Friends of the Earth-U.S. peer review of the "Report of the Ad Hoc Technical Expert Group on Synthetic Biology" and response to decision XII/24 on synthetic biology

January 30, 2016

To: Braulio Ferreira de Souza Dias, Executive Secretary
Secretariat of the Convention on Biological Diversity

Friends of the Earth-U.S. thanks the Secretariat for the opportunity to contribute comments and a peer review of the Report of the meeting of the Ad Hoc Technical Expert Group on Synthetic Biology.

Friends of the Earth-U.S., a certified 501(c)(3), is the North American representative to Friends of the Earth International, the world's largest grassroots federation of environmental organizations, with groups in 77 countries. We have been the progressive leader in the United States on issues of conservation and the sustainable use of biological diversity since our founding over forty years ago, particularly on issues of genetic engineering and genetic diversity, biofuels, forests, and climate change.

Dana Perls, Friends of the Earth-U.S., participated in the online forum convened by the Secretariat, and we are grateful for the variety of participation in the forum. We hope that the prepared documents will be a helpful guide for prioritizing certain discussion points and making decisions at the next SBSTTA 20 meeting in April 2016.

The following pages of comments focus on the report of the Ad Hoc Technical Expert Group on Synthetic Biology.

Sincerely,

Dana Perls
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Friends of the Earth-U.S.

Comments on the Report of the meeting of the Ad Hoc Technical Expert Group on Synthetic Biology.

Overall comments:

This report is a helpful recap of the AHTEG discussion, and raises a number of questions and points for discussion at the upcoming SBSTTA 20 meeting in April 2016.

We would like to emphasize the urgent need to address containment of living and non-living organisms, components and products derived from synthetic biology, and to have robust regulations and assessments which include environmental and socio-economic risks. It is essential to acknowledge that containment synthetic biology organisms is not 100%, even if industrial facilities are set up for "contained use" of synthetic biology organisms, or claim that the organisms would be unlikely to survive outside of containment. Unintentional release could lead to any number of adverse direct and indirect effects, as listed in the AHTEG report.

As suggested by the comments in this report, the "use and release", including "contained" use, must also require robust regulations, oversight and assessment specific to the emerging and new gene editing techniques that fall under the definition of synthetic biology. These domestic and international regulations should, and currently do not, address environmental, health and socio-economic risks that could result from the use and release of synthetic biology organisms, components and products.

In light of this, we recommend that "contained use" of synthetic biology organisms, components and products should not be exempted from thorough risk assessment and that the precautionary approach be rigorously applied. We also recommend that the parties consider the importance of postponing the use and/or release of particular applications of synthetic biology, such as gene drives, onto the market or into the environment until thorough structures and processes for regulating and assessing impacts are established.

Lastly, it is essential moving forward that there be indigenous and local communities represented in the forum. If there is not, it's crucial to establish a forum of communication and ideas exchange that will facilitate more convenient participation for groups that were not represented.

3.1. An operational definition of synthetic biology comprising inclusion and exclusion criteria:

Friends of the Earth-U.S. supports the proposal to use the European Commission's definition of synthetic biology as its operational base, and to refer to the definition of biotechnology as defined in the CODEX Alimentarius. We would like to support the additional concept of genetic

materials and living organisms as being “redesigned”, as this is an important feature of several new synthetic biology techniques and methodologies.

Although the techniques and approaches of that fall under the basket of synthetic biology are rapidly expanding, it may be helpful to develop an annex which includes a sample list of current techniques and approaches and which may be updated as synthetic biology techniques expand.

3.2. Relationship between synthetic biology and biological diversity

We support the view in paragraph 28 that both living organisms and non-living products, as well as components of synthetic biology will effect the achievement of the Convention’s three objectives and therefore must be fully considered. We also want to emphasize the importance of the precautionary approach to synthetic biology, and the need to assess direct and indirect impacts of the use of synthetic biology organisms and their components and products on the sustainable use of biodiversity (paragraph 30). The indirect impacts must not only consider environmental effects, such as unintentional escape or contamination, but also include socio-economic impacts. As suggested in paragraph 28, information should also draw from indigenous and traditional knowledge.

We would like to draw attention to paragraph 27, which proposes a need for “evidence-based information, including peer-reviewed data”. Given a precautionary approach, there may not be available evidence-based data on the direct and indirect impacts of synthetic biology organisms, components and products. We would also like to draw attention to paragraph 29, which states that further research on synthetic biology may facilitate the increased understanding and predictability of organisms’ characteristics. However, it is unclear that this research would necessarily reduce uncertainty in the risk assessment process. Living organisms evolve, and behave differently in different environments. Given the lack of containment, it may be unrealistic to try to predict the traits of a synthetic biology derived organism.

3.3. Similarities between living modified organisms (as defined in the Cartagena Protocol) and organisms, components and products of synthetic biology techniques

We would like to draw attention to paragraph 34. Although the AHTEG suggests here that living organisms developed through applications of synthetic biology are “similar to LMOs”, we would urge this to be reconsidered. Rather, we would support that living organisms developed through applications of synthetic biology *are* LMOs, particularly as there are debatable cases about whether an organism is living or not (as pointed out in paragraph 36).

3.4. Adequacy of other existing national, regional and/or international instruments to regulate the organisms, components or products derived from synthetic biology techniques



We would like to support and emphasize that there are significant gaps in oversight of synthetic biology, and that these gaps must be addressed within the CBD. As paragraph 38 remarks, "many components and products of synthetic biology, while covered by the Convention, are not covered under the scope of the two Protocols and possibly not by some national biosafety frameworks either." In this context, it is also critical that the "use" (and release) of living and non-living organisms, components and products of synthetic biology includes and refers to open *and* closed systems of containment.

As noted in paragraph 42, we also do not consider "the existing national legislation to be adequate for regulating the components of synthetic biology". Currently, several countries have regulations which may exempt "contained" use applications of living organisms derived from synthetic biology from certain regulations, but given the science showing that containment is not reliable, governments should have updated policies and regulations specific to living and non-living organisms, components and products of synthetic biology. Risk assessments should assess not only the indirect and direct environmental and health impacts, but also the socio-economic impacts that may result from the use or release of organisms, components and products of synthetic biology.

Paragraph 41 raises several important points about the need to address the socio-economic impacts of the components and products of synthetic biology. While parties should have regulations to manage the indirect and direct risks, including those risks to sustainable use, we would like to urge that there be a system for redress put in place in the case that the use or release of organisms, components or products of synthetic biology have adverse environmental, health or socio-economic effects. For example, the approval of vanillin and stevia derived from synthetic biology for commercial use, and the market label as "natural", may have significant socio-economic impacts on agricultural communities that typically produce the truly natural form of these products. There may also be damaging environmental impacts, as many of the synthetic biology derived products currently on the market depend on industrial-scale supplies of feedstocks, including sugars derived from agricultural and forest biomass. Increased demand for biomass to feed synthetic microbes could have enormous impacts on biodiversity and the livelihood and food security of local and indigenous communities. If a country's market use of synthetic biology derived ingredients have direct or indirect environmental or socio-economic impacts, either domestically or in another country, there are currently no adequate systems to resolve the conflict or address the problems.

3.5. Potential benefits and risks of organisms, components and products arising from synthetic biology techniques to the conservation and sustainable use of biodiversity

We appreciate the list of potential benefits and adverse effects of synthetic biology, and that the confirmation that these are within the mandate of the Convention and its protocols. While



it is important to assess the wide array of emerging technologies that fall under the scope and definition of synthetic biology, it may be necessary to prioritize assessing the potential risks of certain new and emerging technologies and applications. For example, gene drives and CRISPR-CAS9 are technologies of particular concern because of the potential and unique adverse effects on ecosystems, as well as the rapid pace of development and industry push for the use and release of these applications. The Convention should consider providing particular guidance to parties as to how best to responsibly regulate, evaluate and assess technologies such as gene drives, in accordance to their obligations under the Convention and the precautionary principle.

In paragraph 51, it is suggested that assessments of benefits and adverse effects are at different stages of development, and that some of these application are already on the market. In light of the precautionary principle and the three objectives of the Convention, it may be necessary for parties to withhold permitting or approving particular applications of synthetic biology for market use or environmental release if there are not yet appropriate assessments of the potential effects. If technologies, such as gene drives, which may pose permanent and significant ecological risks, do not yet have appropriate regulations, assessments, systems for oversight and monitoring, parties need to follow the precautionary approach and not approve their use or release. It is critical that the objectives and aims of the Convention are prioritized over market and industry pressure.

As mentioned, we think the list of potential benefits and potential adverse effects is helpful to layout. However, we would like to note that many of these suggested benefits are quite speculative and may be based in assumptions. It is questionable as to whether several of the listed potential benefits are founded in current research or have any supporting data, or are theoretical (as articulated in paragraph 51). For example, it is unclear if there is any existing research or data suggesting the potential benefit of using synthetic biology for bioremediation or restoration of ecosystems (objective 1b). Likewise, it would be helpful to give reference to any research or data that suggests agricultural and agroforestry applications of synthetic biology organisms could be helpful for depleted agricultural land (objective 2e).

3.7. Degree to which existing arrangements constitute a comprehensive framework

We support the statement that current risk assessment approaches and methodologies specific to synthetic biology are needed (paragraph 59). We do not agree that “risk assessment practices currently in place” to assess LMOs and organisms of synthetic biology are adequate (paragraph 58). Existing risk assessments examine organisms that may behave substantially differently from those that have been re-engineered to behave in ways they would not naturally. Given that synthetic biology has the capacity to create novel organisms for which there are no good non-modified comparators, and that current methodologies are inadequate to address the potential adverse environmental and socio-economic impacts of the components and products of synthetic biology (paragraph 60 and 61), it’s all the more critical



that regulations and guidelines for parties be developed before the use and release of synthetic biology organisms, components and products.

It is also critical to look specifically at impacts that may not have been considered yet, such as horizontal gene transfer from synthetic biology derived organisms. Given the current pace and development of synthetic biology organisms, components and products, in combination with weak existing country and regional regulations, which often rely on risk assessments performed by the user/commercial company, we believe that the question and definition of "contained use" of organisms derived from synthetic biology must be urgently prioritized by the Convention.

We would like to raise a question regarding paragraph 62 and 63, which make references to the "assessment of the added value of synthetic biology applications." As mentioned earlier, the potential benefits are speculative, and it would be more balanced and clearer to refer to the "assessment of synthetic biology applications."

Item 4. Conclusions and Ways Forward

Friends of the Earth supports the adoption of the operational definition of synthetic biology (paragraph 66a), but would like to emphasize that "living organisms developed through current and near future applications synthetic biology" should be considered LMOs, not "similar to" (paragraph 66b).

As discussed in paragraph 66c, we would like to encourage establishing a "process to monitor and assess" synthetic biology, including new information, and to establish a process for updating the operational definition as needed. We believe this, in addition to addressing the gaps in oversight with regards to synthetic biology organisms, components and products (paragraph 66j) should be a strong focus for the upcoming SBSTTA 20 meetings.

Lastly, we would like to reemphasize the importance of creating and facilitating an appropriate space for participation of indigenous peoples and local communities in the future conversations and activities regarding synthetic biology. While the on-line forum was helpful and informative, it may not have been accessible to all of the desired participants, and in the future, it would be important to have alternative forums for participation.



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