PROPOSED REPLACEMENT EU ACT
INITIAL ASSESSMENT OF IMPACT

Date: 17/02/2026

DSC REF: COM/2023/411

Proposed Amending 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 – COM(2023)411

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52023PC0411

Amending

Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 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, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation)

https://www.legislation.gov.uk/eur/2017/625

Summary of the Act

This impact assessment relates to the deliberate release of plants that are derived from New Genomic Technologies (NGT) into the environment. This Assessment has been updated to reflect the provisionally agreed text of the proposed European Union (EU) Regulation. It therefore incorporates the most recent legal and policy developments, including amendments made during trilogue negotiations, and provides an updated assessment of the likely impacts arising from those changes. In addition, this version includes a dedicated annex summarising how the Department has addressed the

Committee's additional questions, to support transparent scrutiny and ease of reference. Also to aid the Committee's review, we have included newly provided text in this updated assessment in bold font.

The European Commission has proposed a new regulation concerning plants developed through specific NGTs and their derived food and feed products. This proposal aims to update the existing framework established by Regulation (EU) 2017/625 (the Official Controls Regulation, OCR), which primarily governs controls to ensure the application of food and feed law, animal health and welfare standards, plant health, and plant protection products. The definition of a Genetically Modified Organism, under EU Directive 2001/18/EC will be amended also. The proposed EU Regulation now confirms a two-category framework for plants obtained using certain new genomic techniques. Category 1 NGT plants are treated as equivalent to conventionally bred plants following a verification process and added to a public database, while Category 2 NGT plants remain regulated under existing EU GMO legislation including risk assessment and authorisation requirements.

It is of note that elements of the legislation may only be applicable when the Regulation is published and is assessed within a Withdrawal Agreement Joint Decision.

<u>Summary of the Proposed Regulation:</u>

- *Scope:* The proposed regulation specifically addresses plants obtained through certain NGTs, as well as the food and feed products derived from them.
- *Risk Assessment Procedures:* It introduces tailored risk assessment procedures for category 2 NGT-derived plants, considering their unique characteristics compared to traditionally bred or genetically modified organisms (GMOs).
- *Authorisation Process:* The authorisation process for category 2 NGT plants is proposed to facilitate the entry of NGT-derived products into the market, aiming to promote innovation while ensuring safety.
- *Traceability and Labelling:* The proposed regulation outlines specific requirements for the traceability and labelling of NGT-derived products to inform consumers and maintain transparency in the supply chain.

The proposal creates two distinct pathways for NGT plants to be placed on the market:

- *Category 1 NGT plants:* equivalent to plants that could occur naturally or through conventional breeding methods; they would be exempted from the rules currently

set out in the GMO legislation and would not be labelled; however, seeds produced through those techniques would have to be labelled.
- *Category 2 NGT plants:* all other NGT plants; rules under GMO legislation would apply (including a risk assessment and authorisation before they are placed on the market); they would be labelled as such.

In addition, the proposal excludes the use of NGTs in organic production.

Key Differences from Regulation (EU) 2017/625, the Official Controls Regulation:

- *Specific to NGTs:* While the Official Controls Regulation provides a general framework for official controls across various sectors, the proposed regulation focuses specifically on plants developed through NGTs and their related products.
- *Bespoke Risk Assessments:* The new proposal retains risk assessment procedures that are customised for NGT category 2 derived plants (currently described as GMOs). For NGT category 1 plants, these will be excluded from the requirement of a risk assessment.
- *Authorisation:* In contrast to the more generalised authorisation processes for GMOs, the proposed amendment offers a more efficient pathway for NGT products, aiming to reduce administrative burdens and encourage technological advancement.
- *Enhanced Traceability and Labelling:* The proposal places a stronger emphasis on the traceability and labelling of NGT-derived products, ensuring that consumers are well-informed about the nature and origin of these products, which is a more focused approach than that of the existing regulation.

This proposed regulation hopes to allow for a legislative framework in response to advancements in genomic technologies whilst attempting to balance innovation with safety and transparency.

Department(s) Responsible

The lead Department in relation to the proposed regulation is DAERA.

Food Standards Agency regulates the safety of food and feed, including when produced through the use of new genomic techniques, while DAERA regulates the use of NGT products in relation to cultivation.

Initial Assessment of Impact

The proposed EU regulation on plants developed through the use of certain new genomic techniques could potentially have a notable impact specific to everyday life of communities in Northern Ireland (NI) in a way that is liable to persist due to NI's unique position under the Windsor Framework. While the overall impact statement remains unchanged from the previous version, the Department has undertaken substantial revisions to several key considerations to reflect the implications of the provisionally agreed text. These updates provide greater clarity on regulatory divergence, seed movements, and the practical application of the proposed categories of NGT plants within NI. Below are the key considerations:

Potential Impacts Specific to NI:

Regulatory Alignment with the EU:

Under the Windsor Framework, NI remains aligned with EU regulations on agri-food products, even though the rest of the United Kingdom (UK) does not.

If the proposed regulation is adopted, NGT-derived plants would be approved for the deliberate release into the environment in NI. Whilst similar legislation has been enacted in England through the use of this technology there remains potential for divergence from the regulatory framework applied in Great Britain (GB).

England has progressed with similar gene-editing regulations, referred to as Precision breeding, for both plants and animals. There are current differences between the definition of a NGT in the Genetic Technology (Precision Breeding) Act 2023 versus the current definitions being proposed in the EU. The Precision Breeding Act is not applicable in Scotland and Wales and Precision Breeding products are treated as GMOs under their current regulatory frameworks.

The regulatory approaches taken by the EU and GB (England) differ in scope, definitions, regulatory thresholds, and labelling requirements.

1. Scope of the Legislation

EU: The proposed EU Regulation applies only to plants obtained using certain new genomic techniques. It establishes a legally binding two-category system distinguishing between NGT-1 and NGT-2 plant types.

England: The Genetic Technology (Precision Breeding) Act 2023 applies to both plants and animals, although implementation currently focuses on plants.

2. Definitions and Eligibility Criteria

EU: The EU sets strict criteria defining which plants may be considered NGT-1, including limits on the number and type of genetic edits, and explicitly excludes certain traits—such as herbicide tolerance and production of known insecticidal substances—from qualifying as NGT-1. These excluded traits must be regulated as NGT-2 under full GMO rules.

England: The English system does not impose numerical limits on the number of edits. A plant qualifies as “precision bred” if the genetic changes could have arisen naturally or through traditional breeding. There is no exclusion list, meaning that traits banned from NGT-1 in the EU may still qualify as “precision bred” in England if they meet the broader natural-equivalence criteria.

3. Regulatory Pathway

EU: NGT-1 plants undergo a verification process before being treated as conventional. NGT-2 plants remain fully subject to EU GMO legislation, including risk assessment, traceability and authorisation requirements.

England: England has removed precision-bred organisms (PBOs) from GMO controls. PBOs follow a streamlined two-tier risk assessment system (Tier 1 vs Tier 2) for food and feed only, with no return to GMO legislation unless transgenes are involved.

4. Labelling and Traceability

EU:

- No product labelling for NGT-1 foods, feed or plants;
- Seeds and plant reproductive material for NGT-1 must be labelled, and all NGT plants must be listed in an EU public register;
- NGT-2 plants require full GMO-style labelling and traceability.

England: Precision-bred products do not require labelling.

5. Organic Production

EU: All NGT plants, including NGT-1, are prohibited in organic production.

England: Precision bred and GMO derived plants are prohibited in organic production.

Market Availability and Trade

NI will have access to EU approved NGT plants for cultivation. We expect similar plants will be approved in England also. There may be potential divergence with Scotland and Wales.

Movement of Seeds into NI

There will be no immediate impact on the movement of seeds to NI.

The effect that this proposal would have on the movement of NGT seeds to NI is dependent on its compliance with the EU Plant Reproductive Material (PRM) and Forest Reproductive Material (FRM) proposals.

These proposals are undergoing review and aim to harmonise the marketing legislation, ensuring the availability of seeds, plant and forest reproductive material that are high quality, adaptable to the current and foreseeable climatic changes, and that contributes to food security, sustainable production, and protection of biodiversity. Thus, the objectives of both proposals are compatible.

There may be a conflict created with the organic sector within NI due to co-existence - NGT plants being cultivated near organically cultivated plants.

Agricultural Innovation

The regulation aims to promote innovation in plant breeding, particularly for crops resilient to climate change, pests, and diseases. Adoption of such techniques in NI could benefit local farmers, enhance productivity and improve food security in the long term.

The EU proposal includes provisions where a trial of a NGT plant can take place in a Member State, and pending outcome of that trial, the plant is then approved for marketing in the EU. This requires engagement with the EU as a Member State, and at present NI has no access to the EU institutions that would take this forward. Further assessment will be required in this area as the EU proposal is refined and fully agreed, in-line with any future SPS agreement.

Persistence of Impact

The proposal must undergo further discussion and refinement through the EU legislative processes; it is not possible to assess likely impacts at this stage.

<u>Potential Impacts of Not Applying the Regulation</u>

It appears likely that not applying the proposed replacement EU Act would have a significant impact specific to everyday life of communities in NI in a way that is liable to persist. These impacts may include:

Agricultural Innovation and Competitiveness

Missed Opportunities for Farmers: Without the application of the regulation, Northern Irish farmers and agri-food producers might lose access to NGT-derived crops with enhanced traits like pest resistance, drought tolerance, or higher yields. This could reduce competitiveness compared to counterparts in the EU who adopt these technologies.

Environmental and Food Security Challenges

NGTs offer potential solutions to climate change challenges, such as developing crops that are more resilient to extreme weather conditions. If the regulation is not applied, NI may lag in adopting these innovations, potentially affecting local food security and sustainability.

Failure to adopt climate-resilient agricultural solutions may place an additional burden on NI's agricultural sector, which is already under pressure to meet sustainability and environmental targets.

Consumer Trust and Transparency

The proposed EU regulation includes measures for traceability and labelling of NGT-derived plants and products.

Persistence of Impact

The impact of not applying the regulation would likely persist because of long-term EU alignment obligations. Under the Windsor Framework, NI is required to align with EU standards for agricultural and food products. As such, if the proposed Regulation becomes law but is not applied in NI, this has the potential to create enduring regulatory and trade conflicts between the EU and NI. For example, NI would fall out of step with the EU's updated approach to NGT plants, creating avoidable regulatory tension and making it harder for NI goods to meet EU requirements.

Not applying the Regulation would not have any impact on trade with GB as NI already has unfettered access to the GB market. However, failing to update the rules could instead add complexity, as NI would remain aligned to older EU GMO rules, whilst GB follows its own Precision Breeding framework.

UK Government Explanatory Memorandum

The Explanatory Memorandum is available at:
https://www.gov.uk/government/publications/em-on-amendment-to-eu-regulation-2017625-com2023411

The explanatory memorandum gives an overview regarding the Official Controls Regulation, focusing on the regulatory framework for plants, food, and feed developed using new genomic techniques. It details the proposal's alignment with the UK's policies post-Brexit, especially under the Windsor Framework.

Analysis by the European Commission on its Impact Assessment

An executive summary of the impact assessment is available at:

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52023SC0413

The initiative was published on the Commission's Have Your Say website. The Inception Impact Assessment (IIA) included the context, problem definition and subsidiarity check, presented the objectives and the main components of the policy options, contained a preliminary assessment of expected main impacts and referred to the evidence base and data collection.

70,894 contributions were received overall; 98% (69,414) of the replies were identified as coming from campaigns. The non-campaign replies amounted to 2% of the total (1,480). According to self-categorisation, most contributions in the non-campaign replies came from citizens (70%, 1,030 replies), followed by business organisations/associations, trade unions (14%, 203), academia/research institutions (8%, 115), NGOs and consumer/environmental organisations (5%, 81), public authorities (1%, 9) and others (3%, 42). Contributions (both campaign and non-campaign) originated from 91 countries, including the 27 Member States and 64 non-EU countries. Top contributions from Member States were from Germany (32,694), France (25,544), Belgium (2,732), Netherlands (2,251) and Austria (2,111). Most contributions from non-EU countries came from Switzerland (782), followed by UK (759), USA (228), Argentina (142) and Canada (114). The large number of contributions shows the high interest of citizens and stakeholders in the Commission's policy initiative. DAERA will continue to engage stakeholders through established mechanisms to consider the practical implications of the agreed EU Regulation, particularly in relation to seed supply chains and compliance.

There is no specific stakeholder identified within the report as being representative of NI. DAERA will seek to engage stakeholders through established mechanisms to consider the practical implications of the agreed EU Regulation, particularly in relation to seed supply chains and compliance.

Departmental Engagement

Engagement with the EU in relation to the proposed regulations has been, to date, led by Defra and as such there has been no direct engagement between DAERA and EU regarding this proposal.

The Department meets monthly with Defra as well as the other devolved nations with regular discussions relating to the Gene Editing and the possibility of any change to EU law and its potential impact. This forum provides a basis for considering the implications of the provisionally-agreed EU Regulation for NI.

DAERA continues to engage with Defra on a SPS Agreement between the UK and the EU.

DAERA will seek to engage stakeholders through established mechanisms to consider the practical implications of the agreed EU Regulation, particularly in relation to seed supply chains and compliance. In relation to cultivation and the impact of the legislation we currently engage with stakeholders on an ad hoc basis when approached. Further formal engagement is anticipated in relation to cultivation. FSA are actively engaging with stakeholders in relation to the food implications of the Regulation.

Annex A: Answers to Additional Committee Questions as regards COM/2023/411

Note: much of the detail included in this annex is present in the main body of the Impact Assessment text. However, it is included here for ease of reference for Committee members.

Q. Whether this proposal includes provision for genetically modified organisms?

The proposal does include provision for genetically modified organisms (GMOs), but only in relation to certain plants developed using new genomic techniques.

Under the proposal:

- Category 1 NGT plants are not treated as GMOs.
  These are plants whose genetic changes could also have occurred naturally or through conventional breeding. Once verified, they are treated as equivalent to conventional plants and are exempt from existing GMO legislation.
- Category 2 NGT plants are regulated as GMOs.
  Plants that do not meet the strict criteria for Category 1—such as those involving traits explicitly excluded by the proposal (e.g., herbicide tolerance or production of certain insecticidal substances)—are automatically treated as NGT-2 and therefore fall fully under EU GMO legislation, including requirements for authorisation, risk assessment, traceability and labelling.

Therefore, the proposal does not create a new GMO category, but it does incorporate GMOs where NGT plants fall into Category 2, ensuring these continue to be regulated under existing EU GMO frameworks.

Q. Differences between the UK's legislation (the Precision Breeding Act and Genetic Technologies (Precision Breeding) Regulations 2025) and the proposed EU legislation.

The regulatory approaches taken by the EU and GB (England) differ in scope, definitions, regulatory thresholds, and labelling requirements.

1. Scope of the Legislation

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England: The English system does not impose numerical limits on the number of edits. A plant qualifies as “precision bred” if the genetic changes could have arisen naturally or through traditional breeding. There is no exclusion list, meaning that traits banned from NGT-1 in the EU may still qualify as “precision bred” in England if they meet the broader natural-equivalence criteria.

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4. Labelling and Traceability

EU:

- No product labelling for NGT-1 foods or plants;
- Seeds and plant reproductive material for NGT-1 must be labelled, and all NGT plants must be listed in an EU public register;
- NGT-2 plants require full GMO-style labelling and traceability.

England: Precision-bred products do not require labelling to indicate their precision-bred status.

5. Organic Production

EU: All NGT plants, including NGT-1, are prohibited in organic production.

England: Precision bred plants are prohibited in organic production.

<u>Q. If and how the proposed EU act would impact the movement of seeds to NI?</u>

There will be no immediate impact on the movement of seeds to NI.

The effect that this proposal would have on the movement of NGT seeds to NI is dependent on its compliance with the EU Plant Reproductive Material (PRM) and Forest Reproductive Material (FRM) proposals.

These proposals are undergoing review and aim to harmonise the marketing legislation, ensuring the availability of seeds, plant and forest reproductive material that are high quality, adaptable to the current and foreseeable climatic changes, and that contributes to food security, sustainable production, and protection of biodiversity. Thus, the objectives of both proposals are compatible.

Q. DAERA's engagement with stakeholders on the proposed EU Act.

Engagement with the EU in relation to the proposed regulations has been, to date, led by Defra and as such there has been no direct engagement between DAERA and EU regarding this proposal.

DAERA will seek to engage stakeholders through established mechanisms to consider the practical implications of the agreed EU Regulation, particularly in relation to seed supply chains and compliance. In relation to cultivation and the impact of the legislation we currently engage with stakeholders on an ad hoc basis when approached. Further formal engagement is anticipated in relation to cultivation. FSA are actively engaging with stakeholders in relation to the food implications of the regulations.

Q. DAERA's engagement with UKG on the proposed EU Act.

The Department meets monthly with Defra as well as the other devolved nations with regular discussions relating to the Gene Editing and the possibility of any change to EU law and its potential impact. This forum provides a basis for considering the implications of the provisionally-agreed EU Regulation for NI.

Q. DAERA's engagement with UKG regarding a potential UK-EU SPS Agreement.

DAERA continues to engage with Defra on a SPS Agreement between the UK and the EU.