



**Statement**

European Plant Science Organisation  
[www.epsoweb.org](http://www.epsoweb.org)

## On the EFSA draft opinion on directed mutagenesis

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*Brussels, 25.6.2020*

**EPSO agrees with the general statement of EFSA that risk-assessments should be done in a case-by-case manner and that the suggested procedures for risk assessment of SDN-3 that pertain to risk assessments of transgenes do not apply to SDN-1, SDN-2 and oligonucleotide-directed mutagenesis, and should be simplified for these. Furthermore, EPSO suggests clarifications in the definitions of SDN-1 and SDN-2 and the nature of the introduced base changes using these two techniques.**

**The EFSA public consultation** of the applicability of site-directed nucleases type 3 safety assessments on plants developed using site-directed nucleases type 1, type 2, and oligonucleotide-directed mutagenesis.

EFSA has issued in 2012 a scientific opinion on the safety assessments of plants developed using Site-Directed Nucleases type 3, SDN-3 ([EFSA, 2012](#)). In these plants, site-directed nucleases have been used to introduce exogenous (recombinant) DNA in a site-specific manner through homologous recombination.

In spring 2020, EFSA issued a draft scientific opinion for public consultation on the applicability of the safety assessments of type 3 site-directed nucleases (SDN-3) on plants developed using SDN-1 SDN-2, or oligonucleotide-directed mutagenesis ([EFSA 2020](#)). In plants developed using either of these techniques, no exogenous (recombinant) DNA is inserted into the plants. In SDN-1, predominantly point mutations or short in/dels are introduced through non-homologous end-joining at the target cleavage site. In SDN-2 and oligonucleotide-directed mutagenesis, a short nucleotide sequence is used to guide the inherent DNA-repair mechanism to introduce a few predetermined base changes. Mainly EFSA promotes a case-by-case risk evaluation and outlines possible simplifications concerning specific genome editing methods. If no exogenous (recombinant) DNA is inserted into the plant, the subset of SDN-3 risk assessment protocols that evaluates transgenes are not applicable.

Read the complete EPSO submission at  
<https://ec.europa.eu/eusurvey/printcontribution?code=2afbb313-5b48-4a95-ae36-67cdf90bd7cc>

*This statement summarises EPSO's submission to the EFSA draft opinion on directed mutagenesis. The submission was developed by the EPSO Agricultural Technology*

*Working Group led by Jens Sundstrom and Peter Rogowsky, with input from the EPSO Representatives and approved by the EPSO Board.*

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#### **Useful links**

- EFSA draft scientific opinion on the safety assessments of plants developed using Site-Directed Nucleases type 3, SDN-3  
[https://www.efsa.europa.eu/sites/default/files/consultation/consultation/Scientific\\_opinion\\_SDN1\\_2\\_ODM\\_for\\_PC.pdf](https://www.efsa.europa.eu/sites/default/files/consultation/consultation/Scientific_opinion_SDN1_2_ODM_for_PC.pdf)
- EC study on new genomic techniques (NGTs)  
[https://ec.europa.eu/food/plant/gmo/modern\\_biotech/new-genomic-techniques\\_en](https://ec.europa.eu/food/plant/gmo/modern_biotech/new-genomic-techniques_en)
- Court of Justice of the EU: Judgment in Case C-528/16, 25.7.2018. [English Press Release](#); [Ruling in English](#):

<https://epsoweb.org>

EPSO [Working Group on Agricultural Technologies](#):

Statements drafted by this group and approved by the EPSO representatives are for instance:

- EPSO submission to the EFSA draft scientific opinion on the safety assessments of plants developed using Site-Directed Nucleases type 3, SDN-3, 28.5.2020  
ID: 2afbb313-5b48-4a95-ae36-67cdf90bd7cc  
<https://ec.europa.eu/eusurvey/printcontribution?code=2afbb313-5b48-4a95-ae36-67cdf90bd7cc>
- EPSO contribution to the EC stakeholder consultation on new genomic techniques to contribute to a Commission study requested by the Council, 15.5.2020.  
ID: 9c35adb8-621d-4e6c-a6e7-652c4c6ae06c.pdf <https://bit.ly/2M0SDHe>  
20\_05\_13\_Supporting document 1\_EPSO submission\_Reference list for Q1 to Q29.pdf  
<https://bit.ly/2TG9nrI>
- EPSO updated statement on [Crop Genetic Improvement Technologies](#), 12.01.2017
- EPSO: [Opinion on the SAM Explanatory Note on New Techniques in Agricultural Biotechnology](#), 15.9.2017
- EPSO: [First reaction on the Advocate General's Opinion regarding mutagenesis and the Genetically Modified Organisms Directive](#), 18.1.2018
- EPSO: [Statement on the Court of Justice of the EU ruling regarding mutagenesis and the GMO Directive](#), 19.2.2019
- EPSO: [EPSO welcomes Commissioner Andriukaitis statement and call for action 'New plant breeding techniques need new regulatory framework'](#), 29.3.2019
- EPSO: [Synthetic Biology should not be confused with the application of new breeding techniques](#), updated statement, 30.8.2017
- EPSO: [Comment on the report of the Ad Hoc Technical Expert Group on Synthetic Biology](#), 8.3.2018, [original report of the AHTEG and all submitted comments](#).

EPSO communications: <https://epsoweb.org/news/>

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#### **About EPSO**

EPSO, the European Plant Science Organisation, is an independent academic organisation that represents more than 200 research institutes, departments and universities from 30 countries, mainly from Europe, and 2.600 individual 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