

Dear Members,

The European Food Safety Authority (EFSA) has confirmed in a scientific opinion **that genome editing techniques used to introduce targeted mutations in plants do not pose more hazards than conventional breeding methods.**

The scientific opinion on the “[Applicability of the EFSA Opinion on site-directed nucleases type 3 for the safety assessment of plants developed using site-directed nucleases type 1 and 2 and oligonucleotide-directed mutagenesis](#)” is part of the Commission study on NGTs. The assessment on SDN1/2 and ODM was done in view of the previous [EFSA Opinion on SDN-3](#).

Main Conclusions from the Opinion:

- SDN1/2 technologies aim to modify an endogenous DNA sequence in a targeted manner, and if the final product does not contain any transgene, intragene or cisgene, these plants will not present any of the hazards potentially associated with the inserted transgene, intragene or cisgene found in plants obtained using the SDN-3 approach.
- The GMO Panel considers that the analysis of potential off-targets would be of very limited value for the risk assessment. The EFSA Opinion on SDN-3 stated that backcrossing steps which follow the transformation process would likely remove off-target mutations from the genome of the final product. The GMO Panel considers this aspect still applicable to plants generated via SDN-1, SDN-2 and ODM approaches.
- The GMO Panel did not identify any additional hazard associated with the use of the SDN-1, SDN-2 or ODM approaches as compared with both SDN-3 and conventional breeding techniques which include conventional mutagenesis.
- The GMO Panel concludes that the existing guidance for food and feed (EFSA GMO Panel, 2011) and environmental risk assessment (EFSA GMO Panel, 2010) is sufficient but is only partially applicable for the risk assessment of plants generated via SDN-1, SDN-2 or ODM approaches.

(a number of requirements in the existing guidance that are linked to the presence of a transgene are not relevant for the assessment of SDN-1, SDN-2 or ODM plants which is not the case for SDN1/2 and ODM plants).

- The amount of experimental data needed for the risk assessment will mainly depend on the modified trait introduced and, therefore, the GMO Panel considers that the principle of a case-by-case approach to a risk assessment is particularly relevant for SDN-1, SDN-2 and ODM plants. The case is linked to the “history of safe use” as to the characteristic introduced by SDN1/2 or ODM.

Still, the EFSA Opinion is of course done on the basis of the ECJ ruling that regards results from targeted mutagenesis breeding as GMOs and does not reflect our preferred approach to exclude those plants from the GM-legislation. The consequences of this opinion and the conclusions which will be drawn from them are not clear yet. We got the information that the Commission has asked member states in a Regulatory Committee meeting on 12 November during which the EFSA Opinion was presented about their conclusions and potential consequences. It seems as if member states asked for additional time to assess the report and to come back to Commission **by the end of the year.**

We therefore ask our national association members to approach their national governments and in view of the EFSA opinion and the conclusion that plants from targeted mutagenesis applications do not pose more hazards than conventional breeding methods, again highlight our position that plants resulting from targeted mutagenesis breeding (like SDN-1/2 and ODM) should be excluded from the GMO regulation and treated as conventional varieties.

This will hopefully give an additional push towards the EU Commission to come forward with a legal proposal after finalizing the NGT study. We would appreciate to receive your feedback in case you get any new information regarding the positioning of your national governments.

Kind regards,

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