# PUBLISHED REPLACEMENT EU ACT: CLASSIFICATION, LABELLING AND PACKAGING OF SUBSTANCES AND MIXTURES - INITIAL ASSESSMENT OF IMPACT

**DSC Reference:** DSC/22/2024

## Published Replacement EU Act

### Title of Published Replacement EU Act

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

Published 20th November 2024 in Official Journal (OJ L, 2024/2865, 20.11.2024).

Regulation - EU - 2024/2865 - EN - EUR-Lex

### Title of Act to be Replaced

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 (Text with EEA relevance)

Regulation (EC) No 1272/2008 – classification, labelling and packaging of substances and mixtures

## Summary of the Act

### CLP Regulation Background

European Union (EU) Regulation 1272/2008 on Classification, Labelling and Packaging (CLP) of Substances and Mixtures Regulation set uniform requirements for companies to classify, label and package hazardous chemicals appropriately before placing them on the market. Its purpose was to ensure a high level of protection of health and the environment, and the free movement of substances and mixtures within the EU.

#### Classification

CLP requires manufacturers, importers or downstream users to assess whether the substances and mixtures they place on the market have harmful properties. Substances and mixtures are classified in specific hazard classes (type of hazard) and categories (level of hazard), i.e., physicochemical hazard (e.g. flammable liquid), health hazard (e.g. acute toxicity, carcinogenicity), or environmental hazard (e.g. for the ozone layer, aquatic environment).

A classification can be harmonised and applied across the EU. Harmonised classifications typically apply to the most harmful substances e.g., substances that are carcinogenic, mutagenic or toxic to reproduction. EU Member States may propose harmonised classifications that the European Commission (EC) then makes compulsory by law.

Where harmonised classification does not exist, duty holders must assess and classify their substances and mixtures ('self-classification').

Hazard classes are updated periodically (by EU delegated regulations) to reflect updates to the United Nations' Globally Harmonised System (GHS) and the scientific opinion of the European Chemicals Agency (ECHA) Committee for Risk Assessment.

CLP alone does not, restrict, ban or otherwise control the use or supply of that substance or mixture. However, chemical classification is often used as a starting point for other specific controls or protective measures, including restrictions under the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation, the authorisation/approval process within the Biocidal Products Regulation (BPR) and exclusion criteria for Plant Protection Products (PPP).

### Labelling

Once a company classifies a substance or mixture, they must communicate the identified hazards and steps to manage the associated risks to consumers and other actors in the supply chain.

Substances and mixtures must be labelled with the following information:

- supplier identity
- name of the substance or mixture and/or identification number
- nominal quantity of the substance or mixture in the package
- hazard pictograms (graphic designs combining symbols and other visual elements)
- signal words for the level of hazard ('Warning' or 'Danger')
- risk phrases ('Fire or projection hazard', 'Fatal if swallowed', etc.)
- safety advice ('Keep only in original container', 'Protect from moisture', 'Keep out of reach of children', etc.).

Suppliers of hazardous chemical products must also provide information on the composition of hazardous mixtures (detergents, paints, adhesives, etc.) to poison centres for emergency health response.

### Packaging

CLP sets general packaging standards to ensure the safe supply of hazardous substances and mixtures. The packaging of hazardous substances and mixtures must:

- prevent the contents from escaping;
- be made of materials that are resistant when in contact with the contents;
- be strong and solid; and
- have sealable fastenings. Child-resistant fastenings and tactile warnings may be required.

### Classification and Labelling Inventory

The classification and labelling of any REACH registered or hazardous substance for sale must be notified to ECHA for inclusion in its Classification and Labelling (C&L) Inventory.

## **Changes Introduced to CLP by Regulation 2024/2865**

The EC determined that updates were required to CLP to take account of scientific and technological progress and market developments such as online marketplaces and refilling stations for chemicals. The replacement CLP will optimise labelling rules, address gaps in chemical hazards information, and clarify the roles of different involved parties (manufacturers, importers, distributors).

## Identification and Classification of Hazardous Chemicals

EC identified that chemicals and articles which may pose risks to human health or to the environment are not always properly identified and communicated due to inefficiencies in the procedures for assessing and classifying hazards.

Amendments introduced by the updated CLP regulation include:

- Ability for EC to initiate and fund harmonised classification and labelling dossiers
- New obligations on businesses and ECHA to improve the transparency and predictability of classification of substances
- The addition of six new hazard classes to CLP to support the classification of substances and mixtures deemed very harmful for human health or the environment.

The new hazard classes were brought into force on 20 April 2023 by Commission Delegated Regulation 2023/707 and currently apply to substances and mixtures placed on the NI market.

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

## Improving Communication on Chemical Hazards

EC determined that there is a relatively low level of understanding of certain pictograms, labels and warnings, due to the limited readability of labels, detailed information, technical language and often too small font size.

The updated CLP regulation aims to make labelling more consumer friendly, less burdensome for suppliers and easier to enforce by clarifying rules and providing clear exemptions. Changes include:

- Minimum requirements for hazard communication including obligatory formatting rules, such as minimum font size, line spacing and colour, to improve readability of labels.
- Specific rules for selling chemicals with less severe hazards in refillable containers to ensure that this sales method does not lead to increased risks.
- Voluntary digital labelling of chemicals. Information that is not instrumental in the protection of health and the environment could be moved to the digital label without being included on packaging.
- Use of fold-out labels to take advantage of progress in labelling technologies.
- Derogations for chemicals sold to consumers in bulk, such as fuel, or in very small packaging where current labelling rules are sometimes disproportionately expensive or even impossible in practice.

## Addressing Legal Gaps and High Levels of Non-Compliance

Many chemicals entering the EU market from online marketplaces or actors established outside the EU do not meet legal requirements. Incorrectly classified and incorrectly labelled chemicals result in consumers not being properly informed about the hazards, which ultimately leads to incorrect use, storage or disposal.

To better protect consumers, human health and the environment, the updated CLP regulation introduces amendments including:

- New provisions for distance and online sales, including clear responsibilities for all relevant actors will be introduced. All online sales will require a supplier established in the EU to

ensure that a substance or a mixture placed on the EU market through distance sales meets CLP requirements.
- More hazard information would be required in advertisements of hazardous substances and mixtures, including hazard class, pictograms, signal words and hazard statements. Providers of online marketplaces are required to design and organise their online interfaces in a way that enables suppliers to comply with these obligations.
- Obligations for distributors which rebrand or relabel substances and mixtures, or supply those substances and mixtures across borders, to submit relevant information to poison centres for emergency health response.

### Implementation Dates

The majority of provisions apply from 1st July 2026. This includes:

- Requirement for a supplier established in the EU or NI to be identified on the label.
- Additional allowances for use of fold-out and digital labels.
- Requirements for supply or substances or mixtures at refill stations.
- Requirements for display of hazard pictograms, statements, signal words and other relevant safety information on advertisements of hazardous substances and mixtures.
- Requirements for online sales and distance sales.
- Amendments to notifications to ECHA and information provided by C&L Inventory.
- Outline of additional data sources to be reviewed when determining physical, health or environmental hazards.
- Requirement for the supplier of subs/mixes to update labels within 6 months where their substances or mixtures meet a new or more severe hazard classification. Other changes require labels to be updated within 18 months.

Remaining provisions apply from 1st January 2027:

- Amendments to poison centre notifications.
- New label formatting requirements.

### Application of CLP in Northern Ireland

The CLP regulation is included in Annex 2 of the Windsor Framework (WF). Subject to democratic scrutiny processes, the replacement CLP act will apply to Northern Ireland (NI) under WF Article 13(3). NI-based businesses manufacturing or importing chemical substances or mixtures (including movements of goods into NI from Great Britain (GB)) must therefore fulfil CLP requirements.

In GB the EU CLP Regulation is retained, with amendments, in GB law as GB CLP. GB can make amendments to GB CLP independently of the EU.

NI based businesses maintain unfettered access to supply chemicals directly to GB, provided they are supplying qualifying NI goods, and the chemicals comply with GB CLP requirements.

## 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 HSE 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 Department for Health for cases involving pharmacies.

## Initial Assessment of Impact

### Cost Impact

Impact assessments by the Department for Work and Pensions (DWP) and the EC both recognise that amendments to CLP will lead to increased costs for businesses placing chemicals on the EU and NI market, primarily due to new labelling requirements. Initial costs of compliance will be higher in relative terms for Small and Medium-sized Enterprises (SMEs)

However, both assessments outline available mitigations to reduce relabelling costs, and potential longer-term cost savings due to simplified classification processes, labelling derogations and allowances for fold-out and digital labelling.

Overall costs to NI-based chemicals suppliers may also be offset by wider society cost savings to public health systems and depollution schemes.

### Trade Impact

New CLP requirements, particularly the obligation for non-EU/NI chemical suppliers to be established in the EU/NI, may cause some non-EU/NI-based businesses (including those based in GB) to withdraw from supplying EU/NI markets and disrupt supply chains.

NI-based businesses supplying to GB will be in scope of the United Kingdom (UK) Internal Market Act and can continue moving qualifying chemicals products to GB.

### GB/NI Divergence

Currently the EU and GB CLP regulations are broadly aligned. If EU CLP amendments are adopted, the extent of the impact on GB/NI divergence will depend on the position adopted by the UK Government (UKG) on CLP. UKG continues to assess the amendments to CLP to understand the scientific and technical basis and compatibility with wider government policy which may support the incorporation of similar measures into GB CLP.

UKG has confirmed that there are no plans to establish the new CLP hazard classes introduced by the EU into GB CLP without consensus with the UN GHS. The hazard classes added to CLP have applied in NI since April 2023.

## UK Government Explanatory Memorandum

DWP produced an Explanatory Memorandum (EM) in February 2023. Officials in DfE, DoJ, and HSENI were consulted in the preparation of the EM.

DWP are currently drafting an updated EM, which will set out the UK Government position on the updated CLP regulation. The EM will be submitted to the HSE Minister in DWP in early December.

HSE officials have shared initial analysis from the updated EM, which is summarised below, along with a full summary of the February 2023 EM (Annex A).

## Summary of Draft 2024 EM

Amendments to CLP will place a number of mandatory obligations on NI-based businesses.

Changes aimed at improving hazard communication will require non-compliant labels to be revised. Labelling rules for readability such as minimum font size, line spacing and colour will result in increased costs for duty holders to redesign and relabel products, which may lead to temporary gaps in supply. However, some of the associated costs could potentially be mitigated through alignment with existing re-labelling periods.

A 6-month deadline for updating labels is to be imposed and will apply when the classification and labelling of a hazardous chemical is changed to include a new or more severe hazard class. The deadline may cause some NI-based businesses to incur additional costs to bring product labels into compliance within a potentially shorter timeframe and may lead to temporary gaps in supply. However, businesses may be able to mitigate potential costs should any changes in classification and labelling overlap with product relabelling for other reasons (such as marketing) which is thought to occur every 18 months.

Amendments to the supply of less hazardous chemicals via refill will introduce new hazard communication and risk management requirements on suppliers and is expected to give rise to significant costs for suppliers implementing risk management measures, including:

- minimising human exposure and uncontrolled use by children;
- providing immediate assistance when operating refill stations outdoors;
- ensuring staff are sufficiently trained; and,
- providing labels for the hazardous chemicals supplied.

This may introduce ongoing additional costs for refill suppliers and in cases where compliance with the amendments proves unviable, may ultimately restrict supply in applicable markets including NI. The scale of effects in NI of the amended rules and conditions for refilling will depend on the maturity of the circular economy and existing modes of refill (self-service etc.).

The mandatory obligation to submit emergency heath response information to poison centres will also apply to certain distributors including re-labellers and re-branders to avoid information loss. There are likely to be adverse resource implications arising from familiarisation and compliance for NI-based businesses to whom such requirements may apply.

Other amendments in relation to hazard communication are expected to have minimal adverse impact on NI businesses, as they can be applied on a voluntary basis. Voluntary digital labelling can be used for non-obligatory information, which may allow for enhanced hazard communication as duty holders can present the information in a more accessible way. The advantages of the new digital labelling framework may be of increased significance in an EU context, where its citizens communicate in 24 official languages and approximately 60 regional and minority languages, and so multilingual labelling can be provided for. Limited financial impacts will only be incurred by duty holders who include such features on their labels. Additionally, the broader use of fold-out labels will provide duty holders with more flexibility to fit information on labels to make them more understandable for users of chemicals, which could reduce administrative burdens without lowering safety levels.

To support compliance, a supplier established in the EU/NI will be required when that chemical is placed on the market. This requirement will likely cause non-EU/NI-based businesses (including GB) to incur ongoing compliance costs arising from the extension of business operations to EU/NI or the

employment of a third party to undertake compliance activity. Some exporters to EU/NI may consequently withdraw from supplying the EU/NI markets causing downstream supply chain disruption. NI-based businesses supplying to GB will be in scope of the UK Internal Market Act and therefore, will not have to comply with this requirement.

CLP amendments also require more hazard information to be included in advertisements and distance sales offers of chemicals. The cost incurred by businesses supplying the EU/NI markets may be offset if the transition period for compliance overlaps with the updating of advertisements and sales offers for other reasons, which is thought to occur frequently. However, the frequency of updates may vary depending on the type of advertisement and product sold. Additional obligations in relation to advertisements and sales offers are not expected to limit supply to NI.

## Summary of February 2023 EM

### Implications of Revised CLP on NI businesses

NI-based businesses will be required to comply with amendments on hazard communication, including new label formatting rules. Non-compliant labels will have to be revised. The application of digital labelling is voluntarily, and as this is not obligatory, it should have minimal impact on NI businesses.

NI businesses will be required to comply with changes to the regulation of the sale of chemicals at refill stations, which may bring about changes to labelling and packaging, such as dispensers.

NI-based businesses will be required to apply the CLP Regulation when making online sales; full labelling requirements will have to be displayed when advertising a substance or mixture classified as hazardous. This is intended to improve the regulation of distance sales in the single market by non-EU traders; there may be some minor impacts on NI supply chains.

Additional obligations will fall on NI businesses, including the requirement to notify ECHA of any intention to submit a proposal for harmonised classification and labelling under the CLP Regulation. Furthermore, distributors of hazardous substances and mixtures will be obligated to submit information relating to emergency health response to prevent loss of information where there has been relabelling and rebranding. However, information shared by importers and downstream users can be used. There are additional minor amendments on top of this which seek to reduce ambiguities and provide clarity on applying the CLP Regulation.

Under CLP, NI-based businesses who import substances or mixtures have a legal obligation, to ensure their substances and mixtures are compliant. Where supply chains to NI from GB exist, HSE encourages GB-based suppliers and NI-based businesses through a number of channels to cooperate to meet classification and labelling requirements by sharing any necessary information, evidence or data wherever possible and where business contracts permit.

An approximate estimate of the total administrative annual costs for NI-based suppliers amount to £88,000 per annum which will largely arise from the relabelling of packaging for affected substances or mixtures when they are placed on the NI or EU market; or imported from a non-EU state. Initial relabelling costs may be minimised by virtue of the implementation period, which will allow a period within which businesses in some sectors relabel their goods for marketing purposes. The average period is usually 18-months, however, compliance of the labelling requirements for the new hazard classes under the delegated act will be further deferred to help avoid additional burden on suppliers.

### Implications of the New Hazard Classes

NI businesses are required to consider the new hazard classes and criteria introduced in April 2023. This will result in a cost of training and familiarisation for competent persons to accurately classify the hazards in accordance with the new CLP Regulation and may result in differences in labelling requirements between GB and NI markets for the affected substances.

A deferred application of the new classification and labelling requirements for the new hazard classes is currently in place.

### Implications of CLP on GB and NI Trade

The practical implications of regulatory divergence will depend on the direction of supply (GB to Northern Ireland / Northern Ireland to GB) and the final destination of the substances and mixtures. Businesses supplying to either market must comply with the regulatory requirements of that market. However, provided a compliant CLP hazard label appears on supplied substances and mixtures in each jurisdiction, CLP does not introduce any hindrance to that supply.

Some GB-based businesses may become dissuaded from engaging with the NI market when faced by regulatory barriers, in particular, if policies in GB move in a different direction while NI options are constrained by the Windsor Framework.

Due to NIs unfettered access to the rest of the UK market, substances that meet the technical requirements to be placed on the NI market will be able to be placed on the GB market as long the NI trader completes an online notification to confirm the hazard classification of its chemical(s). Additionally, businesses seeking to change the name of their chemical would be required to notify the UK regulator and complete the process, which is free of charge, to make sure the UK regulator is aware of the chemicals on the GB market.

### Benefits

The overall costs of the legislative package to NI-based suppliers will be offset by the savings to public health systems and depollution schemes which could amount to more than a total of £1.12m per annum. The benefits stem mainly from improvement of the protection of health and the environment.

Some amendments may result in a cost reduction 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.

## Analysis by the European Commission on its Impact Assessment

The EC provided an Impact Assessment Summary (Annex B). A full package of impact assessments and consultation responses can be viewed at - European Commission Impact Assessment of EU CLP Revision. The assessments do not mention NI or NI stakeholder input.

### Environmental and Health Benefits

The EC impact assessment observed that benefits of the amendments mainly related to improvements to protection of health and the environment. The benefits included:

- Improved communication on chemical hazards will support consumers supported to make informed choices and avoid unnecessary risks to health or the environment.
- Changes to classification would support chemicals suppliers, users and public authorities to take measures to manage chemicals risks.
- Closing legal gaps related to online sales and poison centres will support compliance and ultimately lead to better implementation and easier enforcement.
- Savings to public health systems and depollution schemes could amount to more than €300 million per year.
- No significant additional cost to national budgets.

Impacts to Business

- Significant costs for industry actors placing chemicals on the EU market, estimated at €28.47 million annually for administrative costs to comply with the new rules.
- Adjustment costs of €26.40 million across the supply chain for voluntary substitution of substances covered by the new hazard classes.
- Costs for SMEs will be higher in relative terms, as they benefit less from economies of scale and have less capacity to absorb fixed costs.

The EC impact assessment also notes potential benefits to businesses, including:

- New responsibilities for economic actors involved in distance sales, including online sales, from outside or inside the EU will ensure fair and equal competition among all businesses selling chemicals, especially for SMEs who sell mainly within the EU and rely on online platforms to trade their products.
- Measures to simplify classification of identical substances manufactured by different companies will reduce the need for businesses to classify their own substances. This will reduce costs, in particular for SMEs, level the playing field and contribute to fair competition.
- Simplified labelling rules will save costs for some businesses.
- The introduction of new hazard classes, while increasing costs on the short term, will translate into the EU industry being the global front-runner in health and environmental standards, driving the EU industry's leadership in producing and using sustainable chemicals, and thereby allowing it to increase its competitiveness and global market share.

## Departmental Engagement

DfE officials have held monthly meetings with HSE CLP leads throughout the revised EU CLP regulations legislative process. These discussions have focused on assessing potential impacts of the amendments on NI and the potential for divergence if EU and GB CLP requirements move further apart.

DfE also engage ad-hoc with colleagues in HSENI and DoJ on CLP.

## ANNEX A – UK GOVERNMENT EXPLANATORY MEMORANDUM

# EXPLANATORY MEMORANDUM FOR EUROPEAN UNION LEGISLATION WITHIN THE SCOPE OF THE UK/EU WITHDRAWAL AGREEMENT AND NORTHERN IRELAND PROTOCOL 16258/22, COM(22)748 + Adds 1-8

### 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

Add 1: SWD)22)434: Subsidiarity Grid

Add 2: SWD(22)436: Executive Summary of the Impact Assessment Report

Add 3: SWD(22)435: Impact Assessment Report Part 1

Add 4: SWD(22)435: Impact Assessment Report Part 2

Add 5: SWD(22)435: Impact Assessment Report Part 3

Add 6: SWD(22)435: Impact Assessment Report Part 4

Add 7: SWD(22)435: Impact Assessment Report Part 5

Add 8: SEC(22)452: Regulatory Scrutiny Board Opinion

### C(2022) 9383 + Annex

### 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

Submitted by the Department for Work and Pensions on 1 February 2023.

## SUBJECT MATTER

1. This Explanatory Memorandum (EM) relates to the proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures ('EU CLP Regulation'), published on 19 December 2022. This proposal (the "Commission proposal") will make significant changes to the EU CLP Regulation.

2. This EM also covers a Commission Delegated Regulation (EU) of 19.12.2022 ("the delegated act") which introduces new hazard classes and criteria for classifying substances and mixtures.

3. The purpose of the Commission proposal and delegated act is to improve the EU Single Market for chemicals by addressing weaknesses or gaps in the EU CLP Regulation that prevent consumers, businesses and regulatory authorities from fully benefiting from protection against the dangers posed by hazardous chemicals.

4. The EU CLP Regulation is a directly applicable European Union (EU) Regulation that has applied to the supply of chemicals (substances and mixtures) in the EU and European Economic Area (EEA) since January 2009.

5. The Northern Ireland Protocol ("NI Protocol") provides that limited areas of EU law will continue to apply to, and in, the UK in respect of Northern Ireland. Article 5(4) states that provisions of Union law listed in Annex 2 to the NI Protocol shall continue to apply in respect of Northern Ireland. The EU CLP Regulation is listed in Annex 2 under paragraph 23.

*Background to the EU CLP Regulation*

6. The EU CLP Regulation requires EU/EEA and Northern Ireland (NI)based suppliers 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 EU/EEA/NI market. These requirements apply throughout the EU/EEA/NI 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 United Nations Globally Harmonized System of classification and labelling of chemicals (UN GHS) provides a voluntary framework for harmonized hazard communication, to protect human health and the environment, and to facilitate trade.

7. Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures ('EU CLP Regulation') also contains list of substances with harmonised classifications that are mandatory to use when classifying and labelling substances and mixtures. Where no harmonised classification exists, actors in the EU supply chain must self-classify and label substances and mixtures in accordance with the EU CLP Regulation.

*The proposed new hazard classes introduced by the delegated act*

8. The Commission adopted a delegated act in December 2022 to introduce six new hazard classes under the EU CLP Regulation. The proposed new hazard classes are:

- endocrine disrupting ('ED') (one for human health and one for the environment);
- persistent, bioaccumulative and toxic ('PBT');
- very persistent and very bioaccumulative ('vPvB');
- persistent, mobile and toxic ('PMT'); and
- very persistent and very mobile ('vPvM').

The delegated act will add new definitions and scientific and technical criteria to classify substances and mixtures.

9. The established convention for introducing new hazard classes is to first propose they are introduced into a biennium work programme at the UN GHS where they will be considered, assessed and, if agreed in that forum, added into a revised update (an edition) of UN GHS. The published biennium edition is then typically considered by countries and jurisdictions and adopted into international or national domestic chemicals regulations (in the EU, EU CLP, and in GB, the Great Britain Classification Labelling and Packaging Regulation ('GB CLP')). The EU is introducing new hazard classes directly into the EU CLP Regulation via a delegated act prior to pursuing agreement at the UN GHS level.

*The Government's initial assessment of the merits or otherwise of these proposals*

10. The UK has no plans to establish similar hazard classes into the GB CLP Regulation without consensus at UN GHS and will consider its position and feed into discussions at UN GHS in the first instance. The changes to the EU CLP Regulation are intended to increase protection of human health and the environment within the EU but as non-tariff technical barriers to trade, the changes could have an impact on exports and international trade for some years to come until similar or equivalent UN GHS criteria are developed and adopted. However, it is also important to note that it is not certain that following due consideration by the UN GHS Sub-Committee that any of the EU new hazard classes would be introduced into the UN GHS.

*Proposed changes in the Commission proposal*

11. These include:

- **more comprehensive identification and classification of chemical hazards** by improving the efficiency and effectiveness of the EU CLP Regulation's harmonised classification process and strengthening incentives and provisions for duty holders to appropriately classify substances;
- **improved hazard communication** by introducing obligatory labelling rules for readability such as minimum font size and colour; greater use of fold-out labels; a new framework for the sale of chemicals in refillable containers; simplified rules and additional derogations for chemicals sold to consumers in bulk, such as fuel, and in very small packaging; and voluntary digital labelling of chemicals; and
- **addressing legal gaps and ambiguities** in relation to distance sales, including online sales, and extending the requirement to notify hazard information on mixtures to poison centres to include distributors placing chemicals on the market across borders or rebranding/relabelling mixtures.

*The Government's initial assessment of the merits or otherwise of the proposals*

12. The UK will be assessing whether these changes might offer potential opportunities as part of consideration of potential future reforms to the Great Britain Classification Labelling and Packaging Regulation ('GB CLP Regulation').

## SCRUTINY HISTORY

13. The Parliamentary Scrutiny history relevant to this Explanatory Memorandum is contained in **Annex A**.

## MINISTERIAL RESPONSIBILITY

14. The Minister for Social Mobility, Youth and Progression advised by the Health and Safety Executive (HSE), has the main responsibility for policy questions arising from this document.

15. HSE has lead responsibility across Government for classification and labelling of chemicals, including the implementation of the United Nations Globally Harmonized System of classification and labelling of chemicals (UN GHS). This responsibility is exercised in consultation with other interested departments, agencies, and the devolved administrations.

## INTEREST OF THE DEVOLVED ADMINISTRATIONS

16. The Commission proposal and the delegated act will not apply in GB but will be implemented directly in Northern Ireland under the Northern Ireland Protocol.

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

18. Accordingly, Scottish and Welsh Ministers have an interest in the environmental protection and public health aspects of chemicals legislation such as the retained 'GB' CLP Regulation as these areas are devolved and, in most cases, the exercise of the Secretary of State's functions under the retained GB CLP Regulation are subject to the consent of the devolved Ministers.

19. The GB CLP Regulation is covered under the UK Chemicals and Pesticides Provisional Common Framework, developed jointly by the UK Government, Devolved Governments, the Health and Safety Executive 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.

20. In circumstances where proposals for changes in GB are not possible in Northern Ireland the Common Framework should allow for Northern Ireland to participate in discussions, and the views of the Northern Ireland Executive should be taken into account in reaching a decision for GB. The GB administrations will consider how to address any issues raised by the Northern Ireland Executive, including potentially modifying their proposals to mitigate any negative impacts that may have been identified.

21. In Northern Ireland, the responsibilities for occupational health and safety, environmental protection, public health, and the safety of civil explosives are transferred under the devolution settlements.

22. The Northern Ireland Executive and its Ministers have a particular interest in this delegated act because it will impact on Northern Ireland directly by virtue of the UK/EU

Withdrawal Agreement and the NI Protocol. Officials in the Department for Economy, the Department of Justice, HSE Northern Ireland (HSE NI) have been consulted in the preparation of this EM. Other Northern Ireland Executive departments such as the Department of Agriculture, Environment and Rural Affairs (DAERA), have been made aware of the EM and the Commission proposal.

23. Scottish Ministers and Welsh Ministers also have an interest in the delegated act and officials have been consulted in the preparation of this Explanatory Memorandum (EM).

## LEGAL AND PROCEDURAL ISSUES

24. Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures ('EU CLP Regulation') (Regulation (EC) No 1272/2008) is made under Article 114 of the Treaty on the Functioning of the European Union (TFEU).

### Legal Base (Commission proposal)

25. The legal base for the Commission proposal is Article 114 of the TFEU. This proposal also includes amendments to Articles 23, 25 and 29 as well as to Annexes I, II, III, VIII for which the Commission is empowered under Article 53(1) of the CLP Regulation, to adopt delegated acts in order to adapt them to technical and scientific progress.

### Voting Procedure (Commission proposal)

26. As the EU CLP Regulation has been adopted by co-decision, its revision needs to be adopted by ordinary legislative procedure as a directly applicable and binding EU Regulation. While the Annexes to the EU CLP Regulation have been amended several times before to adapt to scientific and technical progress, the Commission proposal is a targeted revision of enacting terms and, where relevant, the related Annexes.

## Timetable for adoption and implementation (Commission proposal)

27. The Commission proposal was published on 19 December 2022. The Commission also began a new eight-week consultation on 20 December on the final proposal and will summarise the comments and present them to the European Parliament and Council as they scrutinise the proposals under the ordinary legislative procedure ahead of potential formal adoption of the Commission proposal in 2023.

## Legal Base (delegated act)

28. The legal base for the delegated act is Article 53(1) of the EU CLP Regulation which empowers the Commission to amend the EU CLP Regulation by delegated acts to reflect technical and scientific progress. The procedure that the Commission is required to follow for the delegated act is set out in Article 53a. Article 3 sets out the obligation to classify under respective hazard classes in Annex I.

## Voting Procedure and Timetable for adoption and implementation (delegated act)

29. The EU Commission proposed delegated act will enter into force on the twentieth day following its publication in the Official Journal of the European Union. The European Parliament and Council have been notified. There is an objection period of two months which may be extended by two months by the European Parliament or Council. If no objection is raised, the delegated act will be published in the Official Journal and enter into force. This is likely to be in summer 2023.

## Other legal and procedural issues

30. Some Member States and EU industry bodies have expressed concerns that the Commission's approach to bring new hazard classes into the EU CLP Regulation before they have been agreed upon and introduced at UN level is contrary to what is stated in recital 75 of the EU CLP Regulation: *"subject to developments at UN level, the classification and labelling of PBT and vPvB substances should be included in this Regulation at a later stage".*

**Does the proposal affect the substance of EU law that will remain in effect under the NI Protocol or is it likely to be the subject of a request by the EU to be added to the NI Protocol under Article 13(4) thereof?**

31. The Northern Ireland Protocol (NI Protocol) provides that limited areas of EU law will continue to apply to and in, the UK in respect of Northern Ireland. Article 5(4) states that provisions of Union law listed in Annex 2 to the NI Protocol shall continue to apply in respect of Northern Ireland. Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures ('EU CLP Regulation') is listed in Annex 2 under paragraph 23. Article 13(3) of the NI Protocol confirms that reference to Union legislation in the NI Protocol is a reference to that legislation as amended or replaced. Once the EU CLP Regulation is amended, it will apply in Northern Ireland by operation of Article 13(3).

## POLICY IMPLICATIONS

*Implications for the application of EU law under the NI Protocol*

32. The Commission proposal and delegated act will apply in Northern Ireland under the terms of the NI Protocol. This is subject to further developments under the Northern Ireland Protocol Bill or, as is the Government's preference, through negotiations with the EU.

*Domestic UK approach to the policy and whether vital national interests are at stake*

33. The adoption and establishment of six new hazard classes into the EU CLP Regulation, without first gaining agreement at the United Nations Globally Harmonized System of classification and labelling of chemicals (UN GHS), is a significant break with the established international convention. This will result in not only greater divergence between the Great Britain Classification Labelling and Packaging Regulation ('GB CLP Regulation') and EU CLP systems but greater differences between the EU CLP Regulation and other countries and jurisdictions that adopt UN GHS. This works against an underlying principle of UN GHS to harmonise regulations at a global level and to facilitate trade.

34. GB now has its own stand-alone GB CLP Regulation; the government will be considering the other amendments in the Commission proposal and the delegated act as part of consideration of potential future reforms to the GB CLP Regulation.

35. The new hazard classes and proposed additional amendments will not be automatically added into the GB CLP Regulation because delegated acts relating to directly acting EU Regulations no longer apply in GB following the UK leaving the EU and the end of the transition period.

*Implications for GB-based and Northern Ireland (NI-based businesses)*

36. The new hazard classes will be added to the list of hazards that normally trigger harmonised classification and labelling in the EU. Northern Ireland (NI)-based businesses will be required to classify and label substances placed on the EU Single Market considering the new hazard classes and criteria where they apply.

37. Where there is no harmonised classification and labelling, NI-based businesses will be required to evaluate and self-classify substances and mixtures criteria for the new hazard classes in EU CLP before they can be placed on the EU Single Market. The introduction of new hazard classes that must be considered when classifying substances and mixtures will result in a cost of training and familiarisation for competent persons to accurately classify the hazards in accordance with the new EU CLP Regulation hazard classes and further obligations set out in the Commission proposal.

38. There will be some differences in labelling requirements between GB and Northern Ireland markets for the affected substances after the Commission proposal and the delegated act takes effect.

39. Article 37 of the EU CLP Regulation will be amended to allow a further deferred application of the new classification and labelling requirements for the new hazard classes. Substances and mixtures already placed on the market before the end of that deferral period, may continue to be placed on the market without applying the new requirements for an additional deferred period of time depending on the hazard class. Additional transitional provisions allow application of the new requirements at an earlier stage on a voluntary basis.

40. There have been a number of amendments proposed on hazard communication. Northern Ireland (NI)-based businesses will be required to comply with new formatting rules which have been proposed; therefore, non-compliant labels will have to be revised. NI-based businesses will have the opportunity to voluntarily apply digital labelling by applying the newly proposed framework; as this is not obligatory, it should have minimal impact on NI businesses. Another framework has been proposed with changes to the regulation of the sale of chemicals (such as, but not limited to, detergents) at refill stations. NI-businesses will be required to comply with this, which may bring about changes to labelling and packaging, such as dispensers.

41. NI-based businesses will be required to apply Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of

substances and mixtures ('EU CLP Regulation') when making online sales; full labelling requirements will have to be displayed when advertising a substance or mixture classified as hazardous. This is intended to improve the regulation of distance sales in the single market by non-EU traders; there may be some minor impacts on NI supply chains.

42. Amendments to change hazard communication and to address legal gaps and ambiguities of existing EU CLP Regulation provisions have been drafted in the context of the EU Single Market and thus, are largely beneficial to suppliers operating within this framework. For example, the advantages of the proposed voluntary provisions for multilingual digital labelling will be of increased significance in an EU context, where its citizens communicate in 24 official languages and approximately 60 regional and minority languages.

43. Additional obligations will fall on NI businesses, including the requirement to notify the European Chemicals Agency (ECHA) of any intention to submit a proposal for harmonised classification and labelling under the EU CLP Regulation. Furthermore, distributors of hazardous substances and mixtures will be obligated to submit information relating to emergency health response to prevent loss of information where there has been relabelling and rebranding. However, information shared by importers and downstream users can be used. There are additional minor amendments on top of this which seek to reduce ambiguities and provide clarity on applying the EU CLP Regulation.

44. Importers have a legal obligation to ensure their substances and mixtures are compliant with EU CLP Regulation requirements. Therefore, it is NIbased businesses who import substances or mixtures that have a legal obligation, rather than GB-based suppliers. However, where supply chains from GB to Northern Ireland exist, HSE, as the GB Classification Labelling and Packaging Agency, encourages GB-based suppliers and NI-based businesses through a number of channels including website guidance, e-bulletins and stakeholder engagement presentations, to cooperate to meet classification and labelling requirements by sharing any necessary information, evidence or data wherever possible and where business contracts permit.

*Practical implications of this delegated act for regulatory divergence between Great Britain and Northern Ireland and for movement of such products between them*

45. The practical implications of regulatory divergence will depend on the direction of supply (GB to Northern Ireland / Northern Ireland to GB) and the final destination of the substances and mixtures. Divergence between
the Great Britain Classification Labelling and Packaging Regulation ('GB CLP Regulation') and EU CLP Regulations has occurred since the UK's withdrawal from the EU and the end of the implementation period but will be exacerbated by the EU's establishment of new hazard classes and where harmonised classifications have been amended to include the new hazard classes. Businesses supplying to either market must comply with the regulatory requirements of that market. However, provided a compliant CLP hazard label appears on supplied substances and mixtures in each jurisdiction, CLP does not introduce any hindrance to that supply.

46. The effects of the Northern Ireland Protocol (NI Protocol), and the primacy of European Union law in that territory, establish two distinct regulatory CLP regimes; one in GB, the other in the EU single market and Northern Ireland. Some GB-based businesses may

become dissuaded from engaging with the Northern Ireland market when faced by regulatory barriers in particular, if policies in England, Scotland or Wales move in a different direction while Northern Ireland's options are constrained by the NI Protocol.

47. 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). Additionally, businesses seeking to change the name of their chemical would be required to notify the UK regulator and complete the process, which is free of charge, to make sure the UK regulator is aware of the chemicals on the GB market.

48. It should be noted that the Government's overriding priority is preserving political stability in Northern Ireland. The situation as it stands with the NI Protocol is undermining the balance established by the Belfast (Good Friday) Agreement and power sharing and with it, political stability in Northern Ireland. It is the Government's preference to resolve this through talks and the Government is engaging in constructive dialogue with the EU to find solutions to these problems. However, the Northern Ireland Protocol Bill will fix the practical problems the NI Protocol has created in Northern Ireland, if the Government cannot find a solution with the EU.

*The impact, if any, of the proposal for Northern Ireland's participation in UK Free Trade Agreement*

49. International Trade policy is an area of reserved competence for the UK Government. Free Trade Agreement requirements will need to take account of the UK's existing obligations under the NI Protocol as UK Free Trade Agreements will continue to apply to Northern Ireland.

50. It is likely that the introduction of new hazard classes unilaterally by the EU without agreement at United Nations Globally Harmonized System of classification and labelling of chemicals (UN GHS) will have a significant impact on trade and the ability of companies outside the EU to access the EU Single Market. The need to comply with them could be seen as offering a competitive advantage in the market to companies in the EU (who need to comply with EU legal requirements to place their products on the market) in relation to accessing the EU Single Market over countries outside of the EU.

## CONSULTATION

51. There has been no formal public consultation by the Health and Safety Executive (HSE) of key external stakeholders on the impact of this Commission proposal and delegated act because this relates to a directly applicable EU Regulation and delegated act that will not apply in GB as a result of the UK's withdrawal from the EU but will apply automatically in Northern Ireland by virtue of the UK/EU Withdrawal Agreement and NI Protocol.

52. Officials from the Northern Ireland Department for Economy (DfE) and Department of Justice (DoJ) have an interest in this proposal as it falls within the scope of the Protocol on Ireland/Northern Ireland. As the proposal may affect multiple policy areas of relevance

for DfE and DoJ and may have impacts on downstream legislation, more time is required to analyse the proposal. Policy officials are liaising with their UK Government policy counterparts to determine what action is required and what possible impacts the proposal may have. Input has been provided at official level and does not represent the views of Northern Ireland Executive Ministers.

53. There was no direct UK Government engagement with the Commission proposal and delegated act in line with UK Government policy. However, HSE UN GHS and GB CLP Regulation policy officials met with the Commission's UN GHS delegation in two bilateral meetings on 26th July 2022 and 30th November 2022 to discuss the draft proposal for the establishment of a new informal working group at the United Nations Globally Harmonized System of classification and labelling of chemicals (UN GHS), prior to the 43rd UN GHS meeting in December 2022.

54. The Health and Safety Executive (HSE) consulted officials in Scotland and Wales on this Commission proposal and delegated act. Officials have previously expressed their interest to be kept informed about substances going through the Great Britain Mandatory Classification and Labelling system.

## FINANCIAL IMPLICATIONS

55. The Commission has carried out an impact assessment for the Commission proposal estimating direct and indirect savings across the EU, of €57.5 million per year for the next 10 years. Amongst the quantified savings, the simplification of the labelling rules would generate more than €39,5 millions of savings per year for the chemical industry. In addition, the impact assessment identified other benefits from a reduced exposure of humans and of the environment to hazardous substances.

56. There will be significant costs for industry actors placing chemicals on the EU market, both administrative annual costs for compliance with the new rules (€28.47 million for the next 10 years) and adjustment costs for voluntary substitution down the supply chain for substances which would be identified as hazardous according to the new hazard classes (€46.04 million for the next 10 years).

57. The UK has not carried out a regulatory impact assessment of the impacts of the proposal because it will not apply in Great Britain but has provisionally estimated the costs of the Commission proposal on NI-based suppliers using information from the summary of the impact assessment by the Commission. It is not possible to fully assess the financial implications of the EU's proposals at this stage as this will depend on the final shape of the legislation and its application to Northern Ireland. However, costs for small and medium-sized enterprises will be higher in relative terms, as they benefit less from economies of scale and have less capacity to absorb fixed costs.

58. An approximate estimate of the total administrative annual costs for NIbased suppliers amount to £88,000 per annum which will largely arise from the relabelling of packaging for affected substances or mixtures when they are placed on the market (internally within Northern Ireland or the EU Single Market); or imported from a non-EU state. Initial relabelling costs may be minimised by virtue of the implementation period (following the

delegated act's entry into force date), which will allow a period within which businesses in some sectors relabel their goods for marketing purposes. The average period is usually 18-months, however, compliance of the labelling requirements for the new hazard classes under the delegated act will be further deferred to help avoid additional burden on suppliers.

59. Familiarisation costs 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. Adjustment costs for voluntary substitution down the supply chain for substances in Northern Ireland which will be covered by new hazard classes costs are approximately a total of £82,000 per annum if applied.

60. Costs arising from the delegated act may occur where supply chains exist between GB and the EU/Northern Ireland. In such cases, relabelling costs may be borne by actors in the supply chain at the point of import, where necessary to comply with Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures ('EU CLP Regulation') or the Great Britain Classification Labelling and Packaging Regulation ('GB CLP Regulation').

61. The overall costs of the legislative package to Northern Ireland (NI)based suppliers will be offset by the savings to public health systems and depollution schemes which could amount to more than a total of £1.12m per annum. The benefits stem mainly from improvement of the protection of health and the environment. The package would strongly contribute to achieving the EU's ambition embedded in the European Green Deal and the Chemicals Strategy for Sustainability in terms of moving toward a toxic free environment, as well as to supporting the green and digital transition of industry, as defined in the Industrial Strategy.

62. Some proposals within the Commission proposal may result in a cost reduction 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 Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures ('EU CLP Regulation') compliance costs. Moreover, the proposed 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.

**MIMS DAVIES**

**Minister for Social Mobility, Youth and Progression Department for Work and Pensions**

**[1] Section 13A of the EU (Withdrawal) Act 2018, as inserted by section 29 of the European Union (Withdrawal Agreement) Act 2020**

## ANNEX B – EUROPEAN COMMISSION IMPACT ASSESSMENT

EUROPEAN
COMMISSION

Brussels, 19.12.2022
SWD(2022) 436 final

**COMMISSION STAFF WORKING DOCUMENT**

**EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT REPORT**

***Accompanying the document***

# Proposal for a Regulation of the European Parliament and of the Council

**amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures**

{COM(2022) 748 final} - {SEC(2022) 452 final} - {SWD(2022) 434 final} - {SWD(2022) 435 final}

**A. Need for action**

**What is the problem and why is it a problem at EU level?**

The problem addressed by the initiative is that the current version of the CLP Regulation insufficiently protects humans and the environment from intrinsic hazards of certain chemicals moving freely within the EU's single market. This problem manifests itself in three areas:

1. Hazardous chemicals are not comprehensively identified and classified. That is true in particular for chemicals that have endocrine disrupting ('ED'), persistent, bioaccumulative and toxic ('PBT'), very persistent and very bioaccumulative ('vPvB'), persistent, mobile and toxic ('PMT'), or very persistent and very mobile ('vPvM') properties, since there is currently no duty to systematically examine and classify such properties.
2. Member State Competent Authorities and the European Chemicals Agency ('ECHA') operate on the limit of their resources to prepare proposals (in the case of Member State Competent Authorities) and Opinions (in the case of ECHA) for harmonised classification and labelling of substances. As a consequence, they do not have the optimal tools to implement homogenous risk management measures for all hazardous chemicals. It also risks fragmenting the single market and un-levelling the playing field for companies operating on it.
3. The communication on chemical hazards is sub-optimal, which results in a lack of knowledge on hazardous properties of chemicals. This leads to a situation where consumers and businesses cannot base their purchase decisions on robust knowledge that enables them to minimise environmental and health risks, leading to potential exposure of consumers, workers and the environment to unnecessary risks. There is a high level of non-compliance with the CLP obligations in the context of e-commerce Information on hazardous mixtures submitted to poison centres for their emergency health response is insufficient in certain cases.

**What should be achieved?**

The three main objectives are:

1. To ensure that critically hazardous chemicals, including those with ED, PBT, vPvB, PMT and vPvM properties, are classified adequately and homogenously throughout the EU;
2. To make chemical hazard communication simpler for economic operators and more accessible and understandable for users of chemicals; and
3. To make sure that the rules on chemicals hazard classification and communication are applied equally by all relevant actors in the supply chain.

**What is the value added of action at the EU level (subsidiarity)?**

Action at EU level is crucial to preserve free movement of chemicals on the single market.

Different actions at national level would impose additional administrative burdens on large operators and SMEs, obstructing free movement. Furthermore, chemical pollution is transboundary in nature and societal costs negatively impact the EU wellbeing and economy. Inaction in one Member State leads to costs in others.

**B. Solutions**

**What are the various options to achieve the objectives? Is there a preferred option?**

Based on evaluations of existing legislation and stakeholder input, a comprehensive list of potential measures was created. Following initial screening, 22 measures were retained for in-depth assessment. In the end, 17 preferred measures were bundled into 3 independent policy options, corresponding to each of the 3 identified problem areas:

1. Adequate classification of critically hazardous chemicals will be ensured by:

- introducing ED, PBT, vPvB, PMT and vPvM as new hazard classes in the CLP Regulation and prioritising them for harmonised classification;
- publishing the reasons for diverging notified self-classifications in ECHA's classification and labelling inventory, along with the names of the notifiers;
- requiring updates of notifications of self-classifications within a certain deadline;
- reinforcing prioritisation for harmonised classification at an early stage; and
- allowing the Commission to initiate and fund more harmonised classification and labelling dossiers, including by mandate to ECHA.

2. Improvement of hazard communication will be ensured by:

- explicitly addressing the concept of refill sales with some derogations from labelling obligations and limiting this practice to mild hazards only;
- increasing readability of CLP labels by regulating label formatting;
- allowing some supplemental information that is not obligatory under UN GHS to go digital where their physical availability on the label is not instrumental for the protection of human health and the environment and creating a framework for further digital labelling of this information;
- allowing broader use of fold-out labels for chemicals traded in several EU countries; and - providing derogation to labelling requirements for chemicals sold to consumers in bulk (e.g., fuel) and very small packaging (e.g., writing instruments).

3. Addressing main legal gaps and ambiguities will be insured by:

- clarifying rules for online offerings and advertising;
- reinforcing the obligation on a responsible economic actor for online sales to comply with the requirements of CLP; and
- introducing targeted obligations for notification to poison centres in case of information loss, e.g., when chemicals move between Member States or are re-labelled.

The above options were preferred over the following discarded ones:

Firstly, regarding hazard classification, the policy option to introduce harmonised human and environmental reference values for toxicity. While such values are useful, CLP cannot provide for their use in other chemical legislation, which would result in additional costs, little added value. Moreover, there was little support for such measure during public consultation. By contrast, the preferred options complement each other, tackle different drivers of the problem at hand and counterbalance the additional costs by additional added value.

Secondly, the policy option calling for an update piece of guidance to clarify the CLP obligations concerning chemicals sold in very small packaging, in bulk and via refill containers does not sufficiently address the problem. As the legal text itself lacks clarity, guidance does not have same legal value as a clarified legal text.

Thirdly, the policy option to run periodic awareness campaigns on the display of labelling elements online. This option is less effective, as consumers might not remember the content of awareness campaigns when buying online, than setting rules on online offerings and reinforcing rules on online advertisings and reinforcing the need of a responsible economic actor in the supply chain. As for the poison centre-notifications, the mutually exclusive measures of full notifications to poison centres by all actors in the supply chain and notifications to poison centres by re-branders and re-labellers were discarded in favour of targeted notification obligations. The latter has the best cost to operators - social benefit ratio, since it prevents multiple cases of information loss without obliging all distributors to notify by default.

**What are different stakeholders' views? Who supports which option?**

The introduction in the CLP Regulation of new hazard classes is generally strongly supported. The EU industry indicated a strong preference, however, for the EU to propose the new hazard classes first at UN level before introducing them in EU legislation. Stakeholders also generally welcome the strengthening of the system for harmonised classification, albeit warning of the resource implications.

Stakeholders generally welcome the new possibilities offered by increased use of foldout labels and the regulation of refill sales, replying that it would ease the burden for SMEs. Certain concerns are expressed about the digital divide, but it is generally accepted that a limited set of information could be provided by digital means only. Strengthening the rules for online sales received strong and unanimous support from all categories of stakeholders. The extension to certain economic operators of the obligation to notify poison centres of chemicals is also generally welcomed.

**C. Impacts of the preferred option**

**What are the benefits of the preferred option?**

The benefits of the preferred option stem mainly from improvement of the protection of health and the environment. Savings to public health systems and depollution schemes could amount to more than EUR 300 million per year. Adequate and homogenous hazard classification allows chemicals suppliers, users and public authorities to take adequate measures to manage chemicals risks while preserving the integrity of the single market and levelling the playing field between economic operators. Improved communication on chemical hazards will allow consumers to make informed choices and avoid unnecessary risks to health or the environment. Finally, simplified labelling rules will save costs for businesses. Closing legal gaps related to online sales and poison centres will ensure better compliance ultimately leading to better implementation and easier enforcement.

**What are the costs of the preferred option?**

The initiative will entail significant costs for industry actors placing chemicals on the EU market, both administrative annual costs for compliance with the new rules (EUR 28.47 million) and adjustment costs for voluntary substitution down the supply chain for substances which will be covered by the new hazard classes (EUR 26.40 million).

**What are the impacts on SMEs and competitiveness?**

Costs for SMEs will be higher in relative terms, as they benefit less from economies of scale and have less capacity to absorb fixed costs. New responsibilities for economic actors involved in distance sales, including online sales, from out- or inside the EU will ensure fair and equal competition among all businesses selling chemicals, especially for SMEs who sell mainly within the EU and rely on online platforms to trade their products.

The introduction of new hazard classes, while increasing costs on the short term, will translate into the EU industry being the global front-runner in health and environmental standards, driving the EU industry's leadership in producing and using sustainable chemicals, and thereby allowing it to increase its competitiveness and global market share.

The measures to ensure homogeneity of classification of identical substances manufactured by different companies will level the playing field and contribute to fair competition, in particular for SMEs. SMEs will be able to rely more on existing self-classifications in the classification and labelling inventory instead of classifying themselves, which is costlier for SMEs than it is for large enterprises.

**Will there be significant impacts on national budgets and administrations?**

| |
|---|
| No. |
| **Will there be other significant impacts?** |
| No. |
| **Proportionality?** |
| The initiative does not go beyond what is necessary to achieve its objectives. |
| **D. Follow up** |
| **When will the policy be reviewed?** |
| The impacts of the initiative will be documented by the indicator framework for the effectiveness of chemicals legislation announced for 2024 by the Chemicals Strategy for Sustainability. The revised CLP Regulation may be (partially) reviewed once evidence will be available under this framework. |