



# COMMISSION ON GENETIC RESOURCES FOR FOOD AND AGRICULTURE

## Item 4.2 of the Provisional Agenda

### Nineteenth Regular Session

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

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## 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:

- The Commission requested the Secretariat to continue monitoring relevant developments under other international agreements and instruments relevant to ABS and report back on them to the Commission.<sup>1</sup>
- The Commission requested the Secretariat to continue raising awareness among key stakeholders and provide capacity-building and training programmes on ABS for GRFA, in particular for developing countries. It requested the Secretariat to collaborate on these activities with relevant international organizations and instruments, including the International Treaty on Plant Genetic Resources for Food and Agriculture (Treaty) and the Convention on Biological Diversity (CBD).<sup>2</sup> In addition, the Secretariat was requested to collaborate with 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> The Commission further tasked the Secretary with bringing 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>4</sup> to the attention of the Open-ended Working Group on the Post-2020 Global Biodiversity Framework.<sup>5</sup>
- In considering the *Survey of access and benefit-sharing country measures accommodating the distinctive features of genetic resources for food and agriculture and associated traditional knowledge*,<sup>6</sup> the Commission requested the preparation of a standalone document providing specific examples of existing country legislative, administrative or policy measures that directly or indirectly accommodate distinctive features of GRFA and TKGRFA.<sup>7</sup>
- Finally, the Commission supported future work that further deepens the empirical evidence needed to understand the effects of ABS measures. In this regard, it requested the Secretariat to prepare, based on responses to a pretested 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>8</sup>

2. This document reports on activities taken by the Secretariat in response to the above requests. 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). It gives an overview of the draft typology of ABS country measures accommodating the distinctive features of GRFA (Section IV). The draft typology, as reviewed and revised by the Team of Technical and Legal Experts on Access and Benefit-sharing (ABS Expert Team) in the light of comments received from the Commission’s intergovernmental technical working

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

<sup>2</sup> CGRFA-18/21/Report, paragraph 28.

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

<sup>4</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*. Rome. <https://www.fao.org/documents/card/en/c/CA5088EN/>

<sup>5</sup> CGRFA-18/21/Report, paragraph 28.

<sup>6</sup> Humphries, F., Laird, S., Wynberg, R., Morrison, C. Lawson, C. & Kolesnikova, A. 2021. *Survey of access and benefit-sharing country measures accommodating the distinctive features of genetic resources for food and agriculture and associated traditional knowledge*. Rome, FAO on behalf of the Commission on Genetic Resources for Food and Agriculture. <https://doi.org/10.4060/cb6525en>.

<sup>7</sup> CGRFA-18/21/Report, paragraph 26.

<sup>8</sup> CGRFA-18/21/Report, paragraph 27.

groups (Working Groups), is given in the document *Access and benefit-sharing and genetic resources for food and agriculture: typology of country measures*.<sup>9</sup> The document further introduces a draft questionnaire developed by the Secretariat for the preparation of a study on the application of ABS country measures to the different sectors of GRFA (Section V). The draft questionnaire, as reviewed and revised by the ABS Expert Team in the light of comments received from the intergovernmental technical working groups, is given in the document *Draft questionnaire on the application of access and benefit-sharing measures to genetic resources for food and agriculture and associated traditional knowledge*.<sup>10</sup>

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

3. Matters related to ABS are addressed under various international instruments and in various fora, including the CBD, the Treaty, the United Nations Convention on the Law of the Sea (UNCLOS), the World Intellectual Property Organization (WIPO) and the World Health Organization (WHO).

### **The Convention on Biological Diversity and 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**

4. 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>11</sup> Access to genetic resources shall be subject to prior informed consent (PIC)<sup>12</sup> and, where granted, shall be on mutually agreed terms (MAT).<sup>13</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>14</sup>

5. 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 (Nagoya Protocol) is the instrument for the implementation of the ABS provisions of the CBD.<sup>15</sup> It covers genetic resources, including GRFA, within the scope of Article 15 of the CBD,<sup>16</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 (“user country compliance measures”) and with the contractual obligations providers and users have mutually agreed on.

6. 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, in its Preamble, also acknowledges the fundamental role of the Treaty and the Commission.<sup>17</sup>

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<sup>9</sup> CGRFA-19/23/4.2/Inf.1.

<sup>10</sup> CGRFA-19/23/4.2/Inf.2.

<sup>11</sup> CBD, Article 15.7.

<sup>12</sup> CBD, Article 15.5.

<sup>13</sup> CBD, Article 15.4.

<sup>14</sup> CBD, Articles 15, 16, 19, 20, 21.

<sup>15</sup> Nagoya Protocol, Article 4.4.

<sup>16</sup> Nagoya Protocol, Article 3.

<sup>17</sup> Nagoya Protocol, Preamble.

7. 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>18</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>19</sup>

*Kunming-Montreal Global Biodiversity Framework*

8. The Kunming-Montreal Global Biodiversity Framework (KM GBF), after four years of consultations and negotiations,<sup>20</sup> was adopted during the fifteenth meeting of the Conference of the Parties to the CBD, held in December 2022, and addresses access to genetic resources and benefit-sharing under its Goal C and Target 13.<sup>21</sup>

**GOAL C**

The monetary and non-monetary benefits from the utilization of genetic resources and digital sequence information on genetic resources, and of traditional knowledge associated with genetic resources, as applicable, are shared fairly and equitably, including, as appropriate with indigenous peoples and local communities, and substantially increased by 2050, while ensuring traditional knowledge associated with genetic resources is appropriately protected, thereby contributing to the conservation and sustainable use of biodiversity, in accordance with internationally agreed access and benefit-sharing instruments.

**TARGET 13**

Take effective legal, policy, administrative and capacity-building measures at all levels, as appropriate, to ensure the fair and equitable sharing of benefits that arise from the utilization of genetic resources and from digital sequence information on genetic resources, as well as traditional knowledge associated with genetic resources, and facilitating appropriate access to genetic resources, and by 2030, facilitating a significant increase of the benefits shared, in accordance with applicable international access and benefit-sharing instruments.

9. Both Goal C and Target 13 aim at a substantial increase of monetary and non-monetary benefits resulting from the utilization of genetic resources and digital sequence information (DSI) on genetic resources. It is not entirely clear how exactly Parties are meant to increase these benefits. However, the KM GBF urges Parties and other governments to implement the framework with a view to fostering the full and effective contribution of all the other stakeholders, including the private and all other sectors.<sup>22</sup> Target 15 requires, in addition, reporting on compliance with ABS regulations and measures, as applicable.

10. The implementation of the KM GBF is addressed in several other decisions taken by the Conference of the Parties to the CBD,<sup>23</sup> including a decision concerning a monitoring framework for the KM GBF.<sup>24</sup> However, there is no agreed and up-to-date methodology for the indicators for Goal C and Target 13 (“indicator on monetary benefits received” and “indicator on non-monetary benefits”). An Ad Hoc Technical Expert Group on Indicators has been established to advise on the further operationalization of the monitoring framework and to complete the scientific and technical review of the framework, for review by the CBD Subsidiary Body on Scientific, Technical and Technological Advice and subsequent consideration by the Subsidiary Body on Implementation and by the Conference of the Parties at its sixteenth meeting.<sup>25</sup>

<sup>18</sup> Nagoya Protocol, Article 8(c).

<sup>19</sup> Nagoya Protocol, Article 8(a).

<sup>20</sup> <https://www.cbd.int/conferences/post2020>

<sup>21</sup> CBD/COP/DEC/15/4.

<sup>22</sup> CBD/COP/DEC/15/4, paragraph 4.

<sup>23</sup> CGRFA-19/23/6.1.

<sup>24</sup> CBD/COP/DEC/15/5.

<sup>25</sup> CBD/COP/DEC/15/5, paragraph 8–9.

11. The Conference of the Parties also decided “to establish, as part of the Kunming-Montreal Global Biodiversity Framework, a multilateral mechanism for benefit-sharing from the use of digital sequence information on genetic resources, including a global fund,” which is discussed in the document *Digital sequence information and genetic resources for food and agriculture*.<sup>26</sup>

*Specialized international access and benefit-sharing instruments*

12. The Nagoya Protocol does not prevent its Parties from developing and implementing other relevant international agreements, including other specialized ABS instruments.<sup>27</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 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 Treaty, which was developed in harmony with the CBD prior to the adoption of the Nagoya Protocol.<sup>28</sup>

13. The Conference of the Parties to the CBD serving as the meeting of the Parties to the Nagoya Protocol (COP-MOP NP), at its fourth meeting (Part II), held in December 2022, considered criteria for specialized international ABS instruments in the context of Article 4, paragraph 4 of the Nagoya Protocol.<sup>29</sup> However, due to the divergence of views among Parties it decided to further review the item at its fifth meeting.<sup>30</sup>

*Global multilateral benefit-sharing mechanism*

14. 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 PIC. At the request of the COP-MOP-NP,<sup>31</sup> a study aimed at identifying specific cases meeting the aforementioned criteria was commissioned.<sup>32</sup> While the study identifies cases for which it is difficult or impossible to grant or obtain PIC (e.g. migratory species, *ex situ* genetic resources with untraceable provenance), Parties to the Nagoya Protocol continue to hold divergent views as to whether these cases necessitate the establishment of a global benefit-sharing mechanism.<sup>33</sup> The COP-MOP-NP therefore decided to revisit the need for and modalities of a global benefit-sharing mechanism as provided for in Article 10 of the Nagoya Protocol at its fifth meeting.<sup>34</sup>

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

15. The Treaty, negotiated under the aegis of the Commission, is a specialized ABS instrument that applies to plant genetic resources for food and agriculture (PGRFA).<sup>35</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 PGRFA that are under their management and control and in the public domain.<sup>36</sup> The MLS also covers CGIAR “in trust” materials, materials held by other international institutions that sign agreements with the Governing Body of the 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

<sup>26</sup> CGRFA-19/23/5.

<sup>27</sup> Nagoya Protocol, Article 4.2.

<sup>28</sup> Treaty, Article 1.1.

<sup>29</sup> CBD/SBI/3/21, Recommendation 3/16.

<sup>30</sup> CBD/NP/MOP/DEC/4/11.

<sup>31</sup> NP-3/13.

<sup>32</sup> CBD/SBI/3/15/Add.1.

<sup>33</sup> CBD/SBI/3/21, Recommendation 3/17.

<sup>34</sup> CBD/NP/MOP/DEC/4/10.

<sup>35</sup> Treaty, Article 3.

<sup>36</sup> Treaty, Article 11.2.

purpose does not include chemical, pharmaceutical and/or other non-food/feed industrial uses.<sup>37</sup> Materials are accessed and benefits shared under conditions set out in the Standard Material Transfer Agreement (SMTA), which binds the initial provider and recipient as well as subsequent users.<sup>38</sup>

16. In 2013, the Governing Body of the Treaty launched a process aimed at enhancing the MLS and established the Ad Hoc Open-ended Working Group to Enhance the Functioning of the Multilateral System of Access and Benefit-sharing.<sup>39</sup> The Working Group considered, among other matters, revisions to the SMTA, as well as possible changes to the coverage of the MLS. In 2019, at its Eighth Session, the Governing Body of the Treaty, despite intense negotiations, could not reach consensus on the enhancement of the MLS or on a formal intersessional process to continue negotiations.

17. After informal consultations held in 2021 and 2022,<sup>40</sup> the Governing Body, at its Ninth Session, held in September 2022, 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 agreed to work 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 PGRFA 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>41</sup>

#### **Agreement under the United Nations Convention on the Law of the Sea on the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction**

18. 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.

19. Marine genetic resources found in areas beyond national jurisdiction, i.e. the high seas and the deep seabed, are outside of the scope of the CBD and the 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>42</sup>

20. After more than 15 years of discussions and negotiations by UN Member States and observers culminating in a resumed Fifth Session of the Intergovernmental Conference on an international legally binding instrument under the UNCLOS on the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction (ABNJ), the text of a draft agreement was finalized and agreed upon on 4 March 2023. The draft agreement, referred to as the *Agreement under the United Nations Convention on the Law of the Sea on the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction*<sup>43</sup> (BBNJ Agreement) is yet to be adopted..

21. The BBNJ Agreement requires Parties to take the necessary measures to ensure that activities with respect to marine genetic resources (MGR) of areas beyond national jurisdiction are notified to a

<sup>37</sup> Treaty, Article 12.3 a.

<sup>38</sup> Treaty, Article 12.4.

<sup>39</sup> IT/GB-5/13/Report, Resolution 2/2013.

<sup>40</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>41</sup> IT/GB/9/22/Report, Resolution 3/2022; see CGRFA-19/23/5.

<sup>42</sup> CBD, Article 4(b).

<sup>43</sup> <https://www.un.org/bbnj/>

newly established clearing-house mechanism (Article 12). While the definition of MGR (Article 1.8) includes fish and other aquatic genetic resources for food and agriculture, the BBNJ Agreement's ABS provisions do not apply to fishing regulated under relevant international law and fishing-related activities or fish or other living marine resources known to have been taken in fishing and fishing-related activities from areas beyond national jurisdiction, except where such fish or other living marine resources are used to conduct research and development on their genetic and/or biochemical composition, including through the application of biotechnology (Articles 10.2 and 1.14). This means that the BBNJ Agreement does not trigger any notification requirements or benefit-sharing obligations for fish traded as commodities. If, on the other hand, a fish is caught in an area beyond national jurisdiction for use in research and development on its genetic and/or biochemical composition, including, for example, for gene sequencing and breeding purposes, the relevant notification and benefit-sharing requirements of the Agreement apply.

22. Parties to the BBNJ Agreement shall take the necessary legislative, administrative or policy measures to ensure that information is notified to the clearing-house mechanism prior to and upon completion of the collection *in situ* of MGR of areas beyond national jurisdiction. The BBNJ Agreement lists in detail the information that needs to be notified (Article 12.2). Upon notification, the clearing-house mechanism shall automatically generate a "BBNJ" standardized batch identifier (Article 12.3). Further information should be notified to the clearing-house mechanism after collection (Article 12.5). Parties shall further ensure that where MGR of areas beyond national jurisdiction, and where practicable, the DSI on such resources are subject to utilization, including commercialization, by natural or juridical persons under their jurisdiction, additional information, including the "BBNJ" standardized batch identifier, if available, be notified to the clearing-house mechanism as soon as such information becomes available. This includes information on the results of the utilization, such as publications and patents granted, if available and to the extent possible, details of the post-collection notification to the clearing-house mechanism, where available, and information on sales of relevant products, if available (Article 12.8).

23. According to the BBNJ Agreement, monetary and non-monetary benefits arising from activities with respect to MGR and DSI on MGR shall be shared in a fair and equitable manner and contribute to the conservation and sustainable use of marine biological diversity (Article 14.1). Non-monetary benefits shall be shared in the form of, *inter alia*: access to samples and DSI in accordance with current international practice; open access to findable, accessible, interoperable and reusable (FAIR) scientific data in accordance with current international practice and open and responsible data governance; transfer of marine technology; and capacity building (Article 14.2).

24. Monetary benefits from the utilization of MGR and DSI on MGR of areas beyond national jurisdiction, including commercialization, shall be shared fairly and equitably, through a newly established financial mechanism (Article 14.5). The BBNJ Agreement establishes an initial monetary benefit-sharing modality whereby developed Parties to the Agreement pay an annual contribution to the financial mechanism in the amount of 50 percent of, and in addition to, their assessed contributions (Article 14.6). The BBNJ Agreement mandates the Conference of the Parties to replace the initial benefit-sharing modality, taking into account the recommendations of the ABS committee, recognizing that such modalities should be mutually supportive of and adaptable to other ABS instruments (Article 14.9). The ABS committee established by the Agreement is tasked with establishing guidelines for benefit-sharing, providing transparency and ensuring a fair and equitable sharing of both monetary and non-monetary benefits (Article 15).

### **World Intellectual Property Organization**

25. The Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC)<sup>44</sup> was established by the WIPO General Assembly in 2000. Since 2001, the IGC has been working on intellectual property issues surrounding traditional knowledge, traditional cultural expressions and genetic resources. In more recent years, it has started to undertake text-based negotiations to finalize an international legal instrument(s) for the protection of traditional knowledge, traditional cultural expressions and genetic resources. Taking centre stage in the

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<sup>44</sup> <https://www.wipo.int/tk/en/igc/>

discussions is a patent disclosure requirement, which would require patent applicants seeking patents for inventions that are based on genetic resources and associated traditional knowledge to include as part of the patent application information about the source or origin of the genetic resources and associated traditional knowledge. Currently, such information is usually not disclosed, as it is generally not considered relevant to the determination of the patentability of an invention.

26. 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, based on a Chair's text<sup>45</sup> and any other contributions by Member States, to be held no later than 2024.<sup>46</sup>

27. The WIPO General Assembly further decided to convene a Preparatory Committee in the second half of 2023, 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>47</sup>

28. 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. The special session will be held from 4 to 8 September 2023.

### World Health Organization

29. Since the last session of the Commission, WHO has continued to address ABS issues in various contexts, including in the context of the Pandemic Influenza Preparedness (PIP) Framework,<sup>48</sup> which aims to improve pandemic influenza preparedness and response, and strengthen protection against pandemic influenza by improving and strengthening the WHO global influenza surveillance and response system, with the objective of achieving 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.

30. As reported to the last session of the Commission, the Seventy-second World Health Assembly (WHA), in May 2019, considered a report on the public health implications of the Nagoya Protocol.<sup>49</sup> The WHA requested the Director-General of WHO to, *inter alia*, 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>50</sup> The report,<sup>51</sup> published in December 2019, led to a decision through which the WHA requested the Director-General of WHO to, *inter alia*, prioritize and contribute to international efforts to sustain and enhance influenza surveillance through the WHO Global Influenza Surveillance and Response System (GISRS) by continuing with Member States, GISRS laboratories and other relevant stakeholders, to: (i) gather and share information about influenza virus sharing and its associated benefits; and (ii) encourage countries to voluntarily share information and best practices on mitigating hindrances to the rapid, systematic and timely international sharing of seasonal and pandemic influenza biological material and to its associated benefits.<sup>52</sup>

31. As requested by the WHA, the Director-General of WHO reported in 2022 through the Executive Board of WHO to the Seventy-fifth WHA on progress in strengthening influenza

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<sup>45</sup> WIPO/GRTKF/IC/43/5.

<sup>46</sup> WO/GA/55/12, 309.

<sup>47</sup> *Ibid.*

<sup>48</sup> WHO. 2021. *Pandemic Influenza Preparedness (PIP) Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits*. Geneva, Switzerland.

<https://www.who.int/publications/i/item/978924002485>

<sup>49</sup> A72/32.

<sup>50</sup> WHA72(12).

<sup>51</sup> EB146/18.

<sup>52</sup> WHA73(14).

preparedness, including on virus sharing and hindrances to the sharing of seasonal and pandemic influenza biological material. Referring to previously reported cases,<sup>53</sup> the Director-General reported additional instances where national ABS requirements have affected the sharing of seasonal influenza viruses, including among countries that are parties to the Nagoya Protocol.<sup>54</sup> The report noted that the WHO Secretariat is engaging with WHO Member States, GISRS members and the CBD Secretariat to “identify solutions and seek greater clarity on the sharing and use of seasonal influenza viruses.”

*Strengthening WHO preparedness for and response to health emergencies*

32. The Seventy-fourth WHA discussed WHO’s work in health emergencies and adopted a resolution on *Strengthening WHO preparedness for and response to health emergencies*.<sup>55</sup> The resolution acknowledges the critical role played by international cooperation and timely and transparent sharing of epidemiological and clinical data, biological samples, knowledge and information, including timely sharing of pathogen genetic sequence data, and in this context also recalls the CBD and the Nagoya Protocol. The resolution also requests the Director-General of WHO to work together with Member States, the medical and scientific community, and laboratory and surveillance networks, to promote early, safe, transparent and rapid sharing of samples and genetic sequence data of pathogens of pandemic and epidemic, or other high-risk, potential, taking into account relevant national and international laws, regulations, obligations and frameworks, including, as appropriate, the International Health Regulations (2005), the CBD, the Nagoya Protocol and the PIP Framework and the importance of ensuring rapid access to human pathogens for public health preparedness and response purposes.

33. The WHA also decided to establish a Member States Working Group on Strengthening WHO Preparedness and Response to Health Emergencies, requested it to prioritize the assessment of the benefits of developing a WHO convention, agreement or other international instrument on pandemic preparedness and response (“WHO CA+”) and requested the Director-General of WHO to convene a special session of the WHA dedicated to considering the potential development of such an agreement.<sup>56</sup> The special session of the WHA, held from 29 November to 1 December 2021, considered a report of the Working Group<sup>57</sup> and decided to establish an intergovernmental body (INB) to draft and negotiate a WHO CA+. <sup>58</sup> The INB first identified substantive elements of the WHO CA+ on the basis of which a working draft was prepared for consideration by the INB at its second meeting. The INB considered the working draft “as a good basis to facilitate the discussions” and agreed that WHO CA+ should be legally binding and contain both legally binding and non-binding elements.<sup>59</sup>

34. As requested by the WHA, WHO conducted two rounds of public hearings in April and September 2022.<sup>60</sup> In addition, the Bureau of the INB held four informal focused consultations to advance understanding of the work of the INB. The consultations, focusing on specific matters, such as intellectual property rights, equity, One Health and legal matters, were held in September and October 2022.

35. At its third meeting in December 2022, the INB considered a conceptual zero draft developed by the Bureau of the INB as a “bridge between the working draft and the future zero draft of the WHO CA+.”<sup>61</sup> The zero draft of the WHO CA+, prepared by the INB Bureau for consideration by the INB at its fourth meeting in March 2023, suggests establishing a multilateral WHO Pathogen Access and Benefit-Sharing System (PABS System) for sharing pathogens with pandemic potential and genomic sequences, and benefits arising therefrom.<sup>62</sup> The draft also proposes a definition of genomic sequences.

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<sup>53</sup> EB146/18.

<sup>54</sup> EB150/19.

<sup>55</sup> WHA74.7.

<sup>56</sup> WHA74(16).

<sup>57</sup> SSA2/3.

<sup>58</sup> SSA2(5).

<sup>59</sup> A/INB/2/5.

<sup>60</sup> <https://inb.who.int/home/public-hearings>

<sup>61</sup> A/INB/3/3.

<sup>62</sup> A/INB/4/3.

36. At its fifth meeting, in April 2023, the INB continued to discuss the zero draft WHO CA+ and agreed on a process forward. The INB will, pursuant to its agreed timeline and deliverables, hold four additional sessions in order to meet the deadline established by the WHA and report its outcome to the Seventy-seventh WHA in May 2024.<sup>63</sup>

#### *International Health Regulations 2005*

37. In response to the final report of the Member States Working Group on Strengthening WHO Preparedness and Response to Health Emergencies,<sup>64</sup> the Seventy-fifth WHA also established a process towards making targeted amendments to the International Health Regulations 2005. At its second meeting in February 2023, the Working Group began considering the more than 300 proposed amendments to these regulations, some of which address ABS.<sup>65</sup>

### **III. AWARENESS-RAISING ACTIVITIES**

38. 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.<sup>66</sup>

39. As requested by the Commission, the Secretariat brought the ABS Elements to the attention of the Open-ended Working Group on the Post-2020 Global Biodiversity Framework.<sup>67</sup> The Secretariat further presented the Commission's work on ABS, including the ABS Elements, at various conferences and webinars, including 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 and a workshop on the "Harmonization of Access and Benefit Sharing of Crop Wild Relatives in Eastern and Southern Africa" organized by the Alliance of Bioversity International and CIAT together with the SADC Plant Genetic Resources Centre (April 2022).<sup>68</sup> The Secretariat continues to contribute to capacity building and development to support the development and implementation of ABS arrangements 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**

40. In response to the Commission's request,<sup>69</sup> the Secretariat commissioned in 2020 a survey of ABS country measures accommodating the distinctive features of GRFA and associated traditional knowledge.<sup>70</sup> In considering the survey, the Commission requested the preparation of a standalone 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>71</sup>

41. Examples of ABS country measures, as reviewed and revised by the Commission's intergovernmental technical working groups and the ABS Expert Team, are contained in the document *Access and benefit-sharing and genetic resources for food and agriculture – Typology of country measures*.<sup>72</sup>

42. It is important to note that not all the measures listed are necessarily specific to GRFA. In fact, while the document focuses on measures accommodating directly or indirectly the distinctive features

<sup>63</sup> A/INB/5/3.

<sup>64</sup> A/75/17.

<sup>65</sup> A/WGIHR/2/10.

<sup>66</sup> CGRFA-18/21/Report, paragraph 28.

<sup>67</sup> CBD/WG2020/3/INF/9.

<sup>68</sup> <https://alliancebioversityciat.org/stories/harmonization-access-and-benefit-sharing-crop-wild-relatives-eastern-and-southern-africa>

<sup>69</sup> CGRFA-17/19/Report, paragraph 19.

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

<sup>71</sup> CGRFA-18/21/Report, paragraph 26.

<sup>72</sup> CGRFA-19/23/4.2/Inf.1.

of GRFA, in order to indicate the wide range of options countries have with regard to regulating ABS for their genetic resources, and in line with the non-prescriptive nature of the ABS Elements, it in some places also lists other measures.

43. Developing and implementing ABS measures is work in progress and so is the development of the ABS Elements and 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 their efforts to develop and implement ABS measures.

44. The typology follows the structure of the five key elements of ABS measures for GRFA identified in the 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**

45. 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>73</sup> The Commission requested that the report be based on a country questionnaire. A draft questionnaire, as reviewed and revised by the Commission's intergovernmental technical working groups and the ABS Expert Team, 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>74</sup>

## **VI. GUIDANCE SOUGHT**

46. The Commission 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 and provide comments on the typology of ABS country measures<sup>75</sup> and request the Secretariat to finalize the document and make it available on the Commission's website; and
- iii. take note of and provide comments on the draft questionnaire<sup>76</sup> and 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 ABS country measures for the use and exchange of GRFA, associated traditional knowledge and the fair and equitable sharing of benefits.

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<sup>73</sup> CGRFA-18/21/Report, paragraph 27.

<sup>74</sup> CGRFA/19/23/4.2/Inf.2.

<sup>75</sup> CGRFA-19/23/4.2/Inf.1.

<sup>76</sup> CGRFA-19/23/4.2/Inf.2.