Addendum to the WiLDSI white paper:

Finding compromise on ABS & DSI in the CBD: requirements & policy ideas from a scientific perspective

February 2021

This addendum was compiled by the WiLDSI project team for two main purposes:

1. To offer answers to questions posed in the Q&A during the DSI policy options launch webinar (Oct 7th 2020) that, due to time constraints, could not be answered live.
2. To publish written feedback received by individuals on the WiLDSI white paper "Finding Compromise on ABS & DSI in the CBD: Requirements & Policy Ideas from a Scientific Perspective". between the launch event and February 1, 2021.

The authors of the white paper are publishing the addendum to maximize transparency and encourage continued discussion in the challenging and technical field of DSI. The addendum does not represent support or agreement on behalf of the authors with the submitters of the feedback.

1. Unanswered Q&A from white paper launch webinar

NOTE: Questions were consolidated and grouped into different options and sections of the paper.

Option 1: Micro-Levy

- Was the criterion of evaluation of "excess burden" (per Rosen, 2004) taken into account?
    - Any form of national regulatory measure, taxation etc. has some cost implications, economists refer to transaction costs. Different jurisdictions apply different tests as to whether a measure should be implemented. An "excess burden" test may be one such test. The aim of this project is to describe options. The micro-levy option, as stated in the report, is based on other examples of micro-levy systems that are already in place and have generated funds, such as the UNITAID airline levy. It will be down to any national government that considers taxation measures how it takes such wider "economic burden" issues into account.
- Wouldn't a micro-levy disadvantage scientists working on projects where no commercial outcome is expected?
    - The levy should be very low (i.e. "micro") and is intended not have a significant negative impact on research. Of course, with all of the options, a financial cost-benefit analysis is recommended before any policy framework is adopted. The option is based on the premise that *many* stakeholders/users pay a relatively small amount of money resulting in a broad social responsibility for biodiversity. Moreover, it is legally possible to carve

out exceptions for particular groups of users within the system, even though that would have an impact on the simplicity of the system.

- How does this micro-levy, if applied on the level of sequencing consumables, address the issue of DSI data re-use?
    - It does not address the issue of DSI data re-use. During the course of our discussions with practicing scientists, targeting DSI data use and re-use opens the door to "tracking and tracing" and brings a significant risk of a complicated, non-simple system. Policy options that address data re-use can be found in Options 4 and 5.
- Wouldn't it be more effective and properly placed if the levy were linked to use of DSI in databases, rather than, for example, reagents? Reagents might, for example, be used for public health diagnostic tests or other purposes that might not be appropriate to "tax".
    - The final "target" of the levy would need to be determined by policymakers. As noted above, levies on database use would create data friction and appear, according to our research, to be considerably more difficult to implement and risk significantly impacting the database infrastructure. Although, essentially, option 3 is a levy on database use (cloud fees model). If a broader "biodiversity use" levy were to be applied across all biological-based products, this might generate more income and avoid unfair burden borne by the research/DSI-generating community.
- Could the micro-levy be raised on the sale of products derived from the use of DSI rather than sequencing machines or services?
    - Guided by the "scientific priorities" in the white paper, the goal to develop a mechanism that would lead to money early on in the R&D process. So not at the end of the line for product sales; perhaps there will be no product – isn't that the situation we are in now with the Nagoya Protocol for ABS concerning Genetic Resources? However, if the time delay was not a concern, this could also be an interesting option to pursue.
- A lot of research can be done with just a PC (no products or services implicated). How would this be subject to the levy-system?
    - This type of research would not be affected by a micro-levy system. Many institutes/researchers that use DSI also generate it as these activities often go hand-in-hand. But this raises an important point: the options can be viewed as complimentary tools. An effective solution for biodiversity will probably require a combination of different policy options.
- What would the cost of this micro-levy be? Which body/authority would set this amount? Would there be a universal fee level?
    - This needs to be explored in more detail if indeed there is sufficient support for this option. It will depend what the levy is charged on: services, reagents, etc. A useful comparison is the UNITAID airline ticket micro-levy profiled in the white paper: different fees for first/second class, domestic/international flights. It could in theory also be country-specific. Who will set the amount depends on whether a multilateral approach would support such a micro-levy or whether the adoption of the micro-levy will be on a country-by-country basis. In the latter case, we will not have universal fee levels, in the

former there may be a scheme for levels with some differentiation/exceptions possible according to the users involved.

- What would the micro-levy be spent on? Who would decide on how this gets used? How do you avoid unhappiness over who receives it, especially if more recipients are found in the global north?
    - It is envisioned that the collected levies would go into a multilateral fund governed by a board that consists of representatives from various stakeholders including low- and middle-income countries and public and private sector scientists. Funds would be spent based on a needs-based assessment.
- Regarding the micro-levy - this would impact services/products/equipment that are used for non-CBD purposes (e.g. human sequencing). How does this option address this issue?
    - This differentiation could theoretically be made (i.e. human sequences could be excluded) but would compromise the system's simplicity.
- How would these micro-levies be assessed?
    - The levies would need to be implemented at the national level and certain industries (e.g. commercial DNA sequencing service) would pass the levy onto customers and contribute these collected funds back into the multilateral fund. Accounting mechanisms and governance will be key for effective implementation.
- How would this affect laboratories at small colleges and universities with limited research budgets? How can we ensure that a micro-levy would not prevent researchers in the Global South from building up their sequencing capacity?
    - See above: exceptions could be built into the policy mechanism, but the level of the levy should be sufficiently low as not to have any significant impacts. Value will be generated by the large numbers of users.
- Some sequencing activities do not generate DSI (e.g. resequencing clones as a control), how can this be accounted for?
    - These activities would still pay the micro-levy. It is highly likely that a clone-re-sequencing scientist also uses DSI in the normal course of their research.

Option 2: membership fees

- Would the fees scale along with the commercial sales of the user or would they be charged at a flat rate?
    - Both approaches are conceivable and would have advantages and disadvantages. A flat rate would provide clarity from the outset. Everyone knows what to expect and what possible costs would have to be taken into account. A percentage-based approach (based on sale volumes) would make DSI access fairer for smaller commercial companies with a lower annual turnover. A combination of flat fees pus percentage-based fees above a certain sales threshold could also be considered.
    - A proportional approach with contributions linked to turnover appear to have a logical appeal. The more successful a product is on the market, the more of its use (market

success) flows into the operation of the infrastructure, the creation of new innovative software tools and into benefit-sharing.

Option 3: cloud-based fees

- How much would the cloud-hosting service earn with this option?
    - These terms would be negotiated at a later point in the policymaking process. A fair-market value would seem likely.
- Is it an issue that those most able to afford the fees are least likely to need to use the services as they have more capacity to do analysis on their own systems?
    - Yes, this could be an issue that would need to be analysed in a cost-benefit analysis. However, only this cloud-based system would ensure legal certainty to the user. A self-built private system would not guarantee legal certainty and clarity.
- How is the system preventing circumvention using the open-access data and making them subject to services outside the cloud system?
    - The existing open-access platform does have some limitations and provides no privacy, registration, or high-performance computing opportunities. The cloud-based system would provide these features plus additional value-added functions, a help desk, and legal certainty. Taken together, these features should incentivize, especially commercial and high-throughput users, to use the ABS-compliant system.

Option 4: commons licenses

- Are you suggesting using CC licenses or was this just an inspiration? What IP right would the licenses be based on?
    - CC licenses would be the initial inspiration for a standard licensing model which is user-friendly. Whether the system would be a CC system ultimately or not would depend on negotiations.
- Would searching the databases (i.e. BLAST) already be restricted by license type?
    - During the multilateral negotiations of the licenses, global uses of DSI would need to be considered and addressed in the terms and conditions of the various licenses. For the user, the ideal approach would be to provide clarity here and the implementing technological platform should, ideally, then account for these variable terms of use.
- Who within countries is responsible for choosing which license is appropriate? The research group? NFPs? Government? Given the rate of DSI generation, how can we ensure countries have the capacity to deal with this workload?
    - It is envisioned that at the point of access the user would be instructed (e.g. through a link to an official record or communication from the NFP or CNA) to use one of the standard licenses if DSI production and public use takes place. This decision is anticipated take place during “normal” PIC/MAT negotiations and the licenses would be standardized.
- Which part of the genome sequence would be "licensed"? All of it or just specific parts that are characteristic for the genetic resource?

    - All DSI generated from GR accessed in a country that has ABS measures in place would presumably need to have a license attached to it.
- Are there only four licenses available? Is it possible to bilaterally agree to other licenses for sequences?
    - If there are too many licenses, the simplicity of the system and ease of use would be lost and, thus, the compliance burden for the user (using thousands or even millions of sequences) would be very high.
- Can't this be avoided by going back to the public database? Who would pay for a secondary license, if there is always the option of going back to the public database?
    - The question is not entirely clear. All sequences in the database would receive a license ranging from extremely permissive (i.e. no restrictions at all) to restrictive. These licenses would be visible in the database and would need to stay attached to the data throughout the value chain. Going back to the databases would not change the conditions of the licenses. However, it would be possible that identical sequencese in the database would have different licenses (e.g., the RuBisCo gene essential for photsynthesis is highly conserved and found in all plants so it could be geographically sourced from USA or Brazil or Germany and would accordingly have different licenses attached to it). This would mean that researchers might be less inclined to use ABS-required sequences than others with no restrictions.

Option 5: blockchain metadata

- Have the high computation power and energy costs necessary been taken into account?
    - High energy consumption is not inherent to blockchain technology but related to the mechanisms chosen to validate transactions. Public Blockchains (Bitcoin and Ethereum) suffer from these drawbacks because they validate transactions based on public consensus which is called “Proof of Work”. The Private and Consortium Blockchain models considered for this option, have a different way of validating transactions based on “Proof of Authority” where only certain designated authority nodes in the network can validate transactions. This means that the validation process does not require excessive computational power and energy costs.
- Could a user not download the bare sequence and then identify it in a background that does not imply benefit sharing, and thereby avoid invoking the smart contract because he/she has basically “found” the same sequence in a different backbone (could be easily imagined with pathogens)?
    - This could indeed be a problem if the interfaces between the DSI and the blockchain are present only at the main databases (e.g. the INSDC). To solve this problem, it is important that the interface/link with the blockchain is established in every database for which the DSI is first submitted, and in the case of redistributions; one of the conditions acknowledged in the smart contracts should be that the users attach to the DSI shared the link to the existing conditions of use (within a blockchain).

- To my knowledge, no Party has suggested Blockchain yet the African Group has suggested "Bounded Openness" in the 2013 Online Discussion and more recently in submissions about the GMBSM. Why is "blockchain" vetted as one of five options, and "bounded openness over natural information" for which a substantial referenced literature exists, not? Does it have to do with rents?
    - Blockchain as an option for connecting ABS to DSI has been discussed in CBD forums: For example, the CBD study on DSI and databases and traceability, the UNDP Nov. 2020 call for proposals for GR and blockchain, and a December 2019 dialogue between Brazil and the EU, amongst at least several others. The scientific literature published on the topic (see citations in the white paper) also leaves a clear paper trail. The aim of including blockchain as one of the options in the white paper was to clarify which implementation approaches are feasible and which are not (e.g., the blockchain technology cannot handle the size/volume of the sequence dataset itself but rather is only suited for metadata and legal documents, which is an important distinction that has not been clearly made before). Furthermore, the compatibility of whether open access to DSI is compatible with a blockchain approach had not been looked at before, to our knowledge.
- Would the private sector be willing to accept this given that it might lead to trade secrets being divulged?
    - One of the advantages of a blockchain system is that the data provider can completely manage which information he/she wants to make available and to whom. In the case of users, they might have to indicate the types of use for the DSI accessed but that could be in general terms such as: basic research (e.g. taxonomy); applied research (e.g. epidemiological study); product development (e.g. diagnostic development). In addition, data providers and users are kept anonymous and their identities cannot be made publicly available. Therefore, there would be no need to reveal trade secrets.
- Who would provide the funding for this?
    - One idea to fund such a system would be through a public-private-partnership; where different stakeholders would be engaged. To start, the main funders could be governments (especially from high- and middle-income countries); the private biotech sector using biodiversity genetic resources; and once functioning, the funds raised from the benefit-sharing measures could also be (partially) applied to the development and maintenance of the system.

DSI and the CBD and Nagoya Protocol

- The Nagoya Protocol has been called an exercise in creative ambiguity, why should this instrument be the basis for a DSI solution?
    - In the paper, we clearly outline why the Nagoya Protocol is not suited for handling DSI (see "a problem of scale" and "learning from the NP" on p.5-8).
- Does the "scientific perspective" mean that the CBD is subordinate to existing publishing and funding norms?

- It is not a question of subordination, it is a question of trade-offs. The implications of regulating access and use of DSI have a significant impact on the frictionless flow of genetic and related data, which has become standard practice across the scientific research community. Introducing frictions to this flow has consequences for innovation and the dissemination of scientific knowledge as well as the first two goals of the CBD. The discussions on DSI needs to take into account these consequences and also consider the historical context for the publishing and funding requirements which currently exist for open access publication of sequence datasets.

Relationship of DSI to international institutions and treaties other than the CBD and the Nagoya Protocol

- How does the TRIPS agreement impact DSI?
  - TRIPS establishes minimum standards for the regulation by national governments of different forms of intellectual property (IP) as applied to nationals of other WTO member nations. There are certain issues/discussions under TRIPS that may have indirect implications for DSI (e.g. concerning the disclosure of country of origin in patent applications, or compulsory licensing).
- Did the Brazil-EU ABS-DSI Dialogue held in Brasilia last December contribute in any way (direct or indirect) to the results of this study? If so, how?
  - This study is a culmination of research conducted by WiLDSI project members (from Sept 2019-October 2020), input received from the three scientific stakeholder workshops organised by the project, as well as ideas gathered along the way from different meetings and informal dialogues. These discussions and meetings influenced the thinking of team members and their understanding of different regulatory frameworks that already address DSI, such as Brazil.
- How will UNDROP be integrated into the project's considerations?
  - The paper and project did not directly address the issue of indigenous peoples rights (such as article 31 and other rights set out within UNDRIP). However, the authors hope that indigenous peoples and local communities will participate in the development and design of any mechanism that would address DSI. However, the research mandate of this project was to understand the German and European scientific perspective.
- What about a license on DSI such as the CC-BY-NC? Perhaps we can ask INSDC to change their conventions?
- Is it not possible to make it mandatory to mention the country of origin of DSI while submitting to INSDC?
  - The country or origin field has been mandatory since 2012 but technical hurdles prevent 100% enforcement of this policy. The INSDC, a scientific collaboration between the European Molecular Biology Laboratory (an inter-governmental treaty organisation of member states), the National Center for Biotechnology Information (a part of the US Government's National Institute of Health's National Library of Medicine) and the DNA Databank of Japan (a part of the Japanese National Institute of Genetics), is under no

formal obligation to make any changes in response to requests from the Convention on Biological Diversity (CBD) or other ABS fora. However, if a formal request were to be made, the INSDC would most likely work with the stakeholders to find feasible/viable solutions if they were compatible with maintaining open access. Within the WiLDSI discussions it was noted that formal dialogue and requests between Parties to the CBD and INSDC and the broader (1700+) biological databases have not been conducted to our knowledge.

- Has a subscription system such as that proposed in the context of the ITPGRFA been considered?
    - Option 2 (Membership Fee) closely reflects the subscription system that was proposed by the International Plant Treaty for Genetic Resources for Food and Agriculture (IPTGRFA) and discussed by Parties in November 2019.
- Is there a possibility of building these options on the existing architecture of the ITPGRFA's multilateral system of access and benefit sharing (MLS)?
    - Yes, or, conversely, the MLS could work with this system. A "universal" solution that addressed DSI use as a comprehensive global dataset (which is how it is used in practice) would be the ideal way forward for scientific users.
- How does the concept of Open Science as advocated by the European Commission in Horizon Europe relate to this topic?
    - The 5 open access policy options attempt to be compliant with Open Science principles put forth by the EU Commission. They all, however, represent some compromise.
- How would these options affect countries that are not party to Nagoya? For example, would NCBI data from organisms found in participating countries be still freely available? If so, would this push researchers to share their data to these "free" repository options?
    - Yes, all options would still enable open access to data found in the INSDC.

Retroactive applicability

- How would these options affect pre-Nagoya collections of tissue and genetic material?
    - With Options 1-3, the issue of retroactive applicability is disregarded. To keep things simple, everyone pays, for everything. For option 2, the entire global DSI dataset is considered as one unit/element (all DSI is in) and in option 3 the database infrastructure is the "unit" upon which ABS is handled. The issue of retroactive applicability would however, come into play for the bilateral options 4 and 5. In case of Option 4 (Commons Licenses), one suggestion would be to assign all DSI already present in the databases to automatically receive License 1.
- How would new sequence data produced from historical specimens fit within the proposed options? For example, if I have a specimen collected in the 1930s from Mexico and sequence data was produced, would those sequences be included in the fee system if shared on a data repository?

- In options 1-3, yes, this would fall under the policy option. For option 4, probably license 1 would be applied. For option 5, it would depend on the details of the system but it could be either in or out of scope.

Externalities

- Have the various options been evaluated based on their environmental impacts (e.g. energy intensiveness)?
  - When considering the specific details of implementation of any option all impacts will need to be carefully considered in a more complex, fine-scale cost-benefit analysis. It was beyond the scope of the project at this point to evaluate environmental impacts.
- All these options would require complex administration for redistribution - who would be tasked with this?
  - There are various potential mechanisms for the potential distribution of monies received, ranging from national processes to multilateral funds. These vary both in complexity and in terms of outcomes. The proposed needs-based approach is for instance a way to ensure that specific ambitions (such as biodiversity conservation) are covered.
- Did the report take into account economic expertise that could help determine an overall cost-benefit analysis (depending on the expected amounts to be generated in the monetary options)?
  - Financial sector expertise was engaged in drafting the report. Cost-benefit analysis is one of several means to assess decisions and is not necessarily linked to monetary options. These types of analyses can and likely need to be done at a later stage in the policy development process but were outside the remit of this project.
- Did the report consult political scientists that could determine whether there would be a risk of disengagement by countries in CBD if it goes down the route of a strong monetary option?
  - The authors and experts consulted in the acknowledgments sections came from a variety of disciplines and backgrounds. The focus of the WiLDSI paper is on the scientific perspective.
- Absent from the Report are the concepts of rents, excess burden and fungibility. Why does the Report preclude the relevant concepts from the economics of information?
  - The DSI field is quite complex and the primary focus of this phase of the project was on assessing the scientific perspective, open access, the technological intersection of these ideas and the trade-offs between non-monetary and monetary benefit-sharing. Economic and financial cost-benefit analyses would undoubtedly add additional input to on-going policy discussions.

Accountability

- What would the burden be on the open access repositories with respect to each of these options? Would the repositories need to distinguish sequences by country of origin and whether they require ABS?

    - This is highly dependent on which option is being referred to. In options 2 and 3, country of origin is less relevant unless the country information were to be used to guide distribution of funds. In option 4, the technical option to attach or indicate a license would be needed. In option 3 and 5, very close collaboration and integration with the databases would be needed far beyond country information.
- How can it be ensured that the money raised by these options is used for the conservation of biodiversity?
    - Funds could also be used for capacity building (especially in genomics and bioinformatics) and the database infrastructure. How funds could and would be used would be addressed through the governance. See above comments on a multi-stakeholder approaches and a needs-based assessment.

Commercialization of DSI

- Several questions related to the difference in using DSI for 'research' (not for profit) vs. using DSI that then results in a commercial product:
    - Several of the options proposed focus on benefit sharing at the time of access to DSI and during the R&D phase. They do not explicitly address the issue of commercial use of DSI and benefit sharing in cases of commercialized products but rather address the use of DSI, irrespective of purpose. As we learned from the Nagoya Protocol, ultimately Parties were reluctant to distinguish between commercial and non-commercial use and thus all researchers, regardless of sector, are usually equally affected by the NP.
- Will we hear more about these topics from WiLDSI or was the work more focused on R&D in general with DSI from public databases?
    - Both the public and private scientists use DSI from the public databases as described in the CBD Study by Rohden et al. The use of DSI generated from GR that never makes it into the public sector does can be handled by the bilateral system more easily than the public databases that are much more inter-linked, re-used, and generate significant downstream scientific use and value. This is why our focus was on public DSI database mechanisms – it reflects how the scientific community uses DSI in practice.
- How to do we ensure that value that DSI contributed to a commercial product is proportionately represented in the amount of benefits to be shared?
    - With the 5 options proposed, such a calculation would not be necessary.
- Governments promote reuse of public sector information (and increasingly 'data') to create 'value', whether this is for non-commercial or commercial purposes. Why should DSI generated with public funding be any different?
    - We agree. This should certainly happen and continue to happen in the future. But the concern within the world of ABS is that commercial development using DSI where no access to GR was required, enables a loophole around ABS obligations. Some Parties have expressed that they recognize that the open access system produces significant non-monetary benefits and that these are in-line with expectations for benefit-sharing from the public sector (i.e., the public sector "is doing their fair share already"). The

question is whether approaches to monetary benefit-sharing can be designed and implemented in a way which creates no or minimal friction to the reuse of DSI in the public domain.

- Which (if any) of the models requires industry to pay into the fund commensurate with the level of use?
    - Options 2-5 could require use-dependent monetary obligations.
- Does the principle of open access to DSI for researchers apply only to academics or also to private sector researchers?
    - Open access to DSI was initially created around efforts to sequence the human genome. At the time, the public sector published DSI into databases but the private sector did not. Today, all scientists that submit a scientific publication that references DSI must submit their DSI to a public database. This requirement from journals applies equally to both public and private sectors although public sector researchers often have a stronger focus/need to publish although there is great variability depending on the scientific field. Additionally, public sector scientists are often required by their funding agreements and their institutional policies (often around "good scientific practice" and scientific integrity guidelines) to publish sequence (and other) data. These requirements do not affect private sector scientists as strongly.

Traceability

- If DSI is decoupled from physical access how can its origin be accounted for?
    - The /country field in the INSDC databases would continue to be available.
- How can we ensure traceability of DSI for ABS given that several compounds conserve the same sequences (e.g. collagen can be obtained from thousands of species)?
    - Options 1-3 do not require traceability. Options 4 and 5 would make this distinction based on the legal conditions associated with those sequences regardless of repetition of that sequence. As noted in the paper, it is likely that DSI with no ABS obligations would be "preferred" by scientists over those DSI with ABS obligations. These models could, then, lead to "jurisdiction shopping" as noted in the comparative table in the white paper.

Feasibility

- Could a sequence be synthesized to specification without recourse to nature or a database and is this possibility taken into account in the report?
    - A synthetic biology approach in which a sequence is designed and synthesised in silico, without recourse to physical genetic material, is feasible and such services are currently available from biofoundaries. The report does not consider synthetic biology although it is mentioned in passing in the scenarios evaluated in the Annex 1 Blockchain model for monitoring DSI based on open-access and controlled-access metadata fields.
- With 50-some (and counting) countries that have already legislated on or de facto regulated DSI through ABS, how could a "universal solution" be applied in a realistic timeframe?

    - Each country has a sovereign right to determine the system that best suits it from an ABS perspective and a universal solution would imply universal consensus. The options in this paper have been designed to strike a balance between access and benefit sharing in a manner intended to reduce friction to innovation and to increase the flow of monetary benefits. It is hoped these dual objectives will incentivise a transition from the status quo in which existing national frameworks appear to achieve one at the expense of the other.
- Wouldn't it be much simpler to just agree worldwide to a fund for biodiversity conservation and sustainable use, to which countries contribute according to a certain specification, and where the money is also distributed according to a certain specification favoring low income and high biodiversity countries?
    - This would indeed be an elegant and simple approach, however, to date there does not appear to have been a political consensus under the CBD or its protocols, or other treaties governing access to GR, for a funding mechanism of this nature.

Financial pressure on researchers

- Should the labs that generated DSI that was used also be entitled to monetary benefits?
    - This approach is not contemplated in any of the models proposed, however,
- All of these options require payment. Science is already under a lot of funding pressure, with new initiatives constantly looking for fees from scientists. Why should the onus to pay land on them?
    - The options presented in the paper attempt to find a compromise between polarized positions on ABS in relation to DSI. As the objective is to find a compromise all options contemplate some form of payment as a middle ground. In all options payments are triggered by utilization of DSI in some form, as this is the ABS trigger for benefit sharing. Accordingly, science and innovation in the life-sciences, being the sectors which utilize DSI, carry the onus to pay under the models proposed.

DSI and indigenous peoples

- Were indigenous knowledge-holders and scientists involved in the development of these policy options?
    - No, indigenous knowledge-holders and scientists were not involved in the drafting of these options. The paper and project did not directly address the issue of indigenous peoples rights (such as article 31 and other rights set out within UNDRIP) because our research mandate was focused on Germany and, secondarily, on the EU. Given the short time constraints of the project and narrow mandate, the project had to prioritize its objectives and outreach strategy. The authors feel strongly that indigenous peoples and local communities should participate in the international process and design of any mechanism that would address DSI but this perspective could not be covered here.
- Does indigenous DSI exist?

    - The authors have not looked within the scope of this project for indigenous DSI and are not aware of any examples off-hand. Importantly, human DSI, even if from indigenous people, is not within the scope of CBD/NP.
- Is implementation of the Nagoya Protocol more complex in countries where a large proportion of the population is indigenous?
    - Implementation of the NP has been challenging for many that have been affected by it. It is unclear if the proportionality of indigenous people plays a decisive role or whether, simply put, the bilateral mechanism is ill-suited to how practicing scientists actually use and re-use GR.

DSI and the developing world

- Were representatives of the Global South involved in the development of these policy options?
    - As indicated in the white paper, interviews and surveys of scientists conducting research in low- and middle-income countries were conducted to determine whether their concerns and thoughts around DSI were aligned with the views we heard from our German and EU stakeholder workshops. See p.14-15 of the paper.
- Does the report take into account the current costs of the technology required for DSI research and the conditions for access to it in the developing world?
    - It is our understanding that sequencing costs are higher and access to DSI reagents and technology are significantly more limited in the developing world than they are in high-income countries. The white paper strongly calls for levelling this playing field wherever possible. However, restricting access to DSI can also have unintended consequences, for example, by making this uneven playing field even more uneven for colleagues in these countries.

Next steps

- How will the white paper be distributed to negotiators? Are there plans on how to use it as a tool in negotiations in the near future?
    - All ABS National Focal Points were invited to the webinar. This white paper was a final project deliverable for the WiLDSI research project that was undertaken by an interdisciplinary group of experts to research viable open access benefit-sharing policy options for digital sequence information (DSI). It was not meant to be an official policy document for negotiations. The white paper is intended as starting point for further discussions to try and find a universal solution that would be compatible with the scientific concerns around open-access and the debates on DSI within the Convention on Biological Diversity. The WiLDSI project is available for country-specific briefings if any Party wishes to have a direct interaction with the project and with scientists both in Europe and around the world.
- How do you think that a political consensus on these issues can be worked towards?
    - ABS is not a funding mechanism that can or will reverse the loss of biodiversity on this planet. To do that, there will need to be significant efforts around resource mobilization,

a better and more integrated involvement of the private sector, and a harder look at how "polluter pays" models can be incorporated into the CBD as they have been, for example, within the UNFCCC. If these efforts are successful, it is possible that the political pressure on the DSI issue could be lowered. Additionally, we strongly encourage negotiators to reach out to scientists working in their countries. Understand what they need and want as those are the people that are building up your bioeconomy every day they go to work.

- Are there any plans to schedule dialogues with different industries?
    - An online workshop was organised by the WiLDSI project in July 2020 to actively involve the private sector scientific stakeholders in Europe. Research done by the WiLDSI project members, the input obtained from the three stakeholder workshops organised by WiLDSI as well as ideas gathered from the various meetings all culminated into the development of this white paper.

Misc.

- What is a BioRevolution?
    - According to a recent 2020 report by the McKinsey Global Institute '*The Bio Revolution: Innovations transforming economies*, *societies, and our lives',* "BioRevolution" is the convergence of recent advances in the field of biological sciences, in biological engineering with rapid development and advances in computing technologies, automation and artificial intelligence that has resulted in significant progress and innovation in various sectors including public health, agriculture and energy.
- How are non-monetary benefits accounted for in any of the models?
    - They are accounted for indirectly in the assessment of whether the primary mechanism of non-monetary DSI benefit-sharing is impacted. Each option assesses how open access is impacted. The quantification of non-monetary benefit-sharing, to our knowledge, has never been robustly attempted.
- Is Blast Search considered a use of DSI?
    - In options 1-4, yes, BLAST would be considered a use of DSI. Examples such as BLAST, which is an all-by-all comparison of every sequence in the database shows why tracking and tracing and bilateral models are unfeasible for benefit-sharing purposes.

Written feedback and comments received from expert individuals

The following comments are reproduced with permission and for convenience, we have broken down the feedback according to the issues addressed and included a title or summary.

1. **Dr. Markus Wyss**

Dr. Markus Wyss was generally supportive of the Whitepaper and shared the following personal views on issues deserving further consideration, which do not represent the views of his employer or of industry in general:

a. Issue: Retroactive application of Option 4 Commons Licenses for DSI
   - Comment: *Page 7, about Commons Licenses: "including retroactively" might trigger the wrong conclusions here. When I read it first, I interpreted it so say that Commons Licenses might be applied retroactively to any type of DSI. However, later in the document, it is clearly stated that DSI already in the databases would automatically receive License 1 (no restrictions on reuse and redistribution). This is somewhat confusing.*

b. Issue: Reasoning on why all the solutions should be restricted to "non-human DSI"
   - Comment: *An important ambition is to keep things simple, and since we are moving anyway away from a direct link between access and benefit sharing, it is not evident why all the solutions should be restricted to "non-human DSI" (particularly, because also there, the cut-off criteria for distinction between human vs. non-human DSI would need to be defined). If the scope restriction on non-human DSI shall be maintained, the document should provide the proper reasoning.*

c. Issue: Approach to 'country of origin' by WiLDSI
   - Comment *Page 12, about "country of origin": I do not like how WiLDSI presents this topic, and you risk opening a pandora box. In the context of the CBD discussions, "Country of origin" and "provider country" are used as (relevant terms), but do not mean the same. The country where a biological resource is collected is not (automatically) the country of origin! Thus, I strongly feel INSDC should not go any further than what is stated in footnote 19: "/country" reads as follows: "locality of isolation of the sequenced organism indicated in terms of political names for nations, oceans or seas, followed by regions and localities." The latter is scientifically valuable information, whereas the WiLDSI interpretation is political – the two should be kept strictly separate, in my eyes.*
   - *Page 13, the two paragraphs indicated with a note: similar to the previous point, this goes way too far for me (particularly also considering that the main funding parties of the INSDC are the US, EU and Japan …)*

d. Issue: Elements/issues that require further consideration
   - *In addition, I have added a few remarks that some of the suggestions may not be fully thought through (in my eyes), e.g. what it would mean if each individual uploading information to INSDC would need to assign the correct licenses or the proper terms of use. The error rate would probably be significant. Who would be doing the curation, how efficient would this be, etc.?*

2. Dr. Christiane Hassenrück (MARUM - Centre for Marine Environmental Sciences, Germany)

a. Issue: Lessons from data management plan tools (DMPT) with standard license options.

- *Comments: I recently used the data management plan tool (DMPT) from GFBio (https://www.gfbio.org/de_DE/plan) for a project proposal. As part of the DMPT, they already asked about which license should be associated with the data. As this is a recognized tool for complying with DMP requirements for e.g. DFG, I was thinking that such an existing tool that uses licenses may make the license model for DSI more acceptable to the wider scientific and policy making community.*

3. **Markus Burchardi (University of Oldenburg, Germany)**
    a. Issue: Representation of the indigenous groups
        - Comments: *[This issue] goes beyond DSI and Benefit-sharing. This topic came up multiple times in the Q&A. I believe there is a case for (proactively) taking this into account in the future. Is there material in the INSDC (the ENA for our purposes) that might be culturally sensitive? If the answer is only slightly yes, the scientific community will have to face related questions sooner or later. The CARE principles for indigenous data sovereignty may be a good first stop: https://www.gida-global.org/care "Be FAIR and CARE" as they say. The Global Indigenous Data Alliance, the US Indigenous Data Sovereignty Network and ORCID Inc. are very active on this front.*
    b. Issue: Policy Option 4 (Common Licenses for DSI)
        - Comments: *I read almost the entire white paper before you started (minus Block-Chain), but I wasn't quite sure whether you want to just build on the CC licenses as inspiration or whether these are actually the licenses that you are proposing for DSI. (?) Some time ago, I had the pleasure to participate in IDigBio's 4th Annual Digital Data Conference at Indiana University and some of the discussions there were overlapping with what we heard today. David Blackburn was talking about data ownership and use agreements (mainly the USC parts on copyright) and reiterated that while many researchers regularly put CC licenses on everything, even on metadata, it doesn't really mean anything. Photographs of certain animals (I am talking Species Occurrence Records in GBIF here) may attract copyright protection. Or drawn maps. But you cannot copyright facts and metadata. Is there a legal case that sequences are protected under copyright law? I do not think so. The whole of the database - that depends on the form. So Option 4 would most likely require some form of sui-generis IP right for DSI. Blackburn noted that user agreements might be the best way forward here. It should also be feasible to regularly integrate specific user agreements from other institutions into download requests (INSDC would have to agree with this, obviously but they could simply pass it along). Just an idea that sounded interesting. Very interesting (but about institutions dealing with online cultural heritage): https://rightsstatements.org/en/*

4. **Szonja Csörgő (Director IP & Legal Affairs) and Anke van den Hurk Chair (Euroseeds Biodiversity Working Group), Euroseeds (see attached)**
    a. Issue: Concerns expressed on behalf of Euroseed and its members concerning the WiLDSI project and Whitepaper

- Comments: *As expressed in a letter dated 2 October 2020 by Euroseeds dated 2 October 2020 accompanied by a Position Paper also dated 2 October 2020 with the title 'The Use of Digital Sequence Information (DSI) and the benefits thereof for the three objectives of the Convention on Biological Diversity'.*

5. **Dr. Joseph Vogel (University of Puerto Rico-Rio Piedras)**
    a. Issue: Concerns regarding insufficient attribution of the terms "bounded openness over natural information" and "jurisdiction shopping"
    b. Comments; As expressed in email correspondence which has been placed in the public domain by the author, dated 11 October 2020, 22 October 2020 (#1), 20 October 2020 (#2), 9 November 2020 and 16 November 2020.

6. **Scientific Council of the Ecology and Environment Institute of the French National Center for Scientific Research (CNRS) CNRS (see attached)**
    a. Issue: Comparison of WiLDSI options and possible negative outcomes on scientific research especially for ecological and biodiversity-related research
    b. Comments: A preference for option 0, followed by option 2.

Written feedback and comments received from expert individuals (summarised and shared on an anonymous basis to respect the participant's privacy)

1. **Concerns regarding participation of indigenous stakeholders relayed by a Senior Government Policy Advisor**

Issue: The Government Advisor was generally supportive of the Whitepaper, however, they relayed a comment received directly from an Indigenous stakeholder that participated in the webinar and expressed concern regarding:

- the representation of the indigenous stakeholders in the discussion surrounding the DSI issue; and
- the manner in which this issue was addressed when this lack of representation was raised in the webinar (paraphrased as "indigenous scientists were not sought out because no time or money and the subject matter is technical") in this context of this particular project, which was construed as dismissive.

The Government advisor noted a lock of participation by indigenous stakeholders in other events focusing on DSI, including events held by or with the funding of Contracting Parties and recommended that initiatives such as WiLDSI find a way to be more inclusive/considerate of this very diverse body of concerned stakeholders.

2. **Concerns regarding attribution by a Researcher from a non-profit civil association promoting environmental policies and legislation in South America**

Issue: The Researcher expressed an opinion that the theory “bounded openness over natural information” which is recorded in the literature and which was also the subject of a side-event at COP 14, has not been appropriately acknowledged and cited in the WiLDSI paper and webinar, despite some of the options appearing to incorporate the theory. Concern was expressed that this appears to continue a trend of other ABS approaches (Mare geneticum, the global commons approach to ABS, bounded research, etc.) which appear to borrow from the theory of “bounded openness over natural information” without due acknowledgement of the theory or credit to the proponents that first articulated this theory.

Euroseeds
Embracing Nature

Position

Brussels, 02 October 2020

The Use of Digital Sequence Information (DSI) and the benefits thereof for the three objectives of the Convention on Biological Diversity

The CBD[1] and its Nagoya Protocol apply to genetic resources (GR) and associated Traditional Knowledge (aTK). In both agreements, the definitions used for GR cover only tangible, functional nucleic acid molecules and not scientific information nor insights developed from genetic resources. Therefore, by definition, intangible digital sequence information[2] (DSI) is out of scope[3] of the CBD and its Nagoya Protocol; DSI cannot constitute a genetic resource.

Continuing to allow access and use of publicly available digital sequence information without administrative burden (and not regulating DSI), will sustain needed innovation. Open and free access to DSI creates a level playing field among public and private entities both in the developed and the developing world.

Not regulating DSI and thus allowing unencumbered access, use and innovation also reduces the time needed to create improved varieties to respond to new challenges like those of climate change and food security.

Not regulating DSI and thus allowing unencumbered access, use and innovation supports efficient conservation and sustainable use of genetic resources themselves.

Given the importance of innovation for ensuring food security, the global trend of exchanging and using sequence information should only be supported and not brought to a halt.

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[1] According to Article 2 of the CBD "genetic resource" is defined as "genetic material of actual or potential value"; and "genetic material" as "any material of plant, animal, microbial or other origin containing functional units of heredity."
[2] Digital sequence information (DSI) is used as a placeholder in the international discussions since the term has not yet been defined.
[3] Euroseeds fully supports the position of ICC, the International Chamber of Commerce, on this matter.

Collaboration and cooperation among countries for food security

The Food and Agriculture Organization of the United Nations forecasts that by 2050 the world's population will have exceeded 9 billion people. This is an increase of 34% compared to the world's population in 2009. The FAO also estimated food production would have to be increased by 70 %, due to the larger, more urban and richer population. Reduction of agricultural land adds further pressures and means that a large part of the increase in food production has to be realized by an increase in yield and cropping intensity. Varieties have to be adapted to local conditions and made more resilient to insects, diseases, viruses as well as more resistant to drought, temperature stresses, and weather extremes from climate change.

In 2015 the FAO Commission on Genetic Resources for Food and Agriculture, emphasized in a publication[4] that to maintain the capacity to respond to these future challenges, agrobiodiversity needs to be maintained and used. Access to Genetic Resources for Food and Agriculture (GRFA) is necessary to address the threats resulting from diseases, pests or changing climates. But in order to achieve and sustain food security, improving the capacity to actually access and use GRFA is critical. The Commission furthermore points out that 'maintaining GRFA is a global task that requires collaboration and cooperation at all levels between all relevant stakeholders.

Collaboration and cooperation are also a recurring theme in the Convention on Biological Diversity and its Nagoya Protocol. For example, in article 10.e of the Convention, where Contracting Parties have committed themselves to encourage cooperation between its governmental organizations and private sector to develop methods for sustainable use of biological resources. In the Annex to the Nagoya Protocol, sharing of know- how, collaboration, cooperation and contribution in scientific research and development programmes are listed as non-monetary benefits.

Good examples of such cooperation are the different public private partnership projects aimed at sequencing specific food crops[5]. With the (financial) support of the private sector, universities and research organisations generate sequence information, which after a short confidentiality period becomes available to the general public worldwide through publications and open access databases. This allows other researchers to apply and build upon these results in their own research, while also improving available sequence information that can generate more biological insights.

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[4] Genetic Resources for Food Security and Nutrition

[5] For examples the Spinach Genome Sequencing Consortium (http://sbc.ucdavis.edu/Research_pages/Spinach/) or the Centre for BioSystems Genomics (http://www.cbsg.nl) or the International Wheat Genome Sequencing Consortium (https://www.wheatgenome.org).

Sequence information exchange supports food security

Ready access to sequence information allows a better understanding of the molecular basis of key agronomic traits, while knowledge of the structure and function of cultivated plant genomes ensures efficient use of limited funds, human resources and most importantly, genetic resources. Better adapted varieties become available in a shorter time frame. It eliminates the need to repeat steps done by others and also the redundant use of scarce genetic resources. It promotes food security world-wide as a global team effort. So, that the focus can be on generating new insights essential for the continued and speedy development of more sustainable agricultural practices to meet the afore-mentioned challenges.

The importance of being able to use available scientific and technical information in research and breeding activities without any burden has clearly been recognized by the Contracting Parties to the CBD. In art. 17 of the CBD, the Contracting Parties to the CBD have committed themselves to facilitate the exchange of information, relevant to the conservation and sustainable use of biological diversity, with an explicit reference to results of technical and scientific research.

Historically, DSI has been made publicly available, unencumbered and free of charge through multiple globally accessible databases. In fact, governments and private actors continue to provide significant and sustained funding for open access public databases. Diverse actors in industry and academia are involved in the generation, storage, curation, dissemination, interpretation and use of DSI globally. Regulation of these processes has been largely self-imposed: the genomics community has a strong history of collaborative data sharing through international research consortia, built on the belief that combining and sharing datasets will accelerate discovery. As another example of successful self-regulation, the policy of the International Nucleotide Sequence Database Collaboration (INSDC) states that "all database records submitted to the INSDC will remain permanently accessible as part of the scientific record".

The benefits of this international collaboration and sharing have provided enormous benefits to society and biodiversity, and it is important that current benefits remain unaffected by the discussions on DSI. Grossly exaggerated expectations of the amount of monetary benefit sharing that will be generated from DSI regulation distract from the more difficult task to quantify the significantly higher non-monetary benefits that are created by plant breeders and others working with agrobiodiversity. Moreover, an effective scheme to regulate DSI is not possible.

On-going wheat sequence information exchange benefits everyone

Consider the critical importance of wheat for food/feed production, nutritional value and food security (most widely grown crop worldwide on over 200 million ha). The International Wheat Genome Sequencing Consortium (IWGSC), with 1 800 members in 62 countries, is an international collaborative consortium, established by a group of wheat growers, plant scientists, and public and private breeders. Its goal is to make a high-quality genome sequence of bread wheat publicly available, in order to lay a foundation for research that will enable breeders to develop improved varieties. It is a global framework for linking genome and genetic analysis to practical breeding and making available new improved varieties for agricultural production.

To efficiently analyse and interpret the bulk of information, many software tools have already been developed, including multiple open-source tools[6]. These tools give researchers and breeders all over the world the possibility to benefit from previously performed research, even those scientists who do not have a lot of resources at their disposal. Expanding the scope of ABS legislation to include the sequence information included in such tools would change the worldwide scientific landscape and will have an immediate negative impact on food production and food security because it will no longer be widely available to all actors in the agriculture sector. Basically, it means going back 20 years in time and reducing the usefulness of modern tools when it comes to assuring food security and conservation of biodiversity, because knowledge generated with those tools can no longer be shared with others.

To allow the sustainable use of genetic resources, these materials need to be characterised and evaluated. The development of genomic, phenotypic and other tools is playing a role in this characterisation and evaluation for both conservation and the adaptation of agriculture production to the challenges. The Nagoya Protocol recognizes the importance of genetic resources for food and agriculture and their special role for food security.

[6] https://en.wikipedia.org/wiki/List_of_open-source_bioinformatics_software

Open and free access to sequence information generates many benefits

Without the ability to screen different genetic resources quickly and cost efficiently, researchers and breeders will in many cases fall back repeatedly on the same genetic resources of which the characteristics are already known to them. Working with the same genetic resources over and over again will however negatively affect the genetic variation of a crop, narrowing its genetic base. While it is the genetic variation that enables plants and animals to adapt and survive in case of a changing environment[7].

Not regulating digital sequence information and thus allowing access, use and innovation creates a level playing field amongst the researchers and breeders in the world. The more limitations or administrative requirements that are imposed on the use of sequence information, the more it will be reserved solely for those researchers and breeders with sufficient funds and resources, which goes counter to the objective of the CBD to consider specifically the needs of developing countries.

Considering the above, Euroseeds is of the view that stretching ABS measures to include digital sequence information would have significant negative impact on the objectives of the CBD, on the already difficult functioning of ABS and on the Sustainable Development Goals (SDGs).

Impact on conservation:

Free access to DSI is essential for ex situ conservation, to identify and eliminate duplicates in collections and reduce cost as well as to ensure that material is being collected and conserved that represents the relevant diversity.

Free access to DSI is needed for in situ conservation, to measure genetic diversity and thereby ensure that we effectively conserve diversity in natural area and in/around the field, and to monitor how it evolves in response to environment changes.

Phenotype observation alone is tedious, expensive and does not provide complete information about diversity.

[7] As mentioned in the 2015 publication of the FAO Commission on Genetic Resources for Food and Agriculture, 'Genetic Resources for Food Security and Nutrition'.

Impact on sustainable use:

Only a very small fraction of collected biodiversity is characterized. If society wants its scientists and breeders to develop climate resilient crops, or address other challenges in food production, more and better characterization of genetic resources is needed, and the free use of DSI is essential.

Impact on SDGs:

Extending ABS to digital sequence information for genetic resources for food and agriculture (GRFA) will hinder achieving the Sustainable Development Goals. Orphan crops, and less productive and less profitable market segments would be among the first to suffer from the complexities and uncertainties created. There will be even less innovation addressing the needs of resource-poor farmers.

Submergence tolerant rice is an example of innovation for resource-poor farmers, enabled by systematic characterization of genetic resources and use of digital sequence information: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3837307/; it is doubtful whether this innovation would have been realized if ABS had applied to digital sequence information.

Impact on capacity building and research

Once information is public, there is no manageable way to constrain the further flow of information. It is valuable for researchers to be able to share their findings that result from academic research projects. E.g. dissertations have to be published. But if no DSI can be revealed, then research will not be realized.

Stretching the scope of ABS frameworks to include DSI should be avoided

In conclusion, for GRFA, expanding the scope of ABS legislation to digital sequence information adds an administrative burden and barrier to effective and beneficial use of such information. In effect, impeding access will substantially and negatively impact conservation, sustainable use and benefit sharing. To reach the objectives of the CBD and support the SDGs, any measures that stretch the scope of the CBD and other ABS frameworks to include DSI should be avoided.

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Ms Amber Scholz
Mr Jens Freitag

2 October, 2020

Subject: Euroseeds comments on WiLDSI project and upcoming event

Reference: 20.0614

Dear Amber,

Dear Jens,

We are writing to you on behalf of Euroseeds and its members, including many scientists involved in plant breeding. We formally express our serious concerns about the process and outcome of the white paper on Digital Sequence Information that will be presented at the October 7, 2020 webinar "Finding compromise on ABS & DSI in the CBD: Requirements & policy ideas from a scientific perspective", and shared only the day before.

Anticipating an incomplete outcome: We appreciate the considerable effort by the WiLDSI project to organize the workshops. As expressed in the workshop in July, many of our members were concerned by the unwillingness to include the option of open, free access to non-confidential DSI to promote significant in-kind benefit sharing and conservation of biodiversity. During the early workshops in the beginning of this year, *many scientists, including pure academics with considerable field experience from around the world, voiced repeated concerns that increased monetary benefit sharing requirements and the associated uncertainties would impede scientific investigation and not help conservation of biodiversity. These fundamental concerns have not been addressed.* As the project continued, workshop participants were insistently told that truly open access was not an acceptable option. We therefore anticipate with concern that the White Paper reflects an incomplete set of recommendations that ignores and/or distorts the thoughtful input from many scientists in a way that does not deserve the label "compromise". Although we have not seen a final draft of the White Paper, based on the previous experience, we sense that our input has been marginalized.

Additional process concerns: We are also concerned about other parts of the process. We feel that the title "policy ideas from a scientific perspective" might not provide the correct impression about the background and origin of the proposals, since most presenters are actually from some public academic and public research institutes. The private sector and input from scientists who are for continuing open access, have been marginalized. Moreover, the White Paper was not shared sufficiently in advance of the webinar to allow for meaningful preparation. We are concerned about the undue sense of pressure to have a unilateral conclusion without a fair discussion; in other words, the process has become top-down and not a compromise from the stakeholders concerned.

Adding our scientific perspective: To give a more complete scientific perspective, please find attached a more complete explanation of the need to keep the access and use of publicly available digital sequence information without administrative burden and regulation in order to sustain the needed scientific innovation. Open and free access to DSI facilitates public-private partnerships. Open and free access to DSI creates a level playing field among public and private entities around the world; greater regulation will not bring the benefits that some imagine. Allowing unregulated, free access to sequence information (and other forms of data), supports efficient conservation; promotes sustainable use of genetic resources themselves; and reduces the time needed to create improved plant varieties to respond to new challenges like those of climate change and food security. These benefits are core to the basic interests for all parties to the CBD.

We are confident that you are going to give due consideration to the above expressed concerns and clearly note this during the upcoming event and into the future.

Respectfully,

Szonja Csörgő
Director IP & Legal Affairs

Anke van den Hurk
Chair Euroseeds Biodiversity Working Group

COMITE NATIONAL DE LA RECHERCHE SCIENTIFIQUE

Conseil scientifique de l'Institut écologie et environnement (INEE)

Recommandation sur l'extension du mécanisme « Accès et Partage des Avantages » aux Digital Sequence Information.

Le conseil scientifique de l'InEE a pris connaissance de la volonté de la COnférence des Parties (COP) de la Convention sur la Diversité Biologique (CBD), de débattre de l'extension du mécanisme « Accès et Partage des Avantages » (APA, Protocole de Nagoya) aux données de séquençage issues des ressources génétiques (DSI pour 'Digital Sequence Information'). Ceci concerne les séquences d'ADN et d'ARN, mais éventuellement aussi (discussion encore en cours sur la définition et les limites des DSI) la structure des protéines et les composés biochimiques, non couverts par le Protocole de Nagoya.

Actuellement la recherche publique internationale produit, diffuse et utilise les ressources génétiques et leurs dérivés selon les deux principes « open access » (libre diffusion) et « FAIR » (Findable, Accessible, Interoperable, Replicable). Le CS de l'InEE souhaite alerter la communauté scientifique, en particulier celle produisant et utilisant ce type de données, et l'ensemble des instances de décision sur le fait que l'application de l'APA aux données moléculaires issues de la ressource génétique, en mettant un frein considérable à leur accès libre et gratuit, aurait un impact négatif fort sur toutes les recherches publiques, menées dans de nombreux domaines scientifiques (y compris dans les domaines de l'écologie et de l'environnement), réalisées avec ce type de données.

Le CS de l'InEE souhaite que la France défende le maintien des conditions actuelles dans les négociations à venir. Cette position correspond à l'option 0 ou « statu quo » dans les différentes options proposées par le groupe de travail « WiLDSI project ». Si ce statut quo s'avérait impossible, l'option la moins pénalisante, et à négocier impérativement pour la recherche publique, serait l'option 2 » (voir les différentes options en cours de négociation en pièce jointe) qui prévoit le paiement d'une adhésion annuelle uniquement dans le cadre d'une utilisation commerciale (et non pour la recherche académique) qui abonderait un fond commun international.

Patricia GIBERT
Présidente du CSI INEE

Recommandation adoptée le 18 Janvier 2021 :
23 votants : 22 oui, 0 non, 1 abstention

Destinataires :

- Mme Frédérique VIDAL, ministre de l'enseignement supérieur, de la recherche et de l'innovation ;
- Mme Barbara POMPILI, ministre de la transition écologique ;
- Mme Bérangère ABBA, secrétaire d'état auprès de la ministre de la transition écologique, chargée de la Biodiversité ;
- M. Antoine PETIT, président directeur général du CNRS
- M. Alain SCHUHL, directeur général délégué à la science du CNRS
- Mme Anne LARIGAUDERIE, secrétaire exécutive de la Plateforme intergouvernementale sur la biodiversité et les services écosystémiques (IPBES)

Copie :
- Mme Stéphanie THIEBAULT, Directrice de l'Institut écologie et environnement du CNRS
- Mme Amber HARTMAN-SCHOLZ, Directrice adjointe de la DSMZ-Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH
- Mesdames les présidentes et messieurs les présidents des conseils scientifiques d'Institut du CNRS
- Mme Dorothée Berthomieu, présidente du Conseil scientifique du CNRS

Annexes à la Recommandation sur l'extension du mécanisme « Accès et Partage des Avantages » aux Digital Sequence Information.

Description des 5 options WiLDSI dans le rapport :

https://www.dsmz.de/fileadmin/user_upload/Presse/WILDSI/Final_WiLDSI_White_Paper_Oct7_2020.pdf

OPTION 1 MICRO-LEVY

Option 1 separates access to DSI from monetary benefit-sharing and instead **collects funds earlier in the R&D process by charging micro-levies on DSI-related charges.** Micro-levies are small charges on high-volume purchases that should not impact the behavior of the purchasing customer. The DSI micro-levy could for instance be linked to aspects of DSI generation and be applied, for example, to DNA sequencing/synthesis services, laboratory reagents, or equipment. Option 1 is **very simple**, is likely to generate significant funding relatively quickly, and completely leaves the status quo open access system intact. **However, micro-levies require national legislation to implement and can be unpopular domestically.** Also, for some Parties, access and benefit-sharing might be perceived as too disconnected.

OPTION 2 MEMBERSHIP FEES

Option 2 would require annual "membership" fees for users of the global DSI dataset **that have sales/income above a specified threshold**. This would mean that **academic (non-commercial) users would generally not pay a membership fee. Access to DSI is NOT behind a paywall – a financial barrier that precedes/prevents access.** Instead, the conditions of use of the databases (e.g. INSDC) would remind users of potential monetary obligations and any monetary payments would be collected by a separate entity. Compliance could be supported by use of the patent disclosure system where DSI is already listed and disclosed. It would not be important to track and trace these sequences but rather it provides **a yes/no check if DSI was used.** Option 2 reflects benefit-sharing discussions under the IPTGRFA. Option 2 is a relatively **simple, easy-to-understand system already discussed by other international fora,** however compliance mechanisms are somewhat weak and negotiating the monetary obligation threshold would likely be contentious.

OPTION 3 CLOUD BASED FEES

In option 3, a **new cloud-based platform for DSI** would be offered **for users seeking legal certainty and "power user" services.** This new system would be **offered on top of the core DSI infrastructure.** The cloud platform would offer **advanced services (e.g. storage, analytics, sector-specific workbenches, etc.) for fees based on, for example, the amount of DSI use or storage or access to specialty features.** The **normal (status quo) open access to DSI via INSDC would remain in place** but cloud portals would additionally offer users full legal certainty and advanced features that are otherwise cost-inefficient for users to build by themselves. A cloud-based system is scalable, responsive, and fees can be directly tied to usage. However new infrastructure costs are likely which would need to be recaptured and non-commercial users might pay proportionally more in this option than in others.

OPTION 4 COMMONS LICENSES FEES

In option 4, Parties could require DSI producers and users to associate a **standardized license to any DSI placed in an open-access database**. A small set of standardized licenses based on open-software commons licenses would be negotiated and direct users on their ABS obligations. Databases would

need to allow licenses to be associated with DSI and **users themselves would need to track and trace DSI** used during utilization and adhere to the conditions in the license. Monetary benefits could be triggered at the point of access for certain users or at the time of commercialization. **Alternatively, a commons license could require users to upload DSI to cloud-based infrastructures (option 3).** Commons licenses are widely proven to work in the field of open-source software development and an entire ecosystem (bigger than ABS) runs on these licenses. However, this option requires the users to track and trace the use of their DSI which, would be challenging. Furthermore, negotiating standardized licenses at the international level might be challenging.

OPTION 5 METADATA & BLOCKCHAIN

Option 5 uses **blockchain technology** not on DSI itself but rather **on the associated legal and scientific metadata -- a "hybrid blockchain" option.** While the DSI itself would continue to be submitted to the core database infrastructure, **certain scientific and legal metadata which would be put into a blockchain layer of records and access would be monitored and controlled**, thus allowing the **tracking of events of data access.** Monetary benefits could be triggered at defined points in the R&D process if events are registered in the blockchain system. Option 5 requires **significant upfront technological investment and costs**, while generation of funds is unknown and likely to be longterm creating a possible imbalance in operating costs. **Option 5 responds to calls for tracking and tracing and bilateralism, but has not yet been proven for use in ABS.**

Le tableau comparatif des options WilDSI :

Table 1. Comparison of key aspects of the 5 policy options

Policy option	1. Micro-levy	2. Membership Fees	3. Cloud-based fees	4. Commons Licenses	5. Blockchain
What DSI is affected?	no effect	All non-human DSI; the whole dataset	All non-human DSI in the database imposing cloud-based fees	All DSI would be tagged with 1 of 4 licenses including retroactively on DSI already in the databases	DSI-associated metadata from Parties claiming sovereign rights
Tracking/tracing required?	No	No	No	Yes	Yes
Jurisdiction shopping possible?	Yes if unevenly implemented	No	No	Yes	Yes
Changes to open access	No. Fees are paid upstream in the DSI generation and research process.	For users below an income threshold, open access use is unchanged. For users above threshold, fees apply.	Status quo access option offered in parallel to a fee-based cloud option that offers legal certainty and advanced user services	Minimally. Licenses with conditions would be applied to all DSI.	Normal open access to DSI offered in parallel to blockchain on legal/scientific metadata
Multilateral or bilateral	Multilateral	Multilateral	Multilateral	Bilateral with multilateral opportunities to standardize licenses	Bilateral with multilateral opportunities to standardize (legal) conditions
Who pays? When?	"Consumers" of particular DSI-related products/services	Annual membership fee paid by users above an income threshold	User pays depending on data use (pay as you go)	Depends on intended use of DSI defined in license option(s)	Defined by the terms in the legal agreements
Legal certainty	Through receipt on payment of micro-levy on DSI products/services	Through membership annual payment	Through use of cloud platform	Established in 4 standardized licenses	Provided by a blockchain layer of records and access management system through identifiers, audit logs and smart contracts.
Compliance	Proof of payment of micro-levy	Monitoring activity likely needed	Monitoring activity likely needed	Monitoring activity likely needed	Through registering transactions in blockchain, smart contracts
Who receives funds?	Multilateral fund for biodiversity and infrastructure	Multilateral fund for biodiversity and infrastructure	Multilateral fund for biodiversity and infrastructure	Individual Parties (depending on contracts)	Individual Parties (depending on contracts) or a multilateral fund for biodiversity and infrastructure
How long until funds accumulate?	Short-mid-term	Short-mid-term	Mid-term	Long-term	Long-term
Opt-in GR possible?	Yes	Yes	No	Yes	Maybe
Simplicity	Simple	Simple	Complex	Simple	Complex