Veille citoyenne d'information sur les OGM et les semences

Since 2018, the EU has been able to regulate GMOs/NGTs

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Prior to 2018, some Member States had decided not to submit certain applications for trials authorisation of GMOs obtained through new techniques (GMOs/NGTs) to the GMO legislation. However, in 2018, a ruling by the Court of Justice of the European Union (CJEU) clarified that these GMOs must indeed be treated as regulated GMOs. According to a 2021 report by the European Commission, these cases of wrongfully deregulated GMOs have been rectified, and the trials in question have been cancelled or brought into compliance with regulations. These cases suggest that regulating such GMOs is indeed feasible.

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In January 2025, a report issued by the Dutch government raised the question of whether the definition of GMOs as established by European Directive 2001/18 was interpreted in the same way by all Member States[i]. The responses received indicate that, prior to 2018, some had already dealt with GMOs/NGTs. In their transparent responses, certain Member States explained that they had then considered these GMOs to fall outside of the scope of Directive 2001/18, classifying them as exempted GMOs. It is a report published by the European Commission in 2021, four years before the Dutch report, that shed some light on these cases of national deregulation decisions. Following the 2018 CJEU's ruling, which reminded everyone that these are regulated GMOs, these national decisions had to be reviewed.

The public declarations

According to the 2025 Dutch report, certain Member States were asked prior to 2018 about the legal status of GMOs obtained through "*directed mutagenesis*". At that time, the CJEU had not yet confirmed the response that these were regulated GMOs. Those Member States had therefore chosen to respond that such GMOs "*were exempted from the application of the GMO legislation*". The same report specifies that in these cases, "*evidence had been asked,* e.g. *by whole genome sequencing, that only the point mutations were present in the material*". Further clarification is provided for cases where "*any other sequence,* e.g. *relating to the transforming plasmid used in the mutation technique, was present, the material was handled as GMO*". After 2018, the "*position [regarding the deregulation of these GMOs] was adjusted following the [CJEU] judgement. This adaptation also required rapid alignment with compliance measures*". Which GMO cases are we talking about, and, more importantly, which Member States are involved?

Adjustment to GMO status in certain states

While preparing its proposal to deregulate numerous GMOs - which it would present two years later - the European Commission published a study on these GMOs/NGTs[ii] in 2021. In the responses of the 27 Member States, two questions are of particular interest.

One question asked whether the Member States had registered "*plant varieties obtained by NGTs*" in their national catalogues. According to the responses received[iii], no varieties genetically modified using new techniques were listed in a national catalogue of plant varieties in 2020. Since such registration is mandatory for marketing seeds of plant varieties, it therefore appears that, officially, for the pre-2020 period, no varieties genetically modified using new techniques were marketed.

Another question concerned "*experience […] on the application of the GMO legislation, including experimental releases (such as field trials and clinical trials), concerning NGT-products*". The responses provide information on trials that may have been planned or conducted prior to 2018 and the regulatory framework that applied to them.

Belgium

Belgium reports that it has processed three applications for field trials. One trial in 2011 involved cisgenic potatoes, and two others, in 2018 and 2019, involved genetically modified corn created using the CRISPR/Cas tool. Belgium specifies that an application for GMO corn (without clarifying whether it refers to one of the two previously mentioned applications) was initially submitted in 2016 and processed as exempt from GMO legislation. Belgium considered at the time that "*the genetic modifications achieved in the plants are similar in type and extent to those that can be*

obtained via *natural or induced (using chemical or physical agents) mutagenesis*" and that they raised no "*additional safety concerns as compared to products developed through conventional mutagenesis techniques*". However, in 2020, the response provided to the European Commission stated that the application had been resubmitted under GMO legislation and was being processed as such.

Denmark

For its part, while Denmark reports that it has not received any applications for the release of GMO/NGT plants, it has received applications for microorganisms in contained environments. It notes that, in the industrial sector, the Ministry "*faces an increase in applications for production activities due to the fact that the gene-editing techniques (CRISPR) make it easier and faster to create new production strains*". Here, the country is referring to genetically modified microorganisms (GMMs) used in fermenters; this is hardly surprising, given that Denmark is home to the world leader in microorganisms, Novonesis.

Italy

Italy also reports having received requests for authorisations or information. One example involved the contained use of genetically modified mosquitoes created through gene drive technology. In 2020, the year the response was provided, Italy stated that this contained use was "*underway at the Innovation Hub of Genomics Genetics and Biology*" as part of the "*Target Malaria*" project. However, the country does not specify how the request was handled, whether within the GMO regulatory framework or not. The University of Milan also inquired in 2017 about potential field trials of various "*varieties of rice with mutations obtained through [...] genome editing techniques*". Without specifying the initial response, Italy explains that since 2018, an application must be submitted in accordance with Directive 2001/18.

Finland

In Finland, the Natural Resources Institute Finland (LUKE) conducted genetic modification research in 2020 using new techniques (which Finland refers to as "*genome editing*") on barley, "*with plans to expand into other crop species*". While Finland notes that managing this research as GMO-related implied "*an increased administrative burden which slows the research*", it does not report any inability to comply with European GMO legislation. The same organisation was also conducting "*GE [genome editing] on animal cell lines, currently only as a research tool with no applications to be released as animals or products*". In full transparency, Finland then explains that, following the 2018 CJEU ruling, "a*n interim decision that in the absence of legal certainty, the [CJEU] ruling is not extended to contained use [of GMOs/NGTs] before a binding legal analysis of it is received from the Commission Legal Service*". In February 2020, Finland also decided, contrary to the CJEU's ruling, not to reverse its previous decisions, which stated that "*deletion mutants obtained with new mutagenesis techniques are not in the scope of Gene Technology Act, if no foreign genetic material remains in the final organism*".

Germany

In Germany, the response indicates that, prior to the CJEU ruling in 2018, the country was already advising petitioners to comply with the requirements of Directive 2001/18. It notes that "*projects involving NGTs have so far been carried out exclusively in closed systems*". However, three requests for clarification on the procedures for managing field trial projects involving GMO/NGT

plants were submitted prior to 2018. Although it does not provide details on these projects, the German government states that "*in one case, sequencing data that was subsequently requested showed that recombinant DNA from an integration event of the corresponding vector design was present. This shows the importance of the comprehensive sequencing of NGT organisms*". Germany concludes this point by noting that, following the CJEU ruling in 2018, the field trial projects were ultimately not conducted in Germany.

Netherlands

In the Netherlands, "*since the 1990s many field trials with GM plants took place in the Netherlands, including trials with plants obtained by cisgenesis and intragenesis*". In a 2020 response to the Commission, the country also noted that a trial was planned for 2021 involving potatoes genetically modified using CRISPR. However, the 2018 CJEU ruling does not appear to have been a problem, as the Netherlands explained that "*specific measures were not deemed necessary. The Netherlands generally considered products of NGTs/new mutagenesis techniques as GMOs before the [CJEU] ruling*".

Romania

For its part, Romania reports an application for authorisation for the contained use of microorganisms modified by "*the classical mutagenesis and CRISPR/Cas 9 technique*". This application, authorised in 2018, was processed in accordance with Directive 2009/41. This directive governs the contained use of GMOs. Since the CJEU ruling concerned Directive 2001/18, it therefore had no implications in that country.

Sweden

In Sweden, the government informed the European Commission that "*one application for introduction of a variety produced with an NGT in the national variety catalogue was withdrawn following the [CJEU] ruling*". It explains that this withdrawal was carried out because the applicant did not want its variety to be considered genetically modified and "*will therefore not commercialisetheproduct in the European Union*". No details regarding the variety in question are provided in the questionnaire returned by Sweden.

Spain's response is difficult to interpret

The response received from the Spanish government is ambiguous, to say the least, regarding whether the government has actually applied the CJEU's decision to applications received before 2018. While it states that "*the case-by-case principle and GMO legislation are applied to the notifications which could arise for contained use or voluntary release of products obtained by NGT*", it refers to tables listing these applications, which it claims are "*notifications for products obtained by NGT presented or, where appropriate, authorised in Spain in line with applicable GMO legislation*". However, the tables provided are not very informative due to truncated rows and a layout split across multiple pages.

Above all, the government states that, for products "*obtained by genetic modification which are excluded from the legislation (*e.g. 'classic*' mutagenesis)*" no specific information is required to

certify that they are not GMOs, except in certain cases (organic products or those subject to specific national monitoring). The meaning of the term "*classical*" mutagenesis is not specified, making the response ambiguous. It appears that as early as 2020, Spain was already surreptitiously classifying new genetic modification techniques as "*classical*" mutagenesis. Regarding the additional information requested for products obtained through new techniques, the Spanish government responds in the future tense, as if the information were not available at the time, two years after the CJEU's decision. It states that "*it will be useful to provide documentary identification only in certain cases where the products obtained by NGT may have been considered either intentionally or unintentionally as standard products*".

No requests in other states

The other European countries, namely, in alphabetical order, Austria, Bulgaria, Croatia, Cyprus, the Czech Republic, Estonia, France, Greece, Hungary, Ireland, Latvia, Lithuania, Luxembourg, Poland, Portugal and Slovenia, responded that they had never received a request for GMO/NGT trials.

Surprisingly, France joins this list of countries with a more convoluted response, stating that "*we do not have any information suggesting that plants obtained from new mutagenesis techniques have been subject to field trials in France*", and specifying that "*we have not received any applications to conduct any such trials*". This response thus overlooks commercial crops of Clearfield rapeseed, which ANSES itself reported in 2019 were obtained through mutagenesis applied to isolated and in vitro-multiplied cell cultures - a method that produces GMOs subject to regulation based on the 2018 CJEU decision[iv].

The French government does, however, point out that trials of genetically modified *Camelina Sativa* plants developed using the CRISPR tool have been conducted in the United Kingdom. As France notes, this clarification stems from the fact that these plants "*were developed in France by the National Institute for Agricultural Research (INRA, now INRAE)*", adding that on January 18, 2019, it sent a note to the European Commission detailing "*the information available to them on the products which might be marketed in non-EU countries and the patents on those products*".

Despite claims by certain Member States or the European Commission regarding the impossibility of implementing the requirements of the legislation on GMOs/NGTs, it is clear that Member States did indeed succeed in doing so after 2018. Especially since, as *Inf'OGM* will report in a forthcoming article, France also outlined in its response the procedures to be followed to ensure that these GMOs/NGTs are detectable and distinguishable. This reality of compliance with current legislation contrasts with the European Commission's argument that this same legislation is not applicable…

i Danish government, « Interpretation of the GMO definition in EU Member States », 20 January 2025.

ii European Commission, « 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.

iii European Commission, EC study on new genomic techniques, « Stakeholders' consultation ».

iv Christophe Noisette, « L'Anses tergiverse sur les variétés tolérantes aux herbicides », *Inf'OGM*, 5 March 2020.

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