

PROPOSED REPLACEMENT EU ACT INITIAL ASSESSMENT OF IMPACT

Date: 11/09/2025

DSC REF: DSC/17a/2025 - Chemical Products (COM/2025/531)

Proposed Replacement EU Act

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EC) No 1272/2008, (EC) No 1223/2009 and (EU) 2019/1009 as regards simplification of certain requirements and procedures for chemical products.

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52025PC0531&qid=1752743412064>

The proposal will amend:

Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003.

Regulation (EU) 2019/1009 already applies in Northern Ireland under Windsor Framework Annex 2, Heading 23 on Chemicals and related.

It also proposes to amend the following Regulations which have not been assessed as part of this Impact Assessment, as they are not under DAERA's remit.

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.

Summary of the Act

The three regulations in scope of COM/2025/531 all concern the supply of chemicals to the European Union (EU) Single Market:

1. Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures.
2. Regulation (EC) No 1223/2009 on cosmetic products.
3. Regulation (EU) 2019/1009 laying down rules on the making available on the market of EU fertilising products (EU-FPR). It establishes obligations for importers, distributors and manufacturers in relation to the safety, quality and labelling of fertilising products placed on the EU market.

The proposals in COM/2025/531 seek to simplify and streamline requirements and procedures of EU-FPR in order to reduce compliance costs and administrative burden for the fertiliser industry.

The proposed amendments are part of a wider simplification package adopted by the European Commission on 8 July 2025 which aims to boost the EU's competitiveness.

Changes to be brought in by the Proposed Regulation

As Regulation (EU) 2019/1009 is the only Regulation which falls under the competence of DAERA, the changes described in this section only cover the amendments made by the proposal to Regulation (EU) 2019/1009.

Fertilising Products Regulation

Changes to EU-FPR will apply 24 months after the proposed regulation comes into force.

EU-FPR categorises fertilising products by Product Function Category (PFC) depending on the function of the fertiliser such as organic fertiliser, liming material, soil improver, inhibitor etc. It further classifies products by Component Material Category (CMC) depending on the constituent materials used to make the fertiliser such as plants, crop digestate, micro-organisms, polymers etc.

REACH registration of substances in EU fertilising products:

- For some substances (virgin substances under CMC 1 and additives or other substances under other CMCs) used in fertilising products, on their own or in mixtures, EU FPR does not apply the gradations of information requirements under Regulation (EC) No 1907/2006 (EU REACH), but requires more extensive information than would be required as standard under EU REACH (referred to as an 'extended REACH registration

requirement'). Some primary components of fertilising products are also produced and used in small amounts and therefore, are affected by this extended REACH registration requirement.

- The proposal amends EU-FPR by removing the requirement to register substances in EU fertilising products in accordance with the requirements outlined above.
- In the absence of any specific requirements under EU-FPR, the general EU REACH provisions, including the relevant gradations depending on quantity, would apply to substances used in EU fertilising products.

Assessment of microorganisms in plant biostimulants:

- The current mechanism for adding new micro-organisms or strains of micro-organisms is creating a bottleneck for the placing on the market of plant biostimulants in the EU.
- It is proposed to provide the Commission with a new empowerment in Article 42 of EU-FPR to amend Annex II, Part II, CMC 7, to set out general safety and agronomic efficiency criteria for micro-organisms and a methodology which manufacturers should use to assess and demonstrate compliance with those criteria and by notified bodies to confirm this assessment.
- The Commission notes that it will make sure that the criteria and methodology that will eventually be introduced allow for a thorough verification that a strain of a micro-organism does not present a risk to human, animal or plant health, to safety or to the environment, and that it ensures agronomic efficiency. Trusting that only qualified and reliable conformity assessment bodies are notified by Member States' notifying authorities, the new mechanism will provide an assessment of, at least, the same quality as under the current empowerment. The current empowerment for the addition of new micro-organisms or strains of micro-organisms to the positive list would be maintained. This would allow the Commission to include the strains currently being assessed and, potentially, further strains in the future. Manufacturers and notified bodies would not need to assess those strains included in the positive list against the general criteria.

Removal of the 'unbundling clause' (Article 43):

- Currently, each CMC in EU-FPR must be amended via separate delegated acts. The proposal is to remove this requirement, to enable the

Commission to adopt delegated acts which amend multiple CMCs at once. This is a technical amendment to simplify and streamline the amendment process.

Digitalisation:

There are several updates proposed to support digitalisation. The Democratic Scrutiny Committee (DSC) has previously considered the impact of the digitalisation of labelling for Fertilisers and the amending EU Regulation was adopted in September 2024 (EU Regulation 2024/2516). These amendments further support this process:

- Specifying that the EU declaration of conformity must be drawn up in electronic form and made accessible through an internet address or data carrier.
- The addition of a 'digital contact' as information to be indicated by economic operators on the products which are placed on the market.
- The amendment of reporting obligations to national authorities that require a 'paper or electronic format' to 'electronic form' only.
- Specifying that documents and exchanges between the economic operators and notified bodies related to conformity assessments shall be in electronic form.
- An obligation that, if a digital label is used, the same data carrier providing access to the digital label should also provide access to the EU declaration of conformity.
- An obligation to provide the information contained in the EU declaration of conformity and, if applicable, digital labelling on the digital product passport when the product is subject to other EU legislation that requires the use of such a digital product passport.

Department(s) Responsible

The Department of Agriculture, Environment and Rural Affairs holds competence for fertiliser policy, with the exception of Ammonium Nitrate fertiliser which is reserved.

The Department for the Economy (DfE) and the Department of Justice (DoJ) share joint competence for Classification, Labelling and Packaging (CLP). However, the remit of DoJ only extends to civil explosives.

The Department of Agriculture, Environment and Rural Affairs and the Department for the Economy share competence for REACH.

Cosmetics are a reserved matter. The Department for Business and Trade is responsible for policy questions arising from this document that relate to the regulation of cosmetic products.

Initial Assessment of Impact

As Regulation (EU) 2019/1009 is the only Regulation which falls under the competence of DAERA, this impact assessment only covers the amendments made by the proposal to Regulation (EU) 2019/1009.

The proposal cuts across the responsibilities of several UK Government departments. The Department for Work and Pensions, in conjunction with the Department for Business and Trade and the Department for Environment, Food and Rural Affairs, has assessed the impact and prepared the UK Explanatory Memorandum.

From the information available, it does not appear likely that the application of the proposed EU Regulation would have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist.

The proposals seek to simplify and streamline requirements and procedures of EU-FPR in order to reduce compliance costs and administrative burden for the fertiliser industry while aiming to ensure the strong protection of human health and environment.

The existing REACH registration requirement under EU-FPR is onerous because of the compliance costs on manufacturers and the removal of the requirement to register substances in EU fertilising products is likely to be welcomed by stakeholders.

The amendment of Annex II, Part II, CMC 7 with regards to the assessment of microorganisms in plant biostimulants is a pragmatic step to encourage and increase product development, whilst maintaining a high level of health and safety assurance.

The digitalisation proposals should reduce the administrative burden for companies, facilitate the exchange, storage and access to information and reduce errors associated with manual processes.

The deletion of Article 43 will streamline the legislative process and reduce the administrative burden associated with amending multiple CMCs at the same time.

The rules and requirements around the manufacturing and marketing of fertilisers are partially harmonised. This means that Regulation (EU) 2019/1009 operates alongside domestic regimes here in Northern Ireland. This means that manufacturers can choose to market their product under either regulatory regime.

This Regulation amends Regulation (EU) 2019/1009, which applies to Northern Ireland under the Windsor Framework, including amendments relating to digital labelling. If this amending regulation is not adopted in Northern Ireland, then regulatory amendments to support digitalisation will not apply to Northern Ireland and more substantive information requirements will continue to apply in relation to the REACH Registration of substances.

It does not appear likely that not applying the proposed 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.

UK Government Explanatory Memorandum

A UK Government Explanatory Memorandum (EM) was published on 26 August 2025 and is attached as Annex A.

Analysis by the European Commission on its Impact Assessment

Given the need to urgently put forward a proposal to address the identified problems in order to reduce administrative burden and excessive costs for businesses it was not possible for the European Commission to prepare a full impact assessment. However, following better regulation principles, this proposal is accompanied by a Commission staff working document (<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52025SC0531>) that includes an analysis of the impacts of the proposed measures, based on existing data and information gathered during the various Reality Checks, written input received from stakeholders and previous analyses, such as the Fitness Check of the most relevant chemicals legislation, the impact assessments on fertilising products and for the CLP revision, and the evaluation of the Detergents Regulation.

In preparation of the proposal, the Commission consulted stakeholders in three Reality Checks, one for each Regulation to be amended, and invited participants to send written feedback after these meetings. Furthermore, various suggestions for simplifying or clarifying certain provisions of chemical legislation and removing the excessive administrative burden stemming from these provisions have

emerged through stakeholders' proposals for simplification of European chemical legislation and numerous position papers received before and after the Reality Checks.

Departmental Engagement

Officials in relevant departments, namely the Department for the Economy, the Department of Justice, Department of Agriculture, Environment and Rural Affairs and the Health and Safety Executive Northern Ireland were consulted during the preparation of the UK Government EM for the proposal.

ATTACHMENTS

Annex A – COM/2025/531 Simplification of certain requirements and procedures for chemical products - UKG Explanatory Memorandum