



EUROPEAN FEDERATION OF
BIOTECHNOLOGY

To Commissioner V. Andriukaitis
Health & Food Safety
European Commission
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Dear Commissioner,

Recommendation. The European Federation of Biotechnology (EFB) is concerned to point out the far-reaching consequences of a legal interpretation of the legislation for genetically modified organisms (GMO). We urge the Commission to maintain a scientifically justified approach that will both provide legal certainty and encourage European innovation. In particular:

- Organisms produced with gene editing techniques (*e.g.* CRISPR/Cas, nucleases, oligo directed mutagenesis) provide up-to-date alternatives to random mutations that, like their less precise equivalents, should be exempted from the application of the GMO legislation.
- Organisms produced with techniques that lead to the stable integration in the host genome of genetic material that will be inherited in subsequent generations can be considered on the basis of the origin of the inserted genetic material.
- Organisms derived from GMOs but not containing the inserted recombinant genetic material anymore (*e.g.* after removal or segregation) should no longer be considered “genetically modified”.

Background information. The EFB is Europe’s non-profit Federation of National Biotechnology Associations, Learned Societies, Universities, Scientific Institutes, Biotech Companies and individual biotechnologists working to promote biotechnology throughout Europe and beyond. The EFB mission is to promote the safe, sustainable and beneficial use of the life sciences, to promote research and innovation at the cutting edge of biotechnology, to provide a forum for interdisciplinary and international cooperation, to improve scientific education and to facilitate an informed dialogue between scientists and the public. The EFB has more than 80 Institutional members, more than 30,000 personal members, and 14 Regional Branch Offices across Europe to support its activities.

The first European Directives on activities with GMOs were established in 1990. The legal framework provided a state-of-the art definition of GMO and determined the scope of application of the legislation. Since then tremendous developments in biological sciences and technology have provided the drivers for the Biobased Knowledge Economy. New technological options require authorities to reinterpret the GMO definition. In 2007 a set of so-called New Plant Breeding Techniques were presented at the meeting of Competent Authorities under Directive 2001/18/EC. The Commission is now expected to resolve whether the products of these techniques should be considered GMO.

EFB wants to stress that the term New Breeding Techniques may misleadingly suggest that these techniques are specific for plant and/or animal improvement. On the contrary, these techniques are essential in research and industrial life science spanning agri-food, industrial and medical sectors. They are internationally recognized as major breakthroughs and given their high precision considered safer than conventional techniques. Subjecting the products developed through them to the stringent GMO legislation is against the precautionary principle.



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In the EU, Member State Competent Authorities for Directive 2001/18 have already assessed some of the techniques. Several Member States (*e.g.* Germany and UK) have indicated that products obtained with Oligo Directed Mutagenesis can be exempted from the GMO legislation as they are considered products of mutagenesis. Recently, Sweden has confirmed that plants in which the genome has been edited using the CRISPR-Cas9 technology do not fall under the European GMO definition. These opinions are in line with the conclusions of the New Techniques Working Group established by the Competent Authorities. Also at an international level, products developed with these techniques have been reviewed as not regulated. A diverging European opinion will create both a competitive disadvantage for European R&D as well as trade issues.

Urgent request: It is important that after more than 8 years of consideration, the Commission communicates an interpretation that provides legal certainty and that is in line with the objectives of the GMO Directives. By following the conclusions of the New Techniques Working Group and the basic principles proposed by EFB, a path forward will be established that guarantees a high level of safety as well as access for European scientists and companies to the latest techniques.

With best wishes

Mathias Uhlen
EFB President