

EFSA holding public consultation on new methods of genetic engineering

Testbiotech demands major revision

11 May 2020 / The European Food Safety Authority (EFSA) is holding a public consultation on plants developed with new methods of genetic engineering (genome editing). The EFSA draft document looks at changes made to the genome using tools such as CRISPR/Cas, but without the insertion of additional gene sequences. Testbiotech has concluded that the published draft suffers extensively from not taking numerous relevant publications and important scientific findings into account.

EFSA gives the impression that new methods of genetic engineering do not pose any new challenges for risk assessment simply because no additional genes are inserted. However, taking a closer look at the EFSA arguments, they seem to be largely shaped by ignorance of the most relevant facts.

In its draft opinion, EFSA did not properly consider the real technological potential of the new technology, especially CRISPR/Cas applications. These show a high chance to penetrate the genome and generate profound changes in the biological characteristics of plants, even without introducing any additional DNA sequences. These changes will typically lead to biological characteristics, such as changes in plant composition, that exceed the range of characteristics achieved using previous plant breeding methods. Therefore, risks associated with the release, cultivation and the consumption of these plants need to be fully investigated in each case before any conclusions on the safety of the new organisms can be drawn.

In addition, there is a wide range of specific unintended effects generated by the new methods of genetic interventions, which in most cases are also combined with methods of previous 'old' genetic engineering, such as the 'gene canon'. All these effects caused by the multistep process of genome editing have to be taken into account.

In contrast to EFSA assumptions, these unintended effects can hardly be compared to those observed in conventional methods of breeding. Tools such as CRISPR/Cas have to be considered to be 'biotechnological mutagens' that, in contrast to chemical or physical mutagens, directly interact with the biological mechanisms on the level of the genome. When these biotechnological mutagens are used, natural mechanisms of gene regulation may be circumvented and the genome is made available for changes to a much greater extent than ever before.

The new challenges in risk assessment include environmental risk assessment, including changes in the composition of plants, which may impact the food web or plant communication and interaction with the environment. In addition, there are specific risks associated with genetically engineered plants if persisting and propagating in the environment.

Testbiotech demands the EFSA draft is extensively revised and that the methodology and guidance for risk assessment are adopted accordingly. Whatever the case, detailed examination of an organism's genetic and overall biological characteristics, starting with the process that was used to generate the plants, is needed to demonstrate their safety.

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Further information: [The draft text published by EFSA for public consultation \(deadline 27 of May 2020\)](#) [2]

[A short summary of the Testbiotech analysis](#) [3]

[Video clips showing differences between breeding and genetic engineering](#) [4]

[Examples for risks of genetically engineered organisms](#) [5]

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