



# New plant-breeding techniques (NBTs): ECJ Advocate General's preliminary conclusions

A first sound and promising basis on which to proceed

*Brussels, January 18<sup>th</sup>*

*"Ever since humans have grown plants and raised animals for food, they have selected plants and animals with beneficial traits for further breeding. Such traits reflected naturally occurring genetic variations and resulted, for example, in an increased yield or resistance to diseases or environmental pressures".*

**EFSA (European Food Safety Authority)**

*"Targeted genome modification techniques could have revolutionary applications in agriculture. They consist in introducing very precise genetic modifications which make it possible to accelerate the selection speed. They represent a fundamental departure from the "old" GMOs, insofar they could occur naturally and are virtually undetectable".*

**French Parliamentary Office for evaluation of scientific and technological options  
(OPECST)**

Today, January 18<sup>th</sup> 2018, the European Court of Justice (ECJ) Advocate General issued preliminary conclusions on whether some of the new genetic engineering techniques fall within the scope of the European legislation on GMOs ([Case C-528/16](#)).

It is true that this is only a first opinion on the long-standing issue, whose final conclusions, and the related framework, are expected to be presented by the ECJ by summer 2018, however it has to be underlined what this outcome may entail for the future of plant improvements at European level.

For an overview of what NBTs are, their legal classification in the EU and in particular the relevance of these New Techniques application in EU agriculture, here you find our report ([LINK](#)).

On this issue, it is absolutely necessary to focus first and foremost on facts, namely scientific arguments.

First of all, what the Advocate General Mr. Michal Bobek did today, was to provide a legal interpretation as a response to France enquiry in 2016, which asked the ECJ to specify whether a type of herbicide-resistant rapeseed obtained through gene-editing should undergo the approval process for GMOs, and so if plants resulting from the new techniques will be covered by the EU GMO legislation – Article 2(2) of GMO Directive 2001/18/EC. To be even more precise, French Council of the State posed to the ECJ four interlocutory questions (available [here](#)) on the scope of the EU's GMO legislation and specifically, (i) if classical and/or newer site-directed

mutagenesis plant breeding techniques produce GMOs and (ii) if EU Member States retain any discretion in transposing these EU Directives to their national laws.

*“Directive 2001/18/EC regulates the deliberate release into the environment of genetically modified organisms (‘GMOs’) and their placing on the market within the Union. In particular, the organisms covered by that directive must be authorized after an environmental risk assessment. They are also subject to traceability, labelling and monitoring obligations”.*

*“Article 3(1), read in conjunction with Annex I B, states that the GMO Directive shall not apply to organisms obtained through certain techniques of genetic modification, such as mutagenesis (‘the mutagenesis exemption’)<sup>1</sup>”.*

The Advocate General's opinion attempts to make clear if and to what extent organisms developed through conventional and innovative plant breeding techniques (specifically mutagenesis), are to be regulated either through the same framework as conventional plant breeding or as genetically modified organisms (GMOs). It is necessary to specify that under the current EU legislative framework, organisms developed through traditional mutagenesis breeding techniques are regulated as conventional and are therefore exempt from the EU's main GMO regulation, [Directive 2001/18/EC](#).

*“In my view, provided that they meet the substantive conditions of Article 2(2) of the GMO Directive, organisms obtained by mutagenesis are GMOs within the meaning of the GMO Directive (a). However, as long as the process of mutagenesis does not involve the use of recombinant nucleic acid molecules or GMOs other than those produced by one or more of the techniques listed in Annex I B, those organisms are exempt from the obligations laid down by the GMO Directive by virtue of Article 3(1) of the GMO Directive, read in conjunction with its Annex I B (b)”.* - Advocate General on the scope of the GMO Directive and of the mutagenesis exemption.

Furthermore, he also specified that: *“Like the Commission, I am of the opinion, that there is only one relevant distinction that should be made in order to clarify the scope of the mutagenesis exemption: the caveat set out in Annex I B, namely whether the mutagenesis technique involves ‘the use of recombinant nucleic acid molecules or [GMOs] other than those produced by ... mutagenesis [or] cell fusion ... of plant cells of organisms which can exchange genetic material through traditional breeding methods’ (‘the Annex I B caveat’)(1). No further distinctions should – or even could – be made judicially”.*

Having in mind that this legal advice is not binding **but** that it is usually followed by European Court of Justice (ECJ) panel of judges, what it states in short is that **crops obtained by the plant breeding technique of mutagenesis do not fall under laws restricting the use of genetically modified organisms (GMOs)** however, and this is a point which has to be thoroughly analyzed, the Advocate General pointed out that the *Directive 2001/18 does not preclude*

---

<sup>1</sup> *“Mutagenesis involves an alteration of the genome of a living species. Unlike Transgenesis, which is a genetic engineering technique that consists in inserting one or more genes from other species into the genome of another species, it does not, in principle, entail the insertion of foreign DNA into a living organism. Techniques of mutagenesis have evolved over time as the result of scientific progress in biotechnology”* **Source:** Case C-528/16 - OPINION OF ADVOCATE GENERAL BOBEK, 18 January 2018(1)

**Member States from adopting measures governing mutagenesis provided that, in so doing, they respect the overarching obligations arising from EU law.**

*“Against this background, I am of the opinion that Member States have the competence to regulate organisms obtained through mutagenesis provided that they comply with their overall EU law obligations, whether of secondary law origins or the rules of primary law, such as Articles 34 and 36 TFEU”.*

For a more precise explanation here below an extract from the Advocate General's conclusion:

*(1) Provided that they meet the substantive criteria of Article 2(2) of Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, organisms obtained by mutagenesis are genetically modified organisms within the meaning of that directive;*

*The exemption laid down in Article 3(1) of Directive 2001/18, read in conjunction with its Annex I B covers all organisms obtained by any technique of mutagenesis, irrespective of their use at the date of the adoption of that directive, on the condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms other than those produced by one or more of the methods listed in Annex I B.*

*(2) Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species is to be interpreted as exempting varieties obtained by mutagenesis from the specific obligations laid down therein for the inclusion of genetically modified varieties in the common catalogue of agricultural plant species.*

*(3) Directive 2001/18 does not preclude Member States from adopting measures governing mutagenesis provided that, in so doing, they respect the overarching obligations arising from EU law.*

As clarified by a [USDA-FAS Report](#) on January 16<sup>th</sup> on the expected legal opinion for New Breeding Techniques in the EU, *“Advocates General are assigned to most cases before the ECJ to serve as an advisor to the court on how the case should be resolved. Their opinions are given considerable weight, and often are followed by the court, but are non-binding in all cases”.* Furthermore, USDA Rapporteur found that by reviewing ECJ case law, what appears is that the majority of ECJ judgements complement the opinions of the advocate general.

In order to provide a brief background on the issue but without going back to the far past, last year, on April 28, 2017 the SAM-HLG (Scientific Advice Mechanism -High Level Group) released its explanatory Note in response to the request, formulated in the Scoping Paper (adopted by the HLG on 25 November 2016), by the European Commission, to provide an up-to-date overview and a comprehensive scientific comparison on *new techniques in agricultural biotechnology*, including their potential agri applications in both fields of synthetic biology and gene drives, considering the key characteristics of each of these new techniques.

Among the others, the Note highlighted that “*all breeding techniques applicable in agriculture (conventional breeding techniques, CBT; established techniques of genetic modification, ETGM; and new breeding techniques, NBT) make use of genetic diversity and change whether naturally occurring or resulting from human intervention, in order to select or generate plants, animals or microorganisms that exhibit preferred characteristics*” and that “*the NBT of genome editing offer not only the ability to target insertions (resulting in comparatively fewer unintended effects on the expression of other genes or their disruption) but also the ability to make small, precise and specific changes, such as point mutations, which can also be observed in nature*”.

This independent explanatory note, as also specified in the Scoping Paper, does not take a position; it does not cover legal issues and it does not make policy recommendations to policymakers. It is another piece to the puzzle.

#### Background notes :

New Plant Breeding Techniques (notably the CRISPR-Cas9, which is basically a technology that uses a DNA-cutting enzyme called nuclease to edit in a very targeted way parts of the genome, by removing, adding or altering sections of the DNA sequence) can play a key role in allowing plant breeders to introduce in an efficient way, very precise, targeted genetic modifications, which have the capacity to fasten the selection speed, when compared with conventional plant-breeding techniques. **NBTs allow to develop plant varieties that can adapt to climatic changing conditions and ensure high level of biodiversity.**

As also outlined in the Explanatory Note, “*the speed with which mutations can be introduced using NBT is often higher (in particular when using the CRISPR-Cas genome editing system) than that which can be achieved with ETGM and CBT, mainly due to the reduced need for time-consuming screening procedures and/or back-crossing, with correspondingly lower costs*”.

CRISPR-Cas9, for instance, is already a technique, which is having a great impact on our society. It is the most tangible example of how biotechnology has been able to make considerable progress with the targeted modification technologies of genome.

By focusing on the potential application in agriculture and food systems, some induced mutations that this technique could target are, among the others:

- “Bad” traits such as allergens or toxins can be selectively inactivated
- Specific mutations (herbicide resistance to more environmentally friendly substances or insect resistance) can be knocked-in
- Flowering time
- Metabolic engineering (starch, fatty acid profile)

On the other side of the Atlantic, the US Department of Agriculture (USDA) has changed the attitude toward genetic engineering, specifically with the new gene-editing techniques of plant breeding. In a [recent article](#) published on Nature

Biotechnology, it is explained that the agency is giving “free-pass” to some plant varieties developed with CRISPR technique. In other words, CRISPR-Cas 9-edited plants can be cultivated and sold free from regulation burden and costs, so they fall outside USDA’s authority. For instance, in April 2016, the USDA clarified that it would not have regulated a non-browning mushroom genetically modified using CRISPR–Cas9 - the first US CRISPR-edited product to obtain “green light”<sup>2</sup>.

Aiming to provide a full picture, there are indeed other agricultural products (i.e. commodity crops such as corn, soybeans, canola, rice, wheat) which are undergoing targeted genetic engineering for drought resistance, pest resistance or higher yields. There is currently a quite wide consensus among **scientists, who believe in the capacity of innovative NBTs to help farmers deal with climate change and a growing population.**

In the overall discussion, taking into account the legal, scientific and of course societal aspects, we should keep in mind that greater priority has to be given to research in this area, since, as also the US concrete and illustrative example shows, the development of NBTs is happening in any case outside Europe.

In this context, there is a clear challenge : not to lose ground at global level and above all, not to neglect the revolutionary contribution and benefits of these new techniques to the sustainability and competitiveness of EU agriculture.

Today’s decision marks another relevant step towards the need for the EU to develop a clear legal framework for the new plant breeding techniques (NBTs), and so enabling these tools of agricultural innovation to be separated to the EU’s current laws on genetically modified organisms (GMOs) and thus **ensuring regulatory clarity** in view of the commercial application of these products, which could bring tangible benefits and potential improvements to crop productivity, quality, sustainable farming methods and, in general, addressing current and future agricultural and food challenges.

---

<sup>2</sup> Available here: <http://www.nature.com/news/gene-edited-crispr-mushroom-escapes-us-regulation-1.19754>