18 May 2018

CONVENTION ON BIOLOGICAL DIVERISTY (Convention)
Synthetic Biology

The Global Industry Coalition (GIC) [1] **reiterates its significant concerns regarding the conduct of the ongoing negotiations on synthetic biology under the Convention. These negotiations continue in the absence of a determination that synthetic biology qualifies as a "new and emerging issue" (NEI) under the Convention, and without a consensus operational definition of "synthetic biology", two prerequisites to justify and frame the direction for future work on the topic. The recommendations for consideration by the Subsidiary Body on Technical and Technological Advice (SBSTTA) envision an extensive program of work that overlooks these prerequisites, do not reflect the views of Parties that consider this work to be unwarranted, and ignore the fact that the provisions of the Cartagena Protocol on Biosafety already apply to products of synthetic biology. To that end, the GIC calls for SBSTTA to first recommend to the Parties to the Convention that they complete the assessment of whether synthetic biology is a NEI before promulgating more work plans on the topic. Should SBSTTA include in recommendations for Parties any subsequent work proposals, 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 Subsidiary Body on Scientific, Technical and Technological Advice (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 "new and emerging issue"[2]. Accordingly, Parties will consider at the 22nd meeting of the SBSTTA (2-7 July 2018, Montreal, Canada) a report summarizing: (a) the submission of information on synthetic biology; (b) an open-ended online forum with discussions on specific topics of synthetic biology; (c) a report from one face-to-face meeting of the AHTEG; and (d) peer review of the same report. SBSTTA-22 is invited to consider recommendations on this issue as outlined below.

B. GIC Views on the Suggested Recommendations on Synthetic Biology for SBSTTA-22[3]

The GIC highlights its concern with the way the negotiations on synthetic biology are being conducted. There are two critical prerequisites before SBSTTA should move forward on recommending a program of work on this topic:

1. **The process to establish a new work program under the Convention requires that the Parties conclude that the matter is a NEI**. In eight years of debate, the Parties to the Convention have not reached such conclusion regarding synthetic biology. Unfortunately, the mere assertion that "synthetic biology" may pose concerns to the three objectives of the Convention has been sufficient to allow on-going activities on this topic, despite lack of evidence supporting the assertion. In the absence of a determination that synthetic biology is a NEI, the GIC questions the rationale behind the recommendation for extension of work programs on the topic beyond information-sharing through the open ended online forum process.

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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] See Section II in https://www.cbd.int/doc/c/6e0d/b361/a877d43db3665160cce5d96e/sbstta-22-04-en.pdf.

2. **The Parties must agree to a clear, operable definition of the term "synthetic biology"**. Without a consensus on what the term encompasses, it is unreasonable to expect that coherent work programs can be developed and that their outcomes can be of added value to the Parties. The lack of common understanding and agreement on an operational definition of "synthetic biology" has led to a lack of focus in discussions and has resulted in highly polarized views from Parties and experts.

What follows are the GIC views on specific paragraphs from the suggested recommendations for SBSTTA's consideration:

Paragraph 2. Notes that synthetic biology is a cross-cutting issue that may concern all three objectives of the Convention on Biological Diversity, and recognizes the need to thoroughly consider the potential benefits and potential adverse effects of synthetic biology applications vis-à-vis the three objectives of the Convention;

The GIC supports the collection and sharing of objective, scientifically-sound information on synthetic biology. However, we note that there exists no consensus agreement on the "*recognition*" of the "*need*" to thoroughly consider the potential benefits and potential adverse effects of synthetic biology applications because it has never been determined to be a NEI under the Convention. The lack of a clear consensus definition leaves it to arbitrary classification regarding what even constitutes synthetic biology applications.

In 2014, SBSTTA-18[4] concluded that there was *insufficient information to finalize an analysis of whether synthetic biology is a new and emerging issue.* Later COP-12[5] established a work program from 2015-2016 which was extended to 2017-2018 by COP-13[6]. The synthetic biology AHTEG in 2015 and SBSTTA-20[7] did not address the outstanding issue of whether synthetic biology is a NEI. Rather, SBSTTA-20 recommended to the 2017 AHTEG on synthetic biology to provide an analysis against the criteria required for identifying new and emerging issues.

This analysis was intended to be provided to the SBSTTA-22 in July 2018. However, the 2017 synthetic biology AHTEG did not address the topic at all in its work. Subsequently, the Secretariat independently produced an "analysis" by extracting phrases from the two ATHEG reports against the criteria required for an issue to be considered a NEI. The GIC emphatically states that this work product does not constitute the intended "analysis" on the matter. The fact that no agreement has been achieved on an operational definition has hindered successful work on the topic. Thus, work programs are proliferating over time, yet the prerequisite determination of NEI remains uncompleted and a clear consensus definition of what constitutes synthetic biology remains absent.
The GIC recommends that paragraph 2 be deleted from the recommendations until and unless there is a decision by the Parties to the Convention that synthetic biology is a NEI under the Convention.

Paragraph 3. Also notes that regular horizon scanning, monitoring and assessing of developments in the field of synthetic biology is needed for reviewing new information regarding the positive and negative impacts of synthetic biology vis-à-vis the three objectives of the Convention and those of its Protocols;

[4] Recommendation XVIII/7
[5] Decision XII/24
[6] Decision XIII/17
[7] Recommendation XX/8

The GIC supports the collection and sharing of objective, scientifically-sound information among Parties in a transparent and inclusive manner. Nevertheless, the GIC views that regular "horizon scanning" on the subject has been in place since 2010.[8] The number of requests for submissions by Parties, other Governments and organizations and the number of on-line fora on synthetic biology already qualify as "horizon scanning". Importantly, the recommendation under paragraph 3 appears to preempt the prerequisite determination by the Parties that synthetic biology is a NEI, and in danger of remaining arbitrary in the absence of agreement on the definition of synthetic biology.
The GIC recommends that paragraph 3 is deleted from the recommendations unless there is a consensus decision by the Parties that synthetic biology is a NEI under the Convention.

Paragraph 4. Recognizes that rapid advances arising from research and development in the field of synthetic biology may pose challenges to the ability of some countries, in particular those with limited experience or resources, to assess the full range of potential impacts of synthetic biology applications;

While "rapid advances in research and development" are suggested by some to be a general challenge to risk assessment, the GIC notes that the challenge does not lie in the perceived speed of the advances *per se*, but rather in the experience and technical capacity existing in some countries. Capacity building and practical experience are issues that can be addressed through other bilateral and multilateral means, including qualified capacity building projects.
The GIC is of the view that this paragraph could be clarified with the deletion of "rapid advances arising from" since the challenge is not related to the pace of development, but to the technical capacity of some countries in the field.

Paragraph 5. Also recognizes the need for a coordinated and non-duplicative approach on issues related to synthetic biology under the Convention and its Protocols, as well as among other conventions and relevant organizations and initiatives;

The GIC agrees that there is a need for a coordinated and non-duplicative approach to discussions on synthetic biology under the Convention and its Protocols should a determination be made that synthetic biology is a NEI. Duplicative work has already taken place because synthetic biology fits within the broader category of modern biotechnology as defined under the Cartagena Protocol on Biosafety (Protocol). The Protocol provides the necessary guidance of how to assess and manage the risks of LMOs. After more than eight years of exchanges under the Convention on the subject of synthetic biology, no credible examples have been presented that would fall outside the scope of the Protocol and which would justify additional work on the subject.
The GIC encourages SBSTTA to carefully compare the proposed recommendations for synthetic biology under the Convention and risk assessment under the Protocol and remove any duplication that is present. We also encourage SBSTTA to consider whether synthetic biology should actually be singled out as it is already subject to the provisions of the Protocol.

Paragraph 6. Further recognizes that, while there could be potential benefits to the development of organisms containing engineered gene drives, additional research and guidance is needed before any organism containing engineered gene drives is considered for release into the environment, including the lands and territories of indigenous peoples and local communities, and, given the current uncertainties regarding engineered gene drives, urges Parties and other Governments to take a precautionary approach in the development and release of organisms containing engineered gene drives, including experimental releases, in order to avoid potentially significant and irreversible adverse effects to biodiversity;

[8] Decision X/13

The GIC notes that the concept of engineered gene drives for supplementary population control solutions of significant disease vectors and crop pests has captured the interest of the scientific community and funders of associated research. Numerous research programs are underway to cautiously apply observations from nature involving biased inheritance patterns. The sponsors and supporters of gene drive research[9] have agreed upon "guiding principles" based on the recommendations of the 2016 NASEM report[10] on gene drives. These principles establish that 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." A number of national and regulatory evaluations[11] have already been conducted on the feasibility, ways of working and precautionary measures that need to be in place in order to address biosafety concerns and to realize the potential of engineered gene drives. This substantial body of work demonstrates that the statement in paragraph 6 is already being addressed in real-world situations. These efforts serve as a basis for any decisions on gene drives under the Convention.

The GIC argues the beginning of paragraph 6 should be deleted, and the final recommendation should read: "Urges Parties and other Governments to take a precautionary approach in the development and release of organisms containing engineered gene drives by adopting guiding principles similar to those that have been peer reviewed and published to date".

Paragraph 7. Calls upon Parties, other Governments and relevant organizations to develop and implement well-designed strategies in order to prevent or minimize the exposure of the environment to organisms, components and products of synthetic biology under contained use;

The GIC notes once more the lack of consensus amongst Parties and experts on what synthetic biology is, and how it may differ from other biotechnological applications. We are not aware of any evidence to support the need for this recommendation and note that adequate provisions (including legislation in many countries) are already in place for working with biological material, including LMOs, under containment. For such recommendation to be acted upon, evidence should be provided demonstrating that existing containment measures have been inadequate.

Paragraph 7 should be deleted unless it could be supplemented by supporting evidence for the need of such action.

Paragraph 8. Also calls upon Parties, other Governments and relevant organizations to disseminate information and share their experiences on scientific assessments of the potential benefits and adverse impacts of synthetic biology, including that of organisms containing engineered gene drives, taking into account but not limiting themselves to information based on modelling and scenarios, data from experiments performed under contained use, and experience gained through the management of pests and invasive alien species and from the use of living modified organisms that have been released into the environment;

The GIC notes that scientific and regulatory bodies have been actively sharing information on engineered gene drives and that a proactive approach has been taken by funders and developers of gene drives (see above). Potential benefits and adverse effects of any organism, including those developed

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9 Emerson C, James S, Littler K, Randazzo F (2017) Principles for gene drive research. Science: 1135-1136

10 NASEM (2016) Gene Drives on the Horizon: Advancing Science, Navigating Uncertainty, and Aligning Research with Public Values;

11 Australian Academy of Science (2017) Synthetic gene drives in Australia: implications of emerging technologies; RIVM Letter report 2016-0023 Gene drives Policy 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). (Paris, HCB), 142 pp. Available online: http://www.hautconseildesbiotechnologies.fr. Lorenz Centre 2017 Challenges for the Regulation of Gene Drive Technology http://www.lorentzcenter.nl/lc/web/2017/872/report.pdf

though "synthetic biology" or these containing engineered gene drives can only be assessed realistically case-by-case under appropriate testing conditions. Therefore, the GIC welcomes the invitation for sharing of information by Parties, Governments and relevant organizations that have such practical experience, but cautions against the reliance and use of hypothetical cases or scenarios that are not backed by robust analytical data.

The GIC strongly supports the recommendation in paragraph 8.

Paragraph 9. Decides to extend the mandate of the Ad Hoc Technical Expert Group on Synthetic Biology and that it should work primarily online and in coordination with the process under the Cartagena Protocol, as appropriate, to: (a) take stock of new developments in synthetic biology since the Ad Hoc Technical Expert Group's last meeting in order to support a regular horizon scanning process; (b) prepare a comprehensive review of the current state of knowledge by compiling and analysing information, including but not limited to peer-reviewed published literature, on the potential positive and negative environmental, cultural, and socioeconomic impacts of current and near future applications of synthetic biology, including genome editing and organisms containing engineered gene drives; (c) prepare a forward-looking analysis on potential positive and negative impacts of synthetic biology applications that are in early stages of research and development; and (d) prepare a report on the outcomes of its work for consideration by the Subsidiary Body on Scientific, Technical and Technological Advice;

The GIC is of the view that the proposed decision embodies the essence of our concerns with the manner in which the discussions on synthetic biology have been conducted to date under the Convention and its Protocols. The proposed actions are not backed by sufficient agreement amongst experts or by factual evidence justifying the need for these activities. The proposed extension of the mandate of the AHTEG is premature as Parties have yet to complete the task of assessing synthetic biology against criteria for inclusion as a NEI. In addition, the operational definition of "synthetic biology" is still only a starting point that unfortunately has not been useful in facilitating scientific and technical discussions and has not enabled the differentiation of synthetic biology from other biotechnologies. SBSTTA should consider the extreme divergence of expertise and opinions among members of the AHTEG on many of the topics discussed, including those proposed for further work in paragraph 9 of the recommendations. Submissions and on-line fora allow for wider and more transparent input from experts, and provide a technically more robust output that an AHTEG could produce. More specifically, the work proposed under paragraph 9(a) is more appropriately addressed by broad submissions of information by Parties, Governments and observers and through online forum discussions. The work proposed under paragraph 9(b) duplicates work proposed under the AHTEG on risk assessment and risk management under the Protocol. The work proposed under 9(c) is also problematic as it would encourage the inclusion of speculative ideas that have little or no potential to be developed and released. Information collection should be governed by standards that identify the reliability of the source and are focused on realistic, real-life applications that are under development and are likely to be released.

Paragraph 9 should be deleted from the recommendations in its entirety.

Paragraph 10. Also decides to extend the Open-ended Online Forum on Synthetic Biology to support the deliberations of the Ad Hoc Technical Expert Group on Synthetic Biology, and invites Parties, other Governments, indigenous and local communities and relevant organizations to continue to nominate experts to take part in the online forum on synthetic biology;

The GIC supports the use of a moderated Open-ended Online Forum on Synthetic Biology as a cost-effective, inclusive and transparent mechanism to advance the sharing of evidence-based and scientifically-sound information on developments in synthetic biology. Online fora provide an efficient way to share and collect expert opinions and monitor developments, while allowing for a broad range of participants from governments, academia, industry and the NGO community. As an open, transparent and inclusive structure, the moderated online forum is the only effective mechanism worth

pursuing to inform any future activities related to synthetic biology that may result from the next meeting of the Parties to the Convention. The GIC supports the recommendation to extend the Open-ended Online Forum on Synthetic Biology and will actively engage in its discussions.
The GIC supports this recommendation (with deletion of "to support the deliberations of the Ad Hoc Technical Expert Group on Synthetic Biology").

Paragraph 11. Invites Parties, other Governments, relevant organizations, indigenous peoples and local communities, and other relevant stakeholders to provide the Executive Secretary with relevant information for inclusion in the review referred to in paragraph 9 above;

While the GIC does not support the extensive work plan outlined in paragraph 9 above, the GIC does support the transparent collection of information in support of the work plan that does result from SBSTTA negotiations by allowing all stakeholders to submit information to the Executive Secretary to inform any ongoing work in this area.
The GIC supports and encourages this recommendation to submit relevant information that will help Parties better understand synthetic biology and ensure it safe development.

Paragraph 12. Requests the Executive Secretary:
(a) To convene moderated online discussions under the Open-ended Online Forum on Synthetic Biology;
(b) To facilitate the work of the Ad Hoc Technical Expert Group on Synthetic Biology, subject to the availability of funds, by, among other things, collecting and synthesizing and arranging for peer review of relevant information, and convening at least one face-to-face meeting;
(c) To further pursue cooperation with other organizations, conventions and initiatives, including academic and research institutions, from all regions, on issues related to synthetic biology and how it may contribute to progress towards the 2030 Agenda for Sustainable Development;
(d) To explore ways to facilitate, promote and support capacity-building and knowledge sharing regarding synthetic biology, taking into account the needs of Parties and of indigenous peoples and local communities, including through necessary funding, and the co-design of training materials in the official languages of the United Nations and, where possible, in local languages.

The GIC notes that our position and concerns are reflected in the text of this recommendation. The GIC supports the collection of evidence-based, scientifically-sound information through submissions and an online forum. However, for the reasons outlined above, we do not support further work of the AHTEG on synthetic biology, nor do we support further work as outlined in paragraphs 12(c) and (d) above, noting that this preempts a decision on whether synthetic even qualifies as a NEI under the Convention.
Should SBSTTA also include a recommendation that the Parties consider whether synthetic biology is a NEI, the GIC would also support recommendations that reference the collection of objective, scientifically-sound information using the online forum. However, subparagraphs (b)-(d) should be deleted from the recommendation.

For more information on this and other issues related to implementation of the Cartagena Protocol on Biosafety, please visit https://croplife.org/plant-biotechnology/convention-on-biological-diversity/synthetic-biology/.