INB related interactive dialogues

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

Discussion questions proposed by the Bureau for resource persons

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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?

Yes, if they agree. International law does not offer clear-cut solutions to the relationship between international agreements. Recognition of a SII is a procedure envisaged under the Nagoya Protocol. In a case where a state is not party to the Nagoya Protocol, it is also not bound by its ABS provisions. However, it could still claim sovereignty over biological resources. To ensure legal clarity and avoid competing claims, a provision could be drafted to recognize PABS as lex specialis—meaning it would take precedence over other relevant laws—both in the context of the Nagoya Protocol and under general international law and within national jurisdictions of the parties. Even then, it would have to be recognized as such by the Nagoya COP/MOP.

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 ?

Not applicable/ I do not wish to respond

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?

Not applicable/ 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?

Not applicable/ 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-Partiy to PABS that is affected by the conclusion of a SII entitled to dispute settlement under Article 27 of the CBD?

Not applicable/ 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?

The most relevant objective of the CBD and Nagoya Protocol concerns the fair and equitable sharing of the benefits arising from the utilisation of genetic resources. Under CBD benefit-sharing includes access to and transfer of technologies, scientific collaborations and participation in biotechnological research.[1] The opening provision of the Nagoya Protocol clarifies that fair and equitable sharing of benefits arising from the utilization of genetic resources is the objective of the Protocol. It further indicates three means for its realization – access to genetic resources, technology transfer, and funding. A core principle articulated in Article 6 of the Nagoya Protocol is that sharing of genetic resources must be based on prior informed consent and on mutually agreed terms. The Nagoya Protocol further provides a detailed, non-exhaustive list of benefits.[2] Though the Nagoya Protocol doesn't specify their practical application, viewing fairness and equity as efforts to form genuine partnerships in contexts of power imbalances may be useful.[3] A PABS system that did not meet these objectives could reasonably be considered inconsistent with CBD/Nagoya.

In the context of ABS for pathogens, rapid access to information is considered a benefit; however it is unlikely to be sufficient in itself to satisfy the objectives of CBD and the Nagoya Protocol. Another form of benefit recognized under the PIP Framework is access to a percentage of health products. Additionally, it has been proposed that a multilateral system

[1] Arts. 16, 18 & 19 CBD.
[2] Art 5.4 and Annex to the Nagoya Protocol.
[3] Morgera, Elisa, Stephanie Switzer, and Elsa Tsioumani. Study into Criteria to Identify a Specialized International Access and Benefit-Sharing Instrument, and a Possible Process for Its Recognition. April 2018. Strathclyde Centre for Environmental Law and Governance. Research assistance by Eleftheria Asim; peer review by Robin Churchill (University of Dundee) and Riccardo Pavoni (University of Siena).

established for this purpose could provide funding for capacity building, scientific infrastructure,[4] technology transfer, and establish a framework for managing intellectual property to promote equity, transparency, and access to health products.[5] Such a framework could include compulsory and voluntary licensing, agreement not to seek IPRs, non-assert commitments, data sharing obligations, or other measures. .However, it is up to the parties to the CBD/Nagoya to determine which measures best satisfy the objectives of the CBD and the Nagoya Protocol while addressing the need for rapid access to health information in an emergency.

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?

Not applicable/ 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?

Registration and terms of access

A system based on registration and agreement to terms of access can help identify users and clarify benefit-sharing obligations. Some databases and research institutions use user agreements to support ABS. For instance, GISAID has a Database Access Agreement (DAA) that includes data usage licenses and benefit sharing provisions, which can be terminated in the case of non-compliance.[6] However, this DAA currently incorporates a much narrower set of benefits than those proposed under PABS – for example, it does not include access to products, technology transfer or intellectual property rights.

Click-through

A click-wrap or click-through agreement requires users to accept terms by clicking before accessing a website or database. Common in software, these agreements face issues like users not reading the terms and potential enforcement difficulties. However, they are seen by some as effective tools for benefit sharing due to their widespread use.

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[4] Amber Hartman Scholz et al., "Multilateral Benefit-Sharing from Digital Sequence Information Will Support Both Science and Biodiversity Conservation," Nature Communications 13, no. 1 (February 23, 2022): 1086, https://doi.org/10.1038/s41467-022-28594-0

[5] Paul Oldham and Siva Thambisetty, "The Pandemic Access and Benefit Sharing System: Four Elements of a Trusted System," LSE Legal Studies Working Paper No. 10, 2024.

[6] Laird, Sarah A., and Rachel P. Wynberg. A Fact-Finding and Scoping Study on Digital Sequence Information on Genetic Resources in the Context of the Convention on Biological Diversity and the Nagoya Protocol. CBD/DSI/AHTEG/2018/1/3. January 10, 2018. Contributions by Arash Iranzadeh and Anna Sliva Koose.

Open Source Agreements

Open source agreements aim to foster innovation and reduce legal and transaction costs compared to traditional licensing. They enable free exchange of information and support collaborative research, with contributors often requesting attribution. Intellectual property rights are generally not enforced if license conditions are met, and there are no royalties for materials or methods. Some agreements require sharing of developments with the community, while others do not.

"Umbrella"

Oldham and Thambisetty propose an umbrella system based on "the WHO Coordinated Laboratory and Database Network," modeled after the Global Biodiversity Information Facility; a "PABS License," and a "PABS Register," modeled after the EU Horizon program funding model.[7] Under WHO coordination, a network of laboratories and GSD-sharing databases would operate with a standard PABS License. Entities agreeing to the licence would join the PABS register and be required to adhere to benefit-sharing obligations, which could differ between non-commercial and commercial users.

Finally, as treaties are legally binding on states parties and not directly on private entities such as firms, it is important to consider how contracts or other agreements could be enforced, and what national laws would be needed to provide sufficient legal basis for ensuring compliance of both public and private parties participating in a PABS system.

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

An option for data is the use of ascension numbers (ANs), which are assigned upon GSD submission to INSDC databases. ANs link each GSD to its metadata, including country of origin, experimental design, and sequencing center.[8] They form the core of a robust traceability network, supported by a complex database schema. DOIs, used by journals and literature databases, connect submitted NSD to publications, extending traceability beyond INSDC databases. Nevertheless, challenges regarding enforcement would arise.

An option for materials is the creation of a central clearing house that would track and make publicly-accessible information on the sharing and receiving of materials, as is currently done for influenza virus of pandemic potential under the PIP Framework.

Under both options, the question of how to legally enforce compliance with contracts or other agreements remains.

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[7] Oldham and Thambisetty, "The Pandemic Access and Benefit Sharing System: Four Elements of a Trusted System."

[8] Fabian Rohden et al., "Combined Study on Digital Sequence Information (DSI) in Public and Private Databases and Traceability" (CBD, January 31, 2020)

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?

On the one hand, manufacturers would benefit from a more reliable, legally-binding, legally-certain system in which they would have rapid access to pathogen material and DSI that is necessary for product development and regulatory review. On the other hand, by committing to donate and/or sell at not-for-profit prices a certain percentage of their production in real time, they would lose the ability to sell this volume at higher prices. Nevertheless, it is important to recall that governments play a central role in markets for pandemic VTD, usually heavily subsidizing the R&D, purchasing products for stockpiles and/or use, and/or providing advance purchase commitments.[9] Therefore, in economic terms, it is actually governments that will bear most of the costs of enabling companies to donate and/or sell products at cost, either through prices for products sold to governments and/or up-front subsidies that make investing in VTD R&D and production an economically feasible activity for private for-profit firms. In other words, companies would pass those costs on to their main customers, governments. For companies, factoring in these obligations becomes a normal cost of doing business in the PPR field. If governments accept that the costs ultimately fall on their shoulders, it should in principle be acceptable to private firms.

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

In the context of the PIP Framework, a study of fourteen SMTA2s found that companies preferred donations and reserving of health products over other forms of benefit sharing, such as licensing or transfer of technologies.[10]

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

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[9] See, for example: Chapman, N., Doubell, A., Tuttle, A., Barnsley, P., Oversteegen, L., Goldstein, M., Candeias, V., Chowdhary, V., Pucher, K., Borri, J., Hynen, A., Olufemi, O., Kearney, M., Clifton, T., Ankomah, A., Adesanya, O. & Tan, J. (2022). *Landscape of emerging infectious disease research and development: From pandemic response to pandemic resilience.* Policy Cures Research.
And Adrián Alonso Ruiz, Anna Bezruki, Erika Shinabargar, Kaitlin Large, Marcela Vieira, Iulia Slovenski, Yiqi Liu, Surabhi Agarwal, Anna Becker, and Suerie Moon. "Which roads lead to access? A global landscape of six COVID-19 vaccine innovation models." *Globalization and Health* 20, no. 1 (2024): 25.

[10] Anthony Rizk et al., “Drivers and Barriers to Pathogen- and Benefit-Sharing (PBS): An Empirical Study of Global Perceptions and Practices and Case Studies from Ebola in Liberia and Zika in Brazil,” Global Health Governance XVII, no. 1 (2022): 4–36.

and sequence information, and incentivize greater manufacturer participation? Would any of these options be preferable to a PABS system?

Whether or not a system is called PABS, it would need to address the same challenges: persuading most or all countries to make legally-binding commitments to sharing pathogen materials and DSI quickly with the international community, and providing a reliable system for fair and equitable sharing of benefits. A voluntary system would be unlikely to provide the certainty that both providers and users of these resources seek. A voluntary system also would not provide the increased security and preparedness required to address future potential pandemics. And if a system is disassociated from the CBD/Nagoya system, parties to CBD/Nagoya could choose simply to rely on the rules negotiated in this forum for ABS, rather than adopt a PABS-like system negotiated elsewhere.

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

From a public health perspective, sharing of benefits should start as early as possible. It may be useful to consider four types of benefits: 1. Benefits relating to scientific cooperation (e.g. co-authorship, scientific collaborations, joint fundraising among research centers) should start as soon as the system is in place and researchers begin to share materials and/or DSI. 2. Benefits relating to financing should flow as soon as the system is in place, in order to finance the functioning of the system itself and activities such as capacity-strengthening and collaboration. If products are developed later and royalties flow into the system, this could increase the financing available. But there is no need to wait for an emergency for financing obligations to enter into force. 3. Benefits relating to technology transfer or licensing on VTDs should start as soon as possible, not waiting for a PHEIC or potential PHEIC to occur, as transferring technology and building production capacity takes time, and production capacity should be in place prior to an emergency, not built after one begins. 4. Finally, benefits relating to supply of VTD products should occur in real time as production takes place, before an emergency where production is already occurring, in order to permit stockpiling for preparedness. In the event of an outbreak or pandemic, as volumes needed surge and – hopefully – production also increases, a proportion of supply should continue to be allocated to WHO. But there is no need to wait for an emergency to allocate some proportion of production to enable preparedness.

Having international stockpiles would also allow for faster response than waiting for countries to decide to share some of their national stockpiles for international needs, a challenge currently playing out for the mpox PHEIC. Pre-existing international stockpiles would also mitigate the threat that export bans would block all supply in the event of an emergency, and ease political pressure on wealthier countries to share scarce supply during a crisis (as some supply would already have been shared pre-crisis). Overall, ensuring the flow of benefits upon establishment of a PABS system would provide reassurance to and build trust among participants that it could deliver in the event of an emergency. It would also provide opportunities to identify and address shortcomings to the system prior to an emergency.

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?

As noted in response to question 3.4, from a public health perspective, benefit sharing should be taking place at all times, prior to a PHEIC, pandemic emergency or pandemic. If this is not possible, benefit-sharing should kick in as early as possible, implying a PHEIC (rather than pandemic emergency or pandemic) to prevent an outbreak from becoming a pandemic or pandemic emergency.

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

If benefit-sharing is taking place at all times, there is no need to consider a trigger or end-point. If, for some products, there is no production until an outbreak occurs then benefit sharing should begin as soon as production begins. For example, if a new vaccine against mpox is developed using mpox materials and/or DSI shared by countries undergoing outbreaks, and production begins in early 2025, benefit-sharing should begin immediately regardless of the status of the mpox outbreak at that point in time. If no vaccines are needed at that point in time, products could go into an international stockpile. If a stockpile reaches a sufficient volume such that no further supplies are needed, WHO could refuse the donation or opt not to purchase.

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?

Not applicable/ I do not wish to respond

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"?

The two clauses imply different potential scopes. Benefits 'arising from the sharing' would require making a link between the sharing of materials/DSI and the generation of a benefit, and drawing this causal link could be challenging, especially for data. Nevertheless, a broad range of benefits could potentially be linked to sharing, including those not yet envisaged or negotiated into a PABS system. So, the scope of benefits could be wide but the need to establish a causal link between the benefit and the sharing could be heavy. On the other hand, 'benefits covered by the PABS system' would obviate the need to draw a causal link, as long as the benefit was included in the PABS system. But any benefit that was not envisaged and explicitly included in the PABS system may not be included. So, the scope could be wide, in principle, but inflexible and therefore poorly-adapted to meet needs in a context of rapid technological change.

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?

There does not appear to be a clear enough logical distinction between the two concepts of benefits arising from the 'sharing' vs the 'utilization,' and the implications should be clarified, potentially via further text.

One possible interpretation is that benefits arising from the "sharing" means that the existence of a benefit must be tied causally to shared materials and/or DSI. Establishing that causal link could be challenging, especially for data. Another possible interpretation is that, by definition, products are developed based on shared materials/DSI because in order to develop a product, shared materials/DSI must be utilized; such an interpretation would obviate the need to establish a causal link. Furthermore, the text could be interpreted to mean that any country that shared material/DSI would have a claim on benefits, but not necessarily countries that did not share; this creates an incentive for all countries to share but could exclude countries in need of VTDs that did not share.

Similarly, benefits arising from the "utilization" implies that only benefits directly linked to the use of material/DSI would fall under the PABS system, which raises the question of what 'utilization' means and how it could be traced. Again, making this causal link would be particularly difficult for data, and could create heavy administrative burdens. Furthermore, some benefits may be diffuse, for example, all countries benefit from the increased health security offered by a system in which all countries regularly, rapidly and openly share materials and data, but it is difficult to link this 'benefit' to a particular user – it is the simple existence of such a system that offers diffuse benefits to all. In conclusion, neither phrase on its own seems to be clear enough regarding its meaning.

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?

Member States can limit the export of VTDs under existing GATT/WTO rules, as they did during the Covid-19 crisis.[11] Several provisions of the GATT allow for trade restrictions in different circumstances. Article XX is the exception most used to justify trade restrictions that would otherwise breach GATT obligations. Article XX (b) refers to measures "necessary to protect human, animal or plant life or health". Article XX (j) addresses exceptional measures "essential to the acquisition or distribution of products in general or local short supply". Article XI.2.(a) in turn provides for an exception to the prohibition of quantitative restrictions on exportation with regard to "Export prohibitions or restrictions temporarily applied to prevent or relieve critical shortages of foodstuffs or other products essential to the exporting contracting party."

[11] See the 2020 note prepared by the WTO Secretariat: 'Article XI:2(a) of the GATT 1994 states that the general prohibition in Article XI:1 "shall not extend" to "[e]xport prohibitions or restrictions temporarily applied to prevent or relieve critical shortages of foodstuffs or other products essential to the exporting [Member]"', available: https://www.wto.org/english/tratop_e/covid19_e/export_prohibitions_report_e.pdf

Negotiations thus far suggest MS are not willing to give up or substantially restrict this legal and policy space, as is reflected in the fact that no agreement to restrict the right to block exports was agreed in the amended IHR. It is for this reason that the likelihood of export restrictions or bans must be taken into account in the design of a PABS system. One implication is that early licensing and technology transfer are important for decentralizing innovative and production capacity for VTDs, and that such licensing and technology transfer should be taking place as a normal activity in inter-pandemic times. Similarly, regional or global stockpiling should take place between pandemics to counteract the problem of likely export bans.

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?

Art. 19 (e.g protocol): While Article 19 concerns agreements and conventions adopted by the WHA, a protocol to the pandemic agreement will most probably be adopted by the Conference of the Parties (COP) of the agreement. In that case, majorities and other conditions for adoption will rest on the relevant clauses in the agreement and/or the rules of procedure and other decisions of the COP. A protocol, as a separate international agreement connected to the primary one, will enter into force only when the required number of ratifications is achieved, which is hard to anticipate. Moreover, it will only apply to the states that have ratified it. The pandemic agreement or the protocol will also have to provide for important issues such as the relationship between the two instruments, the governance of the protocol and the possibility of reservations.

Art. 21 (regulation): Member States will have to agree whether PABS falls within the scope of Article 21 (a). Regulations do not require ratification and enter into force at the same time for all Member States that do not "opt out" by notifying WHO Director-General of their rejection or reservations within a set period of time. WHO Member States agree that regulations are legally binding for them. However, governments (e.g. foreign ministries) would have to decide how to prepare internally for entry into force, implementation and the applicability of the law of treaties to such an instrument. Many see it as a treaty, but practice can vary because of the sui generis character of WHO regulations. The possibility of rejections and reservations to a PABS regulation could also mean that different WHO Member States could become subject to different obligations. Therefore, the effectiveness of a regulation would ultimately depend on a firm political commitment by most WHO Member States to implementing and complying with the WHO regulation. Finally, a complex issue which is not explicitly addressed by the question is the relationship, if any, between a PABS regulation and the pandemic agreement also in view of the likely asymmetry in participation and different legal basis.