# Deregulation of New GE: Reasonable? Proportional?

**Subtitle:** TESTBIOTECH Background 18 - 5 - 2021

The EU Commission has published a report setting out plans to change EU GMO regulation (EU Commission 2021). According to this report plants derived from New GE (new genomic techniques, genome editing), could be exempt from EU regulation if their intended characteristics are already known from conventional breeding and no transgenes have been inserted. In addition, it proposes that potential benefits should be taken into consideration in the respective approval processes.

However, a Testbiotech analysis calls the proportionality of the planned changes into question: the planned changes in regulation will have a serious impact on the interests of consumers, farmers, breeders and food producers. On the other hand, any potential benefits are likely to be minor or insignificant.

In addition, the proposals in the report appear to be ill-considered and not purposeful. There is no scientific justification for declaring whole groups of genetically engineered plants safe. The reason: apart from the intended genetic changes and traits, including their possible combinations, the unintended effects arising from the multistep processes of New GE and their impacts must also be taken into account.

This Testbiotech backgrounder provides a tabular overview of various risk categories. It concludes that, independently of whether there is a change in legislation, every approval of an organism derived from New GE – both now and in future - must include thorough in-depth risk assessment to avoid damage to health or the environment. Substantial risks to health and the environment would be an inevitable consequence if this were to be ignored.

The overview also shows that the European Food Safety Authority (EFSA) has not sufficiently considered unintended effects caused by New GE processes, even though such effects play a key role in EU Commission argumentation to justify possible deregulation.

Testbiotech therefore concludes that the EU Commission report is too one-sided or, at the very least, incomplete.

Testbiotech further recommends that the EU Commission first of all examines existing legislation to determine whether it currently includes enough flexibility to achieve its aims. The EU Commission can, for example, already take potential advantages of genetically engineered plants into consideration in its decisions on EU approvals. In addition, risk assessment standards can, amongst others, be precisely regulated through implementation rules, without having to change the legal framework.

Testbiotech additionally draws attention to the considerable need for research to be carried out in regard to risks and risk assessment methodology. In many cases, current standards of risk assessment need to be significantly raised in order to assess the often highly complex genetic changes.

This all underlines the need to strengthen the precautionary principle, precisely because New GE has a huge potential to generate technical interventions associated with complex risks and potential damage, which often only become apparent after a longer period of time.

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| **File attachments:** Attachment | Size |
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| Deregulation of New GE _reasonable-.pdf [1] | 158.98 KB |

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