Third World Network submission of views on possible new tools and models, such as databases, for making digital sequence information on genetic resources publicly available and accessible

Introduction

Paragraph 4 of Decision 16/2 reads thus: *"Further decides to explore possible new tools and models, such as databases, for making digital sequence information on genetic resources publicly available and accessible in a transparent and accountable manner to all Parties;"*

Pursuant to this, Notification 2024-115 invites Parties, other Governments, indigenous peoples and local communities, and relevant organizations to provide views. The views sought are to be made, in particular, on databases, and also on any other tools and models that can promote transparency and accountability to "all Parties" in making Digital Sequence Information (DSI) on genetic resources publicly available and accessible.

The phrase "all Parties" is a key to the decision in understanding what the databases and other tools or models must do - that they should follow the decisions of the "Parties to the CBD" as well as that of the competent authorities of Parties at various levels.

This TWN submission focuses on databases, because databases provide the cyberspace in which digital use and exchange of genetic resources take place, through the storage, exchange and analysis of DSI. It should also be noted that databases provide core basic structures for data sharing or making data publicly accessible, although front-end access and back-end access to databases may be provided through different software or protocols. Ensuring databases remain accountable and transparent to all Parties is one of the most important priorities in order to ensure justice, fairness and equity relating to the use of genetic resources and associated benefit sharing.

Our submission also touches upon certain governance structures and standards that could be placed on the application of tools used in generating sequences and synthesizing sequences i.e. on activities prior to submission to databases, and activities post access of data from databases, in order to the ensure that the whole data cycle relating to the generation, storage, processing and conversion into synthetic products and deletion etc. remain accountable.

1. Why do we need accountability and transparency to all Parties?

The need for accountability and transparency is summarized in three parts below, first, problems of unaccountability and non-transparency, second, the prospects of promoting guaranteed non-discriminatory access, and third, the need for accountability and transparency to "all Parties, and not only to some".

The problems of unaccountable databases are summarized, with evidence, in a TWN briefing note. The following are bullet points from the same:

1. No checks whether the rights holder consents to uploading the sequences
2. No sharing of benefits with the countries of origin or through the multilateral mechanism

3. Anonymous access
4. Data leaks undermine national laws and/or other benefit sharing regimes
5. No guaranteed access: accounts can be terminated
6. No equal access: different functionalities can discriminate against users
7. Limited access to remedies against data leakage or avoidance of benefit sharing

Additionally, the lack of transparency aggravates the problems of accountability, compromising monitoring and compliance with the Nagoya Protocol, consequently enabling digital biopiracy[1] and undermining fair and equitable sharing of monetary[2] and non-monetary benefits.[3]

As UNCTAD's Data for Development Report (2024) suggests, the issues of accountability and transparency of operations, as well as the overarching question of democratic control over data systems, have become pressing concerns. This is because without legally-binding benefit sharing requirements, a select group of market-dominant players, predominantly situated in the developed countries, monopolize innovations and technologies that are data-driven and built using global collaboration, encompassing contributions from universities, public research institutions, and other providers.

Inequitable data extraction from developing countries

Beyond these problems, the most glaring concern that exists now is the inequitable genetic data extraction from developing countries to developed countries, completely inconsistent with the UNESCO Recommendation on Open Science 2021. Limited digital capacities of the developing countries and an ecosystem of academic publishing compels the users of developing countries to deposit their DSI in databases unaccountable to their governments and that diminishes their own rights to benefit fairly and equitably from the subsequent use of such DSI.

UNCTAD's Digital Economy Report 2021 warns that *"developing countries risk becoming mere providers of raw data to global digital platforms, while having to pay for the digital intelligence obtained from their data"*. This is exactly what happens when DSI Databases are unaccountable and non-transparent, and their users are not obligated to share benefits fairly and equitably.[4]

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[1] Margo A. Bagley (2022), ""Just" Sharing: The Virtues of Digital Sequence Information Benefit-Sharing for the Common Good", *Harvard International Law Journal,* Volume 63, Number 1, Winter 2022: *"vast amounts of what is being called digital sequence information DSI are being used and patented, without permission from the countries that own the genetic resources from which the sequences are derived".*

[2] Jim Thomas (2024),"UN puts AI Titans on the hook for billions of dollars of biopiracy payments.", Scan the Horizon Blog, can provide a fair estimate of the value which is still off the legal hook. See https://www.scanthehorizon.org/p/un-puts-ai-titans-on-the-hook-for

[3] Medical Products for Ebola, M-Pox, Avian Influenza, Covid19 Pandemic could have been accessed promptly by the developing countries, had there been proper ABS regulations in place. See here and here

[4] Carlson CJ, Farrell MJ, Grange Z, Han BA, Mollentze N, Phelan AL, Rasmussen AL, and others, 'The Future of Zoonotic Risk Prediction' (2021) 376 Philosophical Transactions of the Royal Society B: Biological Sciences 20200358, argues in the context of zoonotic risk prediction and benefit sharing, *"scientists who gather novel sequence data may rightfully be hesitant to upload unpublished data to online Web tools for zoonotic risk prediction without clear and enforceable protections" and "without appropriate governance, the countries with the*

Further UNCTAD's Data for Development Report (2024), reconfirms this warning: *"The rising value of data has fuelled competition for its collection, resulting in practices that are often unsustainable and inequitable. Such practices can exacerbate power imbalances, putting developing countries at a disadvantage and potentially widening disparities in their access to and control over valuable data resources."*

Currently, the ownership and control of major DSI databases are concentrated in a few developed countries, which retain the power to set terms for access and usage. For instance, these databases have for decades resisted oversight, including a mandatory field in metadata for the country of origin, effectively controlling access to such information and frustrating countries' ability to seek benefit-sharing. Further, current practices of databases not only compromise benefit sharing but also decontextualize and diminish national sovereignty over genetic resources. It also takes away the control from the real owners of genetic materials and information, while failing to guarantee access to data for scientists. It is interesting that the major DSI databases also do not guarantee access to all users, while some of them even retain the right to unilaterally suspend access to users.

Databases like those participating in the INSDC may claim that they are promoting access. However, according to the terms of use given in the INSDC web-page, they "accept no responsibility for the consequences of any temporary or permanent discontinuity in service". They also under their "sole discretion, without prior notice and without assuming any liability" can rectify, delete, or restrict access to data. At the same time, they gain the right to store data permanently. All these terms of use indicate that the INSDC is regrettably a tool for data extraction, by a few rich countries, including one that is a non-Party to the CBD.

Further, it must be noted that the Data for Development Report argues "*Power dynamics, imbalanced relationships, and barriers to entry often prevent these countries [referring to developing countries] from actively participating in decision-making processes that shape global data policies. As a result, their voices may be marginalized, and their specific needs and concerns may not be adequately addressed*". The classic example of this scenario is where recently, the INSDC management announced their plans to expand membership to new partners, both from the public and private sector, where prospective members will be required to demonstrate eligibility to the founders[5] according to criteria established by them.

Accountability to all Parties essential to guarantee access to DSI, in particular to developing country scientists

It is important for scientists from all backgrounds to have access to DSI, irrespective of distinction of any kind, such as race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status. However in order to achieve this aim, digital infrastructure cannot be left unregulated or left only to a few States.

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highest burden of zoonotic emergence might find their own data (repackaged in an analytic format) sold back to them at a premium by scientists and corporations from high income countries."

[5] The National Library Of Medicine, National Center For Biotechnology Information, U.S.A.; The Research Organization Of Information And Systems, National Institute Of Genetics, Japan And The European Molecular Biology Laboratory - European Bioinformatics Institute.

If left unregulated, DSI access could be subject to the whims and fancies of certain governments. Individual users could be subject to bullying by the database managers. Access could be shut to countries or regions for political or for other reasons. In all these cases, scientists and researchers from developing countries and those who do not have enough institutional funding will not have any remedies or access to justice. Presently, most databases are located in developed countries and so the applicable jurisdiction, if any person has a grievance, is that of the developed countries.

Recently, scientists from the US have raised concerns about the US scientific landscape, due to the revision of language on US government websites and disappearing agency databases, to comply with Executive Orders. Media reports indicate that thousands of datasets and research papers have been taken down. In this context, scientists have also expressed concern about the safety and integrity of genetic sequence information databases, including Genbank, which is part of the INSDC.

Further, data shared in trust can be accessed or altered by certain private individuals close to the database managers or even use such data, without detection, for private monetary and non-monetary gains.

The continuing chaos following change in the US administration should serve as a warning to all Parties to avoid a scenario whereby a few governments are allowed to control DSI shared globally. These governments can at any time take unilateral decisions that adversely impact access and the national interests of other Parties.

Further, there have been several instances where access to DSI has been restricted. For example, scientists were unilaterally denied access to one of the most popular, developed country backed databases, GISAID. The database management was accused of caprice and lack of transparency by scientists, as reported in the Economist and in Science .

Access to the Global Invasive Species Database was also denied to users in the Russian Federation; this is footnoted in CBD Decision 16/18. During the discussions when the Russian Federation raised this issue, it claimed that this suspension of access was due to political reasons. Similar disruptions could occur and may even affect developing countries more, who have less resources to maintain access or seek remedy.

To avoid all these problems, a system and culture of accountability and transparency to all Parties to the CBD is urgently needed.

2. Legal basis of Parties determining regulations and norms for accountable databases

Article 15 of the Convention recognizes a bundle of rights of States under the term “sovereign rights” over natural resources, including the authority to determine access to the genetic resources subject to national laws. Access to genetic resources can be provided through several methods; one of them is by providing access to the genetic sequence information[6]. In this regard, access conditions to genetic sequence information can be determined by the Parties.

CBD Decision 16/2 further recognizes that Parties have and Parties can have national legislation that regulates DSI. This may include generation, storage, third party sharing, including through publicly accessible mediums, subsequent use, deletion of data or taking down of data from certain mediums, portals or information systems. This understanding is very much consistent with the European Commission's guidance on sequence information, which recognizes the fact that the use or publication of such data (GSD/DSI) might be covered by conditions set in the mutually agreed terms, which should be respected. In particular, those who accessed the genetic resources and obtained sequence data from them should respect the conditions of the agreement entered into, and inform subsequent actors about any rights and obligations attached to the data obtained and related to any further uses of it.

The language regarding the scope of the CBD multilateral mechanism implies that the multilateral mechanism expects databases to respect national laws. Further, Paragraph 10 requires databases to perform certain actions and Paragraph 11 requires Parties funding, sponsoring or hosting databases to ensure they take measures for effective implementation of the present decision, as well as future decisions.

It must be noted that international law does not limit the sovereign rights of the Parties over databases that operate within their territory or that share data emanating from their territory, personnels or properties (Tallinn Manual), except to the extent that international law expects Parties to use their digital infrastructure in a manner that respects limits of national jurisdiction, and extraterritorial obligations. This means that it is the duty of Parties in whose territories where databases are physically located or where their owners reside, or from where the databases are actively controlled and managed, to ensure that such databases do not harm the material or other interests of other parties.

Therefore, when a database is operated from the territory of a Party, but actively undermines the sovereign rights of other Parties or the rights of the indigenous peoples and local communities of another country, including the right to receive fair and equitable benefits, then such Party is under an international responsibility to prevent those operations of the databases that undermine such rights. The Parties should also make good the loss the other Party faced due to such operations of the databases, in particular if such databases are operated, hosted and funded by the Parties[7].

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[6] Morgera E, Tsioumani E, and Buck M, Unraveling the Nagoya Protocol: A Commentary on the Nagoya Protocol on Access and Benefit-Sharing to the Convention on Biological Diversity (Brill | Nijhoff 2014) p.140.

[7] Article 28 of Responsibility of States for Internationally Wrongful Acts 2001, International Law Commission talks about legal consequences of international wrongs, while Chapter II, Part I provides for several types of attribution of conduct, which could be applicable in the cases referred above.

3. Making DSI publicly accessible in a manner accountable and transparent to all Parties

The CBD should ensure that there is an environment with several databases that respect and follow CBD requirements and provide wide ranging services, throughout the data cycle. This environment should not be excessively prescriptive such that it affects scientific progress. At the same time, it should not be left unregulated in a manner that allows digital biopiracy to flourish. Thus, there should be a combination of top-down and bottom-up approaches[8], the former meaning governments taking steps to ensure that digital infrastructure remains governed, and the latter meaning allowing for digital infrastructure to adjust and adapt itself to good governance standards.

The former approach can be achieved by a CBD database that is directly accountable to the Convention and its Parties. Other databases can enter into standard agreement with the CBD to create a safe, secure and trusted digital infrastructure for DSI access, functioning side-by-side with the CBD database.

The latter approach would then allow space for other databases to co-exist by adopting comparable protocols and standards applied by the CBD database and entering into agreement with it. While the CBD database and those databases that enter into agreement with the CBD can provide the core systems for primary data storage and data transfers/ replications, the latter will also allow for curated databases for specific scientific purposes and the like.

The CBD database should serve, at the least, two purposes: first, as mentioned above, it should serve as the repository for DSI that is under the scope of the CBD multilateral mechanism and second, it can also provide developing countries the facility to store and share DSI based on nationally determined terms and conditions. The second aspect is crucial, otherwise developing countries, who do not have digital capacities, cannot exercise their rights over genetic resources meaningfully.

Parties can choose their preferred database/databases for uploading DSI in a manner accountable to them. The CBD and its Parties should pay attention to govern the “first point of upload of data” into cyberspace, as it is very critical and is the best interface point at which States and/or international authorities can set a minimum benchmark for data governance. Efforts should be made to ensure data uploading takes place according to national laws.

After successful verification of metadata, national law compliance, and attaching of an accession number and/or other identifiers, access can be provided to all registered users with verified accounts, via a login system and subject to the users agreeing to a set of standard legally-binding terms and conditions of access.

The data uploaded into the first point of upload may be mirrored in those databases that enter into a standard agreement with the CBD agreeing to implement systems for transparency and accountability. Terms of access to the data from these databases should

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[8] Data for Development Report 2024 also suggests a combination of both approaches can provide the data governance inclusiveness and effectiveness.

contain the terms of access as that of the CBD database. These terms of access would also require the user, where applicable, to make contributions to the Cali Fund as well as share non-monetary benefits, in accordance with Decision 16/2 and other future decisions.

Additionally, as mentioned above, the CBD database should also provide assistance, facilities and services to the Parties, in particular developing countries, in making DSI accessible and available to users who undertake to share benefits directly with/through national authorities or their local communities. This means, at the least, that the CBD database, or a few other databases that have entered into agreement with the CBD Secretariat, should undertake to provide services and assistance to developing countries to make the DSI from their genetic resources available, but under the terms and conditions of benefits as determined by their respective national authorities.

This is important because of the rights that Parties have under Article 15 of the CBD, read with Paragraph 1 of the Annex of CBD Decision 16/2: they have the right to legislate the terms and conditions of making DSI accessible as well as the right to determine them in such a way so as to receive fair and equitable benefits.[9] For any right to have genuine meaning, it should empower the States (in this case developing countries) with the agency to exercise such rights thoughtfully, and without undue constraints. Therefore, the CBD accountable databases should take into account the digital divide faced by the developing countries, and offer safe and secure digital infrastructure which they can utilize. It must be noted that the digital divide is not only limited to internet connectivity but also extends to digital infrastructure like data centres.[10]

Finally, creation of the CBD database and providing for agreements for engagement with the CBD does not mean other databases that do not wish to enter into relationship with the CBD should cease to operate. Parties can allow them to operate within their jurisdiction, provided they undertake the required due diligence standards and norms to ensure that the rights of other Parties are not undermined.

The solution proposed above is not based on an overly pessimistic approach, which wrongly assumes that the scientific community would anyway avoid benefit sharing obligations. There are scientists who are willing and more than happy to cooperate with systems that offer more accountability and transparency for promoting benefit sharing and avoiding biopiracy.[11] Such scientists should be given clear guidance and supported by adequate resources such as accountable digital infrastructure to share not only DSI, but also information about their research outcomes.

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[9] This right is consistent with the European Commission's Guidance on ABS.

[10] As per numbers quoted by Data for Development Report 2024, while there are ~3 data centres per million people in North America, the ratio drops to ~0.8 per million in South Asia. Around 65% of the cloud computing market has been cornered by just three firms, Amazon, Google, and Microsoft.

[11] For instance, around 300 scientists called for better benefit sharing obligations under the PABS system in the WHO Pandemic Agreement and called for WHO to establish its own repository or clearinghouse for genetic sequence data and samples. See here. Further bioinformaticians from 10 different countries from 5 different continents came to create a database called Pathoplexus, sharing and analysis of human viral pathogen genomic data and they made a commitment to comply with, endorse and adhere to consensus-driven, international efforts aimed at decreasing disparities and improving equitable global benefits from pathogen sequence sharing. See here.

However, it must be noted that a safe, secure and trusted environment cannot be developed or maintained by relying solely on external entities, where data is transferred to entities outside the management and control of the CBD and its Parties. The CBD and its Parties have to prepare for eventualities, if the CBD requirements are not adhered to due to collusive practices by these entities that may have conflicts of interest. Back-up plans should also be prepared, so that even if these external entities stop services, DSI remains available and accessible to researchers and users from all Parties. This means that, at the very least, the CBD database should remain under a genuinely multilateral system of governance.

4. Some key standard terms and conditions to be followed by the CBD Database and other databases willing to enter into agreement with CBD:

The following key standard terms and conditions are developed based on analysis of existing databases such as Genbank, EMBL-ENA, GISAID, Pathoplexus, and GBIF, as well as references to legal documents. Although all these elements cannot be found all together in any one of the databases, the proposals here are made with a view to maximize legal certainty of benefit sharing, minimize digital biopiracy and guarantee access to all users without discrimination. Some scholars have also expressed similar or parallel ideas under the abbreviation of LISTEN Principles.[12]

1. **Zero anonymous usage.** All the uploaders, as well as all the persons, natural, or legal persons, whether accessing manually or through machine-reading tools, need to be identified. Providing access only to “verified user accounts” is not a principle antithetic to open science or open access. It is a form of providing access to all users without undermining the rights of any other users and the providers, ensuring accountability and governance of open science infrastructure, consistent with UNESCO’s Open Science Recommendation. GISAID is a database that provides some sort of “verified login accounts”, and is recommended by WHO and has received grants including from the European Commission.

2. **Zero discrimination.** All services should be made available to “all verified users” without distinction of any kind, such as race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status.[13]

3. **“Certainty” of account verification and “interoperable verified accounts”.** The databases undertake to provide access to users with verified accounts without discrimination and within a stipulated time frame. An “interoperable verified account” in one of the databases could be used as a login account in another database to improve speed of user access and remove unnecessary duplication of verification

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[12] Carlson, Colin and Granados, Monica and Phelan, Alexandra and Ramakrishnan, Nithin and Poisot, Timothee, Engineering data equity: the LISTEN principles (November 16, 2024). Available at SSRN: https://ssrn.com/abstract=5022896 or http://dx.doi.org/10.2139/ssrn.5022896

[13] UNESCO Recommendation on Open Science 2021.

processes.[14] Account verification could involve institutional intermediaries such as government authorities, universities, research centres, digital identity managers, etc.

4. **Compliance with national law on data upload:** All uploaders of data shall undertake the responsibility of ensuring that they have all the permissions under national law/policy to upload data, including compliance with relevant biosafety and biosecurity law/policy that may regulate uploading and sharing of sequences. They should also declare and provide evidence of such compliance. Another method ensuring compliance is by channeling data uploads through authorized publishers at the national or sub-national level. The Global Biodiversity Information Facility (GBIF) uses a similar approach of “endorsement” for data publishers.

5. **Data access and use agreements to prevent digital biopiracy and ensure benefit sharing:** Users of these databases shall have to accept legally-binding “data access and use agreements”.[15] The data access and use agreements shall stipulate terms and conditions for accessing and using the accessed data, thus preventing digital biopiracy and ensuring benefit sharing in accordance with applicable law.

   (a) Prevent biopiracy: Sharing of data with third parties shall be subject to such third parties being verified users in the CBD database or in the databases in agreement with CBD. Users shall also not upload DSI into databases that are not CBD-compatible.

   (b) Benefit sharing: If use of DSI is within the scope of the multilateral mechanism, then only benefit sharing conditions as per the CBD decision applies. In situations where other systems and laws apply, outside the scope of the multilateral mechanism, access and use of DSI will be subject to such systems and laws. In such cases users should comply with such other applicable systems/laws.[16] This facility is critical for the CBD database to ensure developing countries without national databases have a facility to meaningfully exercise rights over their genetic resources.

6. **Maintenance of user logs:** User logs will be maintained by such databases according to the standards and time frames as stipulated by the Conference of Parties.[17]

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[14] ORCID IDs are a comparable idea used currently.

[15] GISAID uses such agreements. So do GBIF.

[16] EMBL-ENA terms of use shows the possibility of specific data access agreements being attached to specific datasets or participating databases.

[17] Genbank provides user logs in the user dashboard itself. Almost every online activity is archived for the purposes of the user.

7. **No perpetual retention:** The databases shall not have a right to retain data perpetually. The uploader or competent national authorities should have the right to delete data.[18]

8. **Intellectual property policy:** The issue of intellectual property (IP) should also be addressed under the terms and conditions of the databases. It is especially important that IP is not claimed or asserted in a manner that in any way limits access to or use of DSI, by countries making the DSI available.[19]

9. **Facilities to showcase outcomes of R&D:** Users should be provided facilities to showcase their research outcomes using DSI from the databases and such facilities could reference links back to relevant DSI in use.[20] With a view to promote non-monetary benefit sharing, users of databases may also be required to showcase certain types of outcome if they derive from use of the DSI.

10. **Termination of services:** In case the databases decide to terminate services they need to agree to work with competent authorities in order to make arrangements with the CBD database and/or other databases in relationship with the CBD to ensure no data would become unavailable due to the termination of databases.[21]

11. **Sensitive to digital divide.** The terms and conditions of the CBD database and those entering into agreement with CBD should always take into account the digital divide between developing and developed countries, including in the provision of services and facilities, and aim to bridge that divide. For example, databases should try to locate their establishments and storage facilities in developing countries in a manner that promotes the skills of the people of developing countries in data management and digital interfaces. Database terms and conditions should also stipulate a commitment in the data access and use agreements to maximize collaboration with developing country researchers, including by locating research and development processes in provider countries.

12. **Cooperation with, and accountability to, competent legal authorities:** The databases shall agree to provide services as required by CBD COP decisions, in order to maximize benefit sharing. The competent national authorities should have the right to request and obtain access to data and relevant information for the performance of their official duties in accordance with applicable laws.[22]

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[18] E.U. GDPR law shows the possibility of the right to delete one's own data from databases. Similar rights exist for the States with regard to the data of their biological resources that are uploaded without the compliance of national laws, where applicable.

[19] Most of the databases mention their policy regarding IP in their terms of use.

[20] GBIF has a literature tracking programme, which identifies research uses and citations of biodiversity information accessed through GBIF's global infrastructure. Similar programmes combined with facilities where researchers and users can update their outcomes of research is important.

[21] INDSC Founders and Membership Arrangements have similar arrangements.

[22] This requirement is also consistent with EU Regulation on free flow of non-personal data.

13. **Use of appropriate advanced A.I. tools and other technologies like block-chain:** These technologies may be used, according to capacities, to improve accountability and transparency, consequentially promoting realization of objectives mentioned in this section.

5. Regulation or guidance framework for providers of sequencing and/or synthesizing services

It is very clear that Governments need to provide adequate levels and standards of guidance for activities related to digitalization of genetic research and its outcomes. Traditionally, such governance is limited to countries with capacities and has focused on "sequences of concern" - a terminology used in the United States for nucleotide sequences known to contribute to pathogenicity or toxicity, in particular those belonging to formal lists of toxins, etc. However, recent trends are showing that there is a need for governance to expand this model of governance based on "sequences of concern".
The 2013 Screening Framework Guidance for Providers and Users of Synthetic Nucleic Acids states that

> *"regulated pathogens and toxins do not represent the entirety of the potential risks to public health, agriculture, plants, animals, animal or plant products, or the environment that could arise from the misuse of synthetic nucleic acids. Non-regulated pathogens and toxins, as well as other novel types of nucleic acid sequences, may also pose significant risks if they are misused. To minimize these risks, a shift is needed from relying solely on lists of regulated pathogens and toxins to also assessing the risks associated with other nucleic acid sequences that may contribute to pathogenicity or harm if introduced into new genetic frameworks (i.e., Sequences of Concern [SOCs]). Also, modern molecular biological techniques allow the conversion between different types of nucleic acids (e.g., RNA to DNA, and vice versa), so it has become necessary to treat all types of synthetic genetic materials with equal care. Additionally, benchtop nucleic acid synthesis equipment is increasingly common in modern laboratories, which changes the commercial landscape for synthetic nucleic acids. These advances and others motivated the U.S. government to review and revise the 2010 Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA."*

The above screening framework provides for screening of orders made by the customers to providers of synthetic nucleic acids, as well as know-your-customer policies for the providers of such services. The vendors are required to perform sequence screening, verify the identity of their customers, and follow up to verify the legitimacy of the order.

Similar models should be applied to ensure proper compliance with ABS laws. When genetic materials are entrusted to third party sequencing as well as when sequences are provided for generation of synthetic materials, the service-providing entities need to screen the order to ensure materials are permitted for sequencing under national laws and the sequences that are to be synthesized are also compliant with legal requirements of ABS laws.