

INB related interactive dialogues

Topic 1. Article 12 (Pathogen Access and Benefit-Sharing System)

Discussion questions proposed by the Bureau for resource persons

Responses from Frederick M. Abbott, August 27, 2024

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?

If all Member States become party to the PABS Instrument then it should be universally applied among them irrespective of whether they are parties to the Nagoya Protocol, but that does not mean that this universal application is “legally binding” on all WHO Member States. The PIP Framework is not legally binding in the sense of a treaty or international agreement. Reaching consensus on recommended practices during the negotiation and becoming parties to an international agreement with binding effect are different things. If a Member State has not formally acceded to the Pandemic Agreement, and the PABS Instrument is not independently defined and accepted as a standalone international agreement, its terms would not be legally binding.

- 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 Member States that are parties to all three agreements it should be sufficient if they state its status as a SII in the PABS Instrument because this would be a subsequent agreement by the parties to earlier international agreements (i.e. the CBD and Nagoya).
- For non-Parties to CBD and the Nagoya Protocol who are Parties to the Pandemic Agreement?
Non-parties to the CBD and Nagoya Protocol can agree that the PABS is a SII, but their characterization should not determine how the parties to the CBD and Nagoya Protocol characterize the PABS.
- 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 depends on the terms of existing national legislation and the answer will vary. However, as a general rule adopting subsequent national legislation that expressly provides that its rules exclusively govern the subject matter and supersede any prior inconsistent legislation should adequately address the matter.

- 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?

Recognizing that the intent of the CBD and Nagoya are to protect and preserve biological diversity and the environment, and not to protect and preserve dangerous pathogens. A system for sharing dangerous pathogens may well entail obligations to share benefits arising from access for a different purpose (i.e. to promote equitable protection of public health), but a separation should be encouraged between the systems. Benefit-sharing under the CBD was and is intended to provide the resources needed to support preservation of biological diversity (including genetic resource stocks) in line with the objectives of the 1992 Rio Declaration.

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

DSI discussions in CBD (and relevant to Nagoya) appear to be at early stages with multiple issues flagged for consideration. Parties should strive for a conceptual and legal separation of the systems. This may include clearly enumerating the objectives of the PABS to distinguish the objectives of the CBD and Nagoya and include “without prejudice” language in PABS DSI solutions.

- 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?

Apparently yes.

- 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?

An open-ended question and problematic to develop “adverse hypotheticals”. As an illustration, PABS could – but will not - state that WHO Member States do not have sovereign authority over natural resources located within their jurisdictions, which is a long-standing principle of international law.

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?

See Report of the Ad Hoc Open-ended Working Group on Benefit-sharing from the Use of Digital Sequence Information on Genetic Resources on its first meeting, CBD/WGDSI/1/3, 18 November 2023

For a technical explanation and analysis, see on definition: Smith, D., Ryan, M.J. & Buddie, A.G. 2023. The role of digital sequence information in the conservation and sustainable use of genetic resources for food and agriculture: opportunities and challenges. Background Study Paper, No. 73. Commission on Genetic Resources for Food and Agriculture. Rome, FAO.

<https://doi.org/10.4060/cc8502en>

See attached Appendix 1

- 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?

See 2.1. The long history of attempts to control digital information suggest that management in a real time sense presents substantial challenges, and that identifying uses and users may likely be done retrospectively once an “end product” is developed and origin can be investigated and audited. Disclosure of origin in the context of release/approval of a product and/or in submitting patent applications may be considered as part of investigative and auditing process.

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

NA – question for genetic sequencing and IT experts. Requirements to maintain detailed laboratory records, including source of inputs, maybe be useful. Availability of such records might be considered as a precondition to regulatory approval of a product, and/or as a requirement for patent application disclosure.

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 positive consequences for manufacturers include assured and timely access to the pathogen materials and information needed to conduct R&D. This should accelerate bringing products to market and enhance competitive position for sales outside those allocated under PABS. Assuming a larger number of R&D efforts may be undertaken by different groups under PABS the prospects for successfully developing or in-licensing new products may increase. Given the multiplicity of national and international rules surrounding access and benefit sharing and the global nature of markets, a PABS system should mitigate the possibility of legal complications that may arise in different jurisdictions. Assuming that a VDT manufacturer has as part of its “mission” the objective of advancing the interest of global public health, contributing through the PABS system would be part of meeting this objective. Research scientists and others involved in developing and manufacturing products may place a positive value working for an enterprise making a contribution to global health security beyond that provided by salary.

The negative consequences include: (1) if the PABS system makes pathogen materials and information available to all prospective users prepared to accept the terms of a transfer agreement, individual R&D enterprises may forego opportunities for competitive advantage that could be secured through individual negotiations to secure inputs; (2) a requirement to provide a percentage of VDT free or not for profit, assuming a finite supply and excess demand for VDT, would likely result in lower total revenues and lower aggregate profits. Annual financial contributions would represent an additional expense item. Because financial markets value enterprises based on present and future anticipated returns on investment, obligations that

reduce revenues and profits would, all other things being equal, diminish the value of the enterprise in financial markets; (3) assuming that a portion of revenues from the sale of products is retained for future R&D, the effect of reducing revenues may result in a reduction in funds available for that purpose, recognizing the flexibility in enterprise budgets; (4) assuming that enterprises are able to select among prospective purchasers in a market characterized by limited supply of VDT, outsourcing the allocation of VDT to WHO limits opportunities to leverage future business opportunities based on favorable allocations.

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

Private sector enterprises would consider not using the PABS system as part of assessment of business options. Although private sector enterprises may well be sensitive to societal obligation, they are also responsive to shareholders and financial markets and consider a mix of factors when determining where and how to invest resources. If the PABS system is assessed as unduly burdensome it may not be used. This is not to discount the potential positive impact of “intangible benefits” from opting into the system, but public sector enterprises, foundations and other nonprofit-oriented organizations are more likely to be persuaded by “social returns”.

- 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?

Yes, there are other options. The PABS system is being negotiated under the auspices of WHO and on an assumption of wide, if not universal, participation. But, fragmentation of the global political and economic system is an ongoing reality, and countries in different constellations might set up alternative systems for sharing materials and information on a different basis. Also, it is prudent to bear in mind that countries facing real time public health emergencies may seek assistance from the parties they perceive best able to provide that assistance without necessarily using prescribed formal channels. Also, individual public or private sector actors may bilaterally secure access to pathogen materials and information and in that context agree to share monetary and non-monetary benefits with providers. That might well include access to resulting products. Some manufacturers might prefer a bilateral approach that includes benefit sharing.

Whether any of these options would be preferable to a PABS system is difficult to answer in the abstract. It depends on the PABS system. But it should not be assumed that there are no viable alternatives to a widely subscribed PABS multilateral system negotiated under the auspices of WHO. Recognizing the importance of WHO collection centers and other facilities, the international public health system has operated without a PABS system (other than the PIP Framework), and while the existing situation has imperfections that could be improved with a PABS system, the international public health system out of necessity would continue to function without it.

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

Although the declaration of a PHEIC (or pandemic emergency, see 3.5) would presumably be a sufficient trigger for initiation of contributions to WHO of VDT, assuming that the relevant VDT has been developed and manufacturing has been initiated in the absence of a PHEIC, it would appear prudent to allow a quantity of such VDT to be supplied by WHO upon a determination by the Director General that this VDT be supplied at least for health professionals within countries where outbreaks have been detected in advance of a PHEIC. This would help enable effective functioning of the public health system in the relevant countries should an outbreak escalate. Annual monetary contributions by commercial users of the PABS system should be collected at least on a maintenance basis in the absence of a PHEIC. For example, monetary contributions could be used to help fund the construction of vaccine manufacturing facilities in LMICs in inter- pandemic periods.

- 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?

The recently adopted amendments to the IHR add a definition of “pandemic emergency” that supplements PHEIC. There does not appear to be a clear basis to distinguish between these two types of events in the sense of making available VDT, and since an objective is to prevent a pandemic emergency from becoming a PHEIC it may be useful to include pandemic emergency as a triggering event for sharing of VDT. In any case the Pandemic Agreement and IHR should be coordinated and reconciled. If “pandemic” as a specific triggering event is to be considered, the source of an agreed definition should be identified. A “localized” or “regional” pandemic might also be sufficient to trigger benefit sharing.

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

When the DG makes a determination that the PHEIC or pandemic emergency has ended that would be a logical ending point for contributions, but the system could include a mechanism for gradually stepping down the volume of contributions as the public health impact presumably dissipates.

- 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?

Article 10 of the Biological and Toxic Weapons Convention (BTWC) appears to contemplate “peaceful coexistence” with an instrument such as the PABS. The main substantive obligation of the BTWC is not to produce microbial or other biological agents, or toxins that “have no justification for pro-phylactic, protective or other peaceful purposes” (Article I). There does not appear to be a need to reconcile the BTWC with the PABS system as the latter is clearly not intended to promote activities prohibited by the BTWC.

- 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"?

"Benefits covered by the PABS system" may be substantially broader in terms of obligation than "benefits arising from the sharing (of material and sequence information)" because benefits from operation of the system as a whole -- such as preventing wider disease outbreak -- may represent a substantially greater monetary value than the narrower consequences of the production and distribution of particular VDTs. Since the existing language of Article 12(4)(b) refers to the benefits as "including", which is a non-exhaustive term, using the broader language could entail requirement for greater contribution.

- 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?

The term "utilization" is used throughout the Nagoya Protocol and in the context of a variety of rights and obligations. This makes it difficult or impracticable to fix a specific definition of the term. This may change depending on the context in which it is used within the Nagoya Protocol. Therefore, it is difficult or impracticable to make an assessment regarding whether "benefits arising from the utilization" is synonymous with "benefits arising from the sharing" as used in the PIP Framework where the latter phrase is used once in the enumeration of principles.

- 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?

While Article XI of the GATT 1994 generally precludes parties from adopting export restrictions, Article XI(2)(a) of the GATT establishes an exception for "Export prohibitions or restrictions temporarily applied to prevent or relieve critical shortages of foodstuffs or other products essential to the exporting [Member]." In this sense the WTO Agreements do not prohibit a Member State from adopting an export restriction that could impinge on benefit sharing as prescribed by a PABS system. However, the fact that a WTO/GATT rule would allow a Member State to take certain actions would not excuse failure to meet an obligation under the PABS system. There are a variety of WTO rules that might be applicable to various elements of a PABS system. For example, a theoretical PABS obligation to provide targeted financial support or tax benefits to an industry such as pharmaceutical manufacturing to encourage production for export could prima facie be considered an impermissible subsidy, but WTO rules generally provide sufficient flexibility to address legitimate public health concerns and emergencies.

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?

Article 19 of the WHO Constitution prescribes the mechanism for formal adoption of a treaty, convention or international agreement. Except in certain limited cases depending on national constitutions, such international agreements require ratification following parliamentary or national assembly approval. An approved and ratified international agreement typically creates enforceable rights and obligations for the parties that accept it, although it does not bind parties that do not approve and ratify. Article 20 prescribes a time frame for Member States to act (yes or no) and so advise WHO. There is no practical mechanism for causing states to act within that timeline, and ratification processes for international agreements can be delayed. Although the Vienna Convention on the Law of Treaties (Article 18) places an obligation on states that have signed (but not ratified) an international agreement not to defeat its object and purpose unless and until it they have made their intentions clear not to become parties, this may not create affirmative obligations such as might be entailed by PABS.

Article 21 allows the WHA to adopt regulations that do not entail the type of ratification required of an international agreement. A threshold question is whether a PABS system falls within the scope of the IHR, possibly as “other procedures designed to prevent the international spread of disease” (art. 21(a)). Article 21 yet provides the opportunity for Member States to reject an adopted regulation. A decision by the WHA to adopt PABS under the IHR might well run into resistance within Member States, potentially in terms of exceeding executive authority. But in principle it would be more expeditious and would create binding obligations among those parties that did not reject or make reservations.

Article 23 “speaks for itself”. The WHA may make recommendations to Member States. Such recommendations do not create binding obligations on the Member States to which they are directed, although they may in principle have a persuasive force.

Appendix 1 to Question 2.1 (Abbott)

A. From Google Gemini, Aug. 25, 2024:

The Convention on Biological Diversity (CBD) currently **does not have a single, universally agreed-upon definition of digital sequence information (DSI)**. However, it's generally understood to encompass data derived from the genetic sequences of biological resources, including DNA, RNA, and proteins. This data is often represented in digital formats, hence the term "digital sequence information."

Key points to note:

- **Placeholder term:** DSI is considered a placeholder term used in international policy discussions within the CBD. This means that the precise scope and boundaries of DSI are still being debated and negotiated.
- **Genetic resource link:** DSI is inherently linked to genetic resources, which are defined by the CBD as any material of plant, animal, microbial, or other origin containing functional units of heredity.
- **Dematerialization:** DSI often arises from the "dematerialization" of genetic resources, meaning that the genetic information is accessed and utilized without the need for physical samples of the organism.
- **Policy implications:** The lack of a clear definition of DSI creates challenges for implementing access and benefit-sharing (ABS) mechanisms under the CBD and the Nagoya Protocol. These mechanisms aim to ensure that the benefits arising from the utilization of genetic resources, including DSI, are shared equitably with the countries and communities that provide them.

Current discussions:

Ongoing discussions within the CBD are focused on developing a more concrete definition of DSI, addressing issues such as:

- **Scope:** What types of genetic sequence data should be included within the scope of DSI?
- **Use:** How is DSI currently being used and what are the potential future applications?
- **Benefit-sharing:** How can benefit-sharing mechanisms be adapted to address the unique challenges posed by DSI?

Importance:

Reaching a consensus on the definition of DSI is crucial for ensuring the effective implementation of the CBD and the Nagoya Protocol, and for promoting the fair and equitable sharing of benefits arising from the use of genetic resources in the digital age.

B. Quoted from *Smith, D., Ryan, M.J. & Buddie, A.G. 2023. The role of digital sequence information in the conservation and sustainable use of genetic resources for food and agriculture: opportunities and challenges. Background Study Paper, No. 73. Commission on Genetic Resources for Food and Agriculture. Rome, FAO. <https://doi.org/10.4060/cc8502en>, pgs. 2-4:*

The term DSI was originally developed in the context of the CBD and the Nagoya Protocol, although with the caveat that it "may not be the most appropriate term and ... is used as a placeholder until an alternative term is agreed" (CBD, 2018). Although it is still not clearly defined, DSI in its narrowest sense refers to digitally recorded DNA and RNA sequences. However, in many cases the term is also used to refer to data generated from proteomic studies (protein sequences) and sometimes also to data from metabolomics (relating to primary and secondary metabolites, and other chemical entities). So-called "omics"-based techniques provide genomic blueprints of microorganisms, allowing their functions and their roles in water, carbon, nitrogen, phosphorus and sulphur cycles to be elucidated (Zhou et al., 2022).

There is a pressing need for an agreed definition of DSI that can encompass potential future discoveries and new technologies, but this is proving difficult to achieve. It has been suggested that the term could be taken to encompass "the kind of information in, or that might be added to, databases of the kind

currently in use and collated by the scientific journal *Nucleic Acids Research*” (Heinemann, Coray and Thaler, 2018). The authors that made this suggestion cited the 2017 Database Issue of *Nucleic Acids Research* (2017), which documented 54 new databases added since the previous review. Subsequent reassessments have been made annually, with the latest in 2022 (Rigden and Fernández, 2022). This definition is associated with, but goes beyond, DNA sequences in that it encompasses proteomics and metabolomics, which are also included in the *Nucleic Acids Research* database lists.

The AHTEG and the Open-ended Working Group on the Post-2020 Global Biodiversity Framework (OEWG) did not attempt to define DSI. Their approach was to compartmentalize the scope of DSI into three subgroups of information (Table 2) (AHTEG, 2020; OEWG, 2021a). Group-1 includes DNA and RNA. Group-2 includes Group-1 and adds proteins and epigenetic modifications. Group-3 includes Groups 1 and 2 and adds metabolites and macromolecules. However, it was not agreed whether Groups 2 and/or 3 should be considered DSI. Data/information flows linking genetic resources and related NSD generated by research are summarized in Figure 1. According to Lyal (2022), “the main basis for accepting DSI as coming under the CBD and Nagoya Protocol is the (disputed) proposition that DSI is the ‘intangible equivalent’ of a physical genetic resource and as such falls under the sovereign rights of the country from which the original genetic resource was accessed.” Lyal describes DNA or RNA sequences (NSD) as “the closest functional analogy between a genetic resource and an intangible equivalent” and notes that “a number of countries have apparently adopted this concept. ‘GSD’ (genetic sequence data) is used in the World Health Organisation pandemic influenza preparedness framework and has the same meaning. This is the Group-1 of the latest AHTEG” (Lyal, 2022).

Ruiz Muller (2018) introduced the term “natural information” to the debate and defined it as “any non-uniformity, difference, or distinction not intentionally produced by *H. sapiens* which derives from thermodynamically open systems to dissipate energy gradients and create copies of itself”, also putting forward the concept of “bounded openness for natural information”, which includes sequence data and all “natural information”. This would include the “associated information” mentioned in Table 2. Vogel et al. (2022) note that a “more colloquial and maybe legal definition could also be ‘any non-uniform expression, difference or distinction produced by nature.’” They conclude that “natural information (biotic) captures what should fall within the scope of the CBD while excluding information that is artificial or natural but abiotic.” Vogel et al. (2022) include “in silico utilization” (ISU) of genetic resources, genetic information, GSD and NSD of the biotic natural information within the natural information category. They believe that “once artificial or natural information is interpreted as the object of access in R&D, a multilateral system can be constructed in a way that all the international agreements that concern ABS become harmonious.

The optimal modality is bounded openness ...” (Vogel et al., 2022). The authors define “bounded openness”, in turn, as “legal enclosures which default to, yet depart, from *res nullius* [property of no one] to the extent the departures enhance efficiency and equity, which must be balanced when in conflict.” They go on to say that it “satisfies ... three criteria: genetic resources flow freely for R&D ...; royalties are due only on the value added through intellectual property and distributed proportional to custodianship ...; and transaction costs are minimized ...” (Vogel et al., 2022).

The various concepts described here would result in different outcomes if used to define the scope of access and benefit-sharing (ABS) regimes and would result in different levels of complexity in traceability and monitoring. The ultimate outcome depends on how far into the metabolism of the genetic resource (the flow of information) the scope extends and is justifiable; human (research) intervention is required at several stages (see Figure 1). Lyal (2022) discusses the elements along the information flow illustrated in Figure 1 that “reflect the degree of biological processing and the proximity to the underlying genetic resource.” Human interventions include those related to the further analysis of the raw nucleotide sequence, the technical aspects of sequencing, the “associated data” to which the AHTEG referred and metadata from the collection of the genetic resource. They also include additional information processing related to aligned nucleotide sequences, information on sequence assembly, structural annotation of genomic elements, biochemical and biological function, behavioural observations, the structure of

organisms, the molecular structures of gene products and derivatives (cell metabolites, etc.), and patentable discoveries and inventions.