PROPOSED REPLACEMENT EU ACT
INITIAL ASSESSMENT OF IMPACT

Date: 18th March 2026
DSC REF: DSC/06a/2026
Department: Department for the Economy

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

This proposed Regulation would amend:

- **Regulation (EC) No 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies**

- **Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (Text with EEA relevance)**

- **Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (Text with EEA relevance)**

- **Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs**

- **Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin**

- **Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides**

in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC Text with EEA relevance.

- Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing (Text with EEA relevance)

- Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

- Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products Text with EEA relevance

- 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) (Text with EEA relevance)

Summary of the Act

This assessment relates to provisions within the proposed Regulation relating to the Department for the Economy's remit in Northern Ireland, specifically amendments to:

- Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products

The policy intention of this proposal is to enable greater resources to be devoted to completion of the EU review programme by removing the requirement to renew active substances which have already been approved, other than in specific cases.

Under the review programme, active substances can remain on the market through transitional measures until such time as an active substance has been evaluated. Following an evaluation, if an active substance is approved for the EU market, it is for an initial period not exceeding 10 years. Active substances with highly hazardous properties can be approved for lesser initial periods, up to 5 years for those that meet the exclusion criteria and up to 7 years for those that are candidates for substitution.

At the end of the initial period, a renewal of the approval must take place. Active substances can be renewed for a period of up to 15 years and candidates for substitution for a period of up to 7 years.

The review programme was planned to be completed by 14 May 2010, but it was extended for the first time to 14 May 2014, a second time until 31 December 2024 and more recently a third time until 31 December 2030. The delays have occurred due to various operational issues and the programme is currently 51% complete. However, active substances which were approved early in the review programme are now reaching their approval expiry dates due to the time lapsed since the original approval and require renewal. As an active substance will be removed from the market once the approval expiry date has lapsed if not renewed (subject to any phase-outs), resources are being utilised to process these renewal applications. These resources could otherwise be used in completing the review programme.

From a risk-based perspective, it is logical to prioritise evaluations of active substances yet to be approved under the review programme where there may be greater risk, instead of renewing existing approvals where the risks are already largely understood. This is especially important given that biocidal products containing active substances in the review programme which have not yet had their first review are allowed to remain on the market under pre-existing national legislation, where standards may be much less rigorous than under EU BPR.

The proposal is to remove expiry dates from approvals to enable approvals that are not time-limited. This does not include active substances that meet the exclusion criteria or are candidates for substitution. It also will not apply to active substances where the renewal evaluation is ongoing or where no renewal application was received on time.

In order to maintain a high level of protection of human and animal health and the environment, it will still be possible for the European Commission to set time limits for approvals if found appropriate in the light of the outcome of the risk assessment

prior to a decision on an approval. In addition, the proposal foresees that the European Commission may periodically select a number of active substances for which a renewal evaluation would take place while also maintaining the existing possibility to initiate early reviews if there are significant indications that the conditions of approval are no longer met, as set out in Article 15 of EU BPR.

The proposed changes should result in a decreased workload on renewal applications facilitating resources to prioritising completion of the review programme.

Great Britain is facing similar challenges with an increasing number of active substance approvals elapsing and requiring renewal, whilst the GB review programme is ongoing with a similar backlog of first approvals to the EU. Moreover, where HSE is carrying out its own active substance evaluations, priority is already being given to first-time evaluations above renewals, except for renewals of high-hazard active substances, similar to the EU proposal. Therefore, the UK Government considers the EU's proposals to be reasonable.

There is the potential for some short-term divergence between the EU and GB as a result of this proposal. HSE's recent consultation on chemicals reforms, also proposed removal of active substance approval expiry dates. It also included proposals that GB may recognise EU approvals and renewals, with an expectation that GB would align with the EU in the vast majority of cases. If there is a gap between the EU proposals and the GB reforms being enacted, the requirement may exist for a renewal application in GB but not in the EU. Applicants would make a cost benefit analysis of the renewal application based on the GB market alone, which may result in an applicant no longer wishing to support in GB.

Further analysis will be required to understand the likelihood of this scenario and whether any additional mitigatory measures may be needed as part of the reforms, but it is still anticipated to be a small risk.

A second proposal relates to publication requirements for Union Authorisations. The requirement to publish the Commission Implementing Regulation granting a Union Authorisation in the Official Journal of the EU includes a requirement to include the Summary of the Products Characteristics in all official languages of the EU. The European Commission states that this has proven to be cumbersome, leading to delays, and without added value considering that the decision is also disseminated on the ECHA website. Therefore, it is proposed to simplify the publication requirements. Specifically, the individual decisions will take the form of Commission Implementing Decisions notified only to the applicants. Only summaries of those Decisions would be published in the EU Official Journal.

Since EU BPR is listed in Annex 2 of the Windsor Framework, these new proposals will apply in NI subject to Democratic Scrutiny.

Department(s) Responsible

DAERA and FSA have the main interests in this Regulation.

The Department of the Economy has an interest in Regulation (EU) No 528/2012 only.

Initial Assessment of Impact

Very limited or no practical impact on industry or consumers in Northern Ireland is expected.

In general, if fewer renewal applications are required, it is anticipated that this should bring a reduction in costs to businesses who may otherwise have had to apply to renew active substances.

UK Government Explanatory Memorandum

This Explanatory Memorandum covers COM(2025)1030, an EU proposal to simplify and strengthen food, feed, animal health and related safety legislation as part of the Commission's Vision for Agriculture and Food. The package amends multiple EU regulations to reduce unnecessary administrative burdens while maintaining high standards of protection for human and animal health and the environment. The changes are largely deregulatory and procedural

For biocidal products, the proposal amends Regulation (EU) No 528/2012 to prioritise completion of the long-running EU review programme for existing active substances. It removes routine time-limited renewals for most approved active substances, allowing approvals to remain in force indefinitely, except for substances meeting exclusion criteria, candidates for substitution, or those already in renewal. This enables regulatory resources to focus on first-time evaluations where risks may be less well understood, while retaining safeguards such as the Commission's powers to initiate reviews or impose time limits if new risks emerge. A related change simplifies Union Authorisation publication requirements by reducing reliance on full Official Journal publication, as decisions are already made available via ECHA systems..

The overview of the full EM is provided within the DAERA briefing.

Analysis by the European Commission on its Impact Assessment

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. The document clearly explains the proposed measures and present 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. From 2027, business cost savings are estimated at €335,6 million annually, rising by a further €93 million per year from 2029 as plant protection products simplifications take effect. In this mandate, the ten measures are expected to deliver at least €1 billion in 2027–2029, with an additional €2.1 billion in the next mandate.

Public authorities would also gain substantially: administrative costs are projected to fall by € 661 million annually and in total, this amounts to an estimated € 4.6 billion reduction in administrative costs over 2027–2034.

Departmental Engagement

DfE officials have engaged with UK Government counterparts in relation to the proposals so far as they relate to Biocidal Products. DfE worked closely in conjunction with Northern Ireland officials in DAERA and FSA.