



## ***News item on submission***

European Plant Science Organisation  
<https://epsoweb.org>

# **EPSO submission of information on synthetic biology and nomination of experts to participate in the Open-ended Online Forum on Synthetic Biology**

**In response to the COP to the CBD notification to decision 14/19 from Dec 2018**

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*Brussels, 25.3.2019*

**In its decision 14/19, the Conference of the Parties decided to “extend the Online Forum on synthetic biology taking into account the work on risk assessment under the Cartagena protocol, to support the deliberations of the AHTEG”.**

**In response to this decision the Convention on Biological Diversity (CBD) filed a notification to extend the Online Forum on synthetic biology (SB). In this forum several topics which are new since the last discussion round will be evaluated and for a start each participating party was invited to submit new data on SB developments since 2017.**

**EPSO submitted information on 15.2.2019 and nominated Frank Hartung and Thorben Sprink as participants for the Online Forum.**

**As follow up action, the CBD also asked for nominations for the Ad Hoc Technical Expert Group and EPSO nominated both of the Participants on 15.3.2019.**

A major critical point of the online discussion so far raised by several participants is the still unresolved question how to define SB. EPSO already published a statement highlighting the questionable points of the working definition on 30.8.2017 ([https://epsoweb.org/wp-content/uploads/2018/11/17\\_08\\_30\\_EPSO\\_Synthetic-Biology\\_updated-Statement.pdf](https://epsoweb.org/wp-content/uploads/2018/11/17_08_30_EPSO_Synthetic-Biology_updated-Statement.pdf)).

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### **Contacts**

**Frank Hartung & Thorben Sprink**, Julius Kuehn-Institute; [Frank.Hartung@julius-kuehn.de](mailto:Frank.Hartung@julius-kuehn.de); T: +49394647550; [Thorben.Sprink@julius-kuehn.de](mailto:Thorben.Sprink@julius-kuehn.de); T: +49394647560  
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### **Useful links**

EPSO statement that [Synthetic Biology should not be confused with the application of new breeding techniques](#), updated statement, 30.8.2017

EPSO breaking news: <https://epsoweb.org>  
 EPSO publications: <https://epsoweb.org/news/>  
 EPSO member institutes and universities: <https://epsoweb.org/about-eps/eps-members/>  
 EPSO representatives: <https://epsoweb.org/about-eps/representatives/>

**About EPSO**

EPSO, the European Plant Science Organisation, is an independent academic organisation that represents more than 200 research institutes, departments and universities from 31 countries, mainly from Europe, and 3.300 individuals Personal Members, representing over 26 000 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. <https://epsoweb.org> | EU Transparency Register Number 38511867304-09

**Annex**

**Submission of information on synthetic biology and  
 Nomination of experts to participate in the Open-ended Online Forum on  
 Synthetic Biology**

**In response to the COP to the CBD notification to decision 14/19 from Dec 2018**  
 Submitted by EPSO, 14.2.2019 and 14.3.2019

- 1) Contact Information (p.2)
- 2) Submission of information on synthetic biology - regarding the points raised by notification to decision 14/19 (p.3-6)
- 3) Nomination of experts to participate in the Open-ended Online Forum on Synthetic Biology (p. 7)

1 - Contact information:	
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<b>Given Name (1):</b>	Karin
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<b>Given Name (2):</b>	Frank
<b>Government (if applicable):</b>	n.a.
<b>Organization:</b>	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. <a href="https://epsoweb.org">https://epsoweb.org</a>   EU Transparency Register Number 38511867304-09
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<b>Title of document reviewed:</b>	Notification on decision 14/19
<b>Date of submission</b>	14.02.2019

<b>2 - Submission regarding the points raised by notification to decision 14/19:</b>		
<b>Point #</b>		<b>Comment</b>
a		<p><i>(a) The relationship between synthetic biology and the criteria set out in decision IX/29, paragraph 12, in order to contribute to the completion of the assessment requested in decision XII/24, paragraph 2, building on the preliminary analysis prepared by the Executive Secretary in document SBSTTA/22/INF/17;</i></p> <p>The European Plant Science Organisation does not see additional information going beyond the analysis of the AHTEG in the mentioned document SBSTTA. However, as EPSO stated before, "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.</p>
b		<p><i>(b) New technological developments in synthetic biology since the last meeting of the Ad Hoc Technical Expert Group in December 2017, including the consideration, among other things, of concrete applications of genome editing if they relate to synthetic biology, in order to support a broad and regular horizon scanning process;</i></p> <p>EPSO points out that there have been a number of new developments that enable research and application to address different levels of control and/or mutation of nucleic acids, e.g. CasX, Cas13, Split-TALE, Base- and Epigenome-Editing including dCas9 methylation or acetylation (Adli, 2018; Kumlehn et al., 2018; Marzec, and Hensel, 2018; Liu et al., 2019). However, these new developments do not necessarily produce organisms which are beyond LMOs or more dangerous, or directly affecting the environment. This is the case for all singular techniques, but it might be discussed if the existing guidelines are suitable for complex changes.</p>

c		<p><i>(c) The current state of knowledge by analysing information, including but not limited to peer-reviewed published literature, on the potential positive and negative environmental impacts, taking into account human health, cultural and socioeconomic impacts, especially with regard to the value of biodiversity to indigenous peoples and local communities, of current and near-future applications of synthetic biology, including those applications that involve organisms containing engineered gene drives, taking into account the traits and species potentially subject to release and the dynamics of their dissemination;</i></p> <p>Gene drives in plants are still not a feasible technique due to known limitations (Gene Drives on the Horizon: Advancing Science, Navigating Uncertainty, and Aligning Research with Public Values; The national academies of sciences, engineering and medicine (NASEM) 2016)). As SynBio plants have not been released in field trials, at least to our knowledge, we do not have data on positive or negative environmental impacts.</p>
d		<p><i>(d) Living organisms developed thus far through new developments in synthetic biology that may fall outside the definition of living modified organisms as per the Cartagena Protocol.</i></p> <p>To our knowledge to date no plants exist or will be existing in the near future, that have been produced through SynBio application and may fall outside the definition of a LMO.</p>

EPSO	Statement	<p><a href="#"><u>Synthetic Biology should not be confused with the application of new breeding techniques</u></a>, updated statement published 30.8.2017</p> <p>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.</p> <p>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.</p> <p>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.”</p> <p>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.</p> <p>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.</p> <p>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.</p>
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		<p>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.</p> <p>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).</p> <p>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.</p> <p>Synthetic biology was discussed at the EPSO General Meeting in June 2016 and the respective statement at the EPSO Board Meeting in November 2016.</p> <p>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.</p>
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### 3 – Nomination of experts to participate in the Open-ended Online Forum on Synthetic Biology

Nomination of experts:

Herewith I, Karin Metzloff, Executive Director of EPSO, would like to nominate Thorben Sprink and Frank Hartung on behalf of the European Plant Science Organisation for the Online Forum on Synthetic Biology.

Name: Dr. **Thorben Sprink**

Email: [Thorben.Sprink@julius-kuehn.de](mailto:Thorben.Sprink@julius-kuehn.de)

Affiliation: Julius Kuehn-Institute; Inst. for biosafety in plant biotechnology.

Phone: +49394647560

Expertise: Thorben Sprink is a senior scientist leading the working group on genome editing and synthetic biology at the Julius Kuehn-Institute, he is involved in various research projects dealing with the topic genome editing (e.g. CHIC, ELSA-Gea, DeviCCPO). He prepared several publications on these topics and helped EPSO to prepare slides to inform the EC in the past. Thorben Sprink is member of the EPSO working group on New Breeding Techniques.

Name: Dr. **Frank Hartung**

Email: [Frank.Hartung@julius-kuehn.de](mailto:Frank.Hartung@julius-kuehn.de)

Affiliation: Julius Kuehn-Institute; Inst. for biosafety in plant biotechnology.

Phone: +49394647550

Expertise: Frank Hartung is a senior scientist, and leading the working group on basic research on DNA repair and recombination including genome editing at the Julius Kuehn-Institute. He is involved in various research projects dealing with the topic genome editing (e.g. ELSA-Gea, NuVaMax, EVITA etc.). He prepared several publications on these topics and developed the EPSO statement on Synthetic Biology. Frank Hartung is one of the chairs of the EPSO working group on New Breeding Techniques and EPSO member since 2012.