#### Annex A

# PROPOSED REPLACEMENT EU ACT INITIAL ASSESSMENT OF IMPACT

Date: 27.08.25

DSC REF: DSC/16a/2025

## **Proposed Replacement EU Act**

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.

## This Regulation will amend:

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

#### which amended

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

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

## **Summary of the Act**

Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures ('the CLP Regulation') has applied since January 2009. The CLP Regulation imposes requirements on manufacturers, importers, downstream users and distributors to classify and label their chemicals in accordance with an internationally agreed system, the United Nations Globally Harmonized System of classification and labelling of chemicals (UN GHS), and to package them safely before placing them on the market.

The 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 amends 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 seek to defer the application date of measures introduced by Regulation (EU) 2024/2865 by:

- removing the provisions setting time limits for relabelling, advertising, distance selling and measures relating to the labelling of fuel pumps set out in Annex II from the list of provisions which will apply from 1 July 2026;
- ii. removing certain provisions from Annex I on mandatory formatting requirements from the list of provisions that will apply as of 1 January 2027

Deferred application dates will apply for:

- i. Article 30 Deadline for updating labels following a change in chemical classification or labelling.
- ii. Article 48 and 48a Hazard communication rules for advertisements and distance sales offers.
- iii. Part 5 of Annex II Fuelling station label requirements.
- iv. Article 31(3) and sections 1.2.1.4 and 1.2.1.5 of Annex I Mandatory formatting requirements of labels.

The proposed amendments are part of a wider simplification package adopted by the European Commission on 8 July 2025, to strengthen the competitiveness and modernisation of the EU chemical sector. This includes a 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.

### 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 Health and Safety Executive (HSE) provide scientific and expert advice on matters relating to CLP under an Agency Agreement.

CLP is enforced by HSENI and local authorities. The Department of Health has enforcement responsibilities for CLP in registered premises in Northern Ireland. In specific cases other agencies will provide technical and scientific support, i.e., Environment Agency for cases that involve environmental hazards.

## **Initial Assessment of Impact**

It appears unlikely 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. Deferring the application date itself will provide businesses with more time to adapt to the changes. However, the overall

effect of the simplification package means that those measures will no longer apply, resulting in cost savings for businesses that are regulated under the EU CLP Regulation

It appears likely that <u>not</u> applying the proposed replacement EU act would have a significant impact as NI will be unable to benefit from the deferral 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**

To accommodate the measures which seek to simplify CLP provisions introduced by amending Regulation (EU) 2024/2865, the application dates of the measures in the amending Regulation need to be deferred.

Deferring the application date itself will provide businesses with more time to adapt to the changes. However, the overall effect of the simplification package means that those measures will no longer apply, resulting in cost savings for businesses that are regulated under the EU CLP Regulation. The staff working document accompanying the legislative proposals subject to the deferral dates recognises that the existing provisions were going to be more burdensome and costly than originally claimed. Therefore, the deferrals seek to mitigate those impacts.

Although the proposals have no direct impact in GB, the amendments are expected to minimise the risk of any potential trade friction arising as a result of differences between GB and NI. The deferred date which is to coincide with the removal of certain provisions will result in the harmonisation of EU CLP Regulation requirements with GB CLP Regulation requirements, therefore reducing trade friction between GB and NI. HSE will monitor the passage of the proposals through the EU negotiation process and assess any possible policy impacts by the deferred date in the proposed measure.

### **Analysis by the European Commission on its Impact Assessment**

Given the urgent need to reduce administrative burden and excessive costs for businesses and the lack of policy options, it was not 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 proposed measures, based on existing data, inputs received from stakeholders and

previous analyses, such as the Fitness Check of the most relevant chemicals legislation and the impact assessment for the CLP revision.

## **Departmental Engagement**

DfE officials have monthly meetings with HSE CLP leads.

## **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)526

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

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 Regulation (EU) 2024/2865 as regards dates of application and transitional provisions (herein referred to as 25)526), published on 8 July 2025.
- 2. Regulation (EU) 2024/2865, published on 20 November 2024, amended Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures ('the CLP Regulation') which has applied since January 2009. The CLP Regulation imposes requirements on manufacturers, importers, downstream users and distributors to classify and label their chemicals in accordance with an internationally agreed system, the United Nations Globally Harmonized System of classification and labelling of chemicals (UN GHS), and to package them safely before placing them on the market.
- 3. The proposals in COM(2025)526 seek to defer the application date of measures introduced by Regulation (EU) 2024/2865 by:
  - (i) removing the provisions setting time limits for relabelling, advertising, distance selling and measures relating to the labelling of fuel pumps set out in Annex II from the list of provisions which will apply from 1 July 2026;
  - (ii) removing certain provisions from Annex I on mandatory formatting requirements from the list of provisions that will apply as of 1 January 2027.
- 4. The new application date for all above mentioned provisions is 1 January 2028, as set out in Table 1.

Table 1: The deferred application date under COM(2025)526 for EU CLP Regulation provisions introduced by Regulation (EU) 2024/2865.

EU CLP Regulation provision(s)	Application date under Regulation EU 2024/2865	Deferred application
		date under COM 2025 526

Article 30 Deadline for updating labels following a chan e in chemical classification or labellin  Article 48 and 48a Hazard communication rules for advertisements and distance sales offers.	1 July 2026	1 January 2028
Part 5 of Annex II Fuelling station label requirements.		
Article 31(3) and sections 1.2.1.4 and 1.2.1.5 of Annex I Mandatory formatting requirements of labels.	1 January 2027	

- 5. The proposed amendments in COM(2025)526 are part of a wider simplification package adopted by the European Commission on 8 July 2025, to strengthen the competitiveness and modernisation of the EU chemical sector. This includes COM(2025)531, a 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 (please see the EM prepared by the Department of Work and Pensions on COM(2025)531).
- 6. Following the United Kingdom's (UK) withdrawal from the EU, the CLP Regulation was assimilated into domestic legislation which is a similar but separate regime, commonly referred to as 'the assimilated CLP Regulation' or 'the Great Britain (GB) CLP Regulation'. To facilitate its dual access to both the UK Internal Market and EU Single Market, Northern Ireland (NI) applies the EU CLP Regulation under the terms of the Windsor Framework. Therefore, the proposed amendments in COM(2025)526 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.
- 7. 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, the Health and Safety Executive (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 GB. 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.

#### **SCRUTINY HISTORY**

8. The proposals described in this document have not been subject to previous scrutiny. The provisions to which amendments are proposed in

COM(2025)526 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

- The Secretary of State (or if delegated, Ministers) for the Department for Work and Pensions advised by HSE, is responsible for policy questions arising from this document.
- 10. HSE is the policy lead for the GB CLP Regulation and makes recommendations to the . Government on the classification and labelling of chemicals, including the adoption and implementation of the UN GHS through CLP. HSE regularly consults with other interested departments, agencies and the Devolved Governments (DGs).

## INTEREST OF THE DEVOLVED GOVERNMENTS

- 11. Chemicals policy engages a mix of reserved and devolved competence in GB and the EU provisions will apply fully in Northern Ireland (NI) under the terms of the Windsor Framework. Environmental protection and public health are devolved to Scotland and Wales; Scottish and Welsh Ministers therefore have an interest in the elements of chemicals regulation, such as the GB CLP Regulation, that affect these.
- 12. The GB CLP Regulation is in scope of the UK Chemicals and Pesticides Provisional Common Framework which was developed jointly by the UK Government, DGs, HSE and the Environment Agency. Additionally, in most cases, the exercise of the Secretary of State's functions under the GB CLP Regulation is subject to the consent of the DG Ministers (Scotland and Wales only). Accordingly, the DGs will be consulted with respect to any changes in the GB CLP Regulation.
- 13. In NI, the EU CLP Regulation applies under the terms of the Windsor Framework to enable its dual access to both the UK Internal Market and EU Single Market. CLP is a devolved matter with the Department for Economy being the lead NI department. The Department of Justice has responsibility for CLP solely with regards to explosives for civil use. HSE provides scientific and expert advice on matters relating to CLP issues to the NI departments.

#### LEGAL AND PROCEDURAL ISSUES

14.

## (i)Application under the Windsor Framework

When the proposed amendments in COM(2025)526 are presented in a published EU Act, they 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.

## (ii)EU Legal Base

Article 114 of the Treaty on the Functioning of the European Union provides the legal basis for CLP and the proposed legislative amendments to the Regulation set out inCOM(20

## (iii) Voting Procedure

This legislation will need to be adopted via the ordinary legislative procedure. Therefore, the Council of the European Union will vote by qualified majority.

## (iv) Timetable for Adoption and Implementation

The legislative proposal was adopted by the European Commission on 8 July 2025. The proposed Regulation will enter into force on the twentieth day following its publication in the Official Journal of the European Union, and the proposed amendments will apply from the date set out in Table 1.

### POLICY AND LEGAL IMPLICATIONS

- 15. To accommodate the measures which seek to simplify CLP provisions introduced by amending Regulation (EU) 2024/2865, the application dates of the measures in the amending Regulation need to be deferred.
- 16. Deferring the application date itself will provide businesses with more time to adapt to the changes. However, the overall effect of the simplification package means that those measures will no longer apply, resulting in cost savings for businesses that are regulated under the EU CLP Regulation.
- 17. The deferred date which is to coincide with the removal of certain provisions will result in the harmonisation of EU CLP Regulation• requirements with GB CLP Regulation requirements, therefore mitigating the possibility of any trade friction between GB and Nt. HSE will monitor the passage of the proposals through the EU negotiation process and assess any possible policy impacts of the wider simplification package once EU discussions have concluded.

#### CONSULTATION

- 18. A UK consultation on the proposed Regulation is not required as the Regulation defers the application of certain provisions to a date of revocation under COM(2025)531. This action facilitates the alignment of certain CLP hazard communication provisions within the UK, rendering consultation redundant. Regarding the other amendments of Regulation (EU) 2024/2865, the UK Government continues to consult with stakeholders on the impacts of trade within the UK Internal Market.
- 19. HSE has consulted the DGs and NI when preparing this EM.

#### FINANCIAL IMPLICATIONS

- 20. There are no immediate financial implications associated with the proposals in COM(2025)526. Financial implications for the wider measures are included in the EM prepared by the Department of Work and Pensions on COM(2
- 21 . The UK Government will continue to monitor any impacts on the UK Internal Market.

#### MINISTERIAL NAME AND SIGNATURE

Stephen C. (ims

The Rt. Hon. Sir Stephen Timms MP
Minister of State for Social Security and Disability
DEPARTMENT FOR WORK AND PENSIONS

Z-C 2925

#### Annex A

## PARLIAMENTARY SCRUTINY HISTORY RELEVANT TO PROVISIONS OF THE CLP REGULATION IN SCOPE OF COM(2025)526

1. The classification, labelling and packaging (CLP) provisions to which amended application dates are proposed by COM(2025)526 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. The Department for Work and Pensions (DWP) submitted Explanatory Memorandum (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 DWP 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 DWP 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. The report concluded that the aforementioned Regulation significantly differs, in part, from the content or scope of the instrument which it amends (the CLP Regulation). The Committee was unable to reach a view on whether Regulation (EU) 2024/2865 would have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist.
- 7. 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 (EU) 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.
- 8. 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.