*Annex*

**comments on the report of the Ad Hoc Technical Expert Group on Synthetic Biology –** Submitted by EPSO, 27.2.2018

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| **Contact information:** | | | |
| **Surname (1):** | | | Metzlaff |
| **Given Name (1):** | | | Karin |
|  | | |  |
| **Surname (2):** | | | Hartung |
| **Given Name (2):** | | | Frank |
|  | | |  |
| **Government** | | | n.a. |
| **(if applicable):** | | |  |
|  | | |  |
| **Organization:** | | | European Plant Science Organisation, EPSO |
|  | | | EPSO is an independent academic organisation that represents more than 200 research institutes, departments and universities from 27 European countries, Australia and New Zealand. EPSO’s mission is to improve the impact and visibility of plant science in Europe. [www.epsoweb.org](http://www.epsoweb.org) │ EU Transparency Register Number 38511867304-09 |
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| **E-mail (1):** | | | Karin.Metzlaff@epsomail.org |
| **E-mail (2):** | | | Frank.Hartung@julius-kuehn.de |
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| **Comments on the draft documentation for SBSTTA-22:** | | | |
| **Page #** | **Para #** | **Comment** | |
| 0 | 0 | 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](http://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. | |
| 4 | 19/20 | 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”. | |
| 4 | 21 | 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. | |
| 5 | 28 | 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](http://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. | |
| 6 | 33 to 34 | 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. | |
| 6 | 38 | 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. | |
| 6/7 | 40/48 | 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. | |
| 7/8 | 41/43 | (41) 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.  Para (43) is appropriately addressing the specific issues. | |
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|  |  | **Synthetic Biology should not be confused with the application of new breeding techniques**  The European Plant Science Organisation welcomes the debate about the definition, regulation and benefits of synthetic biology under the governance of the Convention on Biological Diversity (CBD). To support the ongoing discussion, EPSO here provides a short statement presenting its views on synthetic biology from the perspective of the plant science community.  As there is still no widely accepted consensus definition of the term synthetic biology, the CBD focuses on two operational definitions which have been put forward earlier. The first one was used in the opinion of the three non-food Scientific Committees (SCHER/SCENIHR and SCCS) submitted to the European Commission in 2014, and the second one was used by the Ad Hoc Technical Expert Group (AHTEG) in an opinion paper provided to the Convention on Biological Diversity (CBD) in 2016.  1. “Synthetic biology is the application of science, technology and engineering to facilitate and accelerate the design, manufacture and/or modification of genetic materials in living organisms.”  2. “Synthetic biology is a further development and new dimension of modern biotechnology that combines science, technology and engineering to facilitate and accelerate the understanding, design, redesign, manufacture and/or modification of genetic materials, living organisms and biological systems.” New dimensions of synthetic biology include (i) rational design approaches which are ideally based on predictive models elaborated by systems biology approaches, (ii) a building process based on both classic and novel techniques often used at a much larger scale than previously possible, and (iii) intensive testing by precision phenotyping. Design, building and testing are linked in a virtuous cycle to optimize the organism/product in an engineering process.  The first definition by the Scientific Committees was complemented by a list of loose criteria (including techniques, organisms and materials) that might be helpful with classifying biotechnology applications as synthetic biology. As helpful as such criteria may be for the identification and discussion of potential synthetic biology applications, the techniques themselves do not define whether an organism or product is of synthetic origin just by their mere application.  EPSO wishes to raise its concerns about the possible use of such definitions or criteria as a basis for regulatory purposes. The basic goal of synthetic biology is to engineer new synthetic organisms or products resulting from such organisms by the genuine combination of a number of modern techniques from biotechnology, computer science and other areas. | |
|  |  | 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. In between the exchange or alteration of single genes and the construction of an entirely synthetic organism lies a wide spectrum of applications using basically the same techniques. Therefore, the techniques applied cannot define whether an organism or a product derived from it falls under the definition of synthetic biology.  In addition to the technical aspects of its generation, a synthetic organism should be substantially different from any organism that can occur in nature. When compared to modern biotechnology (e.g., genetic engineering) the epistemic novelty of synthetic biology lies in the systematic and large-scale use of engineering approaches to intentionally design artificial organisms (Raimbault et al., 2016; PLoS One).  According to EPSO's view, the sort of broad operational definitions of synthetic biology provided by the SCs and AHTEG does not generally apply to the use of specific modern biotechnologies such as sequence-directed nucleases, oligo-directed mutagenesis, or other new breeding techniques. Therefore, the use of any of these techniques as such does not imply the generation of a synthetic biology organism or product. What qualifies as synthetic organisms and products for regulatory purposes should be evaluated case-by-case based on a definition that emphasizes the genuine novelty of such an organism in comparison to natural ones. Declaring all products of a particular technique synthetic biology would result in an unreasonable regulatory burden for already established uses of older and newer biotechnologies, from traditional breeding techniques to computer science and new breeding technologies, which can be sufficiently covered by existing regulatory frameworks.  Synthetic biology was discussed at the EPSO General Meeting in June 2016 and the respective statement at the EPSO Board Meeting in November 2016.  The statement was finalised by the EPSO Working Group on Agricultural Technologies and the EPSO Board. The same procedure was applied in 2017 for the updated statement. | |

1. Completed forms can be sent to Secretariat via e-mail at [synbio@cbd.int](mailto:synbio@cbd.int) or submitted online at <http://bch.cbd.int/managementcentre/edit/submission.shtml>

2. Additional rows can be added to this table by selecting “Table” followed by “insert” and “rows below”