PROPOSED REPLACEMENT EU ACT
INITIAL ASSESSMENT OF IMPACT

Date: 2 March 2026

DSC REF: DSC/06a/2026

Proposed Replacement EU Act

Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EC) No 999/2001, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 852/2004, (EC) No 853/2004, (EC) No 396/2005, (EC) No 1099/2009, (EC) No 1107/2009, (EU) No 528/2012, (EU) 2017/625 as regards the simplification and strengthening of food and feed safety requirements

EUR-Lex - 52025PC1030 - EN - EUR-Lex

This proposed Regulation would amend:

- Regulation (EC) No 999/2001, Annex 2, Heading 37 on Animal disease control, zoonosis control
- Regulation (EC) No 1829/2003, Annex 2, Heading 25 on GMOs
- Regulation (EC) No 1831/2003, Annex 2, Heading 34 on Feed – products and hygiene
- Regulation (EC) No 852/2004, Annex 2, Heading 30 on Food – hygiene
- Regulation (EC) No 853/2004, Annex 2, Heading 30 on Food – hygiene
- Regulation (EC) No 396/2005, Annex 2, Heading 24 on Pesticides, biocides
- Regulation (EC) No 1099/2009, Annex 2, Heading 40 on Animal welfare
- Regulation (EC) No 1107/2009, Annex 2, Heading 24 on Pesticides, biocides
- Regulation (EU) No 528/2012, Annex 2, Heading 24 on Pesticides, biocides
- Regulation (EU) 2017/625, Annex 2, Heading 43 on Official controls, veterinary checks

Summary of the Act

This assessment relates to provisions within the proposed Regulation relating to the Food Standards Agency's remit in Northern Ireland, specifically amendments to:

- Regulation (EC) No 1829/2003 – clarifying the status of food and feed products obtained using genetically modified micro-organisms (GMMs) as production strains

- Regulation (EC) No 1831/2003 – updating the process for authorisation of feed additives
- Regulations (EC) No 852/2004 and 853/2004 – updating the procedure for notifying the European Commission and Member States of some draft national legislation
- Regulation (EU) 2017/625 – providing for future legislation to amend the accreditation requirements for laboratories responsible for maintaining standards in the routine testing of food and feed

The proposed Regulation must be agreed by the European Parliament and EU Member States in the Council of the EU – potentially with amendments – before it can become law.

Genetically Modified Micro-Organisms (GMMs)

Regulation (EC) No 1829/2003 establishes the legal framework for the authorisation and supervision of genetically modified food and feed. The FSA is responsible for the safety, labelling and traceability of Genetically Modified Organisms (GMOs), when used in food and feed.

The proposed Regulation includes an amendment to Regulation (EC) No 1829/2003 to provide explicit confirmation that food and feed fermentation products obtained using genetically modified microorganisms as processing aids are excluded from the definition of “produced from GMOs”.

Under the proposed regulation, article 2, point 10, of Regulation (EC) No 1829/2003 is amended to clarify that the definition of food and feed “produced from GMOs” does not cover food and feed products obtained with GMMs used as production strains.

The amendment has been proposed to allow certainty under Regulation (EC) 1829/2003, as that regulation applies to food and feed “produced from” GMOs, not those “produced with” GMOs. This amendment addresses concerns raised by the food and feed fermentation sector regarding legal uncertainty over products manufactured using GMMs. Specifically, the proposal seeks to clarify the legal status of food and feed fermentation products obtained using GMMs as processing aids, to remove ambiguity and ensure consistent enforcement.

The proposals include an amendment to Regulation 1829/2003 to clarify that Products obtained using GMMs as production strains will not be considered “produced from GMOs” if:

- No viable cells of the GMM remain in the food or feed; and

- The presence of residual recombinant DNA complies with the criteria for residues set out in the definition of processing aid under Regulations (EC) No 1333/2008 or 1831/2003.

There is no change to safety requirements for GMOs under this proposal. The proposed change does not alter authorisation, risk assessment, or labelling requirements for GM food and feed; it only clarifies that products made using GMMs (with non-viable residues and no technological effect) are not considered "produced from GMOs".

This clarification will provide greater legal certainty for businesses using fermentation processes in food production.

Feed Additives

Regulation (EC) No 1831/2003 establishes a legal framework for authorisation and use of feed additives to ensure safety and efficacy in animal nutrition. The European Commission published an evaluation of Regulation (EC) No 1831/2003 in February 2024. The proposed Regulation addresses the three main areas for simplification and reduction of administrative burden identified by this evaluation and subsequent stakeholder feedback: renewal of authorisations, modification of existing authorisations and labelling requirements.

It proposes to amend Article 9 to enable authorisations granted for feed additives to remain valid for an unlimited period of time, rather than the current limited authorisation period of ten years with the exception of additives belonging to the category of coccidiostats and histomonostats. This amendment would align with current requirements in Great Britain for feed additives other than for the coccidiostats and histomonostats. Additives belonging to the category of coccidiostats and histomonostats would continue to be subject to the ten-year renewal requirement, due to their higher safety risk profile in relation to their antimicrobial nature.

Article 13 would continue to provide for modification, suspension or revocation of any authorisation at any time where the safety or efficacy conditions for authorisation are no longer met.

The amendments would also simplify the process for the modification of the name of the authorisation-holder under Article 13. Under the new process, if the holder wants to change their name, they only need to notify the Commission and provide details, whereas the current process necessitates legislative amendment. The holder's name will appear in the Community Register of Feed Additives, not in the authorisation regulation. Article 13 would also be amended to provide for the possibility for any interested party to submit an application for modification of

an authorisation for which there is no specific holder (e.g., technological, sensory, or nutritional additives).

Article 16 would be amended to clarify that the feed business operator responsible for first placing the feed additive or premixture of additives on the market is responsible for labelling. This aligns with the requirements of Regulation (EC) No 767/2009 on the placing on the market and use of feed.

Article 16 would also be amended to permit digital labelling for certain non-safety related information. Currently, labels must be attached to the packaging or container. The proposal would allow some non-safety information, such as the name and address of the responsible person, the approval number of the establishment, and batch details, to be provided digitally.

Notification of national legislation

Regulation (EC) No 852/2004 establishes hygiene requirements to ensure food safety throughout the production process. Regulation (EC) No 853/2004 establishes specific hygiene requirements for food of animal origin. These Regulations provide for the adoption of national measures, allowing for domestic adjustments to requirements covering traditional production methods, regions with geographical constraints, or structure, layout and equipment. National governments must notify these measures to the European Commission and EU Member States. The proposed amendments simplify this notification process. Under the proposal, all notifications of national hygiene measures would need to follow the same process, reducing duplication and improving efficiency.

Laboratories

National Reference Laboratories (NRLs) are specialist laboratories responsible for maintaining standards for the routine testing of feed, food and animal health. They provide advice and support on methods for official control testing, ensuring the delivery of risk-based and proportionate food enforcement to protect consumers. Regulation (EU) 2017/625 sets out requirements for the designation of NRLs. Currently, NRLs are required to include all the methods of laboratory analysis, testing or diagnosis within their accreditation scope.

To reduce cost and resource demands requiring reference laboratories to include all testing methods in their ISO/IEC 17025 accreditation scope, it is proposed that laboratories may be designated, even if not accredited for every single method they use, and that accreditation under equivalent standards (e.g., ISO 15189 – used for medical laboratories) should be accepted for certain biological food safety hazards to avoid duplication and improve efficiency, without compromising reliability.

This proposal gives the European Commission the ability to deliver this change at a later date. Full details are not available at this stage.

Feedback on the proposals has been received from a limited number of laboratories within the FSA's network. While the proposed flexibility is welcomed as a means to reduce administrative burden and enhance operational agility, further detail on the proposal is required to enable a thorough assessment of its implications for Northern Ireland. For example, clarification is needed regarding quality assurance arrangements, the scope of laboratories to which the proposal would apply, and the range of testing activities covered.

Department(s) Responsible

The Food Standards Agency is responsible for food and feed safety in Northern Ireland.

Initial Assessment of Impact

Very limited practical impact on industry or consumers in Northern Ireland is expected.

UK Government Explanatory Memorandum

Defra consulted the FSA during the preparation of the Explanatory Memorandum (EM). We have not yet had sight of the finalised EM.

Analysis by the European Commission on its Impact Assessment

The European Commission states: "The proposed simplification measures are highly technical in nature. There are no viable alternatives to achieve the objectives, and the proposed measures do not alter core policy objectives or introduce significant new obligations. For these reasons, a full impact assessment would not bring added value…it is expected that the amendments would entail significant cost savings for industry and for authorities."

Departmental Engagement

FSA officials continue to engage with UK Government counterparts in relation to the proposals.

As noted above, the FSA has sought initial views from National Reference Laboratories and Northern Ireland-based official laboratories on the laboratory-

related proposals. The general consensus at this stage is that there may be some small benefit or no impact.