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INB related interactive dialogues
Topic 1. Article 12 (Pathogen Access and Benefit-Sharing System)

Discussion questions proposed by the Bureau for resource persons

1. PABS and Nagoya Protocol related matters

If Member States reach consensus on the PABS instrument during the negotiation, including that its design is consistent with, and does not run counter to the objectives of the Convention on Biological Diversity and the Nagoya Protocol, and the INB decides that PABS can be recognized as a specialized international access and benefit-sharing instrument (SII):

1.1. Can PABS, as SII, be universally applied to all Parties to the Pandemic Agreement, i.e. both Parties and non-Parties to the Nagoya Protocol?

The PABS System as a Specialized International Instrument (SII) should apply by default only to Member States Parties to the Nagoya Protocol, with Member States that are non-Parties to the Nagoya Protocol having the option to voluntarily join the PABS System. It is important to ensure that the PABS System is facilitative, but not restrictive or discriminatory, in nature so that it does not become an exclusive instrument covering the sharing of pathogens with pandemic potential and their genetic sequence information. Member States should retain the option to obtain the desired pathogen with pandemic potential or its genetic sequence information from an alternative source, such as through bilateral cooperative agreements or in any other legal manner.

1.2. What criteria and/or mechanism(s) are to be used for the recognition of PABS as a SII?

- For Parties to CBD and the Nagoya Protocol who are Parties to the Pandemic Agreement?
- For non-Parties to CBD and the Nagoya Protocol who are Parties to the Pandemic Agreement?
- What domestic legal arrangements are needed, such as amendment of national ABS laws, to recognize PABS and ensure that PABS materials are not subject to additional or different PIC and MAT ?

For Member States that are parties to the CBD and the Nagoya Protocol, it is necessary to formalize the PABS System as SII at the legislative level by ratifying the WHO Pandemic Agreement. Member States that are non-Parties to the CBD and the Nagoya Protocol and wish to join the PABS System should do the same. In doing so, both types of Member States should take into account the implications/ consequences that recognizing the PABS as SII has for both national and international export control systems in the context of the Biological and Toxin Weapons Convention (BTWC) (see also the comments to paragraph 3.7 below).

1.3. During the INB negotiations, what are the considerations that should guide the INB so as to maintain coherence between the future PABS and the Nagoya Protocol?

I do not wish to respond.

1.4. Are there any specific issues in the PABS under ongoing INB negotiations that may prejudge the ongoing discussions on the handling of DSI within the CBD and the Nagoya Protocol?

I do not wish to respond.

1.5. In principle a non-Party to PABS who is a Party to the Nagoya Protocol could view that PABS is not 'consistent with and not run counter to the objectives of the CBD and the NP'. In this case, is the non-Party to PABS that is affected by the conclusion of a SII entitled to dispute settlement under Article 27 of the CBD?

I do not wish to respond.

1.6. What are elements or designs of PABS that would be inconsistent with and run counter to the objectives of the CBD and the Nagoya Protocol?

I do not wish to respond.

2. Issues related to access to PABS materials and sequence information

2.1. What are the current most up-to-date progresses in CBD on definition and scope of digital sequence data (DSI)? Will the current negotiated text using "sequence information" contradict/hamper the ongoing negotiation of the CBD?

I do not wish to respond.

2.2. What are the effective technical or operational measures to ensure all users (primary users and secondary users shared by primary users) of materials and sequence information account to benefit sharing arise from the use of them?

For instance, it is appropriate to consider the measures implemented in the relevant provisions of the PIP Framework.

2.3. What are the effective "traceability" measures which ensure users of materials and sequence information account to benefit sharing obligations?

For instance, it is appropriate to consider the measures implemented in the relevant provisions of the PIP Framework.

3. Issues related to benefit sharing

3.1. What are the positive or negative consequences to manufacturers should a PABS system be established in which there are a legally binding benefit sharing requirements to allocate certain percentage of vaccines, therapeutics and diagnostics (VTD) on a free-of-charge basis and at not-for-profit prices, as well as annual monetary contribution?

An obvious negative consequence for manufacturers in the event of the introduction of the PABS System will be an increase in the cost of production due to the provision of part of the products to the needs of the PABS System. This will require either an increase in prices for the remaining products or compensation for lost profits at the expense of government funds / from other sources. As a positive consequence, one can note the prompt access of producers to the necessary biological materials / information on genetic sequences.

3.2. Would the manufacturers and commercial users of materials and sequence information consider not using the PABS system because of this required contribution?

I do not wish to respond.

3.3. If not a PABS system, are there other options which could facilitate rapid and timely sharing of materials and sequence information, and on an equal footing, sharing of monetary and non-monetary benefits arising from the use of materials and sequence information, and incentivize greater manufacturer participation? Would any of these options be preferable to a PABS system?

The sharing of materials and information on genetic sequences may be carried out under existing mechanisms, e.g. based on bilateral Material Transfer Agreements, GISAID and GenBank (data on genetic sequences), EVAg (the European Virus Archive - GLOBAL).

3.4. What would be appropriate and sufficient triggers for such benefit sharing under a PABS system?

I do not wish to respond.

3.5. Should benefit sharing of VTDs cover: a) PHEIC, b) pandemic emergency, c) pandemic? What would be the public health impact of each of these options?

I do not wish to respond.

3.6. How should the duration of the benefit sharing of VTDs be determined?

I do not wish to respond.

3.7. Is it necessary to make a reference to the Biological and Toxin Weapons Convention and, if so, what would need to be considered for the development of a PABS system that is consistent with the objectives of this Convention, in particular its article 10?

During the INB negotiations on Article 12, the participants focused on the Convention on Biological Diversity and its Nagoya Protocol, which represent an aspect of countries' rights over genetic resources and, accordingly, in this context, matters of benefit-sharing arise, which are also addressed in Article 12. However, export controls represent an aspect of international security in terms of countries' compliance

with international treaties, such as the BTWC, in case of biological materials and toxins, and this aspect was not initially addressed in Article 12 by the INB negotiators at all. Some participants in the negotiations were of the view that the PABS System could not be considered safe and secure in terms of sharing pathogens with pandemic potential unless the issues of export control legislation in the context of the BTWC were properly and explicitly addressed in Article 12.

It should be noted that the reference in paragraph 3(e) of Article 12 to the need to comply with biosafety and biosecurity requirements and standards only partially reflects export the control requirements, since biosafety and biosecurity generally refer to measures and practices to ensure biosafety and biosecurity in terms of ensuring adequate containment and the availability of trained personnel to handle dangerous and highly dangerous pathogens in a safe manner (biosafety) and to ensuring the safeguarding of such pathogens (biosecurity) from loss, theft, misuse, etc., applied locally in a specific research laboratory or institution, without taking into account security concerns in the context of compliance with the BTWC at the stage of making a decision to share pathogens with an external research laboratory or institution. It is at the stage of making a decision to exchange pathogens with a third party when export control laws come into play, ensuring security in the context of compliance with the BTWC.

The major concern is that the implications of the implementation of the PABS System for the global export control system, in the context of compliance with the BTWC, are not clear or fully understood. From this point of view, in the course of further INB negotiations, I consider it critically important to involve the relevant national agencies and authorities as well as international bodies responsible for export control matters in the context of compliance with the BTWC in the discussion of the issues surrounding the establishment of the PABS System as SII.

I believe that recognizing the PABS System as a “a specialized international access and benefit-sharing instrument,” as proposed in the “New Paragraph” following paragraph 3 of Article 12, as well as in the alternative to paragraph (g) of Article 12, would be completely counterproductive without properly addressing the security concerns in the context of the BTWC and the related export control laws that exist in many countries.

In the event of the emergence of a pathogen with pandemic potential, a Member State (Member States) could promptly add it to the “List of Microorganisms… subject to Export Control” and, from a certain point of time, this microorganism and some related materials and technologies would be subject to export control requirements, including restrictions on their free transfer to third parties. It is, therefore, proposed to address the export control aspects related to the BTWC at an early stage, i.e. in Article 12, rather than face a problem, at a later date, of not being able to implement Article 12 properly. This would allow a full and comprehensive examination of export control issues with the involvement of national agencies and authorities responsible for export control compliance in the context of the BTWC and the representatives of the BTWC Secretariat to the UN. Member States have a strong responsibility to ensure that the proposed PABS System does not undermine the existing export control mechanisms that support Member States’ compliance with their BTWC obligations.

3.8. What are the differences, in terms of legal obligations of those participating in a PABS system, between two terms: a) "benefits arising from the sharing (of material and sequence information)"; and b) "benefits covered by the PABS system"?

I do not wish to respond.

3.9. Are the expressions "benefits arising from the sharing", used in the PIP Framework, and "benefits arising from the utilization", used in the Nagoya Protocol synonymous? If not, what are the consequences of each for the PABS system?

I do not wish to respond.

3.10. What are the WTO rules that should be taken into consideration, if any, in the design of a PABS system? Can Member States limit the export of VTDs that are identified as benefits arising from the PABS system, in light not only of the obligations agreed upon by parties to this system, but also of the public health goals emanating from it?

I do not wish to respond.

4. Legal issues related to the adoption of PABS system

4.1. What are the implications of adopting a PABS system under articles 19 (e.g. as a Protocol), 21 or 23 of the WHO Constitution?

I do not wish to respond.