

Voluntary Report – Voluntary - Public Distribution

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Report Name: Corrected - European Commission Adopts New Regulation for Plants Obtained by Certain New Genomic Techniques

Country: European Union

Post: Brussels USEU

Report Category: Biotechnology and Other New Production Technologies

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Report Highlights:

(To be replaced is "European Commission Adopts New Regulation for Plants Obtained by Certain New Genomic Techniques" of July 24, 2023. Changes are on the date of the new proposal, July not June). On July 5, 2023, the European Commission (EC) adopted a new proposal to regulate plants obtained by certain new genomic techniques (NGTs) and their use for food and feed. The proposal comes at the end of a long process started on July 25, 2018 with the ruling of the European Court of Justice determining that organisms created through NGTs needed to be regulated as “GMOs” and covered by the EU’s current “GMO Directive” of 2001. After a study from the EC concluded that the GMO Directive is not “fit for purpose” for these newer products, a legislative initiative was started on September 24, 2021. The NGT or genome editing proposal was finally presented as part of the adopted package of measures for sustainable use of key natural resources, and it will now be evaluated by the European Parliament and Council of the EU.

General Information:

On July 5, 2023, the [European Commission officially adopted its new proposal to regulate plants obtained by certain new genomic techniques \(NGTs\) such as genome editing and the food and feed produced from them](#). The Commission's proposal was presented as part of the 'Sustainable use of key natural resources' package, designed to strengthen the resilience of EU food systems and farming and thus contributing to the goals of the European Green Deal's Farm to Fork Strategy.

The scope of the proposal are plants produced by NGTs (targeted mutagenesis and cisgenesis, including intragenesis), products containing or consisting of these plants and food and feed containing, consisting or produced from these plants. The proposal sets specific new requirements for NGTs plants but specifies that they will still fall under the overarching legal framework of the current GMOs Directive [Regulation \(EC\) No 1829/2003](#) and [Directive 2001/18/EC](#).

The general objectives of the proposal are to:

- Maintain a high level of protection of human and animal health and of the environment, in accordance with the precautionary principle.
- Enable the development and placing on the market of plants and plant products contributing to the innovation and sustainability objectives of the European Green Deal and of the Farm to Fork and Biodiversity strategies.
- Ensure the effective functioning of the internal market in NGT plants and products and food and feed containing, consisting or produced from NGT plants, and enhance the competitiveness of the Union agri-food sector at the Union and global levels, including a level-playing field for operators.

Specifically, the proposal has the goal to release and place on the market a wide range of NGT plants and the food and feed they produce that are as safe as their conventional counterparts without unnecessary regulatory burden, and to encourage a large number of developers to bring new traits to market that can contribute to a more sustainable agri-food system.

Background:

Organisms derived from all forms of genetic engineering (GE) are currently regulated in EU under [Regulation \(EC\) No 1829/2003](#) and [Directive 2001/18/EC](#). Each year, a range of GE products are approved for import into the EU for food and feed, and the EU does not currently commercially cultivate GE crops (excepting about 1 percent of the corn production in Spain and Portugal). Scientific advances in the last 10 plus years have greatly accelerated the development of new biotechnology products, notably with a relatively new technique: genome editing. The quick pace of change and the diversity of products that can be created with genome editing has sparked an evolving debate in the EU on whether and in what ways existing regulations can be revised to accommodate these scientific advances.

On July 25, 2018, the European Court of Justice determined that organisms created through newer genome editing techniques need to be regulated as "GMOs" and covered by the EU's current "GMO Directive" – even if they could be genetically similar to products of conventional breeding that are exempted from these regulations ([see GAIN here](#)). On November 8, 2019, the Council of the European Union requested the Commission to submit a study examining the status of new genomic techniques in

the EU and a possible policy proposal in light of this ruling, the continued debate, and overall scientific advances since 2001.

On April 29, 2021, the study from the European Commission titled, “[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.](#)” concluded that the “GMO Directive” is not “fit for purpose” for these newer products and a targeted policy action was needed. The study also says that genome editing can contribute to the objectives of the European Green Deal’s Farm to Fork and Biodiversity Strategies. As a consequence, on September 24, 2021, the European Commission launched a policy initiative and roadmap on “Legislation for plants produced by certain new genomic techniques.”

After two public consultations (a 4-week one following the launch of the policy initiative and a more comprehensive 12-week one started in April 2022) and a number of scientific opinions requested from the European Food Safety Authority (EFSA), the EC submitted a mandatory impact assessment to the European Regulatory Scrutiny Board (RSB). The first attempt received a negative opinion and needed to be revised while the second submission was successful.

The Commission finally presented its proposal to create a new regulatory framework for plants obtained from targeted mutagenesis and cisgenesis (new genomic techniques - 'NGTs') and their food and feed as part of the adopted package of measures for a sustainable use of key natural resources on July 5, 2023.

Key Points:

The Commission proposes two categories of NGT plants:

- **Category 1** – NGT plants that **could** also occur naturally or be produced by conventional breeding techniques.
- **Category 2** - NGTs plants that **could not** occur naturally or be produced by conventional breeding techniques.

Particularly, to define the two categories and establish a verification procedure for competent authorities, the proposal sets out criteria on the type and extent of genetic modifications that can be observed in nature or in organisms obtained with conventional breeding techniques, including thresholds for both size and number of genetic modifications.

Category 1 NGT plants will be treated like conventional plants and therefore exempted from the requirements of the GMO legislation. This means that for these plants no risk assessment has to be made and they can be labelled in the same way as conventional plants. The proposal indicates that the Commission will also establish a public database listing the status of category 1 NGT plants.

Category 2 NGT plants will be treated like GMOs following the authorization procedure required in the GMO framework. GMO labelling will be required. The proposal indicates an intent to offer regulatory incentives for Category 2 plants that have a sustainability benefit, though notably it excludes herbicide tolerance traits from these incentives.

NGTs plant reproductive materials (PRM) for both categories will be subject to labelling requirements and will not be allowed in organic farming. The possibility for Member States to restrict or prohibit cultivation in their territory of GMOs pursuant to Directive 2001/18 will not apply to NGT plants.

Next Steps:

The publication of the proposal initiates the beginning of a lengthy legislative process. The adopted act is now [open for feedback](#) for a period of 8 weeks (07 July 2023 - 08 September 2023). All feedback received will be summarized by the European Commission and presented to the European Parliament and Council which, as co-legislators, will have to assess the proposal. Amendments to the legislative proposal are done separately by the Parliament and Council; however, negotiations will eventually occur to find institutional agreement before the proposals are adopted as official EU law. This process can take between 18 months to two years.

Related Reports from FAS Brussels:

Title	Date
European Commission Publishes Biotechnology Study	05/24/2021
European Commission Publishes Roadmap on Legislative Initiative for Plants Produced by Certain Genome Editing Techniques	10/06/2021
European Commission Launches Public Consultation on Genome Editing	05/06/2022
Biotechnology and Other New Production Technologies Annual	12/06/2022

Attachments:

No Attachments.