EU Commission wants to reform GMO regulation

Testbiotech points to already existing legal flexibility

30 April 2021 / The EU Commission has published a report on new genomic techniques (New GE, genome editing) in plants and animals. They have concluded that the current EU GMO regulation should be reformed. Its fundamental goals are to promote New GE applications in agriculture and to foster international trade, technology and product development. The Commission is also demanding that decisions on market approvals should consider the potential benefits and not only the outcome of risk assessment. Safety for health and environment should nevertheless be guaranteed. A public consultation will be held in the coming months to resolve open questions.

Testbiotech plans to contribute to the consultation and also sees the need for some adjustment. One reason: in many cases, the risk assessment of the New GE applications is much more complex compared to 'Old GE'. At the same time, Testbiotech also points out that current regulation provides enough flexibility for adjustments. This is not only relevant for standards in risk assessment. For example, the EU Commission can already take potential benefits into account in its decisions on market approvals. However, as Testbiotech emphasises, these aspects must not be confused with scientific questions of risk assessment.

Furthermore, according to Testbiotech, it is evident that any general exclusions from mandatory approval process cannot be justified, as there are no sufficiently reliable scientific criteria that make it possible to declare specific categories of New GE applications to be safe. Safety of specific organisms can only be concluded after a case by case examination of the risks – but not in advance or solely taking the intended characteristics of the GE organisms into account. The same applies even when no additional genes are inserted.

Testbiotech also remains critical on the methodology of the EU Commission report: the report refers several times to an opinion published by the European Food Safety Authority (EFSA), which claims there are no specific risks associated with New GE applications in plants. At the same time, another recent EFSA opinion shows that the risk assessment of such plants faces huge challenges even if no additional genes are inserted. However, this opinion of EFSA is not mentioned by the EU Commission.

Moreover, there is currently no sufficiently comprehensive evaluation of the unintended effects associated with New GE techniques such as CRISPR/Cas gene scissor applications. For example, in many cases, these technical processes involve a combination of old and new GE, often causing a broad range of unintended genetic changes. However, in supplemental dossiers published together with the report of the EU Commission, only some of these specific unintended effects and the risks going along with it are discussed.

Testbiotech concludes that the EU Commission report is too one-sided or at very least incomplete. In consequence, it may substantially weaken the precautionary principle.

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Further information: The EU Commission report [2]
Information on EFSA report regarding New GE [3]

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