PROPOSED REPLACEMENT EU ACT
INITIAL ASSESSMENT OF IMPACT

Date: 04/04/2025

DSC REF: DSC/06a/2025

Proposed Replacement EU Act

Proposal for a Regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625
EUR-Lex - 52023PC0411 - EN - EUR-Lex

This Regulation will amend:

Regulation (EU) 2017/625 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products
Regulation - EU - 2017/625 - EN - EUR-Lex

In Annex 2 (43 – Official controls, veterinary checks) to the Windsor Framework

The proposed regulation will also introduce new provisions which do not replace or amend existing legislation.

Summary of the Act

This assessment relates to provisions within the *proposal for a Regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625* ("the proposed Regulation") relating to the Food Standards Agency in Northern Ireland's remit, specifically:

- The safety of Genetically Modified Organisms (GMOs) – and NGT plants (obtained by new genomic techniques), when used as Food or Feed
- Labelling and traceability of GMOs (and NGTs) when used as Food or Feed

The proposed Regulation must be agreed by the European Parliament and EU Member States in the Council of the EU – potentially with several amendments – before it can become law. It is unclear when agreement will be reached.

The proposed Regulation would amend Regulation (EU) 2017/625 on official controls, however these amendments are administrative in nature and required to ensure that 2017/625 remains operable with the new categories of NGT plants.

The proposed Regulation on new genomic techniques (NGTs) would be a wide piece of legislation which creates a new regulatory framework for plants, and derived food and feed, developed through NGTs, such as gene editing. This framework includes new requirements for NGT plants obtained by targeted mutagenesis and cisgenesis and food and feed containing, consisting or produced from these plants.

NGT plants currently fall under the scope of EU legislation on GMOs (Directive 2001/18/EC, Regulation (EC) No 1829/2003, Regulation (EC) No 1830/2003). GMOs are covered in more detail below.

New genomic techniques (NGTs) are breeding techniques that can be used to make targeted changes to alter the genetic material of plants, animals or microorganisms. They are used to design new traits of interest or enhance or diminish existing characteristics of an organism and have been trialled on agricultural crops for example to improve yields. While the resulting crop can be indistinguishable from conventionally bred counterparts, the use of NGTs allows for changes to be made at a faster pace than achievable through conventional breeding. NGTs refer to the techniques developed since the adoption of the EU’s Directive on genetically modified organisms (GMO) in 2001.

The European Commission has proposed a new Regulation to create a new regulatory framework for plants which have been obtained by certain NGTs. Currently, all plants obtained by NGTs are subject to the same rules as GMOs. This follows a 2021 European Commission study which found that existing GMO legislation does not reflect scientific and technological progress for NGTs. The European Food Safety Authority has concluded that there are no new hazards specifically associated with NGTs in plants and that risk assessment of these techniques should be adapted accordingly.

The proposed legislation is structured around two categories of plants aiming to distinguish varieties "considered equivalent to conventional plants" – 'NGT 1 plants' – from all other plants obtained through NGTs – 'NGT 2 plants'.

The deliberate release and placing on the market of NGT plants would be subject to one of two procedures: verification (for 'NGT 1 plants') to establish equivalence with conventional products, and authorisation (for 'NGT 2 plants'). All NGT plants will be listed in a public EU database. In addition, their seeds and other plant reproductive material will be labelled, and information on NGT plant reproductive material will be listed in the common EU catalogues of plant varieties.

Verified NGT 1 plants will require notification prior to marketing and entry onto a public register, but will not require any further authorisations or risk assessments. Therefore, they would be exempt from the requirements of GMO legislation. The proposed Regulation may potentially impact the scope of the existing GMO legislation which applies to Northern Ireland.

Applications that do not meet the criteria for NGT 1 verification will require authorisation in line with that for NGT 2. NGT 2 plants will require a more in-depth risk assessment and mandatory labelling and traceability requirements. These NGT 2 plants will be reviewed against an adapted version of the current EU Regulatory framework for GMOs. Existing traceability and labelling requirements would continue to apply, with the possibility to add a factual statement on the intended purpose of the genetic modification.

Existing legislation governing the safety of GMOs for use in food and feed ensures that authorised GM food and feed are safe, GM foods are only authorised for sale if they are judged:

- Not to present a risk to health
- Not to mislead consumers
- Not to have less nutritional value than their non-GM counterpart.

Before a GMO food or feed product can be placed on the market in the EU and Northern Ireland, it must be authorised under Regulation (EC) 1829/2003 on Genetically Modified Food and Feed. GMO food and feed is subject to a rigorous safety assessment process before it can be authorised and applications for authorisation must contain adequate information to enable assessment of the potential long-term adverse effects of the GMO on human health, animal health and the environment. Regulation (EC) No 1830/2003 concerning the traceability and labelling of genetically modified organisms puts in place rules to ensure products containing GMOs can be traced at all stages of the production and distribution chain and to allow consumers to make informed decisions about the food they purchase. The rules cover labelling, monitoring environmental and health risks, and the ability to withdraw products where necessary. NGT 2 plants will continue to be subject to these rules and processes.

The proposed Regulation would apply 2 years after the final legislation is published.

Department(s) Responsible

The Food Standards Agency is responsible for the safety of GMOs for use in Food and Feed in Northern Ireland.

Initial Assessment of Impact

Information on the potential impacts of this proposed legislation are included in the above “Summary of the Act” section.

UK Government Explanatory Memorandum

Defra completed an Explanatory Memorandum in August 2023.

Analysis by the European Commission on its Impact Assessment

The European Commission’s Impact Assessment which accompanied the legislative proposal in July 2023 does not make any mention of Northern Ireland or Northern Ireland stakeholder input.

The Commission states that, of the options assessed in the Impact Assessment, the preferred option which is the basis for the legislative proposal would create an enabling framework meeting the demands for new varieties of plants with traits beneficial to the environment, delivering benefits to consumers. It is comparable to the approach followed in an increasing number of non-EU countries and would be the least disruptive of trade.
European Commission Impact Assessment
European Commission Executive Summary of Impact Assessment

Departmental Engagement

The Food Standards Agency has engaged with our counterparts in UK Government, and Food Standards Scotland on these proposals. The FSA is also working with Defra and FCDO to engage with EU institutions, Member States and stakeholders on gene editing.