



United States Department of State
*Bureau of Oceans and International
Environmental and Scientific Affairs*
Washington, D.C. 20520

23 February 2018

Dr. Cristiana Paşca Palmer
Executive Secretary
Convention on Biological Diversity
413 Saint-Jacques Street, Suite 800
Montréal, Québec, Canada H2Y 1N9

Dear Dr. Paşca Palmer:

The United States appreciates the invitation to provide peer review comments in response to the Secretariat's 15 January 2018 Notification No. 2018-013 regarding the Report of the Ad Hoc Technical Expert Group (AHTEG) on Synthetic Biology. We are pleased to have the opportunity to share our views attached.

Thank you for your consideration.

Sincerely,

A handwritten signature in cursive script that reads "Barbara M. De Rosa-Joynt".

Barbara M. De Rosa-Joynt
U.S. National Focal Point for the
Convention on Biological Diversity
U.S. Department of State
Washington, DC 20520 U.S.A.

Attachment: Peer review of the Report of the AHTEG on Synthetic Biology

Peer Review of the Report of the Ad Hoc Technical Expert Group on Synthetic Biology

Contact information:		
Surname:	DeRosa-Joynt	
Given Name:	Barbara	
Government (if applicable):	United States	
Organization:	U.S. Department of State	
E-mail:	derosabm@state.gov	
Title of document reviewed:	REPORT OF THE AD HOC TECHNICAL EXPERT GROUP ON SYNTHETIC BIOLOGY	
Comments on the draft documentation for SBSTTA-22:		
Page #	Para #	Comment
0	0	In some instances throughout the draft document, it is unclear whether statements are consensus views of the AHTEG, consensus recommendations of the AHTEG, items noted by the AHTEG, or items noted by a few experts or one expert. While some statements are noted in this manner, many are not. Please ensure that the draft report is deliberate and specific about this for each paragraph/each topic addressed.
3	15 (b)	Only synthesis of small whole genomes is possible. Please revise this statement so that it reflects the fact that whole genome synthesis is limited to viruses and only some bacteria.
3	15(g)	Please delete the word “highly.” Novel is novel, no qualifier is necessary. In this form, it provides unnecessary emphasis and appears to show bias.
3	15(h)	Please specify “laboratory” automation
3	15(i)	Please remove item (i) in its entirety. This statement is too specific and calls out one sub-species that has been a target of genetic modification and experimentation for decades. Furthermore, without proper context to explain any particular pond-based facility, it inaccurately implies a broad lack of containment or control. This statement is of little use to be considered by the SBSTTA.
3	15(j)	Please remove item (j) in its entirety. This is not a new field. If this item is to be included, it needs to be nuanced to explain the specific recent technological development in question (if any).
3	15(k)	Please replace “external” with “externally applied.” Specificity is paramount. Technically speaking, all methods of modification start external to the cell and are delivered to internal machinery.
4	20	Horizon-scanning happens at all levels, from an institution up through various government agencies and, in some instances, to international bodies. Please clarify the scope of this point, especially if this refers to the efforts of the AHTEG and/or is redundant with other work of the Convention.
4	21	Please remove the last sentence of this paragraph, so as not to be prescriptive or an overt call for resources: this is not within the AHTEG’s mandate or authority.

4	22	Please delete the second sentence. It is quite vague regarding the technological advances that support this statement, “However, it considered that the potential positive...complexity for use in a range of applications,” and adds nothing of substance for SBSTTA to consider.
4	25	Is this paragraph trying to acknowledge the impact of synthetic biology on the use of knowledge? If so, please revise this statement accordingly. Without “use of,” it implies that the sector as a whole is somehow altering the inherent knowledge of indigenous peoples.
5	25	Please delete “development and” in the phrase “a precautionary approach ... might be warranted in the development and release of organisms containing engineered gene drives, including experimental releases.” Development and testing of organisms containing engineered gene drives - in fully contained environments - will likely be necessary to assess the risks that would be posed by the environmental release of such organisms. Taking a precautionary approach for development of these organisms would preclude the very research and testing necessary to implement a precautionary approach with respect to their release, which requires that the risks associated with releasing such organisms into the environment be assessed and evaluated before any such release occurs.
5	25	Please delete “Furthermore, while there could be...including into lands and territories of IPLCs.” This reads, unfortunately, as a mandate to researchers to follow guidance that does not exist. It could unfairly hamper an R&D industry that has yet to be at fault for any risk to biodiversity. If this statement must stay in, please change the phrasing from “were needed” to “could be useful.”
5	26	Please delete the reference to “Mother Nature” in the first sentence of this paragraph. Neither the CBD nor the UN has universally defined “relationships with Mother Nature” and overall this specific reference doesn’t provide much if any substantive information over what is captured within the paragraph. If alternate phrasing must be used, please use the term “planet Earth and its ecosystems” instead of “Mother Nature” in the places where “Mother Nature” is used.
5	26	Please change “should” to “could” in the first sentence of this paragraph. “The development of such technologies could be accompanied...” It is not necessary that all technology developments involve all aspects of society, nor is it likely possible.
5	28	Please delete the use of the word “most.” Otherwise when paragraph 28 is taken in context with paragraphs 29 and 30 it appears contradictory to the subsequent statements where the AHTEG did not identify any cases of living organisms modified by synthetic biology techniques that would not be considered an LMO.
5	29	Please delete “In the future, however...might be regarded as LMOs.” This is conjecture and not based on scientific evidence.
5	30	Please delete this entire statement. Until a regulatory decision is made, it is irresponsible to point out one category that might or might not be regarded as LMOs. Instead, the statement should read, “Organisms modified through epigenetic engineering are not currently considered LMOs.”

5	31	Please delete this entire paragraph. This is a gross overgeneralization and does not capture the diversity of views held by indigenous peoples and local communities. If a version of the statement is to be included, then please reference the UN Harmony with Nature resolution where the term “Mother Earth” is used in a very specific context (i.e., only some recognize). If the text is retained, alternate phrasing must be used, and in that case please use the term “planet Earth and its ecosystems” instead of “Mother Nature” in the places where “Mother Nature” is used.
6	33	Please insert “using current techniques” in the following, “and when the resulting LMO was indistinguishable, using current techniques, from a naturally occurring or conventionally bred counterpart.” If the LMO is truly indistinguishable in principle from a natural or conventionally bred counterpart, then they are effectively the same, and there can be no difference in function or risk.
6	34	Please clarify if “products of synthetic biology” refer to substances produced by organisms modified through synthetic biology. Note that this usage differs from academic standards like that of the U.S. National Academy of Sciences’ <i>Preparing for Future Products of Biotechnology</i> , in which “products of synthetic biology” include the modified organisms themselves.
6	34	The AHTEG did not reach a consensus that further development in detecting and monitoring are needed. Please delete the last sentence or include a reference that’s “some members of the AHTEG noted...”
6	36	These are not consensus-driven AHTEG conclusions. This paragraph should be eliminated or caveated with “some members of the AHTEG suggested...”
6	37	Again, these are not consensus-driven AHTEG conclusions. Please delete this paragraph or caveat the language with “some members of the AHTEG suggested...”
6	38	Again, these are not consensus-driven AHTEG conclusions. Please delete this paragraph or caveat the language with “some members of the AHTEG suggested...”
7	41 (c)	Please clarify what is meant by “Knowledge gaps in assessing interactions of combinatorial and cumulative effects of multiple organisms developed through synthetic biology being released in the same environment.” Is this referring to multiple organisms containing the same change (i.e. many genetically engineered crop plants), or is this referring to multiple organisms with different changes (i.e. a genetically engineered insect and a genetically engineered bacteria released into the same environment)? The way that it is currently worded implies both — which is problematic and untrue. Scientists and practitioners have decades of experience assessing interactions among multiple organisms of the same species in a given environment (1 st scenario) – including, but not limited to, quantifying effects in agricultural production from invasive species and from re-introduction of native species.
7	42	Parties chose not to endorse the Guidance on Risk Assessment, due to numerous non-evidence based requirements it implies that Parties should implement. For a more balanced approach, the AHTEG report should note the existence of other risk assessment approaches that are present within the BCH alongside this acknowledgement (perhaps as an additional footnote).

7	43	Please delete the reference to “Mother Nature” in this paragraph. Neither the CBD nor the UN has universally defined “relationships with Mother Nature” and overall this specific reference doesn’t much any substantive information over what is captured within the paragraph. If the text is retained, alternate phrasing must be used, and in that case please use the term “planet Earth and its ecosystems” instead of “Mother Nature” in the places where “Mother Nature” is used.
7	43	As it is currently written, this paragraph reads like a call for resources, which is beyond the scope and mandate of the AHTEG. Please rephrase this first line to say “In addition, the AHTEG noted the possibility of developing and conducting assessments...”
7	44	Please clarify that there was no AHTEG consensus in determining that “The development or further development of guidelines on risk assessment of organisms containing engineered gene drives by the Convention, other international organizations, national governments and professional bodies would be useful in that regard.” This is a suggested viewpoint of only some AHTEG members.
7	44	Please include “practitioners” in the development of guidelines. Please also change “and” to “and/or,” e.g., “national governments, practitioners, and/or professional bodies...”
7	45	This was not a consensus statement. Please caveat the second sentence, “However, the step of release into the environment might be irreversible and, therefore, some members of the AHTEG believed that a precautionary approach might be warranted.”
7	46	Please replace the word “support” with “facilitate” so as not to imply financial contribution. Please also insert “voluntary” before “knowledge-sharing.”
7	47	Please replace “imposed” with “implemented.” Please also clarify – adverse effects of what? Is this a specific reference to gene drives or the spectrum all of products synthetic biology? Please replace “prevent adverse effects, taking” with “ensure adverse effects are held to levels that are deemed acceptable, in consideration of the benefits, and taking...” “Preventing” adverse effects, without consideration of benefit, and independent of quantity, is inappropriate. Both the benefits and the adverse effects of new technologies need to be evaluated and compared in any decision to deploy such technologies. The existence of a benefit – notwithstanding any degree of adverse effect – is not sufficient reason to deploy a new technology, just as the existence of an adverse effect – notwithstanding any degree of benefit – is not sufficient reason to preclude it.
7	48	This paragraph is directly contradictory to paragraph 47. The AHTEG noted the need to “impose” management measures, but existing risk management practices “might provide a good basis?” Please clarify if this statement represents the opinion of just some AHTEG members.
7	49	Please specify “the AHTEG noted” or “the AHTEG concluded,” as appropriate.
7	51	Please specify in the first sentence “...the following points were raised by some members of the AHTEG”.

7	51b	Please insert “necessarily” between “not” and “ecologically.” Please also replace “demonstrated” with “determined,” and add “for the purposes of a particular release” at the end. The definition of “contained use” in Article 3 assumes a “physical structure” and would not be appropriate for an island in any case. That said, the requirements for limiting contact with the external environment depend on the details of the release. Conditions that will be perfectly satisfactory for containing rodents may not suffice for containing microorganisms; the same combination of geographical and physical containment may constitute “contained use” in one circumstance but not the other. Moreover, it may be possible to determine that a certain combination of physical, biological, and geographic controls will suffice to ensure biological containment for some particular demonstration, without the need to demonstrate effective containment.
8	52	Please specify “Some members of the AHTEG noted...” This is a very specific call for activities under the Convention, rather than consensus opinion that horizon scanning can be a useful tool for many actors belonging to any number of governments, agencies, industries, or academia.
8	57	Please specify “...was noted by some members of the AHTEG.” Please also insert “of both beneficial and adverse” after “potential.” This paragraph appears to imply that the socio-economic impacts will be negative – i.e., the replacement of naturally occurring products with products of synthetic biology will have adverse impacts, presumably for those collecting the natural products. However, increasing the quantity and quality of the synthetic material will also have societal and economic benefits. These need to be examined together.