

Plants obtained by certain new genomic techniques and their food and feed

2023/0226(COD) - 05/07/2023 - Legislative proposal

PURPOSE: to establish a specific regulatory framework for new genomic techniques (NGT) plants and their products.

PROPOSED ACT: Regulation of the European Parliament and of the Council.

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND: New Genomic Techniques (NGTs) are innovative tools that can help increase the sustainability and resilience of food systems and support the goals of the European Green Deal and the Farm to Fork Strategy. They allow precise and efficient development of improved plant varieties that can be climate resilient, pest resistant, require less fertilisers and pesticides, or ensure higher yields.

Since the adoption of the EU's GMO legislation in 2001, and especially in the last decade, a variety of new genomic techniques (NGTs) have been developed based on advances in biotechnology.

NGTs constitute a diverse group of genomic techniques, and each of them can be used in various ways to achieve different results and products. They can result in organisms with modifications equivalent to what can be obtained by conventional breeding methods or in organisms with more complex modifications.

To have a better understanding of all these recent advances, the Council requested the Commission in November 2019 to provide a study on NGTs. The 2021 Commission study concluded that the current rules - mainly the existing GMO legislation - lag behind scientific and technological progress and do not sufficiently facilitate the development and placing on the market of innovative NGT products. The EU needs an adapted framework for safe NGT plants benefitting farmers, consumers, and the environment.

CONTENT: the Commission is proposing this draft regulation to establish a regulatory framework for NGT plants, and their products. It proposes different procedures for the placing on the market of NGT plants.

The main objectives of the proposal are:

- maintaining a high level of protection of health and the environment;
- steering developments towards contribution to sustainability goals in a wide range of plant species, especially for the agri-food system;
- creating an enabling environment for research and innovation, especially for SMEs.

This proposal only concerns plants produced by targeted mutagenesis and cisgenesis and their food and feed products. Targeted mutagenesis induces mutations in the genome without insertion of foreign genetic material (e.g., changes are made within the same plant species). Cisgenesis is an insertion of genetic material into a recipient organism from a donor that is sexually compatible with the recipient organism (e.g., changes are made between naturally compatible plants).

The proposal does not include plants obtained by NGTs that introduce genetic material from a non-crossable species (transgenesis). Such techniques remain subject to the existing GMO legislation.

More specifically, the proposal seeks to:

- establish two categories of plants obtained by NGTs. Both categories will be subject to different requirements to reach the market taking into account their different characteristics and risk profiles.

1. Category 1 NGT plants: NGT plants comparable to naturally occurring or conventional plants. The plants from the first category will need to be notified. Information on category 1 NGT plants would be provided through the labelling of seeds, in a public database and through the relevant catalogues on plant varieties.

2. Category 2 NGT plants: NGT plants with more complex modifications. The plants from the second category will go through the more extensive process of the GMO directive. They would be subject to risk assessment and authorisation before could be put on the market. They would be traced and labelled as GMOs, with the possibility of a voluntary label to indicate the purpose of the genetic modification. The risk assessment, detection method and monitoring requirements would be adapted to different risk profiles and regulatory incentives would be available for NGT plants featuring traits that can:

- contribute to sustainability goals;
- give incentives to steer the development of plants towards more sustainability;
- ensure transparency about all NGT plants on the EU market (for e.g., through labelling of seeds);
- offer robust monitoring of economic, environmental and social impacts of NGT products.

Budgetary implications

Overall, the proposal will be budget neutral. The costs of this proposal, estimated at EUR 2.434 million will be fully covered by redeployments within existing financial envelopes of the current MFF.

The budgetary implications are mainly related to additional tasks to be carried out by EFSA in terms of new scientific and administrative tasks as regards the adapted risk assessment, the verification procedure for certain NGT plants and pre-submission advice. The Commission

proposes to reinforce the budgetary envelope of EFSA by EUR 2.334 million from the unallocated margin of Heading 2b, which will be compensated through a reduction of the Single Market Programme, whose objectives are directly linked to those of this initiative, resulting in an increase of the unallocated margin of Heading 1.

In addition, new IT tools and database are also needed to implement the legislation. An amount of EUR 100 000 is foreseen under the Single Market Programme to integrate the NGT plants/products in the already existing Food Innovation Platform (FIP) and E-Submission Food Chain (ESFC) system.