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EPSO comment on the report of the Ad Hoc Technical Expert Group on Synthetic Biology

09.03.2018

The European Plant Science Organisation commented on the report of the Ad Hoc Synthetic Technical Expert Group (AHTEG) on Biology (www.cbd.int/doc/c/aa10/9160/6c3fcedf265dbee686715016/synbio-ahteg-2017-01-03en.pdf?download) as we consider that several aspects are presented in an inappropriate context. The main concern of EPSO is the basic operational definition of Synthetic Biology which is covering almost all biotechnologies. As explained in our earlier statement on Synthetic Biology (www.epsoweb.org/webfm_send/2329), the use of any of these techniques is not sufficient to imply the generation of a synthetic biology organism or product. EPSO is also questioning the conclusion that an organism which is indistinguishable from a naturally occurring one or a conventional bred counterpart poses a risk going beyond them. On the other hand, EPSO is supporting the demand for international capacity building and supports the view that existing principles and methodologies for risk assessment and current strategies for risk management provide a good basis but may need a thorough update for their appropriateness.

The Conference of the Parties to the Convention on Biological Diversity, commended the work of the online forum and the Ad Hoc Technical Expert Group (AHTEG) on Synthetic Biology in decision XIII/17. The AHTEG held its meeting and presented its report in December 2017. In order to facilitate the peer review, the Executive Secretary invited Parties to peer review the report of the meeting of the AHTEG no later than 28 February 2018 (https://bch.cbd.int/synbio/peer-review/). The peer reviewed report then will be submitted for consideration by the Subsidiary Body on Scientific, Technical and Technological Advice at its twenty second meeting in Montreal, Canada, from 2 to 7 July 2018.

Comments submitted

<u>Page 0, paragraph 0:</u> The European Plant Science Organisation took notice of the report of the open AHTEG on Synthetic Biology but has considerable concerns on the working definition for Synthetic Biology. As this definition is covering a huge number of different techniques that may yield modified biological entities of various qualities, it implicates misleadingly that the use of any of these techniques is automatically leading to a LMO. Please consult our statement on synthetic biology (www.epsoweb.org/webfm_send/2329; full text at the end of these comments) for more detail on the take home message that "Synthetic Biology should not be confused with the application of new breeding techniques". Moreover, the given use of the term Synthetic Biology collides with the broad understanding of such a term in the scientific community. As outlined in our statement, "a clear-cut example of synthetic biology is the construction of a

bacterium with a synthetic genome that uses a radically different genetic code. On the other hand, the introduction or alteration of one or several genes in an organism would be considered a conventional genetic engineering approach rather than synthetic biology." This means that the type and degree of genome modification needs to be part of the definition of synthetic biology.

<u>Page 4, paragraphs 19-20</u>: Though the dual-use nature of techniques of modern molecular biotechnology is a fact, the context of wording is blurring the actual use of terms and context. 'Dual use' and 'biosecurity' are generally used in the context of bioweapons, bioterrorism etc., which is an area covered by different international treaties. Morevover, the context to the objectives of the Convention seems rather theoretical and abstract. It is suggested to keep the general statement and delete "… in relation to the three objectives of the Convention".

<u>Page 4, paragraph 21:</u> EPSO welcomes the AHTEG statement and shares the opinion that international capacity building is of utmost importance to broadly understand, evaluate and access technologies and share the benefits of modern biotechnology. EPSO is willing to help organise international training programmes by its networks.

<u>Page 5, paragraph 28:</u> We disagree with this conclusion for three reasons: (i) the phrasing " through techniques of synthetic biology" is misleading as explained in detail in our statement on synthetic biology (www.epsoweb.org/webfm_send/2329), since we do not consider that the simple use of a technique belonging to "modern biotechnology" is sufficient to classify the resulting organism under synthetic biology, (ii) the use of "most" is vague and leaves too much room for divergent interpretations, and (iii) since "the definition of LMOs as per the Cartagena Protocol" makes reference to "modern biotechnology" it needs to be clarified which techniques from the AHTEG list are concerned.

<u>Page 6, paragraphs 33-34:</u> An organism which cannot be distinguished from a naturally occurring one or a conventionally bred counterpart cannot pose any particular risk for the environment or biodiversity which goes beyond that of a naturally occurring organism. It should be acknowledged that any breeding program, including intuitive mass selection by human ancestors some 10,000 years ago, actively directs selection and modifies the biodiversity beyond what would be natural without human impact. Therefore, in view of the main goals of the CBD, it is unnecessary to detect, identify or monitor such an organism. EPSO recommends to delete the whole paragraphs 33 and 34.

<u>Page 6, paragraph 38:</u> (In paragraph 38 of the AHTEG report it is suggested that developers of organisms resulting from synthetic biology could be made responsible for providing validated tools and other material that would facilitate the detection, identification and monitoring of these organism.) As pointed out above (comment on paragraphs 33 and 34), this only makes sense for changes other than those indistinguishable from naturally occurring changes, or a conventionally bred counterpart. EPSO suggest to alter the wording in a way that only organisms are covered which possess a detectable difference to natural occurring ones or conventionally bred counterparts.

<u>Pages 6-7, paragraphs 40-48:</u> EPSO underscores the statement that existing principles and methodologies for risk assessment and current strategies for risk management provide a good basis. They indeed need a thorough updating to ensure appropriateness.

<u>Pages 7-8, paragraph 41</u>: The indicated gaps are not specific with regards to Synthetic Biology. They actually describe the limit of our understanding about complex (eco)system dynamics. This raises the general problem to evaluate the actual impact of acting or not acting. In this context, the paragraph is broadly applicable to the CBD concerns and should express this general concern.

Paragraph 43: is appropriately addressing the specific issues.

This comment was developed by Frank Hartung, Ralf Wilhelm, Joachim Schiemann and Peter Rogowsky on behalf of the EPSO Agricultural Technology Working Group. It was approved by the EPSO Board, based on the EPSO statement that Synthetic

Biology should not be confused with the application of new breeding techniques, updated statement, 30.8.2017, which was approved by the EPSO members. The comment was submitted to the AHTEG Synthetic Biology on 27 February 2018.

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ERA-Net COFUND on Synthetic Biology "ERASynBio": www.erasynbio.eu

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EPSO, the European Plant Science Organisation, is an independent academic organisation that represents more than 200 research institutes, departments and universities from 28 European countries, Australia and New Zealand, and 3.300 individuals Personal Members, representing over 27 000 people working in plant science. EPSO's mission is to improve the impact and visibility of plant science in Europe, to provide authoritative source of independent information on plant science including science advice to policy, and to promote training of plant scientists to meet the 21st century challenges in breeding, agriculture, horticulture, forestry, plant ecology and sectors related to plant science. www.epsoweb.org | EU Transparency Register Number 38511867304-09