

# PROPOSED REPLACEMENT EU ACT

## INITIAL ASSESSMENT OF IMPACT

Date: 8/9/25

DSC REF: DSC/16a/2025 – Dates of application and transitional provisions - COM(2025)526

### 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 (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 proposals 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.

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 CLP 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 UN GHS of classification and labelling. General requirements of CLP also include supplier obligations concerning the safe and secure packaging of chemicals.

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 and modernisation of the EU chemical sector, seeking to simplify and streamline requirements and procedures of CLP in order to reduce compliance costs and administrative burden for the chemical industry.

### **Department(s) Responsible**

The Department for the Economy (DfE) and the Department of Justice (DoJ) share joint competence for CLP. DoJ's remit only extends to explosives for civil uses.

The Health and Safety Executive (HSE) provides scientific and expert advice to DfE and DoJ on matters relating to CLP under an Agency Agreement.

CLP is enforced by HSENI and local authorities. In specific cases other agencies will provide technical and scientific support, i.e., Environment Agency for cases that involve environmental hazards, and The General Pharmaceutical Council for cases involving pharmacies.

### **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. 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 CLP Regulation.

It does appear likely that not applying the proposed replacement EU act would have a significant impact as NI would be unable to benefit from the deferral and would seek to comply with measures no longer in effect.

### **UK Government Explanatory Memorandum (attached at Annex A)**

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 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 Great Britain (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 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. The EU's explanatory memorandum is attached at Annex B.

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**

Officials in DoJ were consulted during the preparation of the UKG EM for the proposal.