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

Regulation (EU) 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

Submitted by the Department for Work and Pensions, on 04 December 2024

SUBJECT MATTER

1. This Explanatory Memorandum (EM) relates to Regulation (EU) 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 (the Classification, Labelling and Packaging Regulation or 'CLP Regulation' for short in this EM).

2. The CLP Regulation imposes requirements on manufacturers, importers, downstream users and distributors of substances and mixtures (chemicals). The revision of the CLP Regulation by this new amending Regulation, Regulation (EU) 2024/2865, is intended to address the weaknesses and ambiguities in the existing CLP Regulation in relation to hazard communication and to adapt the CLP Regulation to scientific and technical developments and new means of sale.

3. To facilitate its dual access to both the UK Internal Market and EU Single Market, Northern Ireland applies certain EU rules relating to chemicals, including the CLP Regulation, under the terms of the Windsor Framework. The CLP Regulation is included in Annex 2 to the Windsor Framework. The amendments to the CLP Regulation made through this amending Regulation will therefore apply in Northern Ireland, 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.

4. Following the UK's withdrawal from the EU, the CLP Regulation ceased to apply in Great Britain (GB), which assimilated a similar - but separate - regime into domestic legislation ('the assimilated CLP Regulation'). This, combined with the fact that environmental protection and public health are devolved (transferred) competencies, means that regulation in Northern Ireland operates distinctly separate from that in GB, except for the protections on Northern Ireland's 'Unfettered Access" to the rest of the UK Internal Market under the assimilated CLP Regulation and the United Kingdom Internal Market Act 2020.

5. The measures in Regulation (EU) 2024/2865 aim to improve how chemical hazards are classified, provide clearer safety warnings and improve compliance and user safety, which the UK Government acknowledges may have some merit and is considering incorporating into the domestic regime. Engagement with industry indicates that the overwhelming majority of substances and mixtures sold across the UK will continue to be in line with the general approach of CLP. The changes in Northern Ireland arising from Regulation (EU) 2024/2865 will only take effect gradually over time given the 24-60 month implementation timetable.

6. In addition, given the existing separation of the GB and Northern Ireland regimes - and for the reasons set out in more detail below - it is expected that there will be limited Northern Ireland-specific implications.

Background to the CLP Regulation

7. The CLP Regulation has applied since January 2009 and implements the United Nations Globally Harmonized System of classification and labelling of chemicals (UN GHS) in the EU. The CLP Regulation requires EU/EEA-based suppliers (manufacturers, importers, downstream users and distributors) to classify, label and package them safely before placing them on the EU/EEA market.

8. These requirements apply throughout the EU/EEA supply chain down to the point of use and ensure that workers, professional users, and consumers are given important hazard information about chemicals so that they can be supplied, handled and used safely. The CLP Regulation also contains a list of substances with legally binding harmonised classifications that must be used when classifying and labelling substances and mixtures (Table 3 of Annex VI to the CLP Regulation). Where no harmonised classification and labelling exists, (suppliers must self-classify and label substances and mixtures in accordance with the CLP Regulation.

Changes brought by this amending Regulation

9. Regulation (EU) 2024/2865 aims to provide more comprehensive identification and classification of chemical hazards, improve hazard communication and address legal gaps and ambiguities.

Measures to enhance the efficiency and effectiveness of the harmonised classification and labelling (CLH) system including for the most critical hazards

10. In April 2023, six new hazard classes were added to the CLP Regulation by Commission Delegated Regulation (EU) 2023/70 of 19 December 2022:

    - endocrine disruption (ED) for human health and the environment (separate hazard classes) – 2 new hazard classes;
    - persistent, bioaccumulative, toxic (PBT);
    - very persistent, very bioaccumulative (vPvB);
    - persistent, mobile, toxic (PMT); and
    - very persistent, very mobile (vPvM).

11. According to the European Commission's impact assessment report for the proposed amending Regulation, measures in relation to hazard identification and classification seek to enhance the efficiency and effectiveness of the harmonised classification and labelling (CLH) system. The amending Regulation revises the CLP Regulation by prioritising these six new hazard classes for evaluation under the CLH system alongside the existing priority hazard classes. Any harmonised classification and labelling relating to these hazard classes included in entries in Table 3 of Annex VI to the CLP Regulation will now have to be applied to all substances and mixtures by suppliers. There are currently no harmonised classification and labelling entries for these new hazard classes in Table 3 of Annex VI for any substances. The first harmonised classification entries for the new hazard classes are not expected until 2026 at the earliest.

12. The following hazard classes are already considered for harmonised classification and labelling: carcinogenicity, mutagenicity and reproductive toxicity (CMR) and respiratory sensitisation as they are of highest concern for human health. The six hazard classes will now also be prioritised under the CLH system, alongside active substances used in biocides and pesticides. Where a substance has a harmonised classification for some or all hazard classes, suppliers must apply it and label accordingly.

13. Harmonised classification proposals for groups of substances are permitted, and the mechanism for initiating proposals has been extended to allow the European Commission to develop proposals. Competent Authorities and companies will formally have to notify the European Chemicals Agency (ECHA) of their intention to submit a CLH proposal.

14. Measures in this area also seek to enhance the quality and accuracy of classified substances. Suppliers will be required to provide reasons for any differences when notifying self-classifications to the European Chemicals Agency (ECHA) Classification and Labelling Inventory and notifications are to be updated within 6 months of a decision to change the classification and labelling of a substance having been taken. The approach towards the evaluation and classification of certain chemicals such as multi-constituent substances is clarified.

Hazard communication

15. The amending Regulation aims to improve the efficiency of hazard communication by making labels more accessible and understandable for users of chemicals, and provide companies with more flexibility, thereby reducing the administrative burden without lowering safety levels.

16. To enhance readability, obligatory labelling rules such as minimum font size, line spacing and colour are introduced, whilst the broader use of fold-out labels will be permitted. Derogations for chemicals sold to consumers in bulk (such as fuel) and in very small packaging will be added. Duty holder requirements are established for voluntary digital labelling and the sale of chemicals in refillable containers.

17. A 6-month deadline for updating labels is imposed when changes in classification and labelling which introduce new or more severe hazard categories occur.

18. Measures on hazard communication optimise labelling provisions through the addition of duty holder requirements and exemptions, and the extension of the labelling requirements to technological developments and emerging sectors.

Non-compliance, legal gaps and ambiguities

19. Some measures focus on improving compliance with and enforcement of the CLP Regulation, with emphasis on distance sales. All online distance sales will explicitly require a EU/EEA-based supplier to ensure that a substance or a mixture placed on the EU/EEA market through online distance sales meets the requirements of the CLP Regulation. Certain additional hazard information will be required in online advertisements and a requirement to indicate all applicable label elements in distance sales offers has been introduced. Businesses based in Northern Ireland that already serve the Northern Ireland market will already be in compliance with these new requirements and, as such, will be unaffected.

20. Notification of emergency health response information on mixtures to poison centres will now be applicable to any distributors placing mixtures on the Single Market and also those rebranding or relabelling mixtures.

The Government's assessment of Regulation (EU) 2024/2865

21. The UK Government acknowledges the merit of the Regulation's overall aims to improve the identification and classification of chemical hazards, hazard communication and that address the issues of non-compliance, legal gaps and ambiguities.

22. The UK Government is considering whether to incorporate some of the measures described above into the domestic regime on a UK-wide basis. For example, the introduction of rules pertaining to label formatting and voluntary digital labelling; labelling exemptions for chemicals supplied without packaging or contained in very small packaging; and the requirement to specify more hazard information in advertisements. The UK Government is currently investigating the scientific and technical basis and the wider policy context including developments at UN GHS that may justify the incorporation of similar revision measures into the assimilated CLP Regulation.

SCRUTINY HISTORY

23. The parliamentary scrutiny history relevant to the CLP Regulation is contained in **Annex A**.

MINISTERIAL RESPONSIBILITY

24. The Secretary of State (or if delegated, Ministers) in the Department for Work and Pensions advised by the Health and Safety Executive (HSE), has the overall responsibility for policy questions arising from this document.

25. HSE is the policy lead and is responsible for making recommendations to the Government on the classification and labelling of chemicals, including the adoption and implementation of the United Nations Globally Harmonized System of classification and labelling of chemicals (UN GHS). HSE regularly consults with other interested departments, agencies, and the devolved governments.

INTEREST OF THE DEVOLVED GOVERNMENTS

26. Chemicals policy engages a mix of reserved and devolved competence. In GB, occupational safety and health, consumer safety, and product labelling are generally reserved matters under the devolution settlements while environmental protection and public health are devolved competences to the Devolved Governments.

27. Scottish and Welsh Ministers have an interest in the environmental protection and public health aspects of chemicals legislation such as the assimilated CLP Regulation as these areas are devolved. Additionally, in most cases, the exercise of the Secretary of State's functions under the assimilated CLP Regulation are subject to the consent of the Devolved Government Ministers (Scotland and Wales only). Accordingly, the Devolved Governments will be consulted with respect to any changes in the assimilated CLP Regulation.

28. The assimilated CLP Regulation is covered under the UK Chemicals and Pesticides Provisional Common Framework, developed jointly by the UK Government, Devolved Governments including the Northern Ireland Executive , HSE and the Environment Agency. All provisional frameworks have been shared with committees across UK Parliament and devolved legislatures to enable parliamentary scrutiny before final review and approval by Ministers across the UK Government and Devolved Governments.

29. In Northern Ireland, the responsibilities for occupational health and safety, environmental protection, public health, consumer safety in relation to goods are transferred under the devolution settlements. The security of civil explosives is reserved.

30. Chemicals policy is a devolved matter in Northern Ireland. The Department for the Economy (DfE) and the Department of Justice (DoJ) share joint competence for the CLP Regulation, while the remit of DoJ as the designated competent authority only extends to civil explosives uses. The CLP Regulation is enforced by Health and Safety Executive for Northern Ireland (HSENI) and local authorities. The Department of Health (DoH) also has inspection, surveillance, reporting and enforcement responsibilities in relation to CLP in relevant registered premises in Northern Ireland. The Department of Agriculture, Environment and Rural Affairs (DAERA) also has an interest because of environmental hazards.

31. HSE provides scientific and expert advice on matters relating to the CLP Regulation. The DoJ has a memorandum of understanding (MOU) with the HSE's Explosives Inspectorate which provides technical health and safety support. In specific cases other GB agencies will also provide technical and scientific support, e.g., HSE or The General Pharmaceutical Council for chemical substances or mixtures that fall within scope of the CLP Regulation sold in pharmacies.

LEGAL AND PROCEDURAL ISSUES

32. Regulation (EU) 2024/2865 was made under Article 95 of the Treaty establishing the European Community (now Article 114 of the Treaty on the Functioning of the European Union (TFEU)).

Legal Base

33. The legal base for the CLP Regulation and the new Regulation amending and revising the CLP Regulation, Regulation (EU) 2024/2865, is Article 114 of the TFEU.

Voting Procedure

34. The voting procedure for the amending Regulation revising the CLP Regulation was by qualified majority voting under the ordinary legislative procedure as a directly applicable and binding EU Regulation.

Timetable for adoption, entry into force and full application

35. Regulation (EU) 2024/2865 enters into force on 10 December 2024. To allow businesses time to adapt to the classification and labelling changes for substances and mixtures, the application of some of the provisions of the Regulation have been deferred for a period of up to 18 months for most of the changes and up to 24 months for the changes to the label formats. Substances and mixtures which are already placed on the market before the end of that deferral period, are not required to be reclassified or re-labelled in accordance with this Regulation, to avoid an additional burden on suppliers. The Regulation also includes derogations to allow duty holders to adopt the changes sooner on a voluntary basis.

36. The previous delegated act, Commission Delegated Regulation (EU) 2023/70 of 19 December 2022 that introduced the new hazard classes also sets out the following transitional periods and deadlines:
    a. New substances not yet on the market within the EU/EEA: 24 months
    b. Mixtures not yet on the market within the EU/EEA: 36 months
    c. Substances and mixtures already on the market: 48 months
    d. Mixtures already on the market: 60 months.

POLICY IMPLICATIONS

37. Implications for Northern Ireland-based businesses placing substances and mixtures on the market in Northern Ireland, include:

    a. Application of harmonised classification and labelling relating to new hazard classes.
    b. Hazard communication and labelling changes described above - such as minimum font sizes, line spacing and colour. Relabelling (for non-CLP Regulation reasons) is commonplace and occurs periodically. Should the usual relabelling period overlap with the transitional period for this change, it could ease the process for duty holders.
    c. A broader scope, to include the supply of hazardous chemicals via refill, such as detergents, which will place certain requirements on suppliers in relation to hazard communication and risk management.
    d. New conditions for supply via refill have also been introduced, such as the ability to operate refill stations outdoors and outside of business hours only if 'immediate assistance' can be provided.
    e. The existing requirement to submit emergency health response information to poison centres will be extended to certain distributors, including re-labellers and re-branders to avoid information loss.
    f. A six-month deadline for updating CLP hazard labels has been introduced and will apply when the classification and labelling of a hazardous chemical is changed to include a new or more severe hazard category.
    g. Certain voluntary measures have been introduced - such as voluntary digital labelling.

38. There are transitional periods to ensure businesses have time to adapt and comply with these requirements, ranging from 18 to 24 months for the classification and labelling changes and longer periods for the changes arising from the new hazard classes (24 months to 60 months). Businesses subject to the CLP Regulation can also choose to apply the new hazard classes on a voluntary basis when classifying and labelling chemicals, allowing for requirements to be phased in over time.

39. In principle, there may be some differing requirements around the manufacture and placing of certain substances and mixtures on the market in Northern Ireland compared with GB In practice, however, we would expect that the overwhelming majority of substances and mixtures being sold across the UK will in any case continue to be in line with the general approach of CLP. The changes in Northern Ireland arising from Regulation (EU) 2024/2865 will only take effect gradually over time given the 24-60 month implementation timetable.

40. Under the Government's commitments to Northern Ireland's unfettered access to the rest of the UK market, substances that meet the technical requirements to be placed on the market in Northern Ireland will be able to be placed on the GB market as long the Northern Ireland trader completes an online notification to confirm the hazard classification of its chemical(s) if the hazard classification has changed or if it is being placed on the market for the first time in GB. Additionally, businesses seeking to change the name of their chemical in a mixture would be required to notify HSE and complete the process, which is free of charge, to make sure that HSE is aware of the chemicals on the GB market.

41. Accordingly, and for the reasons outlined at paragraphs 38 to 40 above, overall it is expected that there will be limited Northern Ireland-specific implications. The improvements in the identification and classification of chemical hazards, hazard communication and the action taken to address the issues of non-compliance, legal gaps and ambiguities will help downstream users

and consumers to understand essential information on hazards. The EU's proposals to further establish the new hazard classes in the CLH system may also be beneficial for Northern Ireland-based businesses supplying chemicals to which the new hazard classes apply. Such businesses may save resources applying relevant CLHs to substances and mixtures as opposed to self-classifying.

42. We will keep this under careful review, with a view to ensuring the continued free flow of goods across the whole UK Internal Market. The UK Government is also currently considering the amendments described above, with a view to potential changes to the domestic regime - and in some instances may proceed with similar amendments on a UK-wide basis - which will reflect the Government's commitment to protecting the UK Internal Market.

CONSULTATION

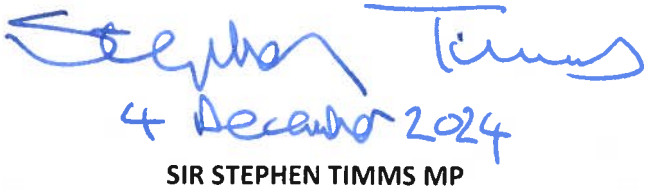
43. HSE is undertaking informal engagement with key internal and external stakeholders to investigate the scientific and technical basis and the wider policy context that may justify the incorporation of similar revision measures into the assimilated CLP Regulation.

FINANCIAL IMPLICATIONS

44. The UK Government is continuing to work to better understand the potential financial impacts - we expect limited Northern Ireland-specific implications.

45. There may be certain familiarisation costs that may be incurred by actors in the supply chain (i.e. chemical manufacturers, importers and downstream users) and by employees who may need to be aware of the new hazard classes at the point of import, manufacture or formulation. Manufacturers, importers and distributors will have to relabel products for the new formatting standards; and larger companies could have to relabel products quicker than currently to adhere to the six-month deadline when changes in classification introduce new or more severe hazard categories. The impacts of distance-selling measures and conditions for refill and how businesses will choose to respond are still being explored. However some of the costs of the legislative package may be offset to a limited extent by the savings from the simplification of the labelling rules.

46. There may also be some cost reductions for impacted NI-based suppliers. For example, the introduction of additional derogations (in relation to chemicals sold to consumers in bulk, such as fuel, and in very small packaging) will exempt some suppliers from incurring CLP Regulation compliance costs. Moreover, the broader use of fold-out labels may result in closer regulatory alignment with international chemical regimes and thus, lead to indirect savings for NI suppliers through the avoidance of relabelling costs.



SIR STEPHEN TIMMS MP

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ANNEX A

PARLIAMENTARY SCRUTINY HISTORY RELEVANT TO THE CLP REGULATION

1. The European Council's proposal for the directly applicable CLP Regulation was first subject to parliamentary scrutiny on 17 July 2007 - Proposal for a Regulation of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, and amending Directive 67/548/EEC and Regulation (EC) No 1907/2006. At the time, the Department of Work and Pensions submitted an Explanatory Memorandum. The relevant document number was 11497/07, COM(07)355.

2. The CLP Regulation was cleared as politically important by the House of Commons European Scrutiny Committee on 30 April 2008 (22nd Report, Session 2007-2008) following a previous report that the proposal had raised issues of political importance (on 10/10/2007 36th Report, Session 2006-07). The House of Lords European Union Select Committee cleared the document from scrutiny on 23 November 2007 (Progress of Scrutiny - 1st Report, Session 2007-2008). The Report was published on 23 November 2007.

3. Parliamentary scrutiny did not apply to subsequent Commission Regulations relating to adaptations to technical and scientific progress (ATPs) to the CLP Regulation or to later Commission Delegated Regulations because the proposed changes to harmonised classification were considered technical and scientific and because they related to a directly applicable EU Single Market Regulation which applied to Member States without further implementation action.

4. The Department of Health and Social Care submitted an Explanatory Memorandum on Commission Delegated Regulation (EU) .../... of 29.10.2019 amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures as regards information relating to emergency health response. This was subject to parliamentary scrutiny and an EM produced on 16 January 2020. The relevant document number was EM 13598/19, C(2019) 7611 final. The House of Commons European Scrutiny Committee cleared the document as not legally or politically important on 4 June 2020 (Tenth Report of Session 2019-21). The House of Lords European Union Select Committee cleared the document from scrutiny in Chairman's Sift No.1671 on 22 January 2020 (Progress of Scrutiny - 1st Edition, Session 2019-21).

5. The Department of Work and Pensions submitted an Explanatory Memorandum on Commission Delegated Regulation (EU) .../... of 11.3.2021 amending, for the purposes of its adaptation to technical and scientific progress, Part 3 of Annex VI ((commonly known as the 17th ATP). This was subject to parliamentary scrutiny and an EM produced on 1 April 2021. The relevant document number was EM 7007/21, C(2021)1533 final. The House of Commons European Scrutiny Committee cleared the document as not legally or politically important on 12 May 2021 (First Report of Session 2021-22). 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 22 April 2021 (Chairs' Sift of 22 April 2021). The Sub-Committee considered this document at its meeting on 19 May 2021. The Chair of the Sub-Committee wrote to the Government seeking further information through Ministerial correspondence during 2021. Substantive scrutiny of this Delegated Regulation was closed on 22 January 2022 with the Government informed in the Chair's letter to the Minister of 14 January 2022.

6. The Department of Work and Pensions submitted an Explanatory Memorandum on Commission Delegated Regulation (EU) .../... of 16.2.2022 amending, for the purposes of its adaptation to technical and scientific progress, Part 3 of Annex VI (commonly known as the 18th ATP). This was subject to parliamentary scrutiny and an EM produced on 24 March 2022. The relevant document number was EM 6328/22 – C(2022)846 final. The House of Commons European Scrutiny Committee cleared the document as not legally or politically important on 28 April 2022 (Twenty-first Report of Session 2021-22). 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 1 April 2022 (Chairs' Sift –of 1 April 2022). The Sub-Committee considered this document at its meeting on 11 May 2022. The Chair of the Sub-Committee wrote to the Government seeking further information through Ministerial correspondence. Substantive scrutiny of this Delegated Regulation was closed on 29 June 2022, with the Government informed in the Chair's letter to the Minister of 1 July 2022.

7. The Department of Work and Pensions submitted an Explanatory Memorandum on a 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 and also Commission Delegated Regulation (EU) .../... of 19.12.2022 amending Regulation (EC) No 1272/2008 as regards hazard classes and criteria for the classification, labelling and packaging of substances and mixtures. This was subject to parliamentary scrutiny and an EM produced on 1 February 2023. The relevant document numbers were EM 16258/22 COM(2022) 748 and EM 16273/22. The House of Commons European Scrutiny Committee considered the EM on the above instruments 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 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.