



Statement

European Plant Science Organisation
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Synthetic Biology should not be confused with the application of new breeding techniques

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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.

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- EPSO Working Group Agricultural Technologies: www.epsoweb.org/agricultural-technologies-wogr
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About EPSO

EPSO, the European Plant Science Organisation, is an independent academic organisation that represents more than 220 research institutes, departments and universities from 28 European countries, Australia, Japan and New Zealand, and 3.300 individuals Personal Members, representing over 28 000 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