PROPOSED REPLACEMENT EU ACT
INITIAL ASSESSMENT OF IMPACT

Date: 27/02/2026

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

Provisional_agreement_NGT_EN.pdf

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 updated provisions within the provisionally agreed text *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 provisionally agreed text follows interinstitutional negotiations. It has been agreed by the European Parliament Committee on the Environment, Public Health and Food Safety (ENVI), with a final vote by the European Parliament

expected in April 2026. The Council of the EU must also formally agree it before the Regulation can become law. It will be published in the Official Journal of the EU shortly after this formal agreement. The Regulation will apply 2 years after final publication, with the exception of two provisions relating to exclusion from patentability which will apply 20 days after final publication.

Annex A to this assessment provides the initial Assessment of Impact on the proposal provided by the FSA to the Democratic Scrutiny Committee in April 2025. This updated assessment covers relevant changes agreed following interinstitutional negotiations.

Overview

The provisionally agreed text remains structured around two categories of plants with the aim of distinguishing varieties that are either:

- considered equivalent to conventional plants – referred to as ‘NGT 1 plants' or
- other plants obtained through NGTs that do not meet the equivalence criteria for NGT 1 – referred to as 'NGT 2 plants'.

In the provisionally agreed text, the deliberate release and placing on the market of NGT plants remains 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.

The initial Assessment provided in April 2025 (included in Annex A) outlines the current system for authorisation of GMOs in Food and Feed, under Regulation (EU) 1829/2003. As previously stated, the proposed Regulation would establish a new regulatory framework for plants developed using NGTs, which are currently classified and regulated as GMOs under existing EU legislation. NGT 1 plants would be exempt from the full GMO authorisation process while NGT 2 plants will still require an in-depth risk assessment, mandatory labelling and traceability requirements which will be reviewed against an adapted version of the current EU regulatory framework for GMOs.

Changes since initial consideration of proposal

NGT 1 Changes

As outlined in the initial impact assessment, NGT 1 plants will undergo a formal verification procedure and be listed on a public EU database before they can be released or placed on the market. The provisionally agreed text now includes detail on information requirements including detail on the technique used,

relevant DNA sequence information and a declaration that no traits listed in the exclusion list are present.

The provisionally agreed text has expanded the scope and transparency of the public database for NGT 1 plants. The database must now include scientific EFSA statements where applicable as well as information on the technique(s) used to obtain trait(s).

While verified NGT 1 plants are exempted from authorisation, the provisionally agreed text has introduced a list of traits that exclude NGT plants from Category 1 status and require them to be classed as NGT 2. This list includes tolerance to herbicides and production of a known insecticidal substance. This narrows the range of plants eligible for NGT 1 status. The provisionally agreed text also establishes a mechanism for Member States to raise “reasoned objections” to a verification report within set deadlines.

Under the provisionally agreed text, NGT 1 plants will not be subject to consumer facing labelling; however, any plant reproductive material containing or consisting of a NGT 1 plant must be labelled with the term ‘cat 1 NGT’ which is an operator-facing label only, intended for breeders, seed suppliers and other supply-chain sellers.

The provisionally agreed text introduces a clear inheritance rule, confirming that any offspring derived from a NGT 1 plant through conventional breeding will automatically retain NGT 1 status, without requiring further verification. However, if additional targeted mutagenesis or cisgenesis is used in developing the progeny, the resulting plants must undergo a new verification process to demonstrate continued compliance with the criteria for equivalence.

Overall, the provisionally agreed text establishes a more stringent and transparent framework for determining NGT 1 status, which enhances clarity for businesses and provides greater assurance regarding food and feed safety considerations within the FSA’s remit.

NGT 2 Changes

The provisionally agreed text does not make any changes to the criteria for NGT 2 plants. Unlike NGT 1 plants, NGT 2 plants will require an in-depth risk assessment alongside 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.

The Commission's original proposal included an optional provision allowing NGT 2 plants and products to be labelled with information on the traits conveyed by the genetic modification. The provisionally agreed text has clarified that where use is made of this provision, the label must specify all traits conveyed by genetic modification.

Differences between the Genetic Technology (Precision Breeding) Act 2025 and the EU proposed Regulation on New Genomic Techniques

The Genetic Technology (Precision Breeding) Act became law in March 2023, creating a new category of precision bred organisms (PBOs) whose gene-edited changes could have occurred naturally or through traditional breeding. The Act removed PBOs from GMO regulations in England and introduced a system for their release and marketing. As a result of the introduction of the Genetic Technology (Precision Breeding) Act in England, the FSA has developed a new authorisation framework to regulate the use of precision bred organisms in food and feed products in England. This framework is underpinned by legislation which came into force in November 2025 – to authorise PB products for use in food and feed.

For food/feed specifically, the FSA operates a two-tier authorisation: Tier 1 (applicant-led safety assessment with notification where risks are understood) and Tier 2 (FSA led safety assessment and risk management where there are potential concerns such as significant changes to nutrition, toxicity or allergenicity, or novel species). Authorised PBO food/feed products are placed on a public register.

This broadly mirrors the approach taken in the NGT proposal, where products meeting equivalence criteria proceed through a more streamlined Category 1 route, while those involving more substantive genetic changes are assessed under the more comprehensive Category 2 route. However, unlike the NGT proposal, there are no additional traceability or labelling requirements for Tier 1 and Tier 2 precision bred food and feed products.

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

The initial assessment of impact remains consistent with the assessment provided by the FSA in April 2025 (attached at Annex A), and information on the potential impacts of the agreed changes to this proposed legislation as a result of

the interinstitutional negotiations 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 continued to engage with our counterparts in UK Government, and Food Standards Scotland on these proposals.

During earlier engagement between the FSA, DAERA and the Democratic Scrutiny Committee in May 2025, it had been discussed that stakeholder engagement would commence once the Regulation was formally published in the Official Journal of the EU. However, on 4 December 2025, the FSA issued an email to over 200 relevant Northern Ireland stakeholders, inviting them to share their views on the proposed Regulation. To date, no responses have been received. Further to this, in the February 2026 edition of the FSA NI Industry Bulletin, the FSA has invited stakeholders to share their views on NGTs. The Industry Bulletin has over 5000 subscribers.

Further stakeholder engagement on NGTs will be carried out when this Regulation is formally published. This stakeholder engagement aims to assess understanding and opinions on NGTs in Northern Ireland as well as inform consumers of what this new legislation will mean for them.

Annex A:

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.