

**Voluntary Report** – Voluntary - Public Distribution

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**Report Name:** European Commission Publishes Biotechnology Study

**Country:** European Union

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**Report Highlights:**

On April 29, 2021, the European Commission published a report 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.” The Court of Justice ruling stated that products of genome editing fall under Directive 2001/18/EC. However, the Commission’s recent study concludes that this Directive is not “fit for purpose” for these newer products and a targeted policy action is needed. The study says that genome editing can contribute to the objectives of the European Green Deal’s Farm to Fork and Biodiversity Strategies, and the Commission will engage in a wide-ranging communication effort with co-legislators and stakeholders in the European Union. In the third quarter of 2021, the Commission intends to publish an inception impact assessment on plants derived from certain applications of genome editing.

## **Executive Summary:**

On May 20, 2020, the European Commission announced the Farm to Fork (F2F) and Biodiversity Strategies as roadmaps for enhancing food and agricultural sustainability by 2030 under the European Green Deal.<sup>1</sup> The Strategies mark the beginning of a multi-step legislative development process that aims to fundamentally change how agriculture operates in the European Union (EU) and how food is produced for, and provided to, EU consumers. On page 10 of the [F2F Strategy](#), the Commission says:

*New innovative techniques, including biotechnology and the development of bio-based products, may play a role in increasing sustainability, provided they are safe for consumers and the environment while bringing benefits for society as a whole.*

Currently within the EU, biotechnology products are subject to an authorization procedure for food or feed use. The steps necessary to obtain authorization for import, distribution, or processing are set out in [Regulation \(EC\) No 1829/2003](#). [Directive 2001/18/EC, the “GMO Directive”](#) outlines the procedure that must be followed to obtain authorization for cultivation.

On April 29, 2021, the European Commission published a report 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.” The Court of Justice ruling stated that products of genome editing fall under the “GMO Directive.” However, the Commission’s recent study concludes that this Directive is not “fit for purpose” for these newer biotechnology products and a targeted policy action is needed. The study says that genome editing can contribute to the objectives of the European Green Deal’s F2F and Biodiversity Strategies thus reinforcing what is stated on page 10 of the F2F Strategy. The Commission will engage in a wide-ranging communication effort with co-legislators and stakeholders in the EU, and it expects to publish an inception impact assessment on plants derived from certain applications of genome editing in the third quarter of 2021.

## **Study:**

- ❖ Letter from Commission to Portuguese Council Presidency:  
[https://ec.europa.eu/food/sites/food/files/plant/docs/gmo\\_mod-bio\\_ngt\\_letter.pdf](https://ec.europa.eu/food/sites/food/files/plant/docs/gmo_mod-bio_ngt_letter.pdf)
- ❖ Executive Summary of Study:  
[https://ec.europa.eu/food/sites/food/files/plant/docs/gmo\\_mod-bio\\_ngt\\_exec-sum\\_en.pdf](https://ec.europa.eu/food/sites/food/files/plant/docs/gmo_mod-bio_ngt_exec-sum_en.pdf)
- ❖ Full Study:  
[https://ec.europa.eu/food/sites/food/files/plant/docs/gmo\\_mod-bio\\_ngt\\_eu-study.pdf](https://ec.europa.eu/food/sites/food/files/plant/docs/gmo_mod-bio_ngt_eu-study.pdf)
- ❖ Webpage with Questions and Answers:  
[https://ec.europa.eu/food/plant/gmo/modern\\_biotech/q-and-a\\_en](https://ec.europa.eu/food/plant/gmo/modern_biotech/q-and-a_en)

## **Main Findings:**

- ✚ Certain applications of genome editing in plants result in the same or lower level of risk as conventional breeding techniques.

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<sup>1</sup> See GAIN report on announcement: <https://www.fas.usda.gov/data/european-union-green-deal-strategies-eu-agri-food-sector-present-politically-ambitious-policy>

- ✦ Directive 2001/18/EC applies broadly to the products of the techniques evaluated in the study, but is not “fit for purpose” for some genome editing techniques and their products.
- ✦ The EU’s current regulatory system that covers genome editing techniques poses implementation and enforcement challenges given the difficulty to distinguish plants obtained by the new techniques from conventional methods.
- ✦ Regulatory uncertainty has put the EU at a disadvantage in research and development, trade, and in accessing the benefits arising from the use of these newer products.
- ✦ There is sufficient evidence and scientific basis to initiate a targeted policy action on plants derived from certain genome editing techniques (targeted mutagenesis and cisgenesis), which will involve an impact assessment and public consultation.

## **Background:**

Regulating biotechnology in the EU has long been a contentious debate. Organisms derived from all forms of genetic engineering (GE) are currently regulated 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, except for about 1 percent of the corn production in Spain and Portugal.<sup>2</sup> 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 are 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](#)). Case C-528/16 initiated a dialogue in the EU, and on January, 7, 2019 the Committees on Agriculture and Environment of the European Parliament met jointly to debate the ruling ([see GAIN here](#)). On November 8, 2019, the Council of the European Union requested the Commission to submit, by April 30, 2021, 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. The Council requested an evaluation of the state-of-play of these newer techniques and regulatory pathways in the EU.

In a [letter dated April 29, 2021](#), the Commission formally delivered the study to the Portuguese Minister of Foreign Affairs as Portugal holds the current Council Presidency. The letter outlined the key findings of the study, detailed the Commission’s intention to conduct a targeted policy action, thanked Member States for their contributions, and asked the Council for support on next steps. In parallel, the Commission formally announced the [public release of the study](#) - “Commission seeks open debate on New Genomic Techniques as study shows potential for sustainable agriculture and need for new policy” and updated its [webpage dedicated to the study](#).

Within the report, the Commission examines the status of genome editing while taking into account the views of EU Member States and stakeholders, which are [available here](#). In the study, new genomic techniques are “defined as techniques capable to change the genetic material of an organism and that

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<sup>2</sup> <https://www.fas.usda.gov/data/european-union-agricultural-biotechnology-annual-0>

have emerged or have been developed since 2001, when the existing “GMO” legislation was adopted.”<sup>3</sup> Within the extensive document, the report covers the use of genome editing in plants and animals as well as micro-organisms for pharmaceutical, industrial, and agri-food applications.

The study’s methodology is informed by several key documents. The European Food Safety Authority (EFSA) developed a scientific [overview on the risk assessment](#) of plants developed through these genomic techniques taking into account its previous Scientific Opinions<sup>4</sup> and its [ongoing work in this area](#). In writing this overview, EFSA considered 16 Opinions issued by EU Member States, which were summarized by the Dutch National Institute for Public Health and the Environment, as well as three “EFSA GMO Panel” Opinions.

In addition, on March 19, 2021, the European Group on Ethics in Science and New Technologies (EGE), an independent advisory body to the Commission, published an [Opinion on the ethics of genome editing](#). The Opinion analyzed ethical questions concerning genome editing in humans, animals, and plants across the health, research, agriculture, and environment sectors. This publication addressed how the EU can shape governance and policies for genome editing and encourage a wide-ranging and inclusive societal debate. In particular, the EGE called for “the development of international standards and guidelines for the ethical and safe use of genome editing across all areas of application” and that “companies introducing new varieties, regardless of method or provenance should be required to identify the impact of their use on both agricultural and natural biodiversity and the environment.”

Finally, additional documents that informed the Commission’s study include the [JRC Technical Report on NGTs: State of the Art Review](#) and [JRC Science for Policy Report: Current and Future Market Applications of NGTs](#). The Commission also took into account expert opinions from the Group of [Chief Scientific Advisors](#) and the [European Network of GMO Laboratories](#).

## **Next Steps**

On May 10, 2021, the Commission presented its study to the European Parliament Committee on the Environment, Public Health, and Food Safety (ENVI) during a [public hearing on “new genomic techniques in the food sector.”](#) From May 26 to May 27, 2021, the Commission will present the study to the Council of the EU’s [Agriculture and Fisheries Council \(AGRIFISH\)](#), which consists of the EU Member State agriculture ministers. In the third quarter of 2021, the Commission will publish an inception impact assessment “building on the study and the exchanges with the co-legislators and stakeholders.” The impact assessment will follow, and the Commission said it “will look into the design of a proposal that combines high levels of safety with clear added value to society and the environment.” In addition, “It should allow reaping benefits from innovation by enabling safe NGT products to contribute to the sustainability and resilience of the EU agri-food system.”<sup>5</sup> The Commission will likely publish the inception impact assessment on the EU [“Have your say” website](#). Further details on the EU decision making process are outlined in [this GAIN](#).

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<sup>3</sup> [https://ec.europa.eu/food/plant/gmo/modern\\_biotech/new-genomic-techniques\\_en](https://ec.europa.eu/food/plant/gmo/modern_biotech/new-genomic-techniques_en)

<sup>4</sup> See more EFSA Opinions here: [Gene drives](#), [Genome editing](#), and [Synthetic Biology](#)

<sup>5</sup> [https://ec.europa.eu/food/sites/food/files/plant/docs/gmo\\_mod-bio\\_ngt\\_letter.pdf](https://ec.europa.eu/food/sites/food/files/plant/docs/gmo_mod-bio_ngt_letter.pdf)

**Attachments:**

No Attachments.