

To:

Sabine Juelicher, Director for Food and Feed Safety, Innovation, DG SANTE
Sirrku Heinimaa, Acting Head of Unit for Biotechnology, DG SANTE

Cc:

Ursula von der Leyen, President of the European Commission
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

26 February 2021

Subject: Letter to request clarification on the legal status of novel genomic techniques

Dear Director,
Dear Head of Unit,

On behalf of the Plant Node, we call upon the European Commission to follow the request of the Council of the European Union¹ and provide a clarification on the legal status of novel genomic techniques, and to acknowledge the current definition in the European Union of a genetically modified organism.

Scientific progress in the molecular and genomic sciences has been immense in the 21st century. This has provided us with tools for an efficient plant and animal breeding, with potential to address the global challenges (such as climate change, environmental degradation, biodiversity loss, and access to food of good quality) and contribute to sustainable food systems, competitive edge of agriculture and reduced use of pesticides as outlined in F2F, a circular bio-economy and the European Green Deal. These tools will also be needed to achieve the goals set up for the UN Food Systems Summit later this year.

There has however been plenty of discussions in the past decade on the **legal status of products developed through innovative novel genomic techniques (NGTs)**, and several EU authorities and advisory bodies have contributed to these discussions.² In July 2018, the Court of Justice of the European Union (CJEU) provided clarification on the mutagenesis exemption, ruling in case C-528/16 that 1) techniques/methods of mutagenesis result in GMOs in the sense of Directive 2001/18/EC, and 2) that organisms obtained by forms of mutagenesis that do not have a long safety record are not exempted from regulation according to the same Directive.

It is clear though that **many other questions regarding NGTs were not presented before CJEU**, such as:

- ✓ What constitutes “mutagenesis” under EU law?
- ✓ What constitutes “a new combination of genetic material” under EU law?
- ✓ What is the scope of the EU GMO definition in relation to the products of NGTs?
- ✓ What is required under EU law to meet the criterion “long history of safe use”?

¹ The Council of the European Union requested the Commission ([Council Decision \(EU\) 2019/1904](#)) to submit, by 30 April 2021, “a study in light of the Court of Justice’s judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law”.

² New Techniques Working Group (2012), Final Report, EC, Brussels; European Food Safety Authority (2015), Subject: Request to EFSA to provide technical assistance on issues related to the legal analysis of new plant breeding techniques, 15 Oct 2015; European Commission High Level Group of the Scientific Advisory Mechanism (2017), New Techniques in Agricultural Biotechnology. Explanatory Note 02, Brussels; European Parliament Research Service (2020), New Plant-Breeding Techniques. Applicability of GM rules, Briefing Nov 2020 PE 659.343.

A recent publication by a multidisciplinary co-author team sheds light on some of these questions, through an analysis of the CJEU ruling, and of the spirit (teleological, functional and consequentialist) of the EU GMO legislation.³ **One of the conclusions** is that for an organism to be a GMO in the sense of the Directive, the technique used, as well as the genetic alteration(s) in the resulting organism, must be considered.⁴

We urge the European Commission to:

1. Meet the request of the Council and provide a report on the status under Union law of novel genomic techniques, and
2. Acknowledge that for an organism to be a GMO in the sense of Directive 2001/18/EC, both the technique used and the genetic alteration in the resulting organism must be considered.

The Plant Node is an independent knowledge hub for plant breeding, its targets, methods and contributions to the development of society. The aim is to support scientifically underpinned decisions and increased understanding of politicians, authorities, industries and other organisations on how development and implementation of the methods of plant breeding can contribute to meeting the global goals for a sustainable development, the SDG goals.

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

Yours sincerely,



Annika Åhnberg

Chair Växtnoden

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³ van der Meer P et al. (2021), The status under EU law of organisms developed through novel genomic techniques, European Journal of Risk Regulation, 1-20, <https://doi:10.1017/err.2020.105>.

⁴ Article 2(2) of Directive 2001/18/EC defines a GMO as “an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination”. First, a literal reading of the term “altered” in Article 2(2) suggests that something has been changed or made different, and if this would have referred to a process then the sentence could not have continued with “by mating and/or natural recombination”. Second, both Article 2 and the heading of Annex I refer to “techniques”. This multiple reference to techniques suggests that the technique relied upon must also be considered. Third, Annex IA, part 1, refers in its point 1 to “recombinant nucleic acid techniques involving the formation of new combinations of genetic material...”. Had the legislator intended that the mere use of certain techniques would result in a GMO, then it would not have added the qualification “new combinations of genetic material”.