EFSA: Risk assessment of New GE plants necessary even if no additional genes are inserted

European Food Safety Authority presents new report

18 February 2021 / The European Food Safety Authority (EFSA) has published another report on the risk assessment of plants developed with new genetic engineering (New GE). The report includes plants generated using gene scissor CRISPR/Cas applications where no new additional genes are inserted (so-called SDN-1 applications). The EFSA report shows that detailed risk assessment must be carried out even if no additional genes are inserted. The report is the outcome of a consultation which included Testbiotech.

The example chosen by EFSA is wheat, derived from application of CRISPR/Cas, with a strongly reduced gluten content. This protein is thought to trigger inflammatory responses. Using CRISPR/Cas meant that several dozen genes and gene copies in the wheat genome were changed at the same time. EFSA rightly concludes that these complex patterns of genetic change go beyond what has been achieved in genetic engineering and conventional breeding thus far. EFSA explained that if an application for market approval was filed, then risk assessment should take issues such as molecular changes, gene expression and the potential impact on health and the environment into account.

Many food plants, such as wheat and maize, have very large genomes inheriting many copies of specific genes or families of similar genes: complex patterns of genetic changes are therefore a typical outcome of the CRISPR/Ca applications. In most cases, all genes with a specific sequence are altered at the same time. This means that the EFSA report is not only relevant to individual cases but will most likely be relevant to the majority of New GE applications in food plants.

EFSA does not give any explanation as to why the relevant risks were not mentioned in its previous report on SDN-1 applications published in November 2020. Furthermore, EFSA now categorises the wheat as ‘Synthetic Biology’. Consequently, EFSA is arbitrarily dividing the gene scissor applications into different categories, making it much more difficult to conclude on the true range of risks associated with SDN-1 applications.

Testbiotech has criticised EFSA for not providing the necessary clarity and instead causing a great deal of confusion. Testbiotech is also worried because the EFSA report only discusses a small selection of the relevant risks. EFSA primarily concentrates on the intended results and mostly neglects the unintended effects caused by the processes of genetic engineering.

Whatever the case, clarity on the risks of New GE is urgently needed. Currently, the EU Parliament is discussing the ‘farm to fork’ strategy proposed by the EU Commission. In this context, some Members of Parliament are demanding the deregulation of New GE plants. In addition, the EU Commission is discussing its own report on New GE which will be published probably in April.

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Weitere Informationen: The EFSA opinion [2]
Information on previous EFSA opinion regarding New GE [3]
Testbiotech report: Frequently Asked Questions on ‘New Genetic Engineering’ and technical backgrounds for CRISPR & Co [4]

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