCLOS) on the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction**

25. UNCLOS is the international agreement that defines the rights and responsibilities of nations with respect to their use of the world's oceans, regulating the conduct of certain economic activities, the protection of the environment, and the conservation and management of marine natural resources.

26. Marine genetic resources found in areas beyond national jurisdiction, i.e. the high seas and the deep seabed (“Area”) are outside of the scope of the CBD and its Nagoya Protocol. However, in the case of processes and activities carried out under the jurisdiction or control of a state, the provisions of both instruments apply, regardless of where their effects occur, within the area or beyond the limits of its national jurisdiction.<sup>40</sup> To which extent marine genetic resources in areas beyond national jurisdiction are covered by UNCLOS is controversial due to different interpretations of certain UNCLOS provisions, including those addressing the high seas, the Area and marine scientific research.<sup>41</sup>

27. Building on the work of its Ad Hoc Open-ended Informal Working Group to Study Issues Relating to the Conservation and Sustainable Use of Marine Biological Diversity Beyond Areas of National Jurisdiction,<sup>42</sup> the United Nations General Assembly decided in June 2015 to negotiate an

<sup>36</sup> International Treaty, Article 12.4.

<sup>37</sup> IT/GB-5/13/Report, Resolution 2/2013.

<sup>38</sup> IT/GB-9/22/9.2; see also IT/GB-9/22/09.2/Inf.1; IT/GB-9/22/09.2/Inf.2.

<sup>39</sup> IT/GB/9/22/Report, Resolution 3/2022.

<sup>40</sup> CBD, Article 4(b).

<sup>41</sup> Scovazzi, T. (2020). Chapter 10 The Rights to Genetic Resources beyond National Jurisdiction: Challenges for the Ongoing Negotiations at the United Nations. In Brill and Nijhoff (eds) *The Law of the Seabed*, Leiden, Netherlands: [https://doi.org/10.1163/9789004391567\\_012](https://doi.org/10.1163/9789004391567_012).

<sup>42</sup> <https://www.un.org/depts/los/biodiversityworkinggroup/biodiversityworkinggroup.htm>

international legally binding instrument under UNCLOS on the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction. In March 2016, the Preparatory Committee established by the UN General Assembly Resolution 69/292<sup>43</sup> started its work to make substantive recommendations to the General Assembly on the elements of a draft text of an international legally binding instrument under UNCLOS and, by the end of 2017, report to the Assembly on its progress.

28. In December 2017, the UN General Assembly decided to convene an Intergovernmental Conference on the Conservation and Sustainable Use of Marine Biological Diversity of Areas Beyond National Jurisdiction, under the auspices of the United Nations, to consider the recommendations of the Preparatory Committee.<sup>44</sup> Negotiations were to address: 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. The Intergovernmental Conference, at its third Session in August 2019, negotiated, for the first time, a text on the basis of a “zero draft” developed by the President of the Conference.

29. A revised draft text of an agreement under the UNCLOS on the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction was prepared by the President of the Intergovernmental Conference for consideration at the Conference’s fourth Session, which was finally held in March 2022.<sup>45</sup> At the request of the fourth Session of the Intergovernmental Conference, its President prepared a further revised draft text for consideration at its fifth Session, which was held from 15 to 26 August 2022.<sup>46</sup>

30. The further revised draft text includes more than 70 articles and falls into twelve parts. Part II addresses marine genetic resources, including questions on the sharing of benefits. Article 1 offers options for the definition of “marine genetic resources”, one of which includes digital sequence information. The further revised text was reviewed and further revised during the fifth Session of the Intergovernmental Conference. On 21 August 2022 a “refreshed text”<sup>47</sup> was made available and on 26 August 2022 a “further revised text.”<sup>48</sup> These documents that are not publicly available are, according to the President of the Intergovernmental Conference, “not necessarily reflective of agreement on all issues of the package, but they do reflect a direction in which a substantial number of delegations were content to proceed, incorporating significant compromises on key issues.”<sup>49</sup>

31. The fifth Session of the Intergovernmental Conference in August 2022 was unable to conclude the negotiations of the instrument. The President of the Intergovernmental Conference therefore suspended the conference, which will be resumed in the near future.

### **World Intellectual Property Organization**

32. The Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC)<sup>50</sup> was established by the General Assembly of the WIPO in 2000. It undertakes text-based negotiations to finalize an agreement on an international legal instrument(s) for the protection of traditional knowledge, traditional cultural expressions and genetic resources.

33. Since the Commission’s last session in October 2021, the IGC met in February/March 2022 (IGC-42) and May/June 2022 (IGC-43) to undertake negotiations on genetic resources with a focus on addressing unresolved issues and considering options for a legal instrument. Both sessions made considerable progress and achieved significant convergence around the Chair’s Text of a Draft

<sup>43</sup> Resolution 69/292.

<sup>44</sup> Resolution 72/249.

<sup>45</sup> A/CONF.232/2020/3.

<sup>46</sup> A/CONF.232/2022/5.

<sup>47</sup> A/CONF.232/2022/CRP.12 and A/CONF.232/2022/CRP.12/ Add.1.

<sup>48</sup> A/CONF.232/2022/CRP.13 and A/CONF.232/2022/CRP.13/Add.1.

<sup>49</sup> A/CONF.232/2022/9.

<sup>50</sup> <https://www.wipo.int/tk/en/igc/>

International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources<sup>51</sup> as a focused, effective, and balanced basis for further engagement.<sup>52</sup> The central provision of the Chair's Text would require Contracting Parties to the international legal instrument to make the disclosure of the country of origin mandatory where a patent application is materially or directly based on genetic resources. In cases where the country of origin is not known to the patent applicant, the applicant would have to disclose the source of the genetic resource. The obligation would apply *mutatis mutandis* to associated traditional knowledge.

34. Hailed by the Director-General of WIPO as a "triumph of multilateralism",<sup>53</sup> the WIPO General Assembly decided in July 2022 to convene a Diplomatic Conference to conclude an International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources. The Diplomatic Conference will be based on the Chair's Text and any other contributions by Member States and be held no later than 2024.

35. The WIPO General Assembly further agreed to convene in the second half of 2023 a Preparatory Committee, to establish the necessary modalities of the Diplomatic Conference. The Preparatory Committee will consider at this time, the draft Rules of Procedure to be presented for adoption to the Diplomatic Conference, the list of invitees to participate in the conference, and the text of the draft letters of invitation, as well as any other document or organizational question relating to the Diplomatic Conference. The Preparatory Committee will also approve the basic proposal for the administrative and final provisions of the international legal instrument.<sup>54</sup>

36. The WIPO General Assembly further directed the IGC to meet in a special session for five days in the second half of 2023, preceding the Preparatory Committee, to further close any existing gaps to a sufficient level.

### World Health Organization

37. The World Health Assembly (WHA) of the World Health Organization addressed access and benefit-sharing in the context of various discussions.

#### *Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits*

38. As reported to the Working Group at its last session, the objective of WHO's Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits (PIP Framework) is to improve pandemic influenza preparedness and response, and strengthen the protection against pandemic influenza by improving and strengthening the WHO global influenza surveillance and response system, with the objective of a fair, transparent, equitable, efficient, effective system, on an equal footing, for:

- (i) the sharing of H5N1 and other influenza viruses with human pandemic potential; and
- (ii) access to vaccines and sharing of other benefits.

39. WHO coordinates the sharing of influenza viruses with pandemic potential through an international network of public health laboratories called the Global Influenza Surveillance and Response System (GISRS). The PIP Framework provides the terms of reference for the sharing of influenza viruses and access to vaccines and other benefits within GISRS (SMTA 1) and with entities outside the system (SMTA 2).<sup>55</sup>

40. Since the publication in 2017 of a study on the *Implementation of the Nagoya Protocol and Pathogen Sharing: Public Health Implications*, which concluded that the Nagoya Protocol has

<sup>51</sup> WIPO/GRTKF/IC/43/5.

<sup>52</sup> WO/GA/55/12, paragraph 308.

<sup>53</sup> [https://www.wipo.int/pressroom/en/articles/2022/article\\_0009.html](https://www.wipo.int/pressroom/en/articles/2022/article_0009.html).

<sup>54</sup> WO/GA/55/12, paragraph 308.

<sup>55</sup> WHO. 2011. Pandemic influenza preparedness framework for the sharing of influenza viruses and access to vaccines and other benefits. Geneva, Switzerland.



implications for the public health response to infectious diseases, including influenza, the WHA requested further work related to access and benefit-sharing.

41. The 72nd WHA requested the WHO Director-General to *inter alia*: (a) work with the GISRS and other partners, and relevant institutions, to collect, analyse and present data on influenza virus sharing in a way that enables a deeper understanding of the challenges, opportunities and implications for public health associated with virus sharing under the GISRS, including by identifying: specific instances where influenza virus sharing has been hindered; and how such instances may be mitigated; and (b) 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<sup>56</sup>.

42. In response to these two requests, WHO developed a report on influenza virus sharing and a summary on national legislation and regulatory measures related to influenza.<sup>57</sup> Referring to specific cases, the report on influenza virus sharing concluded that

“legislation relating to access and benefit sharing, the Nagoya Protocol and human data protection have introduced great uncertainty into the sharing process and, in some cases, have meant that influenza virus and candidate vaccine virus cannot be shared until after the vaccine virus selection and vaccine production process has ended. In September and October 2018, the uncertainties and delays in virus sharing caused by Nagoya Protocol legislation for the first time had a direct impact on vaccine production. If such sharing issues are not resolved, it is likely that GISRS laboratories will become severely limited in their ability to share, receive and forward viruses within the Global Influenza Surveillance and Response System, restricting the availability of optimally protective vaccine viruses and the timely availability of life-saving influenza vaccines.”<sup>58</sup>

*Public health implications of implementation of the Nagoya Protocol*

43. The 72nd WHA also requested its Director-General to broaden engagement with Member States, the Secretariat of the CBD, relevant international organizations and relevant stakeholders: (a) to provide information on current pathogen-sharing practices and arrangements, the implementation of ABS measures, as well as the potential public health outcomes and other implications; and (b) to provide a report to the Seventy-fourth WHA<sup>59</sup>.

44. In response, WHO prepared a report on the public health implications of the Nagoya Protocol which concluded that “in the influenza context, lengthy delays in virus sharing due to national access and benefit-sharing and Nagoya Protocol requirements have implications for public health because they jeopardize the vaccine virus selection process, the timely development of candidate vaccine viruses and access to vaccines. Navigating a system in which each country has different access and benefit-sharing requirements that must be negotiated bilaterally is burdensome and inefficient, and could cause inequities in benefit sharing and limit virus access for research and development of improved influenza vaccines.”<sup>60</sup> The report was brought to the attention of the 74th WHA in May/June 2021.<sup>61</sup>

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<sup>56</sup> WHA72(12).

<sup>57</sup> See [https://www.who.int/initiatives/pandemic-influenza-preparedness-framework/governance/implementation-of-decision-wha72\(12\)](https://www.who.int/initiatives/pandemic-influenza-preparedness-framework/governance/implementation-of-decision-wha72(12))

<sup>58</sup> Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits. Decision WHA72(12), paragraph 1(a) Report on influenza virus sharing. Report by the Director-General.

<sup>59</sup> WHA72(13).

<sup>60</sup> EB148/21.

<sup>61</sup> A74/9, item 19.

*Strengthening WHO preparedness for and response to health emergencies*

45. Access and benefit-sharing may also play a role in the negotiations of a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response, which the Second special session of the WHA initiated in December 2021.<sup>62</sup>

46. The WHA established an intergovernmental negotiating body (the “INB”) and decided that the INB first identify the substantive elements of the instrument and then begin the development of a working draft to be presented, on the basis of progress achieved, for the consideration of the INB at its second meeting. The working draft, presented to the second Session of the INB, held in July 2022, underscores in its Preamble “the importance to promote early, safe, transparent and rapid sharing of samples and genetic sequence data of pathogens, taking into account relevant national and international laws, regulations, obligations and frameworks, including, as appropriate, the International Health Regulations (2005), the Convention on Biological Diversity and the Nagoya Protocol, and the Pandemic Influenza Preparedness Framework.”<sup>63</sup>

47. The working draft, furthermore, refers to “measures to ensure access and benefit sharing, which would include, but not be limited to: rapid, regular and timely sharing of pathogens and genomic sequences through a standardized real-time global platform; and timely access to affordable, safe and effective pandemic response products, including diagnostics, vaccines, personal protective equipment and therapeutics.” It also considers “measures to establish a comprehensive system for access and benefit sharing, including but not limited to, consistency with relevant elements of the Convention on Biodiversity and its Nagoya Protocol, by building upon or adapting mechanisms and/or principles contained in existing or previous instruments” and “measures to promote and facilitate recognition of the system as a specialized comprehensive system for access and benefit sharing system, at the national level.”<sup>64</sup>

48. The INB, at its second Session, considered the working draft “as a good basis to facilitate the discussions” and agreed that the instrument should be legally binding and contain both legally binding as well as non-legally binding elements.<sup>65</sup>

### III. AWARENESS-RAISING ACTIVITIES

49. The Commission requested the Secretariat to continue to raise awareness among key stakeholders, including breeders, and provide capacity-building and training programmes on ABS for GRFA.

50. As requested by the Commission, the Secretary brought the ABS Elements to the attention of the Open-ended Working Group on the Post-2020 Global Biodiversity Framework.<sup>66</sup> The Secretariat further presented the Commission’s work on ABS, including the ABS Elements, at various conferences and webinars, including, for example the symposium on “Access and benefit-sharing and biological control genetic resources” held in July 2022 as part of the 26th International Congress of Entomology.<sup>67</sup> The Secretariat continues to contribute to capacity building and development to support the development and implementation of ABS that accommodate the distinctive features of GRFA, including by participating in the work of the Informal Advisory Committee on Capacity-building for the Implementation of the Nagoya Protocol.

### IV. TYPOLOGY OF ACCESS AND BENEFIT-SHARING COUNTRY MEASURES

51. In response to an earlier request of the Commission<sup>68</sup>, the Secretariat commissioned in 2020 a survey of ABS country measures accommodating the distinctive features of GRFA and associated

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<sup>62</sup> SSA2(5).

<sup>63</sup> A/INB/2/3.

<sup>64</sup> Ibid.

<sup>65</sup> A/INB/2/5.

<sup>66</sup> CBD/WG2020/3/INF/9.

<sup>67</sup> <https://ice2020helsinki.fi/>

<sup>68</sup> CGRFA-17/19/Report, paragraph 19.

traditional knowledge to Griffith University, Australia, for review by the Working Groups and the ABS Expert Team.<sup>69</sup> The survey involved a search for ABS measures in databases of all United Nations Member countries and examined administrative, policy and/or legislative measures or draft laws of 47 countries.

52. In considering the survey, the Commission requested the preparation of a stand-alone document providing specific examples of existing country legislative, administrative or policy measures that directly or indirectly accommodate distinctive features of GRFA and associated traditional knowledge<sup>70</sup>. With the support of the University of Bremen, Germany, the Secretariat produced a typology of ABS country measures reflecting the importance of GRFA, their special role for food security and their distinctive features. A skeleton of the typology is provided in Table 1. The populated typology is contained in the document, *Access and benefit-sharing and genetic resources for food and agriculture – Typology of country measures*.<sup>71</sup>

53. It is important to note that not all the measures listed are necessarily specific to GRFA. In fact, while the document focusses on measures accommodating directly or indirectly the distinctive features of genetic resources for food and agriculture, it also lists, in line with the non-prescriptive nature of the ABS Elements, in some places other measures to indicate the wide range of options countries have in regulating access and benefit-sharing for their genetic resources.

54. Developing and implementing ABS measures is work in progress and so is the development of the ABS Elements and of the typology of country measures. The ABS Elements and the typology are therefore living documents that need to be reviewed, updated and improved regularly. Their primary purpose is to inspire policy- and decision-makers in developing and implementing ABS measures.

55. The typology follows the structure of the five key elements of ABS measures for GRFA identified in FAO's ABS Elements: (1) institutional arrangements; (2) access to and utilization of GRFA; (3) access to and utilization of TKGRFA; (4) benefit-sharing relating to GRFA and TKGRFA; and (5) monitoring and compliance.

## **V. IMPLEMENTATION OF ACCESS AND BENEFIT-SHARING COUNTRY MEASURES**

56. There are increasingly signs that ABS measures may complicate, in some cases even hinder, research and development, including in the food and agriculture sector.<sup>72</sup> While some of the difficulties may be typical teething problems any new type of legislation may face in its initial phase of implementation, complaints about practical constraints and complexities encountered by users of genetic resources when dealing with ABS legislation, seem to be on the rise, rather than a vanishing phenomenon.<sup>73</sup> On the other hand, current discussions on Goal C and Target 13 of the Post-2020 Global Biodiversity Framework indicate a certain degree of dissatisfaction of at least some countries with the benefits generated and shared through existing ABS measures.<sup>74</sup>

<sup>69</sup> Background Study Paper No. 70.

<sup>70</sup> CGRFA-18/21/Report, paragraph 26.

<sup>71</sup> CGRFA/WG-AqGR-4/23/6/Inf.1.

<sup>72</sup> see Silvestri, L., Sosa, A., Mc Kay, F. et al. Implementation of access and benefit-sharing measures has consequences for classical biological control of weeds. *BioControl* 65, 125–141 (2020) <https://doi.org/10.1007/s10526-019-09988-4>.

<sup>73</sup> See, e.g. Michiels, F.; Feiter, U.; Paquin-Jaloux, S.; Jungmann, D.; Braun, A.; Sayoc, M.A.P.; Armengol, R.; Wyss, M.; David, B. Facing the Harsh Reality of Access and Benefit Sharing (ABS) Legislation: An Industry Perspective. *Sustainability* 2022, 14, 277. <https://doi.org/10.3390/su14010277>; Sara, R.; Wyss, M.; Custers, R.; in 't Veld, A.; Muyldermans, D. A need for recalibrating access and benefit sharing. *EMBO Reports* (2022)23:e53973 <https://doi.org/10.15252/embr.202153973>; Dos S Ribeiro C, Koopmans MP, Haringhuizen GB (2018) Threats to timely sharing of pathogen sequence data – The Nagoya Protocol may impose costs and delays. *Science* 362: 404–406.

<sup>74</sup> See above, paragraphs 16-20.

**Table 1: Access and benefit-sharing and genetic resources for food and agriculture: Typology of country measures**

|   |   |
|---|---|
| <b>Element 1: Institutional arrangements</b>  |   |
| <b>1.1</b>  | <b>Institutional responsibility</b>   |
| 1.1.1   | Single institutional responsibility for access and benefit-sharing (ABS)                          |
| 1.1.2   | Shared institutional responsibility for ABS   |
| 1.1.3   | Interagency coordination of ABS decisions   |
| <b>1.2</b>  | <b>Provision of national information on responsible institutions, ABS measures and procedures</b> |
| <b>Element 2: Access to and utilization of genetic resources for food and agriculture (GRFA)</b>                                |   |
| <b>2.1</b>  | <b>Categories of genetic resources (GR) subject to ABS provisions on access</b>                   |
| 2.1.1   | Temporal scope  |
| 2.1.2   | GR for which provider country is country of origin or has acquired GR in accordance with CBD      |
| 2.1.3   | Privately/publicly held GR  |
| 2.1.4   | GR vs biological resources  |
| 2.1.5   | Genetic information   |
| 2.1.6   | GR held by Indigenous Peoples and local communities (IPLC)  |
| 2.1.7   | Exemptions of specific GR   |
| <b>2.2</b>  | <b>Activities triggering/not triggering ABS obligations</b>                                       |
| 2.2.1   | Specific provisions on GRFA-related activities  |
| 2.2.2   | Specific provisions on non-commercial research  |
| 2.2.3   | Specific provisions on activities performed by specific user groups                               |
| <b>2.3</b>  | <b>Authorization procedures applicable under ABS measures</b>                                     |
| 2.3.1   | Simplified approval procedures  |
| 2.3.2   | Procedural simplifications for specific activities  |
| <b>Element 3: Access to and utilization of traditional knowledge associated with genetic resources for food and agriculture</b> |   |
| <b>3.1</b>  | <b>Defining traditional knowledge</b>   |
| 3.1.1   | Excluding from traditional knowledge (relevant to GRFA)   |
| <b>3.2</b>  | <b>Identifying the correct holders of traditional knowledge (TK)</b>                              |
| <b>3.3</b>  | <b>Procedures for obtaining PIC or approval and involvement of IPLC</b>                           |
| <b>Element 4: Fair and equitable sharing of benefits</b>  |   |
| <b>4.1</b>  | <b>Scope of benefit-sharing obligations</b>   |
| 4.1.1   | GR/TK covered   |
| 4.1.2   | Exemptions from benefit-sharing obligations   |
| <b>4.2</b>  | <b>Fair and equitable</b>   |
| 4.2.1   | Determination of benefits   |
| 4.2.2   | Streamlined benefit-sharing   |
| 4.2.3   | Sharing monetary and non-monetary benefits resulting from utilization of GRFA                     |
| 4.2.4   | Facilitating benefit-sharing through model clauses  |
| <b>4.3</b>  | <b>Beneficiaries</b>  |
| 4.3.1   | National benefit-sharing funds  |
| <b>4.4</b>  | <b>Sharing benefits through funds/partnerships/ multilateral benefit-sharing mechanisms</b>       |
| <b>Element 5 : Compliance and monitoring</b>  |   |
| <b>5.1</b>  | <b>Monitoring</b>   |
| <b>5.2</b>  | <b>User country compliance measures</b>   |
| 5.2.1   | General compliance measures   |
| 5.2.2   | Exceptions  |

57. The Commission, at its last session, initiated a report on the practical application of ABS country measures to the different subsectors of GRFA and TKGRFA, including monitoring of ABS compliance, with a view to identifying the effects of ABS measures on the utilization and conservation

of the different subsectors of GRFA and TKGRFA and the sharing of benefits.<sup>75</sup> The Commission requested that the report be based on a country questionnaire. A draft questionnaire is therefore provided in the document, *Draft questionnaire on the implications of access and benefit-sharing measures for the use and exchange of genetic resources for food and agriculture and for benefit-sharing*.<sup>76</sup>

## VI. GUIDANCE SOUGHT

58. The Working Group may wish to:

- i. take note of developments under other international agreements and instruments relevant to ABS and emphasize the need to avoid duplication of work and ensure consistency;
- ii. take note of the typology of ABS country measures, and provide comments and inputs, for consideration by the Commission at its next session;
- iii. take note of the draft questionnaire and recommend that the Commission request the Secretariat to prepare, based on the responses to the questionnaire and other available sources of information, a report on the implications of implementation of access and benefit-sharing country measures for the use and exchange of genetic resources for food and agriculture, associated traditional knowledge and the fair and equitable sharing of benefits; and
- iv. make any other recommendations with regard to the Commission's work on ABS for GRFA and TKGRFA.

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<sup>75</sup> CGRFA-18/21/Report, paragraph 27.

<sup>76</sup> CGRFA/WG-AqGR-4/23/6/Inf.2.