

EU Commission ignores scientific findings on New GE risks

CRISPR/Cas techniques create new hazards

21 December 2021 / Testbiotech has received a letter from the EU Commission setting out its views in relation to new publications on the risks associated with CRISPR/Cas genetic scissors. In their opinion, any hazard potential arising from unintended genetic changes caused by the processes of New GE, is no different to that of conventional breeding. Existing scientific evidence, however, contradicts this view.

According to the Commission, there are no new hazards specifically linked to unintended effects caused by these techniques, provided that no additional genes are inserted. This statement completely ignores experimental scientific evidence to the contrary. While the overall number of research projects on this topic is low, research on rice, oilseed rape, wheat and fish shows that both the intended and unintended effects caused by the gene scissors are associated with new and specific risk potential.

There are several reasons: specific natural mechanisms and factors act in the cells to ensure the frequency of spontaneous mutations, is not equally distributed in the genome. The new genomic techniques, and in particular CRISPR/Cas genetic scissors, can circumvent these natural repair and protection mechanisms. These techniques can thus generate so far unknown genetic changes and new genotypes. This is true for both the intended and unintended effects, and does not depend on the insertion of additional genes. At least three categories have to be taken into account in this context. While these categories are generally well-known, the specific hazards arising from the use of genetic scissors are new:

- (1) Gene function knock out: the technical processes of New GE can cause specific genetic changes outside of the target region of the genetic scissors (off-target). One reason is that the genetic scissors can confuse similar genomic regions, and thus induce unintended genetic changes, or a combination of changes, in the genome - which would otherwise be highly unlikely to occur.
- (2) Insertions, deletions and distortions: the technical processes of New GE can cause larger sequences of DNA to be either unintentionally deleted, additionally inserted or rearranged. Such effects are equally probable at on-target and off-target regions in the genome. The resulting pattern of genetic changes can be highly specific and unlikely to otherwise occur.
- (3) Production of new components: these effects can occur at on-target or off-target sites. Genes which are altered by the genetic scissors may be unexpectedly expressed in a new way and produce, for example, new proteins which would be otherwise unlikely to occur.

Finally, the initial step in CRISPR/Cas plant applications very often involves using 'old' genetic engineering methods. This step is necessary to introduce the DNA required for the genetic scissors into the cells. It is only in the second step that the gene scissors are activated. These 'old' GE techniques have their own risks, and may cause unintended effects which are different to those known in conventional breeding.

The risks are complex: each unintended genetic alteration can affect several biological functions. In many cases, the specific effects are not easy to detect. If New GE organisms were to be approved for release into the environment, the risks would need to be addressed and investigated in advance.

Despite all the scientific evidence, the EU Commission continues to deny the specific risks connected to unintended genetic changes. It may, therefore, be plausibly assumed that one reason for this attitude are political plans to abandon the mandatory risk assessment of New GE. In future, only a few selected New GE organisms might be assessed, and only in regard to their intended characteristics. Testbiotech is warning of the consequences of implementing new GMO regulation

which is not in accordance with the scientific findings.

Furthermore, Testbiotech is very critical of major deficiencies in independent risk assessment. Answering recent questions from the EU Parliament, the EU Commission admitted that they have no overview of risk research projects and had provided no support or encouraged such research. Indeed, it appears that there are no such EU projects at all. Even though the Commission listed some examples, these had no relevance whatsoever to the risks associated with New GE.

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Further information: [The letter from the EU Commission](#) [2]

[The publication from Kawall](#) [3]

[The publication from BfN](#) [4]

[Specific example of the specific risks of new genetic engineering: CRISPR rice](#) [5]

[Answer of the EU Commission to the Parliament's question](#) [6]

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[1] <mailto:info@testbiotech.org>

[2] <https://www.testbiotech.org/content/letter-eu-commission-reply-testbiotech-kawalls-new-publication-dec-2021>

[3] <https://www.mdpi.com/2223-7747/10/11/2259/htm>

[4] <https://www.bfn.de/aktuelle-meldungen/bfn-positions-papier-zu-neuen-gentechniken-und-ihrer-regulierung>

[5] https://www.testbiotech.org/en/limits-to-biotech/crispr-rice/basic_paper

[6] https://www.europarl.europa.eu/doceo/document/E-9-2021-003643-ASW_EN.html