PROPOSED AMENDING EU ACT
INITIAL ASSESSMENT OF IMPACT

Date: 06 March 2026
DSC REF: DSC/06a/2026
Department: Department of Agriculture, Environment and Rural Affairs (DAERA)

Proposed Amending 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

Whilst this proposal, if enacted, will amend several Regulations, the following considers only those within the legislative/policy remit of DAERA.

Overall summary

This proposal is part of the EU's cross-cutting legislative simplification package announced as part of the European Commission's 'Vision for Agriculture and Food'. The aim of this package is to "reduce unnecessary regulatory burdens while maintaining high standards for food and feed safety, and for the protection of human and animal health, and the environment".

Separate Assessments of Impact have been prepared by the Food Standards Agency (FSA) and the Department for Economy (DfE) for the areas for which they have a legislative/policy responsibility. With regards to DAERA, input has been provided from several business areas for regulations being amended which fall under the remit of the Department. These are summarised in the table below. Given the breadth of regulations being amended, we have included short separate sections for each.

Regulation being amended	Regulation-specific Assessment of Impact
Regulation (EU) 2017/625 – Officials Controls – Plant Health aspects	Page 3
Regulation (EU) 2017/625 – Officials Controls – Wider Sanitary and Phytosanitary aspects	Page 5

Input specific to: Regulation (EU) 2017/625 – Officials Controls – Plant Health aspects

Background & summary of the Proposed amending act

Article 50(3)

DAERA officials are required to perform official controls for Plant Health at point of entry. Currently, if sampling is required on part of a consignment, the whole consignment must be detained until test results are available for the sampled goods. The proposed amendment of Article 50(3) to split consignments would allow compliant parts of a consignment to be released prior to test results being available for the sampled goods, reducing delays for compliant goods and risk of deterioration of perishable goods, whilst ensuring phytosanitary measures are maintained.

Articles 41, 93, 100 and 144

Presently, DAERA Plant Health sampling is required to be carried out by official laboratories which operate and are accredited in accordance with EN ISO/IEC 17025 standards, which is costly and complex. The proposed amendments would allow the Commission to adopt delegated acts outlining when and under what conditions, laboratories can be designated as official laboratories, national reference laboratories and EU reference laboratories whilst not operating or being accredited with EN ISO/IEC 17025 standards and/or all the methods they use. This would reduce complex costs and pressures on laboratories in obtaining extensive accreditations.

Department(s) Responsible

DAERA.

Initial Assessment of Impact

Does it appear likely that the application of the proposed amending EU act would have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist?

Splitting of Consignments Article 50(3)

The proposal in respect of the splitting of consignments would not have significant impact specific to everyday life of communities in Northern Ireland which is liable to persist. The proposals would only apply to a small minority of plant health consignments that require sampling, affecting a minimal number of plant health traders in a positive way, as delays to any goods that do not require sampling would be reduced.

Designation of Laboratories Articles 41, 93, 100 and 144

The proposed amendments would not have significant impact specific to everyday life of communities in Northern Ireland in a way which is liable to persist. The proposed amendments would allow the Commission to adopt delegated acts outlining when and under what conditions, laboratories can be designated as official laboratories, national reference laboratories and EU reference laboratories whilst not operating or being accredited with EN ISO/IEC 17025 standards and/or all the methods they use. Should the Commission use these powers in the future to implement further delegated acts, this would impact only upon laboratories. However, there would be positive impacts, through reducing costs and pressures on laboratories in obtaining extensive accreditations.

Does it appear likely that not applying the proposed amending EU act would have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist?

Not applying the proposed amending EU act would not have a significant impact specific to everyday life of communities in Northern Ireland. However, it should be noted that not applying the proposed amending act would mean that the positive impacts would not be realised in the future for: 1. Reduced delays during the sampling of goods, and 2. Possible future reduced cost/pressure on laboratories in obtaining extensive accreditations.

Details of any other matters regarding the proposed amending act that the Department wishes to draw to the DSC's attention.

No other matters to raise.

Input specific to: Regulation (EU) 2017/625 – Officials Controls – Wider Sanitary and Phytosanitary aspects

Background & summary of the Proposed amending act

Regulation (EU) 2017/625 provides that laboratory analyses, tests and diagnoses on samples taken during official controls and other official activities are to be performed by official laboratories which have been designated as such by the competent authorities of the Member States. Official laboratories are assisted by national reference laboratories designated by the Member States, and by European Union reference laboratories designated by the Commission.

Regulation (EU) 2017/625 sets out requirements for the designation of official laboratories and national reference laboratories. Currently these laboratories are required to include all methods of laboratory analysis, testing or diagnosis within their accreditation scope.

Regulation (EU) 2017/625 provides that official laboratories, EU reference and national reference laboratories should operate and be accredited in accordance with the EN ISO/IEC 17025 standard.

The proposed amending act would allow the Commission to adopt delegated acts outlining when and under what conditions member states could designate laboratories which operate and are accredited in accordance with standards other than EN ISO/IEC 17025.

The proposed amending act aims to ensure future flexibility and proportionality without affecting the reliability of results obtained by laboratories. It would enable the possibility of future designation of laboratories which are not accredited for all the methods they use for official controls and other official activities, provided that those laboratories comply with the conditions established by Commission delegated acts.

Department(s) Responsible

DAERA.

Initial Assessment of Impact

Does it appear likely that the application of the proposed amending EU act would have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist?

The application of the proposed amendments for Articles 41, 93, 100 and 144 will have no impact specific to the everyday life of communities in Northern Ireland, in a way that is liable to persist. There would be no impact until the Commission would introduce delegated acts, which would then impact only on laboratories.

If the Commission did introduce such delegated acts, then this may offer flexibility with respect to accreditation. Specifically, this could potentially reduce administrative burden for the NI official laboratory and bring some easement on the pressures for the few areas which the laboratory is still seeking accreditation. Such delegated acts may also bring further easement for the food industry in NI, particularly when DAERA are dealing with unpredictable Intensified Official Controls (IOCs) at the Sanitary and Phytosanitary inspection facilities. However, until such acts are considered, it remains unclear as to their potential impact.

Does it appear likely that not applying the proposed amending EU act would have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist?

Not applying the proposed amending EU act would have minimal impact on the everyday life of communities in NI. Assessing future impact would require further detail on potential delegated acts, and which laboratory tests potential relaxations to accreditation standards would apply to. However, the current assumption is that they would only impact a small section of the Sanitary and Phytosanitary area's DAERA has responsibility for.

Details of any other matters regarding the proposed amending act that the Department wishes to draw to the DSC's attention.

No other matters to raise.

Input specific to: Regulation (EU) 2017/625 – Officials Controls – Animal Feed

Background & summary of the Proposed amending act

Article 50(3)

DAERA officials are required to perform official controls on feed of non-animal origin from third countries when those products are subject to increased checks at the point of entry. Under the current arrangements, if any portion of a consignment needs to be sampled, the entire load must remain on hold until laboratory results are returned. The proposed revision to Article 50(3), which would permit consignments to be divided, introduces a more flexible approach. It would allow the release of those parts of a consignment that meet the required standards, even while test results are still pending for the sampled portion. This change would help minimise delays for compliant goods, while continuing to uphold the necessary regulatory safeguards.

Articles 41, 93, 100 and 144

Presently, DAERA feed sampling is required to be carried out by official laboratories which operate and are accredited in accordance with EN ISO/IEC 17025 standards, which is costly and complex. The proposed amendments would allow the Commission to adopt delegated acts outlining when and under what conditions, laboratories can be designated as official laboratories, national reference laboratories and EU reference laboratories whilst not operating or being accredited with EN ISO/IEC 17025 standards and/or all the methods they use. This would reduce complex costs and pressures on laboratories in obtaining extensive accreditations.

Department(s) Responsible
DAERA.

Initial Assessment of Impact
Does it appear likely that the application of the proposed amending EU act would have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist?

Splitting of Consignments Article 50(3)

Based on the content of the proposed amending EU act, there is no indication that its application would have a significant or persistent impact on the everyday life of communities in Northern Ireland. The proposals would only apply to a small minority of consignments of feed of non-animal origin from third countries subject to a temporary increase of official controls that require sampling. It is likely to

affect only a small number of feed traders and may yield benefits, as delays to any goods not subject to official controls would be avoided.

Designation of Laboratories Articles 41, 93, 100 and 144

No, applying the proposals would not result in significant or persistent everyday impacts on communities in Northern Ireland. The proposed amendments would enable the Commission to adopt delegated acts outlining when and under what conditions, laboratories can be designated as official laboratories, national reference laboratories and EU reference laboratories whilst not operating or being accredited with EN ISO/IEC 17025 standards and/or all the methods they use. Potential easing of these accreditation requirements would yield positive impacts including improvements in rapid testing capacity, which is important for controls on undesirable substances, feed additives and medicated feed, particularly during incident response to potential contamination. It would also benefit laboratories through reduced costs and pressures to obtain extensive accreditations.

Does it appear likely that not applying the proposed amending EU act would have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist?

Not applying the act would also not be expected to produce any significant or lasting impacts on daily life for communities in Northern Ireland. However, it is worth noting that without their application, potential benefits outlined above, including minimising delays for compliant goods and improved flexibility in analytical testing for feed official controls would not be realised.

Details of any other matters regarding the proposed amending act that the Department wishes to draw to the DSC's attention.

Not applicable.

Input specific to: Regulation (EU) 1107/2009 and Regulation (EC) No 396/2005

Background

Regulation (EC) 1107/2009 lays down the EU rules for approving, authorising, and controlling plant protection products (PPPs). It ensures that only substances proven to be effective and not harmful to human or animal health or the environment can be placed on the market.

Active substances undergo a science-based EU-level approval process, (with approvals typically lasting 10–15 years) to ensure regular re-evaluation based on evolving science. After EU approval of active substances, products containing them must also be authorised by Member States. The Regulation is built on the precautionary principle, requiring updated scientific assessment and proper use of PPPs, including adherence to integrated pest management.

Regulation (EC) No 396/2005 sets the maximum residue levels (MRLs) for pesticide residues permitted in or on food and feed of plant and animal origin sold in the EU. Its purpose is to protect human and animal health by ensuring that pesticide residues remain within safe limits. The Regulation establishes specific MRLs for specific active substances in or on defined commodities, and where none are set, a default level of 0.01 mg/kg applies.

The European Food Safety Authority (EFSA) evaluates the safety of MRLs based on toxicity, expected residue levels, and consumer dietary exposure, after which the European Commission sets, updates, or removes MRLs. The Regulation applies to all food and feed placed on the EU market, including imports.

Summary of the proposed amending act

Approval and Renewal of Active Substances:

Current: Regulation (EC) 1107/2009 - requires time-limited approvals (typically 10–15 years) for active substances to ensure regular re-evaluation based on evolving science. Renewal applications must consider latest scientific and technical knowledge.

Proposed amendment via proposal: seeks major changes to pesticide oversight, including removing the current mandatory 10-year renewal cycle for pesticide active substances, meaning approvals will become unlimited except for higher risk substances, for example candidates for substitution The commission will have a programme in place to call substances in for reassessment where needed or if new scientific evidence comes to light.

It would also simplify temporary approvals and extend transitional periods and grace periods for certain products and substances.

The Proposal introduces potentially unlimited authorisation periods, while the current Regulation (Regulation (EC) 1107/2009) mandates fixed-term approvals to safeguard health and the environment.

Treatment and Promotion of Biocontrol / Biopesticides:

Biopesticides (biocontrol products) are plant protection products derived from natural materials—such as micro-organisms, pheromones, plant extracts and other biological substances. They control pests through biological or naturally occurring mechanisms. They are key tools in Integrated Pest Management (IPM) to help reduce reliance on chemical pesticides.

Current: Regulation (EC) 1107/2009 provides a framework for low-risk and basic substances but does not include the streamlined biocontrol pathways proposed in the new regulation.

Proposed amendment via proposal: The proposal aims to accelerate approval of biocontrol (biopesticide) solutions, providing faster procedures to give biocontrol products quicker market access; (1-2 years earlier) clarified definition of biocontrol substances; and provisional approvals based on draft assessment.

The Proposal provides more favourable and accelerated pathways for biocontrol substances; the current Regulation (Regulation (EC) 1107/2009) does not.

Scientific Updates and Risk Assessment Requirements:

Current: Regulation (EC) 1107/2009 explicitly requires Member States and EFSA to use the most up-to-date scientific evidence and technical knowledge when assessing pesticide risks.

Proposed amendment via proposal: the proposal continues to mandate the use of the latest scientific evidence, aligning with Regulation 1107/2009. However, the procedural simplification and longer renewal intervals and the introduction of provisional approvals based on draft assessments for biocontrol substances, could be perceived by some stakeholders as weakening of the scientific updating requirements. Further manufacturers of existing conventional products may perceive the revised renewal regime as unevenly applied as their established products face stricter assessments at renewal.

The current regulation requires the use of the most up-to-date scientific evidence when assessing pesticide risks. The proposal maintains this requirement but adds simplified procedures, longer renewal intervals, and provisional approvals for biocontrol substances.

Data Protection, Transitional Measures, and Grace Periods:

Current: Regulation (EU) 1107/2009 provides strict timelines for withdrawing non-approved substances and tightly limits grace periods.

Proposed amendment via proposal: The proposal expands data protection rules and adjusts transitional mechanisms across multiple areas.

The Proposal introduces longer and more flexible transitional arrangements; the current Regulation (Regulation (EC) 1107/2009) requires stricter phase-outs.

Administrative Simplification vs. Protective Framework:

Current: Regulation (EC) 1107/2009 is built around the precautionary principle, requiring strict scientific assessment, periodic renewals of active substances, and continuous updating of risk evaluations to ensure a high level of health and environmental protection. It is often criticised for being administratively heavy and highly risk-averse.

Proposed amendment via proposal: The EU Simplification Package proposals aim to reduce regulatory burdens by streamlining approval processes, removing mandatory renewal cycles, relaxing scientific updating requirements, extending transitional periods, and accelerating biocontrol approvals.

Current: Regulation (EC) No 396/2005 establishes maximum residue levels (MRLs) for pesticides residues in food and feed of plant and animal origin. Regulation (EC) No 396/2005 also provides the legal basis for MRL-setting, data requirements, monitoring, and enforcement.

Proposed amendment via proposal: The Proposal does not change the scientific principles or risk-assessment basis used to set MRLs. It modifies procedures and reduces administrative burdens and proposes stronger import rules to ensure that imported products meet the same residue-control expectations as EU-produced goods. The proposal strengthens import rules that would enable hazard-based criteria from Regulation (EC) 1107/2009 to be applied in certain MRL decisions under Regulation (EC) 396/2005. This may affect the treatment of some imported food products where there are residues of active substances not approved in the EU due to hazard concerns. This aspect of the proposal is likely to be internationally sensitive and could give rise to trade-related considerations, depending on how it is implemented.

The Proposal emphasises procedural efficiency and simplification whilst maintaining protections; Regulation (EC) 1107/2009 and Regulation (EC) No 396/2005 emphasise precaution and protection even at administrative cost.

Department(s) Responsible

The Competent Authority and Enforcing Authority for Regulation (EC) 1107/2009 & Regulation (EC) No 396/2005 is DAERA.

However, the Chemicals Regulation Division of the Health and Safety Executive (HSE) in Great Britain, under the Agency Agreement, delivers a number of Competent Authority functions on DAERA's behalf including:

- The evaluation and authorisation of pesticides for sale and use in NI;
- Setting out the conditions of use of authorised pesticides;
- Preparing, publishing and submitting to the European Food Safety Authority (EFSA) the annual Northern Ireland Pesticide Residues Control Plan; and
- The operational delivery of our annual monitoring programme for pesticides residues in the UK food supply no matter where it was produced.

Initial Assessment of Impact

Does it appear likely that the application of the proposed amending EU act would have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist?

It does not appear likely that the application of the proposed amending EU act will have a significant impact on everyday life. The effects of the proposed EU simplification package are primarily on certain producers and regulatory authorities, not on the general public as it aims to streamline food and feed safety legislation and reduce administrative burdens. These changes include faster approval pathways for biocontrol substances, clarified rules for pesticide residues, and simplified official control requirements, all intended to enhance efficiency and maintain high safety standards.

Given Northern Ireland's reliance on integrated agri-food supply chains and its continued alignment with EU standards under the Windsor Framework, the proposed reforms could indirectly (positively) influence community life over time by affecting pesticide oversight, the availability of products to farmers, food safety assurance, environmental protections, and the operational pressures on rural businesses. These effects would be indirect and would depend largely on how the final Regulation is implemented.

Does it appear likely that not applying the proposed amending EU act would have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist?

It does not appear likely that not applying the proposed amending EU act would have a significant impact on everyday life. As above the impacts would be primarily on certain producers and regulatory authorities, not on the general public.

Not applying the proposed amending act would maintain stricter, more administratively burdensome systems for pesticide approvals, food safety controls and import checks, slower access to new plant protection tools (including biocontrol), and potential competitiveness issues for farmers compared with the streamlined frameworks envisaged by the EU simplification package.

This would mean NI farmers and food businesses would continue to operate under the existing renewal cycles for pesticide substances and without the accelerated access to biocontrol products and reduced administrative burdens proposed at EU level, potentially affecting long-term farming practices, competitiveness and rural economic stability.

It would also limit the benefits of strengthened and modernised import rules for pesticide residues that aim to improve consumer confidence in food safety. Taken together, these divergences would persist over time.

Given the central role of agriculture in the NI economy and rural communities, these differences would accumulate over time and would have an adverse influence on the stability of farming operations, the cost and availability of plant protection products, and overall confidence in the regulatory environment. Indirectly these effects could (negatively) impact everyday life in a manner likely to persist.

Details of any other matters regarding the proposed amending act that the Department wishes to draw to the DSC's attention.

No other matters to raise.

Input specific to: Council Regulation (EC) No 1099/2009 regarding Protection of Animals at the Time of Killing

Background

The proposal seeks to remove paragraphs 4 and 6 of Article 18 from Regulation (EC) No 1099/2009, due to duplication of returns to the EU from both this regulation and Regulation (EU) 2017/625.

Summary of the Proposed Amending Act

Member State competent authorities are currently required by Regulation (EC) No 1099/2009 (Article 18, Para 4) to submit annual reports to the Commission on depopulation operations carried out the previous year. Member States also must submit similar figures under Regulation (EU) 2017/625 for the welfare of animals at the time of killing, including provisions concerning depopulation operations.

The new proposal will remove Article 18, Paragraph 4 & Paragraph 6 from Regulation (EC) No 1099/2009, to prevent duplication of work. This will save administration time for Member States.

Department(s) Responsible

DAERA is the Competent Authority and Enforcing Authority for Council Regulation (EC) No 1099/2009 of 24 September 2009 on the Protection of Animals at the Time of Killing.

Initial Assessment of Impact

Does it appear likely that the application of the proposed amending EU act would have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist?

The proposal will not have a significant impact specific to the everyday life of communities in Northern Ireland in a way that is liable to persist; it will only reduce the current duplication of administrative tasks sought by both Regulation (EC) No 1099/2009 and Regulation (EU) 2017/625.

Does it appear likely that not applying the proposed amending EU act would have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist?

Not applying the proposal will not have a significant impact specific to the everyday life of communities in Northern Ireland in a way that is liable to persist. However, it would result in continued duplication of work that is not required.

Details of any other matters regarding the proposed amending act that the Department wishes to draw to the DSC's attention

No other matters to raise

Input specific to: Regulation (EC) No 999/2001 regarding laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies

Background

Regulation (EC) 999/2001 requires that cattle falling within certain categories, such as certain age groups or those undergoing emergency slaughter, be tested for presence of bovine spongiform encephalopathy (BSE) upon slaughter. The World Organisation for Animal Health (WOAH) recently revised Chapter 11.4 “Bovine Spongiform Encephalopathy” of the Terrestrial Animal Health Code and amended its recommendation regarding testing of cattle for BSE to recommend that only those cattle showing signs of being infected with BSE should be tested for the disease, rather than all those within specific categories. EU rules are currently misaligned with this revised WOAH recommendation.

Summary of the proposed amending act

Article 6 of Regulation (EC) No 999/2001 requires Member States to implement an annual monitoring programme for transmissible spongiform encephalopathies (TSE). This programme must include both active and passive surveillance in line with Annex III, and it outlines the minimum categories of animals that must be included in monitoring for BSE.

Under the proposed act the current rules regarding surveillance would be reviewed and updated to ensure they remain proportionate to the current level of risk for that disease in the Union. The proposed act allows the Commission to amend the annexes of Regulation (EC) No 999/2001 and to supplement certain provisions concerning surveillance, specified risk material and products of animal origin.

Department(s) Responsible

DAERA is the Competent Authority for Regulation (EC) No 999/2001.

Initial Assessment of Impact

Does it appear likely that the application of the proposed amending EU act would have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist?

The application of the proposed amending EU act would not have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist. Application of this act would result in cost savings to the Department and the Agrifood Sector due to a reduction in the amount of testing required.

Does it appear likely that not applying the proposed amending EU act would have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist?

Not applying the proposed amending EU act would not have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist. However, non-application would mean that cost savings to the Department and the Agrifood Sector due to a reduction in the amount of testing required would not be realised.

Details of any other matters regarding the proposed amending act that the Department wishes to draw to the DSC's attention.

No other matters to raise.

UK Government Explanatory Memorandum

The UK Government Explanatory Memorandum was published on 10 March 2026 and is available here.

Analysis by the European Commission on its Impact Assessment

As per the proposal document, 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. Instead, the proposal is accompanied by an analytical staff working document: EUR-Lex - 52025SC1030 - EN - EUR-Lex. The document clearly explains the proposed measures and presents the underlying evidence, analysis and stakeholders' views, as well as estimating the potential cost savings.

On the basis of the information available, it is expected that the amendments would entail significant cost savings for industry and for authorities. Most measures, e.g. on biocontrol plant protection products, biocides, feed additives, would start yielding benefits quickly, while the broader plant protection products framework simplification, requiring structural changes to renewal, will have a longer transition.

Departmental Engagement

DAERA took part in preliminary cross-government and cross-jurisdictional discussions to consider the proposed amending EU act and its impact in relation to EU Regulations (1107/2009) and (396/2005) concerning Plant Protection Products/Pesticides Residues.

DAERA has had no engagement with stakeholders as regards the other Regulations mentioned in this Assessment, for which it has confirmed it has a policy/legislative interest.