Executive Secretary
Convention on Biological Diversity
United Nations Environmental Program

September 8, 2017

Submission of views and information pursuant to decision CoP XIII/16, paragraph 2, and to Nagoya Protocol NP- 2/14: digital sequence information[1]

Submitted electronically to secretariat@cbd.int

The Institute for Agriculture and Trade Policy (IATP) appreciates this opportunity to submit a short comment on an issue of critical importance before the Conference of the Parties (CoP) to the Convention on Biological Diversity (CBD). IATP is a non-profit, non-governmental organization (501.c3, in U.S. law) headquartered in Minneapolis, MN (U.S.) with offices in Washington, DC and Berlin, Germany.

We offer the following comment on digital sequence information to the CBD to assist it "at the fourteenth meeting of the Conference of the Parties and the third meeting of the Parties to the Nagoya Protocol [concerning] any potential implications of the use of digital sequence information on genetic resources for the three objectives of the Convention, and for the objective of the Nagoya Protocol, respectively."[2] IATP was very engaged in the negotiations leading to the Cartagena Protocol on Biosafety.[3] IATP's most recent communication to the CBD on synthetic biology is from April 30, 2015.[4] Our most recent regulatory comment to the U.S. government on synthetic biology is from June 30, 2017.[5]

As discussed in that comment and a related blog, the Biotechnology Industry Organization and the U.S. Biotech Trade Alliance are lobbying the Trump administration for a policy on agricultural synthetic biology that will enable trade in products derived from synthetic biology techniques based on a proposed regulatory framework that the U.S. Department of Agriculture has itself characterized as policy based, rather than science based. For a forthcoming rule, the USDA has proposed not to collect and evaluate field trial data for most such products.[6] Indeed, USDA approved a gene-edited moth in July 2017, although its product developers would not release cage trial data for peer review before they released the moth into the open environment.[7] The scientific evidence points to the unreliability of kill switches that are supposed to prevent non-target effects of GE products.[8] However, the policy imperative is to commercialize products derived from gene editing techniques even without peer-reviewed data to evaluate risk of those techniques and their products in their life cycles.

The USDA is fulfilling a prediction made by a synthetic biology biosafety research team in 2014: "Synthetic biology and other new genetic engineering techniques will likely lead to an increase in the number of genetically engineered plants that will not be subject to review by USDA, potentially resulting in the cultivation of genetically engineered plants for

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field trials and commercial production without prior regulatory review for possible environmental or safety concerns."[9] European biotechnology companies and some EU member state governments argue, on legal and commercial grounds, that food and agricultural products derived from New Plant Breeding Techniques should be exempted from EU laws governing genetically modified organisms.[10] Consumer organizations have opposed lobbying initiatives to exempt food and agricultural products derived from new genetic engineering techniques from rules governing GMOs, since, among other reasons, those techniques fall under the definition of "modern biotechnology" of the Codex Alimentarius Commission.[11]

The 14th CoP, to promote the realization of the objectives of the CBD and not be pre-empted by deregulatory and non-regulatory pressures, inside and outside the United States,[12] to commercialize and trade products derived from synthetic biology in advance of their risk assessment, must consider whether to amend the terms of Annex III on Risk Assessment of the CBD, and to amend the Cartagena Protocol definition of Living Modified Organism (LMO). One aspect of these amendments will concern what new guidance may be needed to help CBD Members assess the risks of LMOs synthesized from digital sequence information derived directly or indirectly from biological materials.

Insofar as some products of synthetic biology are derived from digital information sequences, rather than from physical germplasm, it is urgent that the 14th CoP take a Decision on the legal status of digital sequence information to enable realization of the objectives of the CBD, and particularly Access and Benefit Sharing (ABS), as defined in the Nagoya Protocol. Sequence data include DNA, RNA, and/or amino acid sequences, as well as the accompanying characterization information for those sequences. Current ABS governance in domestic regulation is implemented through a material transfer agreement (MTA) that requires signing of the agreement prior to transfer of the biological materials containing DNA, RNA or amino sequences and characterization information.

However, MTAs are already subject to abuse and circumvention.[13] The cross-border transfer of digital sequence data can occur via the internet or even on a bootlegged thumb drive. Transferred data can be subsequently be synthesized as LMOs either for non-commercial research or commercial purposes. Under the current terms of the CBD and the Nagoya Protocol, such data transfers and their "booting up" as LMOs will circumvent the current ABS and Prior Informed Consent (PIC) requirements of the Nagoya Protocol.

The simplest form of circumvention is to claim that utilization of digital sequence data is not "access" to genetic resources, and therefore no PIC or ABS for use of those data are required. A corollary, though unproven, argument for not recognizing and meeting PIC and ABS obligations is that to do so will inhibit innovation.[14] Such circumvention, however commercially advantageous in the short term, will deprive CBD Members of adequate resources to conserve *in situ* and *ex situ* the genetic resources and traditional knowledge about those resources upon which digital information sequences depend directly or indirectly.

To achieve the CBD's objectives, particularly regarding ABS, and to prevent the potential misappropriation of genetic resources via circumvention in the digital sequencing of those

resources without PIC and ABS agreements with the country of origin of those resources, IATP urges the following actions be taken:

1. The Digital Sequence Information (DIS) AHTEG should recommend, at its February 13-15, 2018 meeting, to the SBSTTA that sequence data be understood as equivalent to the physical material of LMOs, since such data are derived directly or indirectly from physical material, whether or not they are subsequently synthesized as an LMO. This recommendation should be based on an evaluation of whether non-target or off-target effects of LMOs synthesized from digital sequence information[15] can be adequately risk assessed under the Annex III principles and with an amended definition of LMO that takes into account the increasingly widespread practice of synthesizing LMOs from sequence data. As noted by Dr. Hiroshi Yoshikura, the former Chair of the Codex Task Force on Foods Derived from Modern Biotechnology, in the CBD's electronic Synbio Forum, "the principles delineated in Annex III, Risk Assessment, of CBD, particularly, bullet points 5 and 6, are fully applicable to synthetic biology, because any product of synthetic biology coming in [the] near future will be derived from existing living organism(s) and because synthesized sequence(s) can be evaluated for the potential risk by comparing with existing genetic sequences; namely comparative safety assessment on a case-by-case basis proposed in the Annex is applicable."[16]
2. After review of the DIS AHTEG report, the SBSTTA should recommend to the 14th CoP that the CoP decide in principle that sequence data be understood as equivalent to the physical material of LMOs.
3. That Decision should include a request to the SBSTTA to propose a revision of Appendix III on Risk Assessment that incorporates the CoP Decision on sequence data.
4. That Decision should include a request to the MoP of the Cartagena Protocol to revise the Cartagena Protocol's definition of LMO consistent with the CoP's Decision on sequence data.
5. That Decision should include a request that the DSI AHTEG and the Executive Secretary prepare a report for the SBSTTA on possible risks of cross-border invasive species of LMOs synthesized from cross-border transfer of digital sequence information.
6. That Decision should include a request that the DSI AHTEG and the Executive Secretary prepare a report for the Subsidiary Body on Implementation on possible impacts, including socio-economic impacts, on the sustainable use of biological resources converted into digital sequence information and subsequently to LMOs.
7. The CoP should instruct the MoP of the Nagoya Protocol to request that its ABS Expert Group advise the MoP on how to revise the text of the Protocol and how to implement the Protocol, particularly through the ABS Clearing-House, consistent with the CBD Decision on sequence data.
8. The CoP should instruct the Executive Secretary to request information from CBD Members about governmental and non-governmental repositories of sequence data

and information within their jurisdictions. CBD Members should also inform the Executive Secretary about voluntary guidance and mandatory rules governing access to and utilization of sequence data in their jurisdictions, including agreements on the cross-border transfer and utilization of such data.

9. The Executive Secretary should use the information received from Members under action item 8 to write a report for the CoP to develop rules for digital sequence data repository access and utilization. That report may also be used to help amend the Nagoya Protocol's model contract for ABS to include use of digital sequence information per the Decision recommended in action item 2.
10. The Executive Secretary should recommend to Members that the 14th CoP include a meeting open to all Member delegates on the gene foundry and synthesis equipment industries – companies that specialize in manufacturing synthesis equipment and in providing synthetic sequences to product developers. Because these industries are largely unregulated, the CoP should consider requesting the Executive Secretary and DIS AHTEG to prepare a report on the industries. This report, plus information requested from CBD Members and stakeholders on gene foundries and synthesis equipment, will inform a possible future CoP Decision on authorizing work to develop CBD rules on how Members should regulate those industries, both in their jurisdictions and with regard to cross border data sequence transfer, to achieve the objectives of the CBD.
11. The CoP should request that the CBD Executive Secretary communicate to all relevant intergovernmental organizations its Decision on sequence data, the proposed steps towards implementation of that Decision and the possible consequences of the Decision for ABS among CBD Members.
12. The CBD Executive Secretary should request the Secretariat of the Commission on Genetic Resources for Food and Agriculture (CGRFA) of the Food and Agriculture Organization of the United Nations that the Executive Secretary be invited to collaborate in the organization of the international workshop on ABS recommended by the CGRFA ABS Expert Team.[17] The CBD Executive Secretary should request that this workshop include a discussion of digital sequence information, as was begun by the CGRFA ABS Expert Team at its September 2016 meeting.[18]
13. The CBD Secretariat should recommend to the 14th CoP that the next MoP of the Nagoya Protocol agree on a further specification of the term "utilization" in the Protocol and for use in the ABS Clearing House, the ABS model contract and elsewhere in the CBD. Further specification, including the CBD's understanding of the utilization of digital sequence information, will help the CBD respond to the CGRFA ABS Expert Team's view that "the Nagoya Protocol does not provide any specific guidance as to the nature or type of research and development activities covered by the term "utilization"[19] as they are applied generally, and more specifically to genetic resources for food and agriculture.
14. The CBD Secretariat should request the CGRFA Secretariat to invite Nagoya Protocol ABS experts to discuss the CBD's work on and definitions of the utilization of digital sequence information at the CGRFA international workshop recommended by the CGRFA ABS Expert Team.

The Institute for Agriculture and Trade Policy thanks the Executive Secretary for its consideration of these proposed actions to assist the 14th CoP as it deliberates on how to ensure that scientific developments and regulatory practices governing the use of digital sequence information support—or at least do not impede or pre-empt—the realization of the CBD's objectives. We look forward to further electronic collaboration with the Executive Secretary and the CoP.

Respectfully submitted,

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[1] https://www.cbd.int/doc/decisions/cop-13/cop-13-dec-16-en.pdf

[2] https://www.cbd.int/doc/notifications/2017/ntf-2017-037-abs-en.pdf

[3] E.g. Gurdial Singh Nijar, Kristin Dawkins and Neil Sorensen, "Developing a Liability and Redress Regime for the Cartagena Protocol on Biosafety," Institute for Agriculture and Trade Policy, 2000. https://www.iatp.org/files/Developing_a_Liability_and_Redress_Regime_unde.pdf

[4] "Comment for the Convention on Biological Diversity's Substantive Body on Scientific, Technical and Technological Advice (SBSTTA) in response to Conference of the Parties (CoP) Decision XII/24: New and emerging issues: synthetic biology," Institute for Agriculture and Trade Policy, April 30, 2015.

[5] https://www.iatp.org/sites/default/files/2017-07/APHIS%20biotech%20comment%206.19.17%20FINAL.pdf

[6] Steve Suppan, "The biotech trade empire strikes back—at USDA!" Institute for Agriculture and Trade Policy, July 13, 2017. https://www.iatp.org/blog/201707/biotech-trade-empire-strikes-back-usda

[7] Tara MacIsaac, "GM Moths Released in the U.S. for the First Time" A Major Step for 'Frankenbugs," *The Epoch Times*, September 6, 2016. http://www.theepochtimes.com/n3/2292029-gm-moths-released-in-us-for-first-time-a-major-step-for-frankenbugs/

[8] E.g. "Currently available safety locks used in genetic engineering such as genetic safeguards (e.g. auxotrophy and kill switches) are not yet sufficiently reliable for SynBio. Notably, SynBio approaches that provide additional safety levels, such as the genetic firewalls, may improve containment compared with classical genetic engineering. However, no single technology solves all biosafety risks and many new approaches will be necessary."
http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_048.pdf at 6.

[9] Sarah R. Carter et al., "Synthetic Biology and the U.S. Biotechnology Regulatory System: Challenges and Options," J. Craig Venter Institute, May 2014, 24.
http://www.jcvi.org/cms/fileadmin/site/research/projects/synthetic-biology-andthe-us-regulatorysystem/full-report.pdf

[10] E.g. "Legal Briefing Paper: The regulatory status of plants resulting from New Breeding Techniques," NBT Platform, April 9, 2014. https://www.infogm.org/IMG/pdf/nbt-plateform_statut-ogm_avril2014.pdf and "Proposal for discussion on actions to improve the exemption mechanism under Directive 2001/18/EC 1," Government of the Netherlands, September 1, 2017. http://extranet.greens-efa-service.eu/public/media/file/1/5283

[11] "Resolution on consumer concerns about new genetic engineering techniques," Trans Atlantic Consumer Dialogue, September 7, 2016. http://tacd.org/wp-content/uploads/2016/09/TACD-Resolution-new-genetic-engineering-techniques_with-appendix_7-September.pdf

[12] E.g. "The regulatory status of New Breeding Techniques in countries outside the European Union," Schuttelaar and Partners, June 2015. http://www.nbtplatform.org/background-documents/rep-regulatory-status-of-nbts-oustide-the-eu-june-2015.pdf and "Biotech Ambassadors: How the U.S. State Department Promotes the Seed Industry's Global Agenda," Food and Water Watch, May 2013. https://www.foodandwaterwatch.org/sites/default/files/Biotech%20Ambassadors%20Report%20May%202013.pdf

[13] E.g. Tasnia Bubela, Jenilee Guebert and Amrita Mishra, "Use and Abuse of Material Transfer Agreements: Lessons in Proportionality from Research, Repositories and Litigation," *PLOS Biology*, Published online February 3, 2015. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4315468/

[14] Steve Burgess and Dominic Berry, "Regulating the Use of Genetic Sequence Data," *PLOS Synbio Community*, December 15, 2016. http://blogs.plos.org/synbio/2016/12/15/regulating-the-use-of-genetic-sequence-data/

[15] For an overview of non-target and off-target effects of synthetic biology techniques and their identified risks, see Ricarda Steinbrecher, "Genetic Engineering in Plants and the "New Breeding Techniques (NBTs): Inherent risks and the need to regulate", Econexus, December 2015. http://www.econexus.info/sites/econexus/files/NBT%20Briefing%20-%20EcoNexus%20December%202015.pdf

[16] Message #8729, September 6, 2017.

[17] "Third Session of the Technical and Legal Experts on Access and Benefit Sharing," Commission on Genetic Resources for Food and Agriculture, Food and Agriculture Organization of the United Nations, 13-15 September 2016, CGRFA/TTLE-ABS-3/16/Report, paragraph 39. http://www.fao.org/3/a-bp766e.pdf

[18] Ibid., paragraph 38.

[19] Ibid., paragraph 16.