

**Voluntary Report** – Voluntary - Public Distribution

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**Report Name:** European Commission Publishes Roadmap on Legislative Initiative for Plants Produced by Certain Genome Editing Techniques

**Country:** European Union

**Post:** Brussels USEU

**Report Category:** Biotechnology and Other New Production Technologies, Trade Policy Monitoring

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**Report Highlights:**

On September 24, 2021, the European Commission published its roadmap to develop a legislative initiative for plants produced by certain genome editing techniques. This initiative will propose a legal framework for plants obtained by targeted mutagenesis and cisgenesis and for their food and feed products. The policy roadmap is based on the findings of a Commission study on new genomic techniques, which was published on April 29, 2021. The publication of the roadmap is a first step in the legislative process. It begins with a 4-week consultation period to provide feedback, which ends on October 22, 2021. A more comprehensive public consultation process will take place in 2022.

## Overview:

On September 24, 2021, the European Commission published its [roadmap to develop a legislative initiative for plants produced by certain genome editing techniques](#). This initiative will propose a legal framework for plants obtained by targeted mutagenesis and cisgenesis and for their food and feed products. The policy roadmap is based on the findings of a [Commission study on new genomic techniques](#) in light of the Court of Justice ruling in Case C-528/16, which was published on April 29, 2021 ([GAIN here](#)). While this Court of Justice ruling stated that products of genome editing fall under Directive 2001/18/EC, the Commission's study concluded that this Directive is not "fit for purpose" for these newer products and a targeted policy action is needed. As a result, the Commission has introduced potential policy options for legislation for plants produced by targeted mutagenesis and cisgenesis. The publication of the [roadmap](#) is a first step in the legislative process. It begins with a 4-week consultation period to provide feedback, which ends on October 22, 2021. A more comprehensive public consultation process will take place in 2022.

The different policy elements presented in the roadmap that are considered for the development of the subsequent policy options, include:

- Risk assessment and approval requirements should be proportionate to the risk involved, e.g. in terms of data and studies, in line with risk profiles and on a case-by-case basis, taking into account elements such as the specific technique used, the type of modification or the novelty of the trait.
- A sustainability analysis to examine how these products contribute to sustainability while taking into account the criteria developed under a sustainable food systems framework.
- Appropriate traceability and labeling provisions that are implementable and enforceable and take into account the capacity of plants obtained by targeted mutagenesis and cisgenesis to contribute to a sustainable food system and ensure consumers' right to make informed choices.
- Mechanisms to be able to rapidly adjust elements of the legislation and its implementation over time when science and technology progresses to ensure a future-proof regulatory framework.

The policy options will be developed based on the above elements and public feedback provided on the inception impact assessment and from consultation activities. The information will be assessed against the baseline scenario, and the anticipated final products are a policy initiative and impact assessment.

## Next Steps:

During the second quarter of 2022 (indicative timing), the Commission will hold a 12-week public consultation process. A questionnaire will be available in all EU languages and replies can be made in any official EU language via the Commission's 'Have Your Say' portal. A factual summary of the contributions to the public consultation will be published after its closure. The Commission adoption of a potential policy initiative is targeted for the second quarter of 2023.

## Attachments:

No Attachments.