

**To:**

Sabine Juelicher, Director for Food and Feed Safety, Innovation, DG SANTE  
Irene Sacristán Sánchez, Head of Unit for Biotechnology, DG SANTE

**Cc:**

Frans Timmermans, Executive Vice-President, European Green Deal  
Stella Kyriakides, European Commissioner, Health and Food Safety  
Janusz Wojciechowski, European Commissioner, Agriculture  
Mariya Gabriel, European Commissioner, Innovation, Research, Culture, Education and Youth

27 May 2021

**Subject:** Requesting clarification on certain issues in the European Commission report “*Study on the status of new genomic techniques under Union law and in light of the Court of Justice ruling in Case C-528/16*”, 29 April 2021

Dear Director,  
Dear Head of Unit,

**On behalf of Växtnoden, we request the European Commission to provide clarity on the definitions, or clarity as to the meaning, of key terms in the EU legislation on genetically modified organisms (GMOs), and based on this provide clarity on which new genomic techniques (NGTs) result in organisms that meet the GMO definition.**

In Your response (Ref. Ares(2021)2051216 – 23/03/2021) to a previous letter from us regarding a clarification on the legal status of novel genomic techniques (NGTs), You kindly encouraged us to continue contributing to the discussion on the future of biotechnology in the EU. We appreciate this invitation and will therefore share some reflections on the European Commission report “*Study on the status of new genomic techniques under Union law and in light of the Court of Justice ruling in Case C-528/16*”, dated 29 April 2021.

**First**, the Executive Summary states that “*The study makes it clear that organisms obtained through new genomic techniques are subject to the GMO legislation*”. This main statement is followed immediately by the observation “*However, developments in biotechnology, combined with a lack of definitions (or clarity as to the meaning) of key terms, are still giving rise to ambiguity in the interpretation of some concepts, potentially leading to regulatory uncertainty*”.

We have two observations here:

- 1) **The study itself does not substantiate the main statement** above, for two reasons:  
A) Section 4.2 on the legal status of organisms developed through NGTs covers only some techniques (new mutagenesis; cis-/intragenesis; and epigenome editing). It is therefore not possible to draw any general conclusions on the legal status of the products of all NGTs. B) The study does not contain any analysis of what constitutes a GMO under EU law.
- 2) The recognition that key terms are still not clarified, and potentially leading to regulatory uncertainty, is correct but actually **contradicts the main statement** that all organisms obtained through NGTs are subject to the GMO legislation.

**Second**, we disagree with the conclusion in subsection 4.2.4 that organisms in which the genetic material has been altered without change of the nucleic acid sequence are GMOs subject to the

provisions of the GMO legislation. The main argument in the report for this conclusion is that *“there are no elements in the legislation supporting a restrictive interpretation of this term [altered] as referring only to the alteration of the nucleic acid sequence of the genetic material”*.

**We argue though that there are plenty of such elements** in the legislation: A) Directive 2001/18/EC makes multiple references to “new combinations of genetic material”, B) the EU is Party to the Cartagena Protocol on Biosafety (CPB), which defines “living modified organism” (LMO) as *“any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology”*, and the European Commission has declared in Regulation 1946/2003 on the implementation of the CPB that *“the definition of an LMO under the Protocol is largely consistent with the definition of a Genetically Modified Organism (GMO) under Directive 2001/18”*.

**Third**, in ANNEX A of the report, a scientific explanation of the term “mutagenesis” is provided. However, given the context of this explanation (i.e. being part of the European Commission report on new genomic techniques) we would like to point out that there is a **serious risk of erroneously taking this as a legally valid explanation of the term**. According to Directive 2001/18/EC, mutagenesis is a technique that results in a GMO, i.e. in an organism that meets the GMO definition. This was confirmed by the Court of Justice of the European Union (CJEU) in the ruling of case C-528/16. The provided scientific explanation in ANNEX A of the European Commission report is not such that would meet the GMO definition.

**Our recommendation** is that the European Commission, as a matter of urgency, provides clarification to key terms and definitions under EU law, such as:

- “Genetically modified organism”
- “Altered”
- “Naturally”
- “New combination of genetic material”
- “Mutagenesis”

Based on these clarifications, the **next step should be to clarify which of the NGTs**, result in organisms that do not meet the GMO definition and should not be regulated as GMOs. This next step is urgently needed to bring clarity to plant breeders, importers of plant produce and products thereof, agri-based industries and the agricultural sector per se on which NGTs that can be used without GMO regulation. It will be of great importance for the possibilities of meeting the ambitions of the European Green Deal.

We look forward to Your response to this letter, and remain at Your disposal for further discussions.

Yours sincerely,

*Annika Åhnberg*

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Chair Växtnoden

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