

PRESS BRIEFING

Preliminary ruling of the European Court of Justice on the legal status of plant breeding and genetic engineering techniques C-528/16

On 25 July, the European Court of Justice (ECJ) will issue its decision on the legal case C-528/16, which relates to the legal status of certain plant breeding techniques involving genetic engineering. The ECJ's decision may – or may not – provide some legal clarity on whether some techniques fall into the existing exemption in the GMO legislation foreseen for so-called 'mutagenesis' techniques.

The organic food and farming movement believes that, whatever the ECJ might say about the precise technique at stake in the French legal case, it is unlikely to provide full clarity on the legal status of newer techniques of genetic modification, usually known as 'gene editing' techniques, such as CRISP/Cas9. It believes that the European Commission (EC) should issue a legal interpretation to confirm that such gene editing techniques are not exempted from the legal framework on GMOs and should therefore be subject to prior authorisation and risk assessment, like for GMOs already on the market.

This briefing aims to provide a few background elements to the ECJ's decision and to the legal case in France. IFOAM EU will also issue a statement after the publication of the ECJ's decision on 25 July.

1. Main elements about the Court Case C-528/16

In December 2015, nine French NGOs and farmers unions initiated a court case in front of the highest French administrative court - Conseil d'Etat (Confédération Paysanne, Réseau Semences Paysannes, les Amis de la Terre France, Collectif Vigilance OGM et Pesticides 16, Vigilance OG2M, CSFV 49, OGM : dangers, Vigilance OGM 33, Fédération Nature & Progrès).

The debate on the scope of Directive 2001/18 on the deliberate release of GMOs into the environment:

According to the definition of [Directive 2001/18](#) (Article 2): "*genetically modified organism (GMO) means 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*". But the Directive (initially established in 1990 and reviewed in 2001) excludes from its scope (Recital 17 and Annex I B) certain techniques like mutagenesis and cell fusion, even though these techniques are recognised explicitly as "*techniques of genetic modification*". The reason given for the exclusion, already in 1990, was the "*long safety record*" of these techniques. The term 'mutagenesis' referred to techniques used since the 1960s aimed at increasing the rate of mutation by submitting whole plants or their reproductive organs (seeds) to irradiation or to chemicals. These old mutagenesis techniques are very different from new genetic engineering techniques developed in recent years such as zinc finger nuclease, ODM or CRISPR/Cas9, also sometimes called gene editing techniques.

But proponents of the deregulation of new genetic engineering techniques create confusion by calling some of the new techniques 'directed mutagenesis' or 'targeted mutagenesis'. They hope that the EC or the ECJ could consider that some of the new techniques fall into the existing exemptions, although these techniques are GMOs, they were developed recently and do not have the long record of safety.

Why was this court case initiated? Though it is difficult to assess, it is estimated that hundreds of varieties obtained through mutagenesis were put on the market even before 1990. Some plants (e.g., canola and sunflowers) however, obtained from techniques different from the mutagenesis techniques known when the GMO legislation was adopted, have been put on the market in more recent years outside of the scope of the GMO legislation and with no prior authorisation, using the ambiguity of the term mutagenesis, with no information on the exact technique used: Clearfield from BASF, and ExpressSun from Pioneer. The legal status of these plants made tolerant to herbicides through undetermined techniques is the starting point of the European Court Case [C-528/16](#). The French organisations that initiated the court case in France consider that these plants are GMOs and that the European legislation on GMOs ([Directive 2001/18](#)) should apply.

The [nine NGOs also contest the absence of risk assessment](#) of varieties made tolerant to herbicides and ask for a moratorium on cultivation of these plants.

On 3 October 2016, the French Court used the preliminary ruling mechanism to ask [four questions](#) to the ECJ on the interpretation of the European Law:

- Are organisms obtained by mutagenesis, in particular new directed mutagenesis, GMOs?
- How are Directive 2001/18 on GMOs and Directive 2002/53 on the common catalogue of varieties working together, regarding the definition of GMOs and their respective fields of application?
- In case all types of mutagenesis are excluded from the scope of Directive 2001/18, could Member States implement their own regulation?
- Does Directive 2001/18 (GMOs definition, and its scope) comply with the precautionary principle regarding new genetic engineering techniques?

2. The opinion of the Advocate General

On 18 January 2018, the Advocate General of the ECJ published his preliminary opinion. In his conclusions, the Advocate General confirmed the existing exemption of mutagenesis from the scope of Directive 2001/18, but he also confirmed that organisms made from mutagenesis are GMOs and that “the insertion of foreign DNA into a living organism” is not a criterion to define GMOs. “Insertion of foreign DNA into a living organism” refers to ‘transgenesis’, a genetic engineering technique used to create the GMOs which have been put on the market since 1996 (such as GM maize MON810), and which, according to some proponents of deregulation, should be the only technique considered as leading to a GMO. The Advocate General therefore denied such a narrow interpretation.

On the other hand, he left open the possibility to consider that the existing exemption should not only apply to mutagenesis techniques already known in 2001, when Directive 2001/18 was adopted. Instead he proposed to use a criterion already mentioned in Directive 2001/18 – the use of ‘recombinant nucleic acid’ – to determine if a technique should be covered by the GMOs legislation, or should fall in the existing exemption for mutagenesis techniques. But this criterion is itself open to interpretation.

[IFOAM EU issued a position on the opinion of the Advocate General](#). His opinion does not bring full clarity regarding the legal status of new genetic engineering techniques as the criteria put forward by the Advocate General are not well defined. It is unlikely that the ECJ will provide more clarification in that regard. The EC and Member States will have a crucial role to play to bring more clarity on the legal status of new genetic engineering techniques.

3. The position of the organic sector on new genetic engineering techniques

Organic agriculture excludes GMOs from its production processes (Regulation 834/2007, Recitals 9 and 30, and Article 9), and [the organic sector considers that new genetic engineering techniques are GMOs falling under the scope of the GMO regulation](#). The deregulation or exemption of new genetic engineering techniques and their products would unfairly force the organic sector and the GMO-free sector to take extra measures to exclude GMOs from its production processes and would have severe economic consequences for the whole European agriculture, which is overwhelmingly free of GMOs.

4. Why are GMOs regulated in the European Union and why should new genetic engineering techniques also be regulated as GMOs?

From the first Directive on GMOs ([Directive 90/220/EEC](#)) to the current legislation ([Directive 2001/18](#) and [Regulation 1829/2003](#)), the legislator's main goal was to "avoid adverse effects on human health and on the environment", in accordance with the precautionary principle ([Article 191](#), Treaty on the Functioning of the European Union).

Because GMOs can potentially cause 'adverse effects', it was considered necessary that GMOs may not be deliberately released into the environment or placed on the market without risk assessment, prior authorisation, monitoring plan and traceability and labelling.

Because new genetic engineering techniques raise similar concerns to transgenesis in terms of risks towards human health and the environment, the precautionary principle should also apply to those techniques. It is crucial that these techniques fall in the scope of the GMOs regulation in order to:

- Subject new genetic engineering techniques to a risk assessment before products obtained through these techniques are marketed;
- Subject to an authorisation process involving Member States;
- Give the opportunity to Member States to opt-out their cultivation;
- Ensure transparency and the freedom not to use genetic engineering for breeders, farmers and consumers, through mandatory labelling and traceability.

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