1 October 2018

CONVENTION ON BIOLOGICAL DIVERSITY (Convention)
14th Conference of the Parties to the Convention (COP-14)
Synthetic Biology

The Global Industry Coalition (GIC)[1] continues to have significant concerns regarding the ongoing negotiations on synthetic biology under the Convention and its Protocols. These negotiations continue in the absence of a determination that synthetic biology qualifies as a "new and emerging issue" (NEI) under the Convention. The draft decision from recommendation 22/3 of the twenty-second meeting of the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) continues and expands the synthetic biology work program, which does not reflect the views of Parties that consider this work to be unwarranted, and ignores the fact that the provisions of the Cartagena Protocol on Biosafety (Protocol) already apply to products of synthetic biology. To that end, the GIC calls for Parties to complete the assessment of whether synthetic biology is a NEI before promulgating more work plans. The GIC views the continuation and expansion of the synthetic biology work program beyond information sharing unjustifiable in the absence of this determination. Should the Parties decide to continue this work, the GIC exclusively supports efforts to collect objective, science-based information based on real-world experiences with synthetic biology through submissions and online fora in a coordinated, non-duplicative manner.

A. Background

At their 13th meeting in 2016, the Parties to the Convention adopted a decision on synthetic biology which, *inter alia*, invited submissions of information and supporting documentation on synthetic biology, extended the mandate of an Ad Hoc Technical Expert Group (AHTEG) on Synthetic Biology, and extended an open-ended online forum to support the work of the AHTEG. The decision also requested the SBSTTA to review the recommendations of the AHTEG on Synthetic Biology and make further recommendations to the Conference of the Parties, including an analysis of whether the issue of synthetic biology meets the criteria of a NEI relevant to the conservation and sustainable use of biological diversity[2], during their meeting in July 2018. Accordingly, Parties will consider at COP-14, taking place in Sharm El-Sheikh, Egypt from 17-29 November 2018, a proposed draft decision on synthetic biology based on the SBSTTA's recommendations. What follows is the GIC's views on the elements of the draft decision.

B. GIC Views on the Draft Decision on Synthetic Biology for COP-14[3]

1. New and emerging issue (paras 5, 19(b) and Annex (a) of Item 27 in CBD/COP/14/2)

The GIC supports paragraph 5 of the draft decision, with slight revisions, specifically, that there is a need to complete the assessment of whether synthetic biology qualifies as a NEI. This analysis needs to be conducted not only against the criteria set out in paragraph 12 of decision IX/29, but also the requirements of paragraph 11 of that decision. In the absence of such a determination by the Parties, the GIC questions the rationale for continued extension and expansion of the synthetic biology work program beyond information-sharing through the Open-ended Online Forum.

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[1] The Global Industry Coalition (GIC) for the Cartagena Protocol on Biosafety receives input and direction from trade associations representing thousands of companies from all over the world. Participants include associations representing and companies engaged in a variety of industrial sectors such as plant science, seeds, agricultural biotechnology, food production, animal agriculture, human and animal health care, and the environment.

[2] See Decision IX/29, paragraph 12.

[3] CBD/COP/14/2 (https://www.cbd.int/doc/c/9baf/c5c1/a05ee6526773a9ec9b487442/cop-14-02-en.pdf).

Decision IX/29 sets out the NEI process, whereby proposals are reviewed by SBSTTA, and where SBSTTA identifies a NEI, it will *elaborate a scientific and technical analysis with options for action for consideration* by COP. NEI proposals on synthetic biology were first made in 2010, and following consideration of submitted information invited to address the decision IX/29 criteria, SBSTTA-18[4] concluded that there was *insufficient information to finalize an analysis of whether synthetic biology is a new and emerging issue.* A synthetic biology work program was subsequently established in 2014[5] and extended in 2016[6], and these have included further information submissions as well as online discussions on a range of topics and deliberations of these topics by two AHTEGs. Despite all these activities, the NEI analysis has not been addressed again. The GIC is concerned that synthetic biology work programs are being extended indefinitely, and questions how much information needs to be collected and debated before the subject is resolved. If the Parties decide to extend the AHTEG on Synthetic Biology (paragraph 15 of the draft decision), its terms of reference should be limited to specifically contribute to the completion of this assessment by SBSTTA. The work of the AHTEG can be supported by the existing mechanisms of information submissions and the Open-ended Online Forum. However, the GIC emphasizes that all these mechanisms need to be focused on providing the information that SBSTTA is lacking to finalize its analysis - this has not been clearly indicated and the terms of reference for the AHTEG as stated are, in essence, repeating previous work programs.

The GIC does not support any consideration of the "preliminary analysis" by the Executive Secretary[7] as a contribution to the NEI analysis (paragraph 19(b) and Annex (a) of the draft decision). This analysis was prepared *by linking relevant statements in the AHTEG reports to the criteria* of paragraph 12 in decision IX/29. The result is misleading because the AHTEG reports are not consensus documents, and the selected statements that have been compiled may reflect the views, in some cases, of one individual and not of the AHTEG as the analysis indicates. In fact, the analysis does not reach any particular conclusion on the issue. Additionally, it is not clear how the Secretariat decided what constitutes "relevant statements" for inclusion in their report.

The GIC recommends that the draft decision reflects the need to complete the assessment of whether synthetic biology qualifies as a NEI as a fundamental first step before establishing a further work plan on synthetic biology.

(a) Paragraph 5 should be edited to state:

Recognizes the need to conduct an analysis of synthetic biology against the criteria in decision IX/29, paragraph 12, in order to complete the analysis requested in decisions XII/24, paragraph 2, and XIII/17, paragraph 13, and that this analysis is necessary to justify the need for, and define the scope of, future activities on this topic under the Convention.

Paragraph 19(b) should be deleted in its entirety.

2. Horizon scanning process and Genome Editing (Paragraphs 3 and 4 (of Item 27 in CBD/COP/14/2))

The GIC supports the collection and sharing of objective, scientifically-sound information among Parties in a transparent and inclusive manner. However, the GIC does not support proposals to establish new "horizon scanning" mechanisms referenced in paragraphs 3 and 4, and recommends

[4] Recommendation XVIII/7.
[5] Decision XII/24.
[6] CBD/COP/DEC/XIII/17.
[7] SBSTTA/22/INF/17.

that both paragraphs be deleted. Open exchange of information has been in place for synthetic biology under the Convention since 2010, with several requests for information submissions and online discussions on a range of topics. These mechanisms are transparent and inclusive, and the GIC supports the proposal to extend the Open-ended Online Forum on Synthetic Biology (paragraph 16 of the draft decision) to continue this work. Establishing new and additional mechanisms will simply generate more of the same information, but in a less transparent and less inclusive way. This constitutes an expansion of the synthetic biology work program under the Convention without justification, as the assessment of whether synthetic biology is a NEI remains incomplete. This also continues the unfocussed collection and consideration of information that does not contribute to the completion of this assessment.

If the Parties decide to retain paragraph 3, the GIC strongly opposes retaining the text referring to **genome editing** (in square brackets). The inclusion of this text implies that there is consensus that "genome editing" is synthetic biology, or that it is a synthetic biology criterion. There is no consensus on how synthetic biology is defined, what applications constitute synthetic biology, or that certain applications of genome editing or the broad group of technologies this term is used to represent should be defined as such. Genome editing is better described as an *enabling technology* that may be used in certain *applications*, some of which may result in a living modified organism (LMO), while others may not. For example, in plants, the outcomes of certain genome editing applications are similar to transgenics, and are therefore LMOs within the scope of the Protocol, while others are similar to plants developed with conventional breeding tools (not LMOs). Neither of these outcomes are synthetic biology, and they do not represent "new developments" in terms of their potential impacts on the objectives of the Convention or its Protocols. The reference to "genome editing" broadly in paragraph 3 is inappropriate and should be deleted.

The GIC recommends that paragraphs 3 and 4 are deleted entirely. If Parties decide to retain paragraph 3, the GIC strongly recommends that "including those that result from genome editing" is deleted.

3. Gene drives (paras 10, 11, 12, 14 and Annex (c) of Item 27 in CBD/COP/14/2)

GIC agrees that a precautionary approach, provided it is evidence-based, should be taken regarding the release of engineered gene drives into the environment. The GIC notes that the gene drive research community and LMO regulators have proactively engaged in evaluations of existing regulatory oversight, additional governance mechanisms and guidance, and of current knowledge gaps and the research needed to address these in order to identify and manage risks and realize the potential of engineered gene drives.[8] Further, the sponsors and supporters of gene drive research have developed a set of "guiding principles"[9] that are based on the recommendations of the 2016 report of the

8 Adelman Z, Akbari O, Bauer J, Bier E, Bloss C, Carter SR, Callender C, Costero-Saint Denis A, Cowhey P, Dass B, Delborne J, Devereaux M, Ellsworth P, Friedman RM, Gantz V, Gibson C, Hay BA, Hoddle M, James AA, James S, Jorgenson L, Kalichman M, Marshall J, McGinnis W, Newman J, Pearson A, Quemada H, Rudenko L, Shelton A, Vinetz JM, Weisman J, Wong B, Wozniak C (2017) Rules of the Road for Insect Gene Drive Research and Testing, *Nature Biotechnology* 35:716-718; Australian Academy of Science (2017) Synthetic Gene Drives in Australia: Implications of Emerging Technologies, Discussion Paper; Carter SR and Friedman RM (2016) Policy and Regulatory Issues for Gene Drives in Insects, Workshop Report; HCB Scientific Committee (2017) Scientific Opinion of the High Council for Biotechnology concerning use of genetically modified mosquitoes for vector control in response to the referral of 12 October 2015 (Ref. HCB-2017.06.07) (http://www.hautconseildesbiotechnologies.fr); James S, Collins FH, Welkhoff PA, Emerson C, Godfray HCJ, Gottlieb M, Greenwood B, Lindsay SW, Mbogo CM, Okuma FO, Quemada H, Savadogo M, Singh JA, Tountas KH, Touré YT (2018) Pathway to Deployment of Gene Drive Mosquitoes as a Potential Biocontrol Tool for Elimination of Malaria in Sub-Saharan Africa: Recommendations of a Scientific Working Group, *American Journal of Topical Medicine and Hygiene* 98 (Suppl 6):1-49; Lorentz Centre (2017) Challenges for the Regulation of Gene Drive Technology (http://www.lorentzcenter.nl/lc/web/2017/872/report.pdf); van der Vlugt CJB, van den Akker HCM, Roesink CH, Westra J, Risk Assessment Method for Activities Involving Organisms with a Gene Drive Under Contained Use, RIVM Letter Report 2018-0090; Westra J, van der Vlugt CJB, Roesink CH, Hogervorst PAM, Glandorf DCM, Gene Drives Policy Report, RIVM Letter report 2016-0023.

9 Emerson C, James S, Littler K, Randazzo F (2017) Principles for Gene Drive Research, *Science* 358:1135-1136.

National Academies of Science, Engineering and Medicine.[10] These principles establish that gene drive research should be *conducted with respect and humility for the broader ecosystem in which humans live, taking into account the potential immediate and longer-term effects through appropriate ecological risk assessment, which is a hallmark of both good stewardship and good governance*. In view of this substantial body of ongoing work, the GIC asserts that a *de facto* moratorium is contra-indicated by evidence. Therefore, the language "and refrain from" (in square brackets) should be removed from paragraph 10, and "with regard to" (in square brackets) retained.

The GIC also does not agree that the development of specific guidance by the Convention or the Protocol may be useful to support risk assessment of gene drives, as stated in paragraph 11. The GIC notes that Parties to the Protocol will address this issue in the draft decision on risk assessment and risk management of LMOs at COP/MOP-9[11], which recommends Parties consider whether specific guidance for risk assessment of gene drives is necessary at COP/MOP-10 in 2020, informed by processes decided on at COP/MOP-9. Paragraph 11 therefore preempts the outcomes of those processes and decisions by the Parties to the Protocol at COP/MOP-9 and COP/MOP-10, respectively.

The GIC recommends that:

(a) "and refrain from" is deleted from paragraph 10, and "in regard to" retained.

(b) Paragraph 11 is deleted entirely.

4. AHTEG (para 15 and Annex of Item 27 in CBD/COP/14/2)

The proposed draft decision recommends extension of the AHTEG and elaborates its associated terms of reference. The GIC is firmly of the view that extension of the AHTEG should not be supported, until and unless the Parties agree to a consensus decision that synthetic biology is a NEI under the Convention at their 15th meeting. The terms of reference, as currently stated, propose new work on synthetic biology that goes beyond what is appropriate for an issue that is yet to be determined to be part of the official agenda under the Convention. In addition, the work proposed in the terms of refence duplicates work and initiatives already completed or in progress through other mechanisms.

As noted above, if the Parties decide to extend the AHTEG, it's terms of reference should be limited to specifically contribute to the completion of the NEI assessment by SBSTTA. The work of the AHTEG can be supported by the existing transparent and inclusive mechanisms of information submissions and the Open-ended Online Forum, provided that these mechanisms are also focused on completing this assessment and providing the information that SBSTTA requires.

The GIC recommends that:

(a) Paragraph 15 is edited to include AHTEG term of reference (a), stating:

> *Decides to extend the Ad Hoc Technical Expert Group on Synthetic Biology ~~with renewed membership,~~ taking into account, inter alia, the work on risk assessment under the Cartagena Protocol~~, to work in accordance with the terms of reference annexed hereto~~ to provide an advice on the relationship between synthetic biology and the criteria set out in decision IX/29, paragraph 12, within the framework of paragraph 11 of decision IX/29, in order to contribute to the completion of the assessment requested in decision XII/24, paragraph 2.*

10 National Academies of Sciences, Engineering and Medicine (2016) Gene Drives on the Horizon: Advancing Science, Navigating Uncertainty, and Aligning Research with Public Values; National Academies Press.

11 CBD/CP/MOP/9/7.

(b) Annex (AHTEG terms of reference) is deleted in its entirety.

5. Other items

Detection Methods (paras 13 and 18(f) of Item 27 in CBD/COP/14/2)

The GIC welcomes the recommendation to collaborate with the Network of Laboratories for the Detection and Identification of Living Modified Organisms, to share experiences on the detection, identification and monitoring of organisms, components and products of synthetic biology. However, this should be undertaken with the understanding that products of synthetic biology are subject to the provisions of the Protocol and thus already covered by much of the work this Network has completed to date.

The GIC recommends that Paragraph 18(f) is edited to recognize the extensive existing information and guidance for detection methods, and the applicability of the provisions of the Protocol.

Contained Use (para 13 of Item 27 in CBD/COP/14/2)

The GIC highlights that contained use practices are well-established and have existed for more than 30 years - predating LMO regulation. Extensive and robust international, regional and national regulations and guidance exist for the receiving, handling, storage, culture, containment, inactivation, waste management, transport, packaging and identification of biological organisms under contained use to ensure the protection of human health and the environment. The same principles apply to different types of organisms, including LMOs. The world-recognized leading source of guidance is the World Health Organization *Laboratory Safety Manual*.[12]

The GIC recommends that Paragraph 13 is edited to reflect the extensive existing information and guidance for contained use, rather than propose the development of new measures.

[12] Available at: http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en/. Other sources include (but are not limited to): World Health Organization – Biorisk management – Laboratory biosecurity guidance (http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6.pdf); Biological agents: Managing the Risks in Laboratories and Healthcare Premises (UK) (http://www.hse.gov.uk/biosafety/biologagents.pdf); The Genetically Modified Organisms (Contained Use) Regulations 2014. Guidance on regulations. HSE (UK) (http://www.hse.gov.uk/pubns/priced/l29.pdf); Biosafety in Microbiological and Biomedical Laboratories (USA) (http://www.cdc.gov/biosafety/publications/bmbl5/); NIH Guidelines for research involving recombinant or synthetic nucleic acid molecules (http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html); A practical guide to containment – Plant biosafety in research greenhouses (USA) (http://www.isb.vt.edu/Containment-guide.aspx); Canadian Biosafety Standards and Guidelines - Safe handling of human and animal pathogens, toxins and plant pests in laboratories and containment zones (https://www.canada.ca/en/public-health/services/canadian-biosafety-standards-guidelines.html); Containment Standards for Facilities Handling Plant Pathogens. Canadian Food Inspection Agency Canada (http://www.inspection.gc.ca/plants/plant-pests-invasive-species/biocontainment/containment-standards/eng/1412353866032/1412354048442?chap=0); OIE Standard for Managing Biorisk in the Veterinary Laboratory and Animal Facility (http://www.oie.int/fileadmin/Home/fr/Health_standards/tahm/3.5_BIOL_AGENT_SPECIF_RA.pdf); Office of Gene Technology Regulator (OGTR) – list of guidelines (Australia) (http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/content/guidelines-1); Manuel du HCB sur l'utilisation confinée d'organismes génétiquement modifiés (France) (http://www.hautconseildesbiotechnologies.fr/fr/system/files/file_fields/2015/06/30/manuelduconfine.pdf); Directive 2009/41/EC on the contained use of genetically modified microorganisms (EU) (http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=URISERV:sa0015&from=EN); Laboratory Biosafety Guidebook (Pakistan) (http://www.internationalbiosafety.org/images/IFBA_docs/Pakistan%20Biosafety%20Guidebook.pdf); Laboratory Biosafety and Biosecurity Policy Guidelines (Kenya) (http://www.internationalbiosafety.org/images/IFBA_docs/Kenya%20Biosafety%20Guidelines.pdf); Laboratory biorisk management. CWA 15793:2011 (International) (http://www.uab.cat/doc/CWA15793_2011); Laboratory biorisk management – Guidelines for the implementation of CWA 15793:2008. (International (ftp://ftp.cen.eu/CEN/Sectors/List/ICT/Workshops/CWA%2016393.pdf); Biosafety professionals as stakeholders in the BTWC: Biosafety, biosecurity and the BTWC (http://www.internationalbiosafety.org/images/IFBA_docs/Biosafety%20&%20BTWC.pdf); Genetic Modification Advisory Committee (GMAC) - Singapore Biosafety Guidelines for Research on Genetically Modified Organisms (GMOs) (Singapore) (https://www.gmac.sg/Index_Singapore_Biosafety_Guidelines_for_Research_on_GMOs.html); Vlaams Instituut voor Biotechnologie (VIB) – Biosafety in the laboratory (Belgium) (http://www.vib.be/en/training/Documents/Biosafety%20in%20the%20laboratory.pdf).