19 August 2024

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):

Art.12 as currently drafted cannot be a Specialized International Instrument (SII) under the Nagoya Protocol. This is because Article 12 as drafted currently presents a framework of a PABS instrument. Article 12.6 specifically states that "The modalities, terms and conditions, and operational dimensions of the PABS System shall be further defined in a legally binding instrument that will be operational no later than 31 May 2026 ." These elements are critical to determining whether the PABS instrument may constitute an SII in terms of the Nagoya Protocol that is consistent with and does not run counter to the objectives of the Nagoya Protocol and the Convention on Biological Diversity (CBD). Also, INB cannot decide if an instrument is an SII under Nagoya Protocol. The appropriate forum for this determination is the COP/MOP of the Nagoya Protocol. The criteria for this determination is being discussed in the COP/MOP, and is on the agenda of the upcoming COP/MOP to be held in Cali, Colombia.

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?

A PABS instrument, whether construed as a SII under Nagoya Protocol or not, can be universally applied to all parties to the Pandemic Agreement. This would have a similar effect as the FAO Treaty on Plant Genetic Resources for Food and Agriculture. This treaty applies to countries that are parties thereto but not the Nagoya Protocol, e.g., US, Canada and Russia. Also, the WHO PIP Framework applies to all WHO member States including non-Parties to the Nagoya Protocol.

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?
- Art.4.4 of Nagoya lays down the basic criteria – that the instrument "is consistent with, and does not run counter to the objectives of" the CBD and the Nagoya Protocol. Further detailed criteria are being discussed by MOP.
- For non-Parties to CBD and the Nagoya Protocol who are Parties to the Pandemic Agreement? This is not a relevant issue for non-Parties to the Nagoya Protocol because

they will be bound by the PABS instrument regardless of whether it is an SII under Nagoya or not.

- 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 ? This will depend on terms of the instrument. Agreeing to a multilateral framework for access and sharing of PABS material and digital sequence information should be consistent with meeting the obligations of the CBD/NP, including regulated access linked to prior informed consent and benefit sharing on mutually agreed terms (MAT). If a Standard Material Transfer Agreement(s) (SMTA) is agreed upon as part of the PABS that addresses access and benefit-sharing on equal footing, this will ensure that PIC and benefit sharing on MAT at national level are not required for PABS material on a case by case basis. The PABS system would be applicable only for materials and digital sequence information covered by it, and for the purposes of utilization specified.

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?

In terms of article 4.4 of the Nagoya Protocol, the primary consideration for coherence between PABS and the Nagoya Protocol is that the PABS instrument must be consistent with and not run counter to the objectives of the CBD and the Nagoya Protocol. Therefore, it is important to ensure that access and benefit-sharing (ABS) are linked in the PABS instrument. Access to pathogen material and digital sequence information, therefore, must be subject to benefit-sharing under an SMTA setting the terms thereof. Materials and digital sequences should not be used beyond the scope of the PABS (preparedness and response to public health emergencies of international concern and pandemic emergencies). For any such use generally applicable ABS principles of Nagoya and CBD would apply.

1.3. 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?

The negotiations would not prejudge the ongoing discussions in the CBD and Nagoya Protocol COPs on the establishment of a multilateral mechanism for benefit-sharing from the use of digital sequence information on genetic resources, including a global fund. Nothing in the Protocol prevents developing ABS instruments for specific Genetic Resources provided they are consistent with the Protocol. The Nagoya Protocol MOP Decision 15/9 allows other fora to adopt specialized approaches for DSI.

1.4. 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?

If PABS is an SII under art 4.4 of Nagoya Protocol, the Nagoya Protocol including article 27 of the Protocol will not apply to the SII, as it would have been a decision of the Nagoya Protocol MOP. This is why the consideration of whether PABS is an SII or not has to be decided by Parties to the Nagoya Protocol as the MOP. If the MOP decides that it is an SII, no Contracting party to the Protocol that is not a party to the PABS will be allowed to contest the PABS consistency with the Protocol.

1.5. 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?

The following elements that have been proposed by some member States, if agreed in PABS, will be inconsistent with and run counter to the objectives of the CBD and Nagoya Protocol:

- Requirement that access to samples and sequence data granted without conditions to requesting recipients
- Non-binding guidelines for recognition of laboratories, biorepositories and databases capable of receiving samples and sequence data
- Governance of the PABS system by a multistakeholder partnership instead of governance by WHO member States
- Obligating sharing of any existing or new viruses/organisms as well as any variants that cause(s), or can cause a disease to its human host, that expands the scope of PABS beyond public health emergencies of international concern and pandemics.
- Non-binding guidelines instead of SMTA setting the terms of access and benefit-sharing of PABS material
- Terms and conditions that create impediments to rapid fair and equitable benefit-sharing
- No benefit sharing (monetary or non monetary)
- No use restrictions or monitoring of the utilization of the PABS material and sequence data

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?

There is no agreement on definition or scope of DSI in the CBD/Nagoya Protocol. DSI is a term that is being used as a placeholder. Hence, use of the term "Sequence Information" will not hamper ongoing negotiations in the CBD. The definition of sequence information will only apply within the scope of the PABS instrument.

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?

SMTA and Data access agreements (DAA) are the most critical measures in this regard. Users accessing PABS material and sequence information have to agree to these prior to or at the point of access.

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

SMTA, DAA, specialized databases implementing DAA. For DSI, accession numbers (AN) as unique identifiers in databases, labelling of sequences.

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?

The biopharmaceutical industry has pledged to reserve an allocation of real-time production of VTDs for distribution to priority populations in low income countries during pandemics. This can have positive implications in terms of the social responsibility of the biopharmaceutical industry. The impact of any monetary contribution on the biopharmaceutical industry will be minimal. A trade-off is made for increased legal certainty provided by the PABS in accessing PABS material and DSI, against the requirement of allocation of products and an annual contribution. Moreover, monetary contributions can assist in building capacities that will be useful for capacity building for surveillance and laboratories and contribute to information sharing which will be positive for the industry.

It will be important to establish a PABS system that is legally binding and comprehensive with a large number of country Parties, for manufacturers not to find loopholes to gain access pathogen samples and DSI outside of the PABS.

The legal certainty of the PABS system could facilitate access to pathogen material and sequences for the development of VTD, and obviate the need for negotiating access bilaterally with individual countries and complying with varying national ABS requirements

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

Manufacturers and commercial users are likely to be encouraged to use the PABS system due to the legal certainty that a multilateral PABS system offers. The experience of the the contributions made by manufacturers under the PIP Framework supports this assumption.

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?

No. The alternative are voluntary initiatives, such as the WHO BioHub, or the existing PIP Framework. However, this will not increase the legal certainty of the conditions for access and sharing of material and DSI, as these will not be considered SII under the CBD/Nagoya Protocol.

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

The trigger should be access to the pathogen or sequence inforamtion; this could eventually take place even before a declaration is made. The PABS system .should clearly specify when access to the pathogen and sequence information is to be provided, is it for pandemic preparedness (any time) or only when a PHEIC or pandemic emergency is determined. Any products developed using the material should require fair allocation, including diagnostics

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?

PHEIC, Pandemic , pre-PHEIC (preparedness)

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

Member States should determine the duration in accordance with PABS terms. Parties can decide a duration that applies beyond the pandemic situations, if they desire.

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?

Yes. Art 10 of BTWC states that States Parties undertake to facilitate, and have the right to participate in, the fullest possible exchange of equipment, materials and scientific and technological information for the use of bacteriological (biological) agents and toxins for peaceful purposes. This means that materials and sequence information shared under the PABS system must be used for peaceful purposes (for public health need of PHEIC and pandemic preparedness and response). Moreover, article 10 of the BTWC states that Parties to the Convention in a position to do so shall also co-operate in contributing individually or together with other States or international organisations to the further development and application of scientific discoveries in the field of bacteriology (biology) for the prevention of disease, or for other peaceful purposes.

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"?

Option (a) is preferable. It covers benefits arising from the shared PABS material or sequence information. B) assumes that the PABS system per se delivers benefits. delinks from sharing and is not therefore not consistent with art.4.4. Nagoya Protocol. The CBD and Nagoya Protocol apply to benefit-sharing “arising” from the utilization of genetic resources and not to a select specified list of benefits. Thus limiting benefit-sharing to specified benefits covered by PABS would be inconsistent with the Nagoya Protocol.

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?
No. To be consistent, language could be “benefits arising from the sharing of the material and sequence information for utilization”... as the purpose of sharing will be for utilization, which means “to conduct research and development” in the Nagoya Protocol. It should be noted that sharing under the PIP Framework is for the utilization of the PIP material by entities accessing such material.

If PABS has to be consistent with Nagoya Protocol, consistency with the Protocol’s language is critical; hence, the adopted wording should be as close as possible to that of the Nagoya Protocol

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?
There are various issues on which the WTO rules could have an impact on PABS, including the extent to which intellectual property rights may be claimed on PABS material and sequence information. The INB is already addressing as part of the negotiations of the pandemic instrument the issue of limiting situations in which members may introduce export restrictions during pandemics.

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?

PABS system as a protocol under 19 will have the status of an independent treaty complementary to the Pandemic agreement. Nevertheless, it will not bind all parties to the pandemic agreement but only those that sign and ratify the PABS treaty or accede to it. This implies that it is possible that such a protocol could have a significant number of countries not becoming parties to it while remaining parties to the Pandemic Agreement.

On the other hand an article 21 instrument will apply to all WHO member States, including non-parties to the Pandemic Agreement, unless any party specifically opts out from the instrument. As a PABS instrument will be an instrument focused on a specific issue, in comparison to the IHR that focuses on a number of different issues relating to international health emergencies, it is possible that parties that may not sign or ratify a PABS instrument under article 19 could issue an opt out notification from the article 21 instrument also.

Nevertheless, it should be noted that regardless of whether the PABS instrument is anchored under article 19 or article 21, both instruments will be a legal treaty in terms of the Vienna Convention on the Law of Treaties.

In this context, the relevant consideration should be how soon should the PABS instrument come into operation. If member States desire that the PABS instrument should be operational by 2026 or earlier, an article 21 instrument is likely to lead to speedy implementation as it does not require legislative ratification but mere executive consent. A PABS instrument under article 21 will come into effect as soon as the World Health Assembly adopts a resolution adopting the PABS instrument as a Regulation under article 21.

However, the most important consideration in the choice of the WHO constitutional provision under which the PABS system should be based is whether the chosen approach ensures that the PABS system is applicable to all WHO members.