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

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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. ***The fact that the PABS System is given the additional status of SII does not interfere with universal applicability, including to non-Parties to the Nagoya Protocol****. The status of SII is of particular importance to Parties to the Nagoya Protocol, to guarantee legal certainty, by determining that undersigning the PABS System does not run counter to the Nagoya Protocol.*

More precisely: undersigning the Pandemic Agreement would establish new ABS rules (for the materials/data within the scope) for Parties that are non-Parties to the Nagoya Protocol, and Parties that have decided not to regulate ABS for their genetic resources. For Parties that are Parties to the Nagoya Protocol and have domestic implementation of ABS legislation, the status of SII, with the official recognition of the PABS by the COP-MOP of the Nagoya Protocol, would create an obligation for them to align these existing regulations with the new provisions of the PABS System, facilitating implementation, legal certainty and avoiding overlapping of rules.

However, all Parties to the Pandemic Agreement would be able to implement the provisions of the PABS System independently if it receives the status of SII (by the Nagoya COP-MOP). This would be done by adapting their domestic practices and regulations, as appropriate and according to the provisions ultimately defined, agreed and operationalized in the PABS System.

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 ?

The recognition of the PABS System as an SII is an important consideration for the universal development, operationalization and implementation of the system. However, ***the process for establishing PABS should not be conditional to and hampered by this consideration*** *for the following reasons:*

- *Making a SII under the CBD/Nagoya Protocol is of limited importance, as it guarantee legal certainty only to parties to the Nagoya Protocol.*
- *There is no detailed criteria and procedure for recognizing a SII, and no clarity on how long it would take for this, and how it would be adopted and function in practice.*

The criteria and mechanism for recognizing PABS as a SII cannot be described as it would very much depend on the outcomes of the negotiations on the Nagoya Protocol COP-MOP and the legal nature and operationalization of the PABS System. Nevertheless, the experience from the PIP Framework and the Plant Treaty reveal that a multilateral ABS system does not need to be formally recognized as an SII to function as one. The implementation of the Nagoya Protocol is done through national legislation and countries have complete freedom to determine if and how ABS should be applied, including the use of PIC/MAT and the scope or coverage of ABS measures. In addition, there are countries that have ABS measures outside the scope of the Nagoya Protocol, because e.g. they are not Parties to it. That said, Parties to the Pandemic Agreement, independently of their profiles (if they are Parties, or not, to the Nagoya Protocol and/or if have in place, or not, national ABS legislation) are able to recognize PABS as the governing ABS rules for pathogens (as ultimately defined under the scope), and to commit to adapt national practices and rules accordingly when and if necessary.

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?

As mentioned in the answer to the previous questions, coherence with the Nagoya Protocol and alignment with existing domestic ABS laws, is without a doubt, important considerations for the development, operationalization and implementation of the system. In that regard, it is important that the PABS System is recognized such as the following:

1. *A special consideration as described in **Article 8(b)** of the Nagoya Protocol: PABS is without a doubt addressing genetic resources that present a threat to human health, and as such, needs expeditious access and fair and equitable sharing of benefits, including access to affordable countermeasures.*
2. *A global multilateral benefit-sharing mechanism as described in **Article 10** of the Nagoya Protocol: pathogens occur, without a doubt, in transboundary situations and need rapid and timely sharing, making it unfeasible bilateral negotiations such as for the grating of PIC and MAT.*
3. *A specialized ABS agreement as described in **Article 4** of the Nagoya Protocol: the PABS should be supportive and not run counter the objectives of the CBD and the Nagoya Protocol, and as such should not hamper but enhance both access and benefit-sharing.*

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?

The inclusion of "sequence information" under PABS makes it relevant for the ongoing negotiations for developing a multilateral system for DSI under the CBD. In this case, the PABS System should recognize and be coherent not only with the Nagoya Protocol, but also the CBD multilateral system for DSI. Coherence between these ABS mechanisms and domestic ABS regulations is essential to avoid creating overlap of rules which would lead to complexity, extra costs and lack of legal certainty.

*In this regard, the INB should **take note of the CBD decision 15/9, which describes a set of criteria** for developing a multilateral mechanism for DSI, which should also be acknowledged at the PABS and inform its development in line with the following:*

- *be efficient, feasible and practical;*
- *generate more benefits, including both monetary and non-monetary, than costs;*
- *be effective;*
- *provide certainty and legal clarity for providers and users of digital sequence information on genetic resources;*
- *not hinder research and innovation;*
- *be consistent with open access to data;*
- *not be incompatible with international legal obligations;*
- *be mutually supportive of other access and benefit-sharing instruments.*

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?

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?

Not applicable/ 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)?

Not applicable/ I do not wish to respond

2.1.1. Will the current negotiated text using "sequence information" contradict/hamper the ongoing negotiation of the CBD?

The current negotiated text uses the term "sequence information" without a definition clarifying its scope. Technically speaking, "sequence information" is not a standing alone term as it does not have a widely agreed (scientific) definition, and therefore can mean different things. While "sequences" can be understood as any set of objects arranged in a sequential order, in biological sciences, sequences are usually related to biological molecules such as the sequence of nucleotides or amino acids within a DNA, RNA or proteins. The term "information," on its turn, can have a much broader range of meanings from the information/data contained in biological sequences (genes, genomes) to gene expression, functions, ecological interactions, and any metadata related to sequences (processing, ownership, citations etc.). The influence that the use of the term "sequence information" can

have on the ongoing CBD negotiation is hard to predict and will depend very much on how the scope is ultimately defined in both processes.

But looking beyond this question, into what would be the impact for the implementation and usability of both systems, it is relevant to consider that a ***non-alignment in scope (coverage rather than terminology) might increase complexity, administrative and compliance burden, costs, and decrease benefits shared****. For instance, if nucleotide sequence data of pathogens is covered by the PABS while other related information are covered by the CBD multilateral system on DSI this can create data fragmentation, challenges for assessing compliance rules and mechanisms, lack of legal certainty, and lack of incentives for stakeholder to engage.*

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 compliance and accountability, a first step is ***to inform users of which materials/data have ABS conditions, which are these conditions and how they can comply with them****. Implementation of such notification and information channels can be done in different ways, but to be effective, they need to be flexible in adapting to the models/practices used by the scientific infrastructures (biobanks and databases), incentivizing widespread adoption. An example that is easy and inexpensive to implement building on mechanisms that are already in use is the combination of tags/identifiers with a link for legal information. Tags are metadata fields that are linked to the submission of materials/data, and can accompany them throughout their life cycle. Further legal information and routes for compliance can be linked to samples/data (online) catalogues and redirect users to relevant websites.*

The second step is to enable ***binding commitments from relevant users****. This can be done either by binding users directly through contracts, by binding State Parties through the international treaty, or by a combination of both. However, it is important that access to data in not conditional to undersigning benefit sharing agreements as this would limit the efficiency in which data are accessed, redistributed, and used for pandemic prevention preparedness and response; by impacting open access, data interoperability and reusability.*

A third step is to establish a ***monitoring mechanism*** *that can help to identify relevant users, reiterate relevant expectations/conditions regarding benefit sharing, and support the application of measures for accountability. Downstream monitoring of the use of PABS materials/data (when applied in end-products), is the most feasible and effective way of doing it as it avoids costly traceability mechanisms and damaging the timeliness and openness in which data is shared. This can be done by checking different R&D milestones for which transparency measures are already in place.*

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

Data/information is a very particular type of asset, which differently from materials/samples, are fluid, easily copied, and shared in great scale, speed and all over the globe. In addition, the value of data is dependent of context (how they interact with other data and metadata), and it enhances the more data is shared and used. These inherent characteristics of data create huge

challenges and disadvantages for trying to develop a full-proof traceability mechanism that is based on controlling, recording and reporting every single step and transaction on the data life cycle.

On the other hand, there are transparency mechanisms already widely used, in which users of data present their outcomes, and in doing so, need to disclose information on the basis of what was used to produce such outcomes. The use of PABS materials/data can be identified in different R&D milestones such as: scientific publications, patent applications, clinical trial files, and regulatory approval files. ***Monitoring (or tracking) the use of PABS data downstream to support accountability would certainly be more targeted and produce less side effects, than trying to do it upstream (at the level of access).*** *In order to capture the information disclosed and use it in a comprehensive monitoring and accountability system, a search engine would need to be established, similar to what is in place for scholarly literature or patents. Such a tool would retrieve available information and compile it into a central and accessible database to be used by all stakeholders (WHO, Member States and society) to e.g. support a balanced incentive-system with additional push and pull factors.*

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?

There are at least three positive consequences to manufactures should a multilateral system for pathogen access and benefit sharing be established:

- *Legal certainty: the establishment of clear and standardized rules for pathogen ABS, that would decrease costs and administrative burden for ABS compliance and bring more efficiency and predictability for R&D. However, these benefits can only be realized if the established PABS System becomes the* ***unique ABS scheme governing pathogens****, without overlap with other ABS systems and domestic legislation, and if* ***compliance mechanisms are simple and user-friendly****.*
- *Rapid access to pathogen materials and data from diverse geographic locations and freedom to re-use such resources for pandemic R&D: by engaging in the PABS System, manufacturers can enable conditions for the timely sharing of pathogen materials/data from all Parties, guarantee the maintenance and enhancement of the open access infrastructures and practices, increase speed, efficiency and possibilities for pandemic-related R&D. However, these benefits are only possible if the PABS System is compatible with and supportive of* ***open access, full data interoperability and re-usability and is future proof*** *allowing the application of new technologies and methodologies that rely on open and big data.*
- *Corporate social responsibility: following the COVID-19 pandemic, society is more than ever sensitive to and requesting a more* ***ethical behavior from companies and countries regarding equitable access to medical countermeasures*** *that can stop pandemics and epidemics and save lives. Also considering that there are substantive investment of public money to enable the rapid development of such countermeasures. Engaging in the PABS System would be seen as a response from manufacturers and other stakeholders to these societal needs and demands,*

improving public perception of specific companies or the sector as a whole, depending on adoption and impact of the system.

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

As far as manufacturers and other stakeholders are free to engage in the PABS System there will be considerations to not do so in face of obligations to share monetary benefits. However, ***a failure of the PABS System****, either because of the lack of agreement among Parties, low adoption or engagement from relevant stakeholders,* ***would have a substantial negative impact on global health security and related R&D****. This would reflect lack of solidarity and further spread distrust among countries and stakeholders, leading to the proliferation of domestic legislation restricting the sharing of pathogens, as well as making the ABS negotiations in other international Fora even more challenging. The legal barriers and mistrust will further limit international collaboration for pandemic-related research and cause substantial delays, extra costs and other barriers for the development of products such as pharmaceutical countermeasures.*

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?

There are certainly measures that can be implemented to enhance access to and sharing of pathogen samples and data, as well as the equitable sharing of monetary and non-monetary benefits that can be implemented independently of the establishment of a PABS System. The challenge, however, is that pathogens are already in the scope of the Nagoya Protocol and the CBD's multilateral system for DSI, so it is unavoidable that ABS related to them will be regulated. That said, ***the lack of an alternative multilateral ABS system for pathogens and associated materials and data means that they will be covered by ABS measures under other regulatory frameworks,*** *which might never realize and even be on the way of critical global health security goals such as: rapid and timely sharing and use of pathogens, and equitable access to medical countermeasures.*

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

The objectives of the PABS System is to enhance access and benefit sharing on an equal footing. Triggering benefit sharing at the level of access (e.g. by putting conditions for the access to and distribution of pathogen samples and data such as payments, signing of contracts, subscriptions and traceability) will work against the objectives of the system as access will not be enhanced but rather hampered. ***Triggers for benefit sharing should be on the moment that users are actually benefiting from the use of samples and data****, meaning at the level in which outcomes are being presented and intended to be commercialized such as: publication, patent applications, and seeking for market approval.*

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?

From a public health perspective, and to reach the objectives of the treaty (pandemic prevention, preparedness and response) ***benefit sharing of VTDs should cover all the presented options****:*

- *PHEIC: making VTDs available to countries that are fighting a PHEIC is an essential step to control the epidemic and prevent that it becomes a pandemic.*
- *Pandemic emergency and pandemics: equitable access to VTDs is the best strategy to control pandemics, prevent the development of new variants of concern, and save lives.*

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

The duration of benefit sharing of VTDs should be ***based on the WHO's risk assessment****, in consultation with experts (e.g. Emergency Committee) and as such, linked to* ***the DG's determination and ending of the PHEIC*** *status (considering that pandemic emergencies, and pandemics are also PHEICs).*

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"?

It ultimately ***depends on how the terms are understood in the context of the PABS System****. "Benefits arising from the sharing" can be interpreted at least in two different ways:*

1- Only the benefits that are directly dependent on the access to and use of pathogen samples and/or data (e.g. involve direct use of the materials/data on the development of the product) would be in the scope of the PABS System.

In this case, there would be implications for access and benefit sharing. Trying to control data access and tracking which materials were access and used throughout the R&D cycle would increase substantially burden and costs for providers and users, and hamper R&D. It would also create possibilities for compliance-avoidance (by e.g. choosing not to use specific samples/data covered by the system), raising distrust among participants. Finally, it would ultimately decrease the possibilities and amount of benefits shared, as countermeasures that are relevant for fighting the outbreak, but did not involve direct access and use of materials/data of the pathogens within the scope, would not have to be shared equitably.

2- Because there is sharing of material and samples, there are benefits generated, and those have to be shared with the global community.

From this perspective, the two terms would not differ substantially, and would be operationalized depending on the scope of benefits that are to be defined under the PABS System. Types of benefits would not be limited neither. Because even if an applicable countermeasure is developed without directly accessing and using PABS materials/data, its specific application to fight the disease caused by the PABS pathogen will have benefited from the sharing of PABS samples/data, as those are essential to

understand causative agent, pathogenicity, transmissibility, and others relevant aspects to select, adapt/repurpose and/or develop countermeasures.

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?

Once again, whether the two terms can be used interchangeably, depends very much to the context and interpretation. As explained in the answer to the previous question, "benefits arising from the sharing" can be interpreted in different ways: a more narrow interpretation in which it cover only benefits that are produced based on the direct access and use of pathogens materials/data under the scope of the PABS System; or more broadly, considering all activities that directly or indirectly benefited from the enhanced sharing of materials/data considering also the knowledge and understanding of the outbreak that was enabled by such sharing.

"Benefits arising from the utilization" tends to the narrower interpretation, making a specific link to "utilization," and as such, limiting the possibilities of benefits to be shared (e.g. only countermeasures that directly used the samples/data for their development). Even though this is the term used in the Nagoya Protocol, it is important to stress that the objectives of the PABS system, under the Pandemic Agreement, is also support pandemic prevention, preparedness, and response. To limit the scope of products that would be shared equitably is to limit the ability to reach these objectives.

Finally, as it is shown by the experience of the PIP Framework, using an alternative language that would embrace other societal benefits linked to global health security, did not stop the framework of being a functional ABS system. ***Ultimately the Parties need to clarify the understanding and applicability of the term, consider the inclusion of data/information and their particularities, to avoid diverse interpretations and unwanted limitations to the ABS system.***

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?

Not applicable/ 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?

Not applicable/ I do not wish to respond