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Briefings for UN 1 Biodiversity Conference

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“Digital DNA” and Biopiracy: Protecting Benefit-Sharing as Synthetic Biology Changes Access to Genetic Resources

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Synthetic biology is transforming access to genetic resources. While yesterday’s biopirate hid seeds in his luggage, tomorrow’s gene thief may smuggle her loot on a thumb drive ... or upload it to the cloud. With guidance from the Convention on Biological Diversity (CBD) and its Nagoya Protocol, access and benefit-sharing (ABS) laws urgently need to adopt updated approaches to address this emerging reality, and public databases hosting genetic sequence data must be obliged to ensure that “open access” does not mean trampling on the rights of provider countries.

Technological Transformation of Access to Genetic Resources

Today, the easiest place to see the technological transformation currently underway is with the smallest organisms. In the health sector, cheap, deep, and fast gene sequencing means that the full sequence of influenza viruses can be determined within hours of their isolation. And if that sequence is uploaded into an Internet database, or sent attached to an e-mail, gene synthesis technologies make it possible to recreate a living virus in under three days, at an appropriately equipped lab anywhere in the world.

In fact, today, some virus samples can be shared more quickly through the medium of digital sequence data than a physical sample – with an accompanying material transfer agreement – can be shipped across the world by a courier such as

DHL. To put it concisely, digital access to some small organisms today is “Faster than FedEx.”

And at the same time, the complexity of organisms (measured by the size of their genome) that can be synthesized from a digital sequence is increasing. Poliovirus, the first virus to be wholly synthesized in the lab, in 2002, is about 7,500 nucleotides long. Ten years later, in 2012, a 14,500 nucleotide influenza virus could be synthesized in under 72 hours (with the help of a technique called reverse genetics) – more than twice as large and far faster. Most recently, in November 2016, an American scientific team announced whole synthesis of adenovirus, with a genome of 34,000 nucleotides, more than two times the size of influenza and four and a half times that of poliovirus.

Of course, it is presently not possible to synthesize from scratch more complex organisms such as crop seeds and medicinal plants, but that may never be necessary. By combining sequence data with gene editing technologies, such as CRISPR/Cas9, genetic diversity from one place can be introduced in organisms in another without physical access taking place, and without a material transfer agreement.

For example, corporate crop breeders interested in making tomatoes¹ more tolerant of salty conditions

¹ Tomatoes are not among the crops listed in Annex 1 of the International Treaty on Plant Genetic Resources for Food and

might turn their attention to the genetic sequences of tomato plants from the Galapagos Islands and coastal areas of Ecuador and Peru. With enough genetic data, they might identify mutations that make the plants salt-tolerant, from the digital sequences of these tomato plants. Gene editing techniques can then be used to introduce those mutations into commercial cultivars for sale in North America or Europe.

Salt-tolerant tomatoes are merely a hypothetical example, but the number of other traits in other crops that might similarly be accessed through data, and not physical transfer of materials, is practically infinite. Centres of diversity of crops and other species thus may unwittingly be allowing access to their genetic resources when gene sequences of their biodiversity are placed online without adequate controls.

Another example is genes that encode active compounds in medicinal plants, which could be used to manufacture pharmaceuticals. Rather than physically accessing the plant, a company might access the plant's sequence on an Internet database, or via an e-mail from an allied researcher. The company may then adjust ("optimize") that sequence for expression in fermentable microbes and become able to manufacture the medicinal compound – all without ever accessing the material, and without ever signing a material transfer agreement and making benefit-sharing commitments.

Notably, this means that exports of non-reproducing biodiversity samples for scientific research, e.g. "killed" or lyophilized plant tissue or microbial cultures, can effectively be the same as exporting viable organisms. If "dead" samples are sequenced and that data then used by synthetic biologists, entire microorganisms and/or key traits from more complex species can be brought back to life.

Arrival of ABS and (Digital) Genetic Sequence Data on the International Agenda

The far-reaching impact of the combination of advanced sequencing and synthesis technologies, particularly CRISPR/Cas9, is simultaneously arriving on the agenda of at least three international discussions. Of these, the discussion

of genetic sequence data (sometimes called "digital sequence data") by the CBD is certainly the most important as it is the overarching agreement on biodiversity to which other efforts seek harmony and consistency.

While the implications of genetic sequence data (GSD) have been informally discussed and anticipated for several years, the origin of the present discussion by the CBD is found in the report of the Ad Hoc Technical Expert Group (AHTEG) on Synthetic Biology,² which identified this important synthetic biology impact – "*access without benefit sharing*" - on the Convention (p. 9).

The AHTEG's report was further discussed by SBSTTA-20. There, Northern delegations, particularly Japan, Canada, and some European countries, launched an effort to derail the CBD's consideration of GSD by using a procedural argument – one that cloaks an intent to stop discussion of the issue altogether.

Those Northern countries argued that the Synthetic Biology AHTEG could not offer technical analysis on ABS-related aspects of synthetic biology because that was the domain of the Nagoya Protocol. But this argument misrepresents the reality that the AHTEG was convened and expected to consider technical advice on impacts of synthetic biology across the Convention, including not only potentially ABS-related issues but also biosafety-related considerations relevant to the Cartagena Protocol on Biosafety.

Developing countries and a smaller number of Northern countries supported a "two-step process" wherein the Synthetic Biology AHTEG would consider GSD at its next meeting. The AHTEG would spell out the technical implications ("elements") for ABS of the combination of gene sequencing and gene editing and then submit its findings to the Nagoya Protocol for consideration and (presumably) policy action by its COP-MOP.

In the two-step process, the GSD issue will arrive at the Nagoya Protocol ripe for prompt action by the COP-MOP, with the underlying technical work already accomplished by the AHTEG. (And, indeed, technical analysis of the implications of synthetic biology across the Convention is precisely the AHTEG's *raison d'être*.)

Agriculture and, thus, access and benefit-sharing for the crop falls under the CBD.

² UNEP/CBD/SYNBIO/AHTEG/2015/1/3

The two-step process remains in brackets in the draft COP decision.³ It is imperative that COP13, meeting in Cancun from 4th to 17th December 2016, remove these brackets and include, in the Terms of Reference for the Synthetic Biology AHTEG, a charge to develop elements for the Nagoya Protocol.

Specifically, this means **removing the brackets presently found in paragraph (o) of the draft decision AND removing the brackets in subparagraph 1(e) of the Terms of Reference for the Synthetic Biology AHTEG.** Both sets of brackets must be removed in order for the two-step approach to take effect. (The draft decision is under Agenda Item 17, Synthetic Biology.)

Parties should welcome this two-step approach and may consider adding specificity to the AHTEG's charge with respect to the ABS implications of gene sequencing and synthesis.⁴

The North Tries to Bury the Issue by Sleight of Hand

It is important to understand the strategy and motivation of many Northern countries in seeking to stop the AHTEG from considering GSD. It is part of a strategy to stop all discussion of genetic sequence data under the CBD. These countries seem determined to first prevent the AHTEG from considering GSD by incorrectly claiming that the AHTEG is not positioned to provide technical advice on ABS-related issues. Then, when the GSD issue is brought into the Nagoya Protocol, many of the same countries plan to say that genetic sequence data is outside the Protocol's scope. In this way they hope to prevent action.

For example Japan, with support from Canada, openly stated at SBSTTA-20 that it believes that sequence data are outside the Convention and thus cannot be discussed. Privately, representatives from some European countries have said that they agree. By seeking to stop or delay action as long as possible, these countries will allow more and more genetic sequence data to be generated and distributed in online databases, which their

companies and research institutes could then take advantage of. Once posted and distributed in databases without access conditions, the more difficult enforcing benefit-sharing obligations for this data becomes.

This sleight of hand – trying to prevent AHTEG discussion by saying the Nagoya Protocol should discuss it, only to try to kill the issue inside the Nagoya Protocol by saying it is outside the Protocol's scope – cannot be allowed to happen if developing countries wish for equitable sharing of benefits from the use of their biodiversity.

Consideration Elsewhere: WHO and FAO

In addition to discussions at the CBD, the question of access and benefit-sharing and genetic sequence data for some specific circumstances is being discussed at both the World Health Organization (WHO) and by the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) of the Food and Agriculture Organization (FAO).

In the first case, because vaccine and other influenza viruses can be transmitted digitally in the form of sequence data, WHO is considering how to implement the Pandemic Influenza Preparedness Framework (PIP Framework) in the face of this new reality. Consideration of the issue by WHO has included attention to the terms of access to scientific databases, and consideration of if and how user access agreements to those databases might be used to ensure benefit-sharing.

The PIP Framework is an international access and benefit-sharing arrangement specific to potentially pandemic influenza viruses (and not all influenza viruses) and is the most advanced specific discussion of ABS issues at the WHO. Member States of the WHO, however, have noted that the Nagoya Protocol has wider potential relevance to human health, for example, access to samples of other pathogens, and plant sources of medicines, and has commissioned a report on the Protocol to be considered at its next meeting.

Questions about ABS for genetic sequence data have also arisen in recent meetings of the Governing Body of the ITPGRFA and, at its last meeting, the Governing Body referred the issue for consideration by the Ad Hoc Open-ended Working Group to Enhance the Functioning of the Multilateral System of Access and Benefit-sharing.

³ See pages 122–125 of the Draft Decisions for COP 13 (UNEP/CBD/COP/13/2).

⁴ A more detailed account of the SBSTTA's discussion may be found at: Hammond E 2016. Synthetic biology debate ahead of biodiversity treaty's top meeting. TWN Information Service on Sustainable Development, 6 May. URL: <http://www.twn.my/title2/unsd/2016/unsd160502.htm>

This Working Group has, in turn, requested a report on the issue for its next meeting, planned for March 2017.

Ultimately, it is necessary that the approaches to ABS for GSD that are taken by the WHO and ITPGRFA be highly consistent with that of the CBD, the overarching agreement applicable to all biodiversity. The need to avoid inconsistent international treatment of access and benefit-sharing for GSD underscores the importance of the CBD taking up this issue quickly and effectively, to ensure that coherence is achieved between the different but related international processes.

Conclusion

Avoiding wholesale digital theft of genetic resources requires developing countries to overcome the economically motivated and self-interested positions of the Northern countries who seek to undermine CBD principles by delaying and derailing discussion of how to ensure that synthetic biology does not undermine 25 years of efforts to implement the Convention's access and benefit-sharing provisions.

Concretely, this means that COP13 should provide the Synthetic Biology AHTEG with a mandate to develop technical analysis and to forward that analysis to the Nagoya COP-MOP for it to take policy decisions and make recommendations.

Stopping digital biopiracy is an issue that will continue to gain importance on the international agenda, particularly at the CBD, and it is important that the CBD's discussion advances quickly, so that developing countries' rights are not harmed by more years of "open" sharing of genetic sequence data in ways that are irresponsible toward provider countries and provider peoples.

Early discussions among experts suggest that much more careful attention must be paid to data access agreements at online databases, including so-called "open access" databases. Creating more specific user agreements with legally-binding access and benefit-sharing stipulations may be necessary in order to prevent a digital DNA "darkweb" where genetic resources are distributed and claimed in violation of access and benefit-sharing principles and rules.