

Biased questions and flawed assumptions

How the EU Commission and EFSA are paving the way for deregulation of New GE

30 June 2022 / Testbiotech recently participated in an European Food Safety Authority (EFSA) consultation on guidelines for the risk assessment of 'cisgenic' plants, which ended at the beginning of this week. The 'cisgenic' plants are genetically engineered, but, in contrast to transgenic plants, contain no genetic material from other species. EFSA suggests that most applications of CRISPR/Cas can be put into this category. The consultation is, therefore, generally relevant to the risk assessment of plants derived from New GE (also called new genomic techniques, NGT). However, the way in which EFSA deals with this issue appears to be completely inadequate.

The EU Commission asked EFSA in 2021 to draft an opinion on the risk assessment of 'cisgenic' plants, also taking the processes of New GE into account. The document for public consultation appeared on the EFSA website in May 2022.

The wording of the EU Commission request to EFSA shows that it is based on some highly questionable assumptions, which now appear to have influenced the outcome. For example, the EU Commission states that most plants derived from the New GE techniques would not pose any "new hazards compared to conventionally bred and transgenic plants". Thus creating the impression that risks associated with New GE can be equated to those in conventional breeding.

Despite this assumption being obviously incorrect, it was used as a starting point to draw up the EFSA draft opinion that was made available for the public consultation. This could be a reason why EFSA has ignored most of the relevant scientific publications showing that the characteristics of New GE plants can be very different to those found in conventional breeding. These differences concern both intended and unintended effects, which occur independently of whether additional foreign genes are integrated or not. As a consequence, there are specific risks of which there are many examples:

CRISPR/Cas was used to genetically engineer wild tomatoes to make them look similar to conventionally-bred tomato varieties. Even though no new genes are integrated, they are clearly very different in composition to conventionally-bred tomatoes. They may, therefore, not be safe for human consumption and would need to undergo in-depth risk assessment. EFSA failed to mention this in their current draft.

A recent study found that the natural diversity of genetic variations in plant populations can be decisive for the stability of the associated ecosystems. In this regard, New GE poses new specific risks to the environment, as it can very efficiently and extensively make different genetic variations (alleles) much more 'uniform' in plant populations in comparison to conventional breeding. This could be a factor in the destabilization of ecosystems. EFSA did not take this into consideration.

Even the intended genetic changes resulting from the multistep processes of New GE can be clearly different to those resulting from conventional breeding: additional DNA is frequently integrated into the genome where it can cause unexpected changes. Even though this finding has been reported in various scientific publications, EFSA has mostly failed to take it into consideration.

Testbiotech is concerned that the science in this debate is increasingly becoming a 'pawn' in the economic interests of the industry. A further EU Commission consultation on the future regulation of New GE only serves to reinforce this impression. Several observers have already noticed the one-sided approach in the questions, and are, therefore, concerned that this could influence the outcome of the consultation. A one-sided outcome could lead the EU Commission to propose deregulating most plants derived from New GE, i.e. exempting them from mandatory risk assessment.

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Further information: [Text of the EFSA consultation](#) [2]

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