PROPOSED REPLACEMENT EU ACT

INITIAL ASSESSMENT OF IMPACT

Date: 27.08.25

DSC REF: DSC/17a/2025 – Chemical Products

Proposed Replacement EU Act

Proposal for a 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.

Amending:

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

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

(Windsor Framework Annex 2, Heading 23 on Chemicals and related and Heading 17 on cosmetics, toys).

Summary of the Act

The three regulations in scope 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 (‘European Union the Classification, Labelling and Packaging Regulation; EU CLP’). The Regulation imposes requirements on manufacturers, importers, downstream users and distributors to identify and communicate the hazards of their chemicals in accordance with an internationally agreed system, the United Nations’ Globally Harmonized System of classification and labelling. General requirements of CLP also include supplier obligations concerning the safe and secure packaging of chemicals.

2. Regulation (EC) No 1223/2009 on cosmetic products (‘the EU Cosmetic Products Regulation; EU CPR’) governs the manufacture, safety and labelling of cosmetics available within the Single Market by establishing obligations that persons or companies assigned to these products (known as ‘Responsible Persons’) must ensure are met and by restricting or banning the use of severely hazardous substances in cosmetics.

3. Regulation (EU) 2019/1009 laying down rules on the making available on the market of EU fertilising products (‘the EU Fertilising Products Regulation; EU FRP’). The Regulation establishes obligations for importers, distributors and manufacturers (or their appointed representatives) in relation to the safety, quality and labelling of products on the EU market that are used to improve plant growth.

The proposals seek to simplify and streamline requirements and procedures of EU CLP, CPR and FPR in order to reduce compliance costs and administrative burden for the chemical 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

<u>Classification, Labelling and Packaging Regulation</u>

Focuses on provisions recently introduced into EU CLP by the amending Regulation (EU) 2024/2865. Regulation (EU) 2024/2865 imposed a series of new requirements on suppliers concerning hazard identification and communication in order to provide more comprehensive identification and classification of chemical hazards, improve

hazard communication by making labels more accessible and understandable and address legal gaps and ambiguities.

Either reverses or further clarifies certain labelling and other hazard communication provisions introduced by Regulation (EU) 2024/2865 covering:

- Mandatory labelling rules regarding minimum font size and colour, background colour and line and letter spacing are removed.
- The 6-month deadline within which suppliers must update their product labels following a change of classification or labelling that results in the addition of a new hazard class, in a more severe classification or new supplemental information is removed. Instead, labels must be updated ‘without undue delay’ once new data is obtained or communicated to the supplier.
- Requirements to reflect the applicable hazard pictograms, signal words, hazard statements and obligatory supplemental statements in advertisements are removed and the scope of advertisements and distance (online) sales requirements is reduced to the general public so as to exclude professional transactions from these obligations.
- Labelling rules applicable to fuelling stations are relaxed through removal of the requirement to include the following label elements on fuel pumps: name and contact details of supplier, nominal quantity of the supplied chemical and Unique Formula Identifier number.
- Derogations from labelling requirements for chemicals in very small packaging under 10 ml are clarified to ensure their applicability without the need to first prove that the packaging is either in such a shape or form or is so small that it is impossible to meet full labelling requirements.

Provisions of EU CLP that incorporate digital technologies are further developed by replacing the need for suppliers to provide their telephone number on labels with the mandatory requirement to include a ‘digital contact’—any up-to-date and accessible online communication channel through which economic operators can be reached or engaged

<u>Cosmetic Products Regulation</u>

Seeks to introduce a procedure for requesting the inclusion of substances used as colourants, preservatives and UV filters in the relevant annexes (Annexes IV-VI to CPR) to provide greater legal clarity and certainty for applicants requesting approval of the use of these substances in cosmetic products.

Amendments to the derogation process in Article 15 governing the use of severely hazardous chemicals in cosmetic products (carcinogenic, mutagenic or toxic for reproduction (CMR) substances of categories 1A and 1B) have also been proposed to:

- Establish fixed periods for derogation requests. A deadline for submission of a derogation request within three months of the substances' classification as a CMR under the EU CLP Regulation is introduced.
- Introduce transitional periods for compliance with new bans or restrictions. 12 months for products placed on the market, and 24 months for products available on the market following the entry into force of the amendments to the relevant annexes of EU CPR.
- Simplify derogation criteria under Article 15(2) by eliminating the "food safety requirements" criterion and merging the "particular use" criterion with the Scientific Committee on Consumer Safety (SCCS) safety assessment requirement.
- Clarify the approach to natural complex substances containing CMR constituents. When a constituent of a multi-constituent substance has been classified as a CMR, the prohibition from Article 15 would not apply if the substance was extracted from plants or plant parts and not chemically modified. However, to address any safety concerns, a SCCS assessment may still be required.
- Adopt a route-based approach to CMR bans. The classification of a substance as a CMR would only trigger a ban under Article 15 of EU CPR if the scientific evidence on which the classification is based shows that the CMR properties are due to dermal exposure, rather than a blanket ban applying regardless of exposure route.

Seeks to remove obligations from businesses, the European Commission and EU Member States to remove burdens. The requirement for cosmetics containing nanomaterial to be notified to the Commission six months before the product is placed on the market is to be removed. Instead, the relevant information is to be included in the cosmetic product safety report.

Additionally, the obligation for the Commission to compile and publish a glossary of common ingredient names in the Official Journal is to be replaced with a reference to internationally recognised nomenclature and electronic provision in a Commission database. The requirement for Member States to review and report on their market surveillance activities every four years will would also be revoked as the EU believes that this obligation is now redundant due to introduction of the Information and Communication System on Market Surveillance (ICSMS).

<u>Fertilising Products Regulation</u>

REACH registration of substances in EU fertilising products:

- For substances (virgin substances under Component Material Category (CMC) 1 and additives or other substances under other CMCs) used in EU 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.
- Proposes to delete the requirement to register substances in EU fertilising products in accordance with the requirements outlined in a. above from EU FPR.
- In 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.

Deletion 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.

Digitalisation: There are several updates proposed to support digitalisation:

- 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

Chemicals policy is a devolved matter.

The Department for the Economy (DfE) and the Department of Justice (DoJ) share joint competence for 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. The Department of Agriculture, Environment and Rural Affairs holds competence for fertilisers.

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

It does not appear likely that the application of 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. The proposals seek to simplify and streamline requirements and procedures of EU CLP, CPR and FPR in order to reduce compliance costs and administrative burden for the chemical industry while aiming to ensure the strong protection of human health and environment

It does 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. NI would be unable to benefit from the simplification and would seek to comply with measures no longer in effect

As these measures form part of the EU's Simplification agenda, we are able to provide more comment on the Assessment of Impact than is possible in most instances, this relies on the broadly shared assessments of the EU and UK. The department recognises it remains a function of this committee to establish its own view on these matters.

UK Government Explanatory Memorandum

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

- Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures ('European Union the Classification, Labelling and Packaging Regulation; EU CLP'). The Regulation imposes requirements on manufacturers, importers, downstream users and distributors to identify and communicate the hazards of their chemicals in accordance with an internationally agreed system, the United Nations' Globally Harmonized System of classification and labelling. General requirements of CLP also include supplier obligations concerning the safe and secure packaging of chemicals.
- Regulation (EC) No 1223/2009 on cosmetic products ('the EU Cosmetic Products Regulation; EU CPR') governs the manufacture, safety and labelling of cosmetics available within the Single Market by establishing obligations that persons or companies assigned to these products (known as 'Responsible Persons') must ensure are met and by restricting or banning the use of severely hazardous substances in cosmetics.

- Regulation (EU) 2019/1009 laying down rules on the making available on the market of EU fertilising products (‘the EU Fertilising Products Regulation; EU FRP’). The Regulation establishes obligations for importers, distributors and manufacturers (or their appointed representatives) in relation to the safety, quality and labelling of products on the EU market that are used to improve plant growth.

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

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.

Following the UK’s withdrawal from the EU, CLP, CPR and FPR were assimilated into GB law and operate separately to their corresponding EU regimes. As such, the amendments proposed will not apply to the regulation of chemicals classification, labelling and packaging, cosmetic products and fertilising products in GB.

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 been possible to prepare a full impact assessment. However, following better regulation principles, this proposal is accompanied by a Commission staff working document that includes an analysis of the impacts of the proposed measures, based on existing data and information gathered during 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 23 and numerous position papers received before and after the Reality Checks.

Departmental Engagement

Officials in relevant departments, namely the Department for 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 EM for the proposal.

Annex 1 UK Government Explanatory Memorandum

EXPLANATORY MEMORANDUM FOR EUROPEAN UNION LEGISLATION PROPOSALS WITHIN THE SCOPE OF THE UK/EU WITHDRAWAL AGREEMENT AND THE WINDSOR FRAMEWORK

COM(2025)531

Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EC) No 127212008, (EC) No 1223/2009 and (EU) 2019/1009 as regards simplification of certain requirements and procedures for chemical products

Submitted by the Department for Work and Pensions, on 26/08/2025.

SUBJECT MATTER

1. This Explanatory Memorandum (EM) relates to the proposal for a 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 (hereinafter referred to as 25)531), published on 8 July 2025.

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

- Regulation (EC) No 127212008 on the classification, labelling and packaging of substances and mixtures ('the EU Classification, Labelling and Packaging Regulation; EU CLP'). The Regulation imposes requirements on manufacturers, importers, downstream users and distributors to identify and communicate the hazards of their chemicals in accordance with an internationally agreed system, the United Nations' Globally Harmonized System of classification and labelling. General requirements of EU CLP also include supplier obligations concerning the safe and secure packaging of chemicals.
- Regulation (EC) No 1223/2009 on cosmetic products ('the EU Cosmetic Products Regulation; EU CPR') governs the manufacture, safety and labelling of cosmetics available within the Single Market by establishing obligations that persons or companies assigned to these products (known as 'Responsible Persons') must ensure are met and by restricting or banning the use of severely hazardous substances in cosmetics.
- Regulation (EU) 2019/1009 laying down rules on the making available on the market of EU fertilising products (the EU Fertilising Products Regulation; EU FPR'). The Regulation establishes obligations for importers, distributors and manufacturers (or their appointed representatives) in relation to the safety, quality and labelling of products on the EU market that are used to improve plant growth.

3. The proposals in COM(2025)531 seek to simplify and streamline requirements and procedures of EU CLP, CPR and FPR in order to reduce compliance costs and administrative burden for the chemical industry while aiming to ensure the strong protection of human health and environment.

4. 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. The package also includes COM(2025)526, a proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) 2024/2865 as regards dates of application and transitional provisions (please see the EM submitted by the Department of Work and Pensions on COM(2025)526).

5. To facilitate its dual access to both the United Kingdom (UK) Internal Market and EU Single Market, Northern Ireland (NI) applies certain EU rules relating to chemicals under the terms of the Windsor Framework. EU CLP, CPR and FPR are included in Annex 2 to the Windsor Framework, therefore, the proposed amendments to these regulations set out in COM(2025)531 will apply in NI, subject to the democratic scrutiny mechanisms set out in Article 13(3) of the Windsor Framework and schedule 6B of the Northern Ireland Act 1998.

6. Following the UK's withdrawal from the EU, EU CLP, CPR and FPR were assimilated into the law of Great Britain (GB) and operate separately to their corresponding EU regimes. As such, the amendments proposed by COM(2025)531 will not apply to the regulation of chemicals classification, labelling and packaging, cosmetic products and fertilising products in GB. In this document, the EU-derived CLP, CPR and FPR Regulations in force in GB are referred to as assimilated regulations or in the case of CLP, the GB CLP Regulation.

Changes to be brought in by the Proposed Regulation

Classification. Labelling and Packaging Regulation

7. In relation to EU CLP, COM(2025)531 largely focuses on provisions recently introduced into EU CLP by the amending Regulation (EU) 2024/2865. Regulation (EU) 2024/2865 imposed a series of new requirements on suppliers concerning hazard identification and communication in order to provide more comprehensive identification and classification of chemical hazards, improve hazard communication by making labels more accessible and understandable and address legal gaps and ambiguities. (Please refer to the EM submitted by the Department of Work and Pensions to the NI Assembly on 4 December 2024 for further detail).

8. COM (2025)531 either reverses or further clarifies certain labelling and other hazard communication provisions introduced by Regulation (EU) 2024/2865:

- Mandatory labelling rules regarding minimum font size and colour, background colour and line and letter spacing are removed.
- The 6-month deadline by which suppliers must update their product labels following a change of classification or labelling that results in the addition of a new hazard class, in a more severe classification or new supplemental information is removed. Instead, labels must be updated 'without undue delay' once new data is obtained by or communicated to the supplier.
- Requirements to reflect the applicable hazard pictograms, signal words, hazard statements and obligatory supplemental statements in advertisements are removed and the scope of advertisements and distance (online) sales requirements is reduced to the general public so as to exclude professional transactions from these obligations.

- Labelling rules applicable to fuelling stations are relaxed through removal of the requirement to include the following label elements on fuel pumps: name and contact details of supplier, nominal quantity of the supplied chemical and Unique Formula Identifier number.
- Derogations from labelling requirements for chemicals in very small packaging under 10 ml are clarified to ensure their applicability without the need to first prove that the packaging is either in such a shape or form or is so small that it is impossible to meet full labelling requirements.

9. Additionally, the provisions of EU CLP that incorporate digital technologies are further developed by replacing the need for suppliers to provide their telephone number on labels with the mandatory requirement to include a 'digital contact'—any up-to-date and accessible online communication channel through which economic operators can be reached or engaged. This proposed amendment to EU CLP builds on the digital labelling provisions introduced into EU CLP by Regulation (EC) 2024/2865 which allowed for voluntary use of digital labelling to reflect certain non-obligatory labelling elements.

Cosmetic Products Regulation

10. COM(2025)531 seeks to introduce a procedure for requesting the inclusion of substances used as colourants, preservatives and UV filters in the relevant annexes (Annexes IV-VI to EU CPR) to provide greater legal clarity and certainty for applicants requesting approval of the use of these substances in cosmetic products.

11. Amendments to the derogation process in Article 15 governing the use of severely hazardous chemicals in cosmetic products (carcinogenic, mutagenic or toxic for reproduction (CMR) substances of categories IA and 1B) have also been proposed to:

- Establish fixed periods for derogation requests. A deadline for submission of a derogation request within three months of the substances' classification as a CMR under the EU CLP Regulation is introduced.
- Introduce transitional periods for compliance with new bans or restrictions. 12 months for products placed on the market, and 24 months for products available on the market following the entry into force of the amendments to the relevant annexes of EU CPR
- Simplify derogation criteria under Article 15(2) by eliminating the "food safety requirements" criterion and merging the "particular use" criterion with the Scientific Committee on Consumer Safety (SCCS) safety assessment requirement.
- Clarify the approach to natural complex substances containing CMR constituents. When a constituent of a multi-constituent substance has been classified as a CMR, the prohibition from Article 15 would not apply if the substance was extracted from plants or plant parts and not chemically modified. However, to address any safety concerns, a SCCS assessment may still be required.
- Adopt a route-based approach to CMR bans. The classification of a substance as a CMR would only trigger a ban under Article 15 of EU CPR

if the scientific evidence on which the classification is based shows that the CMR properties are due to dermal exposure, rather than a blanket ban applying regardless of exposure route.

12. COM(2025)531 also seeks to remove obligations from businesses, the European Commission and EU Member States so as to remove burdens. The requirement for cosmetics containing nanomaterial to be notified to the Commission six months before the product is placed on the market is to be removed. Instead, the relevant information is to be included in the cosmetic product safety report.

13. Additionally, the obligation for the Commission to compile and publish a glossary of common ingredient names in the Official Journal is to be replaced with a reference to internationally recognised nomenclature and electronic provision in a Commission database. The requirement for Member States to review and report on their market surveillance activities every four years will would also be revoked as the EU believes that this obligation is now redundant due to introduction of the Information and Communication System on Market Surveillance (ICSMS).

Fertilising Products Regulation

14. REACH registration of substances in EU fertilising products:

a. For substances (virgin substances under Component Material Category (CMC) 1 and additives or other substances under other CMCs) used in EU 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.

b. COM(2025)531 proposes to delete the requirement to register substances in EU fertilising products in accordance with the requirements outlined in a. above from EU FPR.

c. In 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.

15. Assessment of microorganisms in plant biostimulants:

a. The current mechanism for adding new micro-organisms or strains of microorganisms is creating a bottleneck for the placing on the market of plant biostimulants in the El-J.

b. It is proposed in COM(2025)531 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.

c. 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 microorganisms 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.

16. Deletion 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.

17. Digitalisation: There are several updates proposed to support digitalisation:

a. Specifying that the EU declaration of conformity must be drawn up in electronic form and made accessible through an internet address or data carrier.

b. The addition of a 'digital contact' as information to be indicated by economic operators on the products which are placed on the market.

c. The amendment of reporting obligations to national authorities that require a 'paper or electronic format' to 'electronic form' only.

d. Specifying that documents and exchanges between the economic operators and notified bodies related to conformity assessments shall be in electronic form.

e. 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.

f. 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.

SCRUTINY HISTORY

18. The proposed simplification measures described in this document have not been subject to previous scrutiny. The EU CLP provisions to which amendments are proposed in COM(2025)531 have been scrutinised previously by the UK Parliament and NI Assembly. The relevant scrutiny history is set out in Annex A to this EM.

MINISTERIAL RESPONSIBILITY

19. Policy areas within which COM(2025)531 proposes amendments concern different departments of the UK Government. The Secretary of State (or if delegated, Ministers) in the Department for Work and Pensions advised by the Health and Safety Executive (HSE), is responsible for policy questions arising from this document that relate to the classification, labelling and packaging of chemicals.

20. The Secretary of State (or if delegated, Ministers) in the Department for Business and Trade is responsible for policy questions arising from this document that relate to the regulation of cosmetic products.

21. The Secretary of State (or if delegated, Ministers) in the Department for Environment, Food and Rural Affairs is responsible for policy questions arising from this document that relate to the regulation of fertilising products.

INTEREST OF THE DEVOLVED GOVERNMENTS (DGs)

22. The proposed Regulation concerns policy areas that are a mix of reserved and devolved competence. Occupational safety and health, consumer safety, and product labelling are reserved matters under the devolution settlements of Scotland, Wales and NI. Environmental protection and public health are devolved matters in Scotland and Wales and transferred matters in NI. Fertiliser policy is within devolved and transferred competence with the exception of decisions relating to ammonium nitrate which are a reserved matter in GB insofar as they relate to health and safety, and in NI insofar as they relate to explosives.

23. The GB CLP Regulation is in scope of the UK Chemicals and Pesticides Provisional Common Framework which was developed jointly by the UK Government, Devolved Governments, HSE and the Environment Agency. In most cases, the exercise of the Secretary of State's functions under the GB CLP Regulation is subject to the consent of DG Ministers (Scotland and Wales only). Accordingly, the DGs will be consulted with respect to any changes to the GB CLP Regulation. The assimilated Fertilising Products Regulation is in scope of the Fertilisers Provisional Common Framework which was developed by the UK and Devolved Governments.

24. Officials in relevant departments of the NI Executive, namely the Department for Economy (CLP), the Department of Justice (CLP, solely in respect of explosives for civil use), Department of Agriculture, Environment and Rural Affairs (Fertilisers) and the Health and Safety Executive Northern Ireland were consulted during the preparation of this EM. Scottish Ministers and Welsh Ministers also have an interest in the proposed legislation and their officials were consulted in the development of this EM.

LEGAL AND PROCEDURAL ISSUES

25.

(i) Application under the Windsor Framework

COM(2025)531 proposes amendments to EU CLR CPR and FPR—regulations that are included in Annex 2 of the Windsor Framework and continue to apply in NI. The proposed amendments will be subject to democratic scrutiny under the terms of Article 6B of the Northern Ireland Act 1998.

(ii) EU Legal Base

Article 114 of the Treaty on the Functioning of the European Union provides the legal basis for EU CLR CPR, FPR and the proposed legislative amendments to those Regulations set out in COM(2025)531. The European Commission is empowered to amend certain annexes to the EU CLP Regulation (under Article 53) and EU FPR Regulation (under Article 42(1)). However, the European Commission has deemed that the ordinary legislative procedure is the most appropriate legal mechanism for making all changes.

(iii) Voting Procedure .

COM(2025)531 will need to be adopted by the ordinary legislative procedure and voting will be via qualified majority.

(iv) Timetable for Adoption and Implementation

Once adopted by the European Parliament and Council, the Regulation is due to enter into force on the twentieth day following its publication in the Official Journal of the European Union. The proposed amendments to EU CLP, CPR and FPR will apply from the dates set out in the Table 1.

Proposed amendments to EU CLP with an application date of 1 January 2028 revise provisions that were introduced by Regulation (EU) 2024/2865 and do not yet fully apply. To facilitate their revision, the application dates of corresponding provisions in Regulation (EU) 2024/2865 are to be deferred until 1 January 2028 under a proposed Regulation published by the European Commission on 8 July 2025 (.COM 2025)526).

Table 1: Application dates of provisions in COM(2025)531

Proposed Regulatory Amendment		Application Date
The Classification, Labelling and Packaging Regulation	Clarification and simplification of labelling derogations for chemicals under 10 ml.	1 July 2026
	Removal of the 6-month deadline to update labels following a change in chemical classification or labelling.	1 January 2028
	Reduced scope and simplification of advertisements and distance sales requirements.	

	Removal of mandatory labelling rules regarding minimum font size and colour, background colour and line and letter spacing.	
	Reduction of the labelling information required on fuel pumps.	
	New requirement for suppliers to include a digital contact on labels.	36 months after the entry into force of the proposed Regulation.
The Cosmetic Products Regulation	All proposed amendments to the Cosmetic Products Regulation.	Date of entry into force of the proposed Regulation.
The Fertilising Products Regulation	All proposed amendments to the Fertilising Products Regulation.	24 months after entry into force of the proposed Regulation.

POLICY AND LEGAL IMPLICATIONS

Classification, Labelling and Packaging

26. The proposed Regulation aims to simplify certain hazard communication rules through clarification or removal of EU CLP provisions recently introduced by Regulation (EU) 2024/2865 concerning labelling exemptions for chemicals under 10 ml, deadlines for labelling updates, label formatting and hazard information to be provided in advertisements, certain distance sales offers and at fuel pumps.

27. Removal of the designated provisions partially reverts the EU CLP Regulation to a previous version that has been retained in GB law (and currently subject to consultation on reform).

28. In line with the Government's commitment to ensuring NI-based businesses have unfettered access to the rest of the UK Internal Market, the proposed measures will in no way impede the movement of chemicals as qualifying NI goods from NI to GB. Chemicals supplied from NI will also continue to benefit from the market access principles set out in the United Kingdom Internal Market Act 2020. Accordingly, so long as those goods meet NI standards, they can be sold anywhere in the UK Internal Market.

29. The proposed changes to EU CLP are expected to be generally beneficial as they seek to reduce the complexity and administrative burdens of regulation, making it easier for suppliers of chemicals to EU and NI markets to understand and comply with the EU CLP Regulation and to place products on those markets. The proposed changes may generate cost

savings for businesses which are discussed in the financial implications section of this EM.

30. Data gathered by HSE from a survey of UK chemical suppliers conducted in September 2024 indicates that removal of the 6-month deadline by which suppliers must update their labels to reflect certain changes in classification or labelling would have a minimally beneficial effect. The survey data suggests that on average UK suppliers relabel within approximately 2.7 months following a change to a more severe classification or labelling, although around 36% of large companies take longer than six months. For suppliers operating in NI, survey data was limited in its capture of micro, small and medium businesses, but indicated that average relabelling periods were similar to those across the UK. However, data indicates that around 44% of large suppliers operating in NI currently take longer than six months. This suggests that the removal of the 6-month relabelling deadline may be of increased benefit to large suppliers, particularly those operating in NI.

31 . In principle, the proposed requirement for suppliers to include on their labels a digital contact in place of a telephone number presents divergence in the chemical labelling rules of GB and the EU/NI. However, the practical effects of such divergence will be minimal as the supplemental labelling rules of EU CLP would permit the inclusion of both telephone and digital contact details on labels, allowing suppliers to simultaneously satisfy the contact detail requirements of GB and EU/NI. Moreover, the ramifications of this divergence are nullified for GB-based suppliers to NI by the incoming requirement for chemicals being placed on the EU and NI markets to have an EU/NI-based supplier reflected on the label which witl apply from 1 July 2026 and necessitate changes to the contact details of the supplier on the label.

32. In recognising the issues raised during the notification of Regulation (EU) 2024/2865, the Government committed to taking any future steps necessary to protect the UK's Internal Market and avoid new barriers for traders arising from classification, labelling and packaging regimes in place in NI and the rest of the UK. To fulfil this commitment, HSE conducted a public consultation between 23 June and 18 August 2025 in which it considered whether to include relevant EU CLP measures applicable under Regulation (EU) 2024/2865 on a UK-wide basis, where relevant for Great Britain. The EU's proposed changes to its CLP regime mean that divergence between GB and NI will be minimised. HSE will nonetheless consider responses and will provide a consultation response in due course, and will consider future changes to ensure the smooth flow of goods across the UK Internal Market.

33. Cosmetic Products Regulation.

34. The proposed Regulation aims to enhance safety and reduce the administrative burdens of EU CPR. Specifically, it aims to provide greater clarity by introducing a procedure for requesting the inclusion of substances used as colourants, preservatives and UV filters in Annexes IV-VI to EU CPR.

35. Subject to the democratic scrutiny mechanisms of the Windsor Framework, these proposals would apply in relation to cosmetics placed on the NI market after the EU Regulation enters into force. Under the Government's commitments to NI's unfettered access to the rest of the UK

market, cosmetics that meet the technical requirements to be placed on the market in NI would be able to be placed on the GB market.

36. Any future implementation of these proposals will not change the requirements for products placed on the GB market. On 24 October 2023, a consultation on the future of the UK's Product Safety Regulatory framework concluded, which sought views on proposals to modernise the framework to ensure that it remains fit for purpose to provide protection for consumers now and in the future. In particular, it explored proposals to ensure the regulatory framework is agile and able to deal with new and emerging issues, for example supporting innovation and the changing way consumers buy and use products. It is intended that sector specific legislation, such as that covering cosmetics, will also be reviewed to fit within any emerging changes that might be considered for the framework as a whole. The Government will consider the benefits and risks of adopting similar measures as set out in the EU's proposal in the light of any wider considerations as a result of analysis of the responses received to the consultation on the Product Safety Review.

37. Fertilising Products Regulation

38. With regards to REACH registration of substances, the existing extended REACH registration requirement under EU FPR is a disproportionate burden because of the costs on manufacturers for complying with this requirement.

39. With regards to assessment of microorganisms in plant biostimulants, the proposal 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 is a pragmatic step to stimulate an increase in product development, whilst maintaining a high level of health and safety assurance.

40. 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 to enable the Commission to adopt delegated acts amending several CMCs at once will streamline legislative process and reduce administrative burden. We have no policy concerns with any of these streamlining proposals, and the operation of EU FPR in NI.

41. There are no legal implications arising from COM (2025)531. The UK Government will monitor the passage of the proposals through the EU negotiation process and assess any possible policy impacts by the dates of application.

CONSULTATION

42. To aid the development of its proposals, the European Commission held a series of workshops with stakeholders from industry, consumer and environmental groups, legal practitioners and competent authorities to understand the impact of EU CLP, CPR and FPR requirements and to

explore possibilities for simplification, cost savings and burden reduction. Following these meetings, the Commission received more than 150 detailed position papers from stakeholders which supported previously expressed views and provided additional suggestions for improvement, data and cost estimates.

41 . Stakeholder engagement conducted by the Commission in relation to EU CLP centred on new provisions introduced by Regulation (EU) 2024/2865. The UK Government has continuously engaged with UK stakeholders to understand the implications of these provisions. In September 2024, HSE surveyed UK businesses supplying chemicals domestically with the aim of generating data on potential changes to how chemicals are classified, labelled and packaged in GB to reflect amongst other things, EU-driven developments stemming from Regulation (EU) 2024/2865. Additionally, HSE and the Cabinet Office informally engaged with UK industry stakeholders on 21 October 2024 and 28 April 2025 on the domestic application of the newly introduced EU CLP provisions. This engagement is ongoing and future discussion will explore the ramifications of the proposed measures in COM(2025)531 for UK-based suppliers.

42. Whilst COM(2025)531 does not affect the regulation of fertilising and cosmetics products supplied to the GB market, the UK Government will continue to engage with stakeholders to understand any possible wider impacts of the proposals on their activities.

FINANCIAL IMPLICATIONS

43. The amendment of EU CLP, CPR and FPR is expected to generate cost savings for businesses placing products on the EU and NI markets. The European Commission estimates annual cost savings to the EU chemicals industry to be at least E314 million (at an exchange rate of 1 EUR = 0.86 GBP), with the greatest proportion of cost savings arising from the proposed changes to EU CLP label formatting rules which the Commission expects will save industry at least 2288 million. These costs would be incurred if the measures introduced by Regulation (EU) 2024/2865 went ahead as currently enacted. By amending EU CLP, these costs will be avoided in the future, but they are not currently being incurred by suppliers. The cost savings reported by the European Commission are contained in the Staff Working Document accompanying COM(2025)531 (SWD(2025)531) and have not been reviewed independently by HSEs economists.

44. The easement of EU CLP rules concerning label formatting and the hazard information provided on advertisements and certain distance sales offers will avert future costs to businesses arising from the redesign and redistribution of labels, advertisements and distance sales offers in order to ensure compliance with the corresponding provisions of Regulation (EU) 2024/2865. Additionally, reducing the required chemical hazard information in audiovisual advertisements would avoid the loss of valuable consumer engagement time and consequently, conserve advertising value.

45. Data generated from the survey of UK chemical suppliers conducted by HSE in September 2024 indicates that relabelling products to comply with

label formatting rules would cost affected UK micro and small businesses between around E 14,000 and €20,000, with medium businesses' costs reaching up to around E35,OOO. Large businesses reported costs between around 2430,000 and 21.5 million each, with figures for large firms operating in NI between around E880,000 and El .7 million each.

46. Although these hazard communication provisions introduced by Regulation (EU) 2024/2865 do not yet fully apply, some businesses may have already undertaken anticipatory redesign and redistribution activities. Accordingly, the scale of cost saving for such businesses will be reduced.

47. In accordance with Regulation (EU) 2024/2865, the 6-month deadline by which labels must be updated to reflect more severe classifications and labelling changes does not apply on a mandatory basis until 1 July 2026. However, the removal of the fixed relabelling deadline proposed by COM (2025)531 maintains the current flexibility afforded to businesses to align this type of labelling updates with labelling changes for other purposes (e.g. marketing) and thus, avoids higher compliance costs for businesses in future.

48. Some proposed changes to EU CLP are expected to generate minimal transition and implementation costs. The revision of EU CLP supplier requirements will result in familiarisation costs for businesses. However, these costs are expected to be minimal given that, in many cases, the proposed action reverses changes to EU CLP that have not yet taken effect. The proposed labelling requirement to include a digital contact in place of a telephone number will necessitate the relabelling of chemicals supplied to the EU/NI markets. However, given that the transition period associated with this change is approximately 3 years and stakeholder responses to the survey conducted by HSE in September 2024 suggest that (depending on business size) UK businesses typically relabel between around 55% and 72% of their product lines within three years anyway, relabelling costs may be reduced by the ability of businesses to comply with the digital contact requirement within the regular relabelling periods of their products.

MINISTERIAL NAME AND SIGNATURE

The Rt. Hon. Sir Stephen Timms MP

Minister of State for Social Security and Disability

DEPARTMENT FOR WORK AND PENSIONS

Annex A

PARLIAMENTARY SCRUTINY HISTORY RELEVANT TO PROVISIONS OF THE CLP REGULATION IN SCOPE OF COM(2025)531

1. The EU CLP provisions to which amendments are proposed by COM(2025)531 were first set out in the Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (COM(2022)748) published on 19 December 2022 by the European Commission. The legislative changes described in COM(2022)748 were given legal effect by Regulation 2024/2865 of the European Parliament and of the Council of 23 October 2024 amending Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

United Kingdom Parliament scrutiny:

2. DWP submitted EM 16258/22 on COM(2022)748 on 1 February 2023. The House of Commons European Scrutiny Committee considered the EM on 12 July 2023. The Chair of the Committee wrote to the Government seeking further information through Ministerial correspondence. The House of Commons European Scrutiny Committee cleared the document as politically important on 6 September 2023 and drew the Minister's reply of 1 August 2023 and its report to the attention of the Northern Ireland (NI) Affairs Committee (Twenty-second Report of Session 2022-23). The House of Lords European Union Select Committee sifted the document for examination by the House of Lords Protocol on Ireland/Northern Ireland Sub-Committee on 10 February 2023 (Chairs' Sift of 10 February 2023). The Sub-Committee considered this document at its meeting on 22 February 2023. The Chair of the Sub-Committee wrote to the Government seeking further information on Ministerial correspondence during 2023. Substantive scrutiny of this Delegated Regulation was closed with the Government informed in the Chair's letter to the Minister of 8 June 2023.

Northern Ireland Assembly scrutiny:

3. EM 16258/22 was also considered by the NI Assembly Windsor Framework Democratic Scrutiny Committee at its meeting on 24 October 2024. During this time, the Committee agreed to seek stakeholder views on Regulation 2024/2865 via a Citizen Space survey which closed on 12 November 2024. Pursuant to paragraph 8(1) of Schedule 6B to the Northern Ireland Act 1998, the Committee decided to conduct an inquiry into Regulation (EU) 2024/2865 which concluded on 20 January 2025.

4. During the scrutiny period of the inquiry, the Committee wrote to the UK Government on the following occasions:

- 25 October 2024 to request information from His Majesty's Revenue and Customs on the scale of trade between Great Britain and Northern Ireland in the chemicals sector.

- 29 November 2024 to seek views on the ramification of Regulation 2024/2865's application in NI and comments from the

Government on views it had received from a stakeholder during its consultation on Regulation (EU) 2024/2865.

- 7 December 2024 to request an updated EM reflecting the publication of Regulation 2024/2865.

5. DWP submitted an EM on Regulation (EU) 2024/2865 to the NI Assembly on 4 December 2024 which addressed questions raised by the Committee in its letter of 29 November 2024 regarding the potential impact of application. Correspondence from the Cabinet Office on 11 December 2024 provided information regarding the requested trade data and the UK Government's response to stakeholder views received during the Committee's consultation on Regulation (EU) 2024/2865.

6. The Committees' inquiry report on Regulation (EU) 2024/2865 (NIA 64/22-27) was published on 19 December 2024. On 20 December 2024, the Speaker of the NI Assembly wrote to the Secretary of State for NI to provide written notification under Part 3 of Schedule 6B of the Northern Ireland Act 1998 ('Stormont Brake') to prevent the application of Regulation (EL^{I}) 2024/2865 in NI, having received support for such action from 35 Members of the Legislative Assembly. The Secretary of State for NI responded to the Speaker of the NI Assembly on 20 January 2025 explaining that substantive tests governing the use of the Stormont Brake had not been met, meaning that the Brake could not be applied in relation to Regulation (EU) 2024/2865.

7. The correspondence of 20 January 2025 includes a commitment by the UK Government to consult publicly on how best to safeguard the UK Internal Market, including on whether to apply a consistent regime across the UK. To fulfil this commitment, the Health and Safety Executive conducted a public consultation between 23 June and 18 August 2025 concerning potential changes to the domestic regulation of chemicals.