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CONFERENCE OF THE PARTIES TO THE CONVENTION ON BIOLOGICAL DIVERSITY SERVING AS THE MEETING OF THE PARTIES TO THE NAGOYA PROTOCOL ON ACCESS TO GENETIC RESOURCES AND THE FAIR AND EQUITABLE SHARING OF BENEFITS ARISING FROM THEIR UTILIZATION
Fourth meeting – Part II
Montreal, Canada, 7 to 19 December 2022
Agenda item 11

FURTHER INFORMATION FROM INTERNATIONAL PROCESSES RELATED TO ACCESS AND BENEFIT-SHARING

Note by the Executive Secretary

1. Decision NP-3/7 on cooperation with other conventions, international organizations and initiatives requested the Executive Secretary to continue to engage with relevant ongoing processes and policy debates, and liaise with other conventions, international organizations and initiatives, as appropriate, to provide and collect information on current discussions on matters related to access and benefit-sharing, and in particular on public health issues (paragraph 2). The Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol also requested the Executive Secretary to prepare a report on activities undertaken, including key developments under international agreements and instruments of relevance to the implementation of the Nagoya Protocol for the consideration of the fourth meeting of the Parties to the Protocol (decision NP-3/7, paragraph 3). This was complemented by the decision to include a standing item on "cooperation with other international organizations" on the agenda of future meetings of the Parties to the Protocol to take stock of developments in relevant international forums (decision NP-3/14, paragraph 6).

2. This information document complements document CBD/NP/MOP/4/8, in particular by providing supplementary information on processes related to the law of the sea and processes under the World Health Organization. The information in this document is up-to-date as of 10 October 2022.

I. FURTHER INFORMATION FROM THE INTERGOVERNMENTAL CONFERENCE ON AN INTERNATIONAL LEGALLY BINDING INSTRUMENT 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

3. As explained in document CBD/NP/MOP/4/8, a further revised draft text[1] of an 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 was prepared by the President of the Intergovernmental Conference for consideration at its fifth session.

[1] Document A/CONF.232/2022/5, available at: https://undocs.org/A/CONF.232/2022/5.

4. The further revised draft text included more than 70 articles across twelve parts. A summary is provided below of some key provisions related to access and benefit-sharing as they were set out in the further revised draft text from July 2022. This text was revised, however, based on proposals made during the fifth session of the Intergovernmental Conference in August 2022 and in-session "refreshed texts" were issued. These "refreshed texts" were not available at the time of writing. Accordingly, the overview below is based on the most recent information that is publicly available; however, the language in the draft international legally binding instrument is likely to have changed.

5. Part I of the further revised draft text contained "general provisions" and Article 1 addressed the use of terms. It included draft text on the definitions of "derivative", "marine genetic resources" and "utilization of marine genetic resources".

6. The draft text of the definition of "derivative" used identical wording as the definition of the same term in the Nagoya Protocol. There were two options for the definition of "marine genetic resources". Both options incorporated wording of the two separate definitions of "genetic material" and "genetic resources" in the Convention on Biological Diversity (CBD); however, option A of the definition incorporated additional wording not found in the CBD.

7. There were also two options for the draft definition of "utilization of marine genetic resources". Option B tracked the wording of the definition of "utilization of genetic resources" in the Nagoya Protocol. Option A had similar wording to the definition of "utilization of genetic resources" in the Nagoya Protocol but incorporated some additional language.

8. In addition, Article 1 of the draft text included a proposed definition of "access *ex situ*, including as digital sequence information", which is not a term defined under the CBD or the Nagoya Protocol. As presented in the draft text, the definition read as follows:

> 1. "Access *ex situ*, including as digital sequence information", in relation to marine genetic resources of areas beyond national jurisdiction, means access to samples, data and information, including digital sequence information.

9. Part II of the further revised draft text addressed "marine genetic resources, including questions on the sharing of benefits". The further revised draft text included language on objectives; application; activities with respect to marine genetic resources of areas beyond national jurisdiction; collection in situ of marine genetic resources of areas beyond national jurisdiction; access to traditional knowledge of indigenous peoples and local communities associated with marine genetic resources of areas beyond national jurisdiction; fair and equitable benefit sharing; access and benefit-sharing mechanism; intellectual property rights; and monitoring and transparency/transparency system for benefit-sharing. Some articles included different options which set out quite different approaches to access and benefit-sharing.

10. Some language on marine genetic resources also appeared in Part V of the further revised draft text which addressed "capacity-building and transfer of marine technology" (see in particular Article 42).

11. Also of note is part VI on "institutional arrangements", which included Article 51 on a "clearing-house mechanism". The further revised draft text foresees the establishment of a clearing-house mechanism that could facilitate information exchange on areas such as marine genetic resources of areas beyond national jurisdiction (including traditional knowledge associated therewith).

12. It should also be noted that while there were relatively few square brackets in the further revised draft text, this was not to be understood to mean there was agreement on the text.

II. FURTHER INFORMATION FROM PROCESSES UNDER THE WORLD HEALTH ORGANIZATION

A. Further details on work undertaken in response to decision WHA72(12) on "Pandemic Influenza Preparedness Framework for sharing of influenza viruses and access to vaccines"

13. As outlined in paragraph 40 of document CBD/NP/MOP/4/8, the Pandemic Influenza Preparedness (PIP) Framework Advisory Group has been considering a number of aspects related to genetic sequence data since at least 2013. At its meeting in October 2018, the Advisory Group recognized that in the future, it may be possible to bring to market influenza-related products using the genetic sequence data of influenza viruses with human pandemic potential (IVPP) independently of PIP biological materials and that in such a situation, the obligation to sign an SMTA2 would not be triggered (i.e. the standard material transfer agreement between WHO and an influenza product manufacturer, research institution or other entity that receives PIP biological materials from a laboratory that is part of the Global Influenza Surveillance Response System (GISRS)). The Advisory Group recognized that this was a concern. To address this concern and to continue to strengthen IVPP access and benefit-sharing, the Advisory Group decided to revisit some of its earlier work.

14. Subsequently, the seventy-second World Health Assembly (WHA) in May 2019 agreed to decision WHA72(12). The text in section II.E.1 of document CBD/NP/MOP/4/8 referred to the request in paragraph 1(b) of the decision but the requests in the other subparagraphs are also of relevance so they are also included below. Paragraph 1 of the decision requested the Director-General:

(a) To work with GISRS and other partners 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;

(b) To prepare a report, with inputs from Member States and stakeholders, as appropriate, 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 on Biological Diversity as appropriate;

(c) To provide more information on the functioning, usefulness and limitations of the prototype search engine;[2]

(d) To explore, including through soliciting input from Member States, possible next steps in raising awareness of the PIP Framework among relevant databases and initiatives, data providers and data users, and in promoting the acknowledgment of data providers and collaboration between data providers and data users;

(e) To continue providing information on new challenges posed and opportunities provided by new technologies in the context of the PIP Framework for the sharing of influenza viruses and access to vaccines and other benefits and possible approaches to them.

15. The Director-General was also requested to report on the implementation of the decision to the seventy-third WHA through the 146th session of the Executive Board.

16. A report by the Director-General on "Influenza preparedness" (document EB146/18) was made available for the 146th session of the Executive Board in February 2020. The document addressed implementation of decision WHA72(12), among other issues. It summarized actions taken and information compiled to respond to the requests in the decision. An overview of the work undertaken further to the requests in paragraphs (a) to (e) above is provided below.

[2] This is a search engine that the PIP Framework Advisory Group had previously requested the WHO Secretariat to develop. See further explanation below.

Paragraph 1(a): Data and analysis related to influenza virus sharing

17. The report indicated that the WHO Secretariat was aware of four specific instances to that point in time in which national measures impacted virus sharing or other aspects of the work of GISRS. The report summarized the four situations and suggested that national ABS measures had played a role in delaying the sharing of influenza viruses in each case.

18. The report stated that the Secretariat would work with GISRS to gather further information to allow a thorough analysis and presentation of data on influenza virus sharing under GISRS to enable a deeper understanding of the challenges, opportunities and implications for public health, including identifying specific instances where influenza virus sharing has been hindered and how such instances may be mitigated.

19. To this end, questionnaires were developed to collect information on experiences with virus sharing from different types of GISRS and non-GISRS laboratories. The outcomes of this research were presented in a "Report on influenza virus sharing" made available in February 2020 and also submitted to the seventy-third WHA.[3]

20. The "Report on influenza virus sharing" distinguished between experience sharing seasonal influenza viruses on the one hand and experience sharing influenza viruses with human pandemic potential on the other. A number of reasons for delays in the sharing of seasonal influenza viruses were identified including limited or costly courier services; issues with national import or export permits, e.g. where samples also contain "animal products"; lack of clarity on requirements under ABS legislation; and challenges due to institutional policies and regional measures, e.g. restrictions on sharing human genetic material under new data protection rules.

21. Challenges in the sharing of influenza viruses with human pandemic potential included biosafety and biosecurity issues; and complex and restrictive import or export permit or license requirements, e.g. where the IVPP could be considered to have "dual use' potential.

22. The report concluded by noting that sharing of influenza viruses within GISRS and with non-GISRS partners had become increasingly complex in recent years. It stated that there had been both technical issues and international legislation contributing to delays in sharing seasonal viruses and the delays due to technical reasons have been resolved in a shorter time frame than delays due to international legislation. It pointed to uncertainty that has been introduced to the virus sharing process due to ABS rules and human data protection legislation. It indicated that for the first time, uncertainties and delays in virus sharing due to measures to implement the Nagoya Protocol had directly impacted vaccine production in September/October 2018. It concluded that "[i]f 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 GISRS network, restricting the availability of optimally protective vaccine viruses and the timely availability of life-saving influenza vaccines" (para. 35). The report stated that solutions to issues around the sharing of influenza viruses will require commitment and action from WHO, GISRS and Member States.

Paragraph 1(b): Legislation and regulations related to influenza virus sharing

23. To address the request concerning legislation and regulations related to influenza virus sharing, the Director-General's report to 146th session of the Executive Board indicated that the WHO Secretariat would, in consultation with the CBD Secretariat,

(a) Conduct a desk review of available existing legislation and regulations that may impact the sharing of influenza viruses, including by using information available on the Convention on Biological Diversity Access and Benefit-Sharing Clearing-House; and

[3] "Report on influenza virus sharing", February 2020. See also "Consolidated report by the Director-General", document A73/4, 12 May 2020, especially section 13.3.

(b) Based on the desk review, prepare a document summarizing the key components of available national legislation or regulatory measures that are relevant to influenza virus sharing and the public health considerations thereof.

24. A "Draft report on decision WHA72(12), paragraph 1(b)" was made available in March 2020 and was also submitted to the seventy-third WHA.[4] The report reviewed records on legislative, administrative and policy measures in the ABS Clearing-House according to a number of different criteria:

- the definition of "genetic resources" in the measures and whether pathogens would be included or excluded from the definition;
- whether influenza is explicitly addressed in the measures, if the measures distinguish between seasonal and pandemic influenza, whether they make reference to the PIP Framework and whether they consider the PIP Framework a specialized international access and benefit-sharing instrument;
- whether the measures make reference to Article 4(4) of the Nagoya Protocol in general (i.e. not specifically in connection to the PIP Framework);
- whether the measures make reference to Article 8(b) of the Nagoya Protocol regarding health emergencies and also whether the measures reference human health in general; and
- whether and how the measures make reference to the International Health Regulations (2005).

25. The report included tables with provisions from the different measures as they relate to the above criteria.

Paragraph 1(c): Functioning, usefulness and limitations of prototype search engine

26. Further information on the prototype search engine was provided in a combined report on paragraphs 1(c), (d) and (e) of decision WHA72(12) made available in March 2020 and also submitted to the seventy-third WHA.[5]

27. The report explained that the Partnership Contribution is one of the benefit-sharing mechanisms under the PIP Framework. Contributions to the Partnership Contribution are triggered by "use of GISRS" which is understood to mean "that a company/institution used or received: … information (e.g. sequence information, epidemiological data, antiviral susceptibility data, pre- and post-vaccine composition meeting reports); developed and/or provided by or through GISRS."[6] Accordingly, use of the genetic sequence data of influenza viruses with human pandemic potential obtained through GISRS is considered "use of GISRS" and so cash contributions should be made to the Partnership Contribution.

28. A challenge arises, however, in that, while the Influenza Virus Traceability Mechanism is used to trace transfers of physical samples of influenza viruses, there is no comparable traceability system for the genetic sequence data of influenza viruses.

29. In its discussions on genetic sequence data, the PIP Advisory Group had considered systems to monitor the use of IVPP genetic sequence data (GSD) in end products and to this end, had recommended that the WHO Secretariat continue its collaboration with the World Federation for Culture Collections and its World Data Centre for Microorganisms.

30. WHO worked with the World Federation for Culture Collections and the World Data Centre for Microorganisms to develop a prototype search engine that could "monitor the use of IVPP GSD in the development of influenza-related end-products (such as vaccines, antivirals and diagnostics), thereby

[4] "Draft report on decision WHA72(12), paragraph 1(b)", March 2020. See also "Consolidated report by the Director-General", document A73/4, 12 May 2020, especially section 13.3.

[5] "Draft report on decision WHA72(12) 1(c), (d), (e)", March 2020. See also "Consolidated report by the Director-General", document A73/4, 12 May 2020, especially section 13.3.

[6] "Draft report on decision WHA72(12) 1(c), (d), (e)" at p. 8.

allowing identification of entities that have used IVPP GSD to develop such products" (para. 7). A pilot test of the search engine was carried out in 2016 and "resulted in the identification of 10 end-products manufactured using IVPP GSD, by 8 companies that are not listed in the IVTM because they did not receive PIP BM" (para. 7). The report does not indicate whether these companies were then contacted to make Partnership Contributions.

31. The prototype search engine can be used to search data in publicly available platforms such as scientific publications, patents, clinical trial files and regulatory approval files.

32. The report identified a number of limitations of the search engine. These included certain intrinsic limitations such as inconsistent practice in identifying genetic sequence data in database records and confidentiality of data in some cases. In addition, some databases require users to register and accept a data access and use agreement before being able to search the database. Accordingly, terms would need to be agreed to with such databases before they could be included in the search engine. The report also outlined some further developments that could be made to enhance the search engine.

33. The report concluded that the results of the pilot test of the search engine were generally positive. The conclusions also acknowledged the intrinsic limitations to the search engine as outlined above and indicated that "[i]t is clear that the search engine cannot be transformed into a tool to monitor all uses of IVPP GSD by companies" (para. 40).

34. It is not clear whether further work has been undertaken on the prototype search engine. There was no reference to the search engine in decision WHA73(14) on "influenza preparedness".

Paragraph 1(d): Databases and initiatives, data providers and data users

35. The combined report on paragraphs 1(c), (d) and (e) of decision WHA72(12) provided a number of options to raise awareness of the PIP Framework among databases and initiatives, data providers and data users, in particular expanding outreach efforts to these different groups. For outreach to databases, the report noted that many publicly accessible databases already contain notification statements (such as a general statement that data may be subject to intellectual property rights or access and benefit-sharing requirements) and suggested that a statement on the PIP Framework could be added to alert users to the Framework and its objectives. It also suggested that IVPP sequences in databases could be flagged to alert users of the link to the PIP Framework.

36. For outreach to journals, the report suggested contacting the editors of relevant journals to present the PIP Framework and its objectives. It indicated that this would go along with a suggestion "that the Secretariat promote acknowledgement of data providers with journals with a view to securing an undertaking from them to acknowledge the contributions of data providers, as well as originating laboratories, in scientific publications and other works" (para. 47).

37. It is not clear whether efforts have been made to undertake the outreach activities suggested in the report. There was no reference to further work on raising awareness with databases in decision WHA73(14) on "influenza preparedness".

Paragraph 1(e): New developments

38. The combined report on paragraphs 1(c), (d) and (e) of decision WHA72(12) addressed the request in paragraph 1(e) of the decision by referring to the "Global Influenza Strategy 2019-2030" launched by WHO in March 2019. The Strategy highlights the need for better tools to prevent, detect, control and treat influenza. To this end, the WHO Secretariat had held a technical consultation on influenza product research and innovation and is planning follow-up activities. Furthermore, there is a plan to release biennial reports on the state of better global tools as part of the monitoring and evaluation of the Strategy.

B. Further details on the work of the Member States Working Group on Strengthening WHO Preparedness and Response to Health Emergencies (WGPR)

39. The WGPR met four times following the special session of the WHA held in November-December 2021.

40. The WGPR submitted an interim report to the 150th session of the Executive Board in January 2022. The Executive Board agreed to decision EB150(3) on "Strengthening the International Health Regulations (2005): a process for their revision through potential amendment". In paragraph 2 of the decision, the Executive Board decided:

> To urge Member States to take all appropriate measures to consider potential amendments to the International Health Regulations (2005), with the understanding that this would not lead to reopening the entire instrument for renegotiation. Such amendments should be limited in scope and address specific and clearly identified issues, challenges, including equity, technological or other developments, or gaps that could not effectively be addressed otherwise but are critical to supporting effective implementation and compliance of the International Health Regulations (2005), and their universal application for the protection of all people of the world from the international spread of disease in an equitable manner.

41. As mentioned in paragraph 60 of document CBD/NP/MOP/4/8, the final report of the WGPR was submitted to the seventy-fifth WHA (document A75/17), fulfilling the WGPR's mandate from resolution WHA74.7. The issue of equity featured prominently in the report. The report also made reference to a number of initiatives, including the BioHub System, that had been launched by WHO in response to the COVID-19 pandemic. The report indicated that Member States requested further consultation on the BioHub System as well as clarification on how it relates to existing instruments and frameworks such as GISRS, the PIP Framework and the WHO Hub for Pandemic and Epidemic Intelligence (para. 8(j)). The WGPR also expressed the need for Member States to further discuss the sustainability of the different initiatives launched in response to the pandemic: "Specifically, there was a need to revamp their working principles, governing structures, legality and scope through intergovernmental processes, as necessary, for consistency with equity considerations. In this regard, the WGPR further discussed interest in developing a comprehensive access and benefit-sharing (ABS) mechanism" (para. 31).

42. Also on ABS, the WGPR discussed sharing of genomic sequence data, information and samples as well as fair and equitable sharing of benefits arising out of the use of such data, information and samples. "Specific issues raised by Member States included incentivizing (and not penalizing) Member States sharing information and/or samples, reconfirming the importance of a multilateral approach for sharing information and samples, and the need to strive for consistency with existing legal frameworks like the Convention on Biological Diversity and its Nagoya Protocol" (para. 8(i)).

43. The WHA adopted decision WHA75(9) on "Strengthening WHO preparedness for and response to health emergencies". In the decision, the WHA welcomed the final report of the WGPR and decided to continue the WGPR with a new mandate and name. It is now called the "Working Group on Amendments to the International Health Regulations (2005)" (WGIHR) and its mandate is to work exclusively on consideration of proposed targeted amendments to the International Health Regulations (2005) ("IHR"), consistent with decision EB150(3). The decision established a process for this work including inviting proposed amendments, work by a Review Committee on the IHR and coordination between the WGIHR and the INB. The WGIHR is to propose a package of targeted amendments for consideration by the seventy-seventh WHA (tentatively foreseen for May 2024).

44. Submissions of proposed amendments to the IHR were due by 30 September 2022 and the Review Committee portion of the process began its work on 6 October 2022. A document on the terms of reference

for the Review Committee[7] states that the technical recommendations of the Committee are to "be based on, address, and document in the final report" four main areas including an analysis of each of the submitted proposed amendments to the IHR in terms of, among other things, "[c]ompatibility and consistency with provisions of other relevant WHO frameworks and relevant international legal instruments under the auspices of other intergovernmental and international organizations such as … [the] Convention on Biological Diversity".

45. The first meeting of the WGIHR is to be held no later than 15 November 2022.

C. Further details on the work of the Intergovernmental Negotiating Body

46. As described in paragraph 59 of document CBD/NP/MOP/4/8, at its special session held in November-December 2021, the World Health Assembly decided to establish an intergovernmental negotiating body (INB) to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response.

47. As referred to in paragraph 61 of document CBD/NP/MOP/4/8, the documentation for the second meeting of the INB (held in July 2022) included a working draft of a WHO convention, agreement or other international instrument ("instrument" hereinafter) on pandemic prevention, preparedness and response for the consideration of the INB (document A/INB/2/3). The working draft presented a proposed structure for the instrument including a preamble and six parts. Within each part, the working draft identified articles that could be addressed as well as ideas that could be part of the text of the articles.

48. The working draft began with text for a preamble to the instrument, which included the following paragraph:

> *Underscoring* 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 on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, and the Pandemic Influenza Preparedness Framework;

49. Part I of the working draft covered introductory provisions including an article on definitions and use of terms. It suggested that terms that could be defined could include access, equity, genomic sequence data and utilization of genetic resources, among others. Part IV presented different themes that could be addressed in the instrument and included suggestions for specific provisions, areas, elements or obligations that could be covered under each theme. The first theme was "achieving equity". It stated that:

> Equity is central to achieving and sustaining the objective(s) of [the instrument]. In developing international, regional or national legislative, administrative, technical and/or other measures for pandemic prevention, preparedness and response, the following should be taken into account, among others:
>
> …
>
> (c) 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 resource productions, including diagnostics, vaccines, personal protective equipment and therapeutics;

50. The second theme in part IV was "fair, equitable and timely access and benefit sharing". The description of this theme read as follows:

[7] "IHR Review Committee regarding amendments to the International Health Regulations (2005): Terms of Reference" (6 October 2022).

> Establishing a comprehensive system for access and benefit sharing is a cornerstone to achieving and sustaining the objective(s) of this [instrument]. In developing international, regional or national legislative, administrative, technical and/or other measures for pandemic prevention, preparedness and response, the following should be taken into account, among others:
>
> (a) 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;
>
> (b) measures to promote and facilitate recognition of the system as a specialized comprehensive system for access and benefit sharing system, at the national level;
>
> (c) measures to engage with all relevant actors in the design, development and implementation of the comprehensive system for access and benefit sharing;
>
> (d) measures to ensure timely sharing of pathogens and genomic sequence data through one or more standardized real-time platforms available to all Parties.

51. The seventh theme in part IV is "One Health" which included text suggesting that "measures to strengthen regular monitoring and sharing of pathogens with pandemic potential from wildlife and domesticated livestock" should be taken into account in the development of measures for pandemic prevention, preparedness and response.

52. As indicated in paragraph 62 of document CBD/NP/MOP/4/8, the INB agreed that the instrument it is negotiating should be legally binding and that Article 19 of the WHO Constitution is the comprehensive provision under which the instrument should be adopted. Under this article, the WHA has the authority to adopt conventions or agreements with respect to any matter within the competence of the Organization. A two-thirds vote of the WHA is required for the adoption of such conventions or agreements and these conventions or agreements come into force for each WHO Member when accepted by it in accordance with its constitutional processes.

53. The INB also agreed that the treaty could include some non-binding clauses and also that it could still consider the suitability of Article 21 of the WHO Constitution, as the work progresses. Article 21 allows the WHA to adopt regulations in respect of certain areas including "sanitary and quarantine requirements and other procedures designed to prevent the international spread of disease". Regulations adopted under Article 21 are considered to be legally-binding and only require a simple majority in the WHA for their adoption. These regulations come into force for all WHO Members after due notice has been given of their adoption by the WHA, except for such Members who may notify the Director-General of rejection or reservations during the period stated in the notice.[8]

D. Further details on the BioHub system

54. As described in paragraph 68 of document CBD/NP/MOP/4/8, pilot testing of the BioHub System has included the development of two standard material transfer agreements. SMTA 1 is for countries that wish to voluntarily share BMEPP with a WHO BioHub Facility while SMTA 2 is for a WHO BioHub Facility to share BMEPP with a "Qualified Entity".

55. Both SMTAs have provisions requiring the BMEPP to be handled in accordance with all applicable WHO, international, and national regulations and standards which are specified to include national measures on access and benefit-sharing (see Art. 3.1.2 in both SMTAs). They also include an article on fair and equitable benefit-sharing (Art. 5 in SMTA1; Art. 4 in SMTA2).

[8] See "Background information related to the identification by the Intergovernmental Negotiating Body of the provision of the WHO Constitution under which the instrument should be adopted", document A/INB/2/INF./1 (11 July 2022).

56. Article 3 of SMTA1 addresses the rights and obligations of the WHO BioHub Facility and provides, in paragraph 3.1.3, that the WHO BioHub Facility undertakes to "upload BMEPP genetic sequence data that it generates, in a timely manner, to one or more publicly accessible genetic sequence databases (e.g. GISAID, INSDC Databases)".

57. Further to this, SMTA1 includes annex 2 which contains a "voluntary transfer form for SARS-CoV-2 BMEPP". While the act of transferring SARS-CoV-2 BMEPP to a WHO BioHub Facility is voluntary, the use of the transfer form appears to be mandatory when a transfer is actually to be made. Section III of annex 2 addresses "acknowledgement of genetic sequence database for upload of BMEPP Genetic Sequence Data". The annex states: "The WHO BioHub Facility will upload BMEPP GSD that it generates, in a timely manner, to one or more publicly accessible genetic sequence databases, including for example GISAID or INSDC. WHO will inform the Provider of the upload of GSD and will post the information on where the BMEPP has been uploaded, as part of the publicly available catalogue hosted on the WHO's website." There is a space below for the provider to sign.

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