Statement

European Plant Science Organisation
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On the French draft legal proposal amending the list of techniques for obtaining genetically modified organisms

Brussels, 8.7.2020

Summary
The European Plant Science Organisation (EPSO) is concerned about the draft legal proposal on the genetic modification techniques mentioned in Article L531-2 of the French Environment Code, which would modify the list of techniques of mutagenesis exempt from the scope of the regulations on GMOs[1]. In particular, the draft legal proposal would revoke the exception of in vitro random mutagenesis consisting of subjecting plant cells cultivated in vitro to chemical or physical mutagenic agents. This unilateral restriction of GMO Directive 2001/18/EC disregards scientific literature evidencing the history of safe use of in vitro random mutagenesis, ignores the ruling of the European Court of Justice (ECJ, case C-528/16) reiterating the exemption of all random mutagenesis techniques established before 2001, establishes barriers for research and innovation between member states and will be difficult to enforce by French authorities. **EPSO urges the European Commission to take action to prevent the French draft legal proposal from being enacted.**

In vitro random mutagenesis is a technique with a history of safe use
The French draft legal proposal is meant to implement the decision of the French Council of State delivered on 7 February 2020, which concludes (i) that the technique of in vitro random mutagenesis subjecting plant cells to chemical or physical mutagenic agents is not a conventionally used technique which has a long safety record, having appeared or having mainly been developed since the adoption of Directive 2001/18/EC and (ii) that the organisms obtained via this technique must be subject to the regulations on GMOs. This argument does not take into account scientific literature. EMS mutagenesis of tobacco cell suspensions and the regeneration of auxotrophic mutant tobacco was documented more than 30 years before the adoption of Directive 2001/18/EC[2]. Moreover, the usefulness of random mutagenesis of in vitro grown plant material was reinforced in the same era in other species, including soybean and carrot[3]. The history of herbicide tolerant crops shows that in the early 90s several techniques, including in vitro random mutagenesis, were employed in parallel. Selection of in vitro cultured cells followed by regeneration (maize)[4], in vivo random mutagenesis of seeds (wheat)[5], in vitro random mutagenesis of microspores followed by regeneration (oilseed rape)[6], as well as spontaneous mutants in wild relatives (sunflower)[7] provided the alleles of the commercial varieties emerging at the end of the last century. The European legislator had these elements in hand when he exempted mutagenesis from the GMO evaluation procedure in 2001 without making a distinction between in vivo and in vitro random mutagenesis. In addition, after several decades of culture of herbicide tolerant crop varieties, there is no evidence for any particular harm linked to varieties obtained by in vitro random mutagenesis in comparison to varieties obtained by other techniques. Taken together,

all these arguments lead EPSO to consider that in vitro random mutagenesis is a technique with a history of safe use.
A more detailed analysis of the history and impact of in vitro mutagenesis is provided in the opinion on the French draft legal proposal by the European Technology Platform "Plants for the Future"[8], to which EPSO contributed and which EPSO fully supports.

Barriers for research and innovation

Beyond these scientific arguments of particular importance to EPSO, several other aspects need to be considered. The draft legal proposal would lead to a distortion in research and varietal innovation depriving scientists and breeders active in France or on the French market not only from the use of the technique, but also from the breeder's privilege to further improve varieties that involved in vitro random mutagenesis somewhere in their pedigree. The draft legal proposal would also be problematic to enforce, since it is difficult to know, after several decades of non-regulated use of the technique, whether a present variety has been produced by in vitro random mutagenesis or obtained by crossing with a variety obtained by the technique. Furthermore, even if a mutation providing an advantageous trait possibly could be detected, it would be impossible to prove that is has been obtained by in vitro or in vivo mutagenesis, selective in vitro culture or spontaneously. The resulting legal uncertainty would negatively impact research and development in Europe.

Conclusion

The French draft legal proposal disregards scientific evidence and action by the European Commission is needed to prevent it from being acted.

This statement summarises EPSO's input into the opinion on the French draft legal proposal of the European Technology Platform "Plants for the Future". It was developed by EPSO Agricultural Technology Working Group members and approved by the EPSO Representatives and Board.

References

[1] French draft Decree amending the list of techniques for obtaining genetically modified organisms traditionally used without any noted drawbacks with regard to public health or the environment (https://ec.europa.eu/growth/tools-databases/tris/en/index.cfm/search/?trisaction=search.detail&year=2020&num=280&mLang=EN)

[2] Carlson PS (1970) Induction and isolation of auxotrophic mutants in somatic cell cultures of *Nicotiana tabacum*. Science 168:487-489

[3] Sung ZR (1976). Mutagenesis of cultured plant cells. Genetics, 84: 51-57 (PMID: 17248732).

[4] Anderson PA, Georgeson M (1989) Herbicide-tolerant mutants of corn. Genome 31:994-999 (doi: 10.1139/g89-173).

[5] Newhouse K, Smith WA, Starrett MA, Schaefer TJ, Singh BK (1992) Tolerance to imidazolinone herbicides in wheat. Plant Physiol 100:882–886.

[6] Swanson EB, Herrgesell MJ, Arnoldo M, Sippell DW, Wong RSC (1989). Microspore mutagenesis and selection: Canola plants with field tolerance to the imidazolinones. Theor Appl Genet 78:525-530 (doi: 10.1007/BF00290837).

[7] Al-Khatib K, Baumgartner JR, Peterson DE and Currie RS (1998) Imazethapyr resistance in common sunflower (Helianthus annuus). Weed Sci 46:403–407.

[8] Opinion on the French decree proposal by the European Technology Platform "Plants for the Future" www.plantetp.org/system/files/publications/files/plantetp_fd_opinion_20200707.pdf

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Useful links
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 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: Statement on the EC study on New Genomic Techniques (NGTs), 27.5.2020
- EPSO statement on the EFSA draft opinion on directed mutagenesis, 25.6.2020
- 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.

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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