

PUBLISHED REPLACEMENT EU ACT ASSESSMENT OF IMPACT

Reference: Regulation (EU) 2026/1388

Date: 03/07/2026

Department: DAERA

Published Replacement EU Act

[Regulation \(EU\) 2026/1388 on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation \(EU\) 2017/625](#)
(Article 37 only)

OJ L, 2026/1388, 26.6.2026.

This Regulation amends [Regulation \(EU\) 2017/625](#) on official controls, referenced in Annex 2 (Section 43 – Official controls) of the Windsor Framework. In accordance with Article 13(3) of the Windsor Framework, Article 37 of Regulation (EU) 2026/1388 will therefore apply to the UK in respect of NI and is subject to the democratic scrutiny mechanisms set out in Article 13(3a) of the Windsor Framework and Schedule 6B of the NI Act 1998.

An assessment of impact for further Articles of Regulation (EU) 2026/1388 would be provided in the event that they need to be considered under Article 13(4).

Summary of the Act

As per notification, this Assessment of Impact relates specifically to Article 37 of Regulation (EU) 2026/1388, which amends Regulation (EU) 2017/625 on official controls.

Article 37 provides powers for the European Commission to adopt delegated and implementing acts relating to official controls and verification arrangements associated with plants obtained through certain new genomic techniques.

Article 37 forms part of the wider Regulation (EU) 2026/1388, which establishes a regulatory framework for plants obtained through certain new genomic techniques and their products. The wider Regulation has previously been considered by the Committee during scrutiny of the legislative proposal.

The Department considers that Article 37 does not itself introduce substantive policy changes specific to Northern Ireland. Rather, it provides a legal mechanism through which the European Commission may adopt future technical provisions relating to official controls and verification arrangements.

Department(s) Responsible

DAERA is the lead Department.

The Food Standards Agency is responsible for the safety of Genetically Modified Organisms (GMOs) and New Genomic Techniques (NGT) derived food and feed in Northern Ireland.

Assessment of Impact

Impact of applying the Regulation

It does not appear likely that the application of Article 37 of the replacement EU act would have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist.

Article 37 concerns powers enabling the European Commission to adopt detailed provisions relating to official controls and verification arrangements within the wider NGT framework. The provision is administrative and regulatory in nature and does not itself alter consumer access to products, food safety requirements or day-to-day activities.

While any future measures adopted under these powers may have operational implications for competent authorities or regulated businesses, Article 37 itself does not introduce immediate requirements likely to have a significant or persistent impact specific to the everyday life of communities in Northern Ireland.

The Department notes that the wider Regulation (EU) 2026/1388 has previously been assessed and does not consider that the final published Regulation introduces substantive changes beyond those already considered during scrutiny of the proposal.

Impact of not applying the Regulation

It does appear likely that non-application of Article 37 of the replacement EU act would have a significant impact on the everyday life of communities in Northern Ireland in a way that is liable to persist.

It is likely that non-application of Article 37 would result in a persistent divergence between the regulatory framework operating in Northern Ireland and that applying in the European Union in relation to official controls associated with plants obtained through certain new genomic techniques.

The Department also notes that non-application of Article 37 could further contribute to differences in the regulatory framework operating in Northern Ireland and Great Britain in this area, potentially creating additional complexity for stakeholders operating across jurisdictions.

As Article 37 amends Regulation (EU) 2017/625, which applies in Northern Ireland under the Windsor Framework, non-application could create regulatory

uncertainty regarding the future operation of official controls and verification arrangements in this area.

The resulting divergence would be liable to persist and could affect the coherent operation of the regulatory framework governing agri-food products in Northern Ireland.

Other relevant matters

The Regulation introduces a structure broadly comparable to the Precision Breeding framework operating in Great Britain, although differences remain, particularly in relation to labelling, traceability and regulatory oversight. The Department will continue to monitor developments in both regulatory systems and assess any implications for Northern Ireland stakeholders.

While the current notification relates solely to Article 37 of Regulation (EU) 2026/1388, the Department notes that the provision forms part of the wider NGT framework established by the Regulation. Reference to the wider Regulation has been included where necessary to provide context and reflect previous engagement with the Democratic Scrutiny Committee.

UK Government Explanatory Memorandum

The UK Government published an Explanatory Memorandum (EM) in August 2023 relating to the original legislative proposal which subsequently became Regulation (EU) 2026/1388.

https://assets.publishing.service.gov.uk/media/64e353c63309b7000d1c9bb2/EM_COM_23_411_PDF_WITH_CORRECT_DATE.pdf

The EM explains the wider objectives of the Regulation and notes that Northern Ireland considerations arise through continued application of relevant EU legislation under the Windsor Framework. The Department engaged with UK Government colleagues during the preparation of the EM, to ensure Northern Ireland interests were appropriately reflected.

Defra have advised that an updated EM specific to Article 37 should be available by Thursday 9th of July, though DAERA have not received sight of this yet.

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.

- https://food.ec.europa.eu/document/download/f1142e86-43df-4791-9df2-563e696c59cf_en?filename=gmo_biotech_ngt_ia_report.pdf
- https://food.ec.europa.eu/document/download/0d7eddf8-e968-415c-8a77-91709a39d276_en?filename=gmo_biotech_ngt_ia_report_swd-2023-413_en.pdf

Departmental Engagement

The Food Standards Agency has continued to engage with counterparts in UK Government and Food Standards Scotland on these proposals.

During earlier engagement between the Food Standards Agency, DAERA and the Democratic Scrutiny Committee in May 2025, it was discussed that stakeholder engagement would commence following publication of the Regulation in the Official Journal of the European Union. As part of preparations for that stakeholder engagement, the Food Standards Agency subsequently undertook an exercise to gather stakeholder views on the proposed Regulation.

On 4 December 2025, the Food Standards Agency 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.

In addition, the Food Standards Agency used the February 2026 edition of its Northern Ireland Industry Bulletin to invite stakeholders to provide views on new genomic techniques. The Industry Bulletin has over 5,000 subscribers.

Further stakeholder engagement will now be undertaken, with the aim of assessing stakeholder understanding and views, identifying any practical implementation issues, and informing consumers and businesses of the implications of the new framework.

As Article 37 of Regulation (EU) 2026/1388 is directly applicable in Northern Ireland under the Windsor Framework, future engagement activity will be focused primarily on awareness raising, information sharing and understanding any practical impacts arising from implementation. Based on the engagement undertaken to date, no specific Northern Ireland stakeholder concerns have been identified.