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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

(Text with EEA relevance)

{SEC(2022) 452 final} - {SWD(2022) 434 final} - {SWD(2022) 435 final} -
{SWD(2022) 436 final}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

Among its actions, the European Green Deal provides for the strengthening and simplification of the legal framework for chemicals to ensure a toxic-free environment[1]. The revision of Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures ('CLP Regulation')[2] was announced by the Chemicals Strategy for Sustainability[3], adopted on 14 October 2020. The targeted revision of the CLP Regulation, as part of the strategy, was welcomed by the Council[4] and the European Parliament[5].

The Union has overall been successful in creating an efficient single market for chemicals. However, some weaknesses or gaps in the CLP Regulation described below prevent consumers, companies, and authorities from fully benefiting from protection against the dangers posed by hazardous chemicals. As the EU is committed to the 2030 Agenda for Sustainable Development[6] and its Sustainable Development Goals (SDGs)[7], this proposal contributes to several of the SDGs, including those to ensure good health and well-being, sustainable consumption and production patterns, and clean water and sanitation[8].

Better identifying and classifying hazardous chemicals

First, although certain chemicals and articles may pose risks to human health or to the environment, their hazards are not always properly identified and communicated. The main driver behind this issue are inefficiencies in the procedures for assessing and classifying hazards. Shortcomings in hazard communication also impair consumers' ability to make informed choices.

Second, there is a high number of erroneous or obsolete classifications of substances, as well as diverging classifications for the same substance in the European Chemical Agency's classification and labelling inventory ('inventory), with almost 60% of companies having multiple notified classifications for a single substance[9]. The issue of erroneous, obsolete and/or diverging classification leads to information deficiencies for users of chemicals, which may increase their exposure to those chemicals.

As part of the CLP Regulation revision package, a delegated act will add definitions and scientific and technical criteria to enable substances and mixtures that have endocrine

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1 The European Green Deal, Communication from the Commission, Brussels, 11.12.2019, p. 15 (COM(2019) 640 final).

2 European Commission, Revision of EU legislation on hazard classification, labelling and packaging of chemicals.

3 Chemicals Strategy for Sustainability, Communication from the Commission, Brussels, 14.10.2020 (COM(2020) 667 final).

4 Council Conclusions on Sustainable Chemicals Strategy of the Union, 2021.

5 European Parliament, Resolution of 10 July 2020 on the Chemicals Strategy for Sustainability, 2020 (2020/2531(RSP)).

6 https://www.un.org/ga/search/view_doc.asp?symbol=A/RES/70/1&Lang=E.

7 https://sdgs.un.org/goals.

8 SDG #3 Good health and well-being, SDG #6 Clean water and sanitation, SDG #9 Industry, innovation and infrastructure, and SDG #12 Ensure sustainable consumption and production patterns.

9 Amec Foster Wheeler et al., A Study to gather insights on the drivers, barriers, costs and benefits for updating REACH registration and CLP notification dossiers, 2017.

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 to be classified into established hazard classes. The impact of adding these new hazard classes has been assessed as part of the overall impact assessment on the revision of the CLP Regulation[10].

Improving communication on chemical hazards

Appropriate hazard classification determines, among others, the appropriate labelling and packaging of the chemicals in the supply chain, in particular to protect workers, consumers and the environment, but also to enable the single market to function properly. An estimated 55% of EU citizens consider themselves not well informed about the potential hazards of chemicals in consumer products[11]. This is also due to a relatively low level of understanding of certain pictograms, labels and warnings, not least due to the limited readability of labels, detailed information, technical language and often too small font size. This proposal aims to make labelling more consumer friendly, less burdensome for suppliers and easier to enforce by clarifying rules and providing clear exemptions. To this end, it will clarify the concept of refill sales and introduce provisions to facilitate the use of fold-out labels as well as provisions for minimum formatting rules to make labels more readable for consumers. In addition, certain labelling exemptions are provided for chemicals supplied without packaging such as fuel at filling stations, chemicals contained in very small packaging such as pens below 10 ml, chemicals with mild hazards supplied in bulk, and ammunition under specific conditions.

Addressing legal gaps and high levels of non-compliance

The Chemicals Strategy for Sustainability identifies imported chemicals and online sales as a particular challenge and priority area for action. Many chemicals[12] sold online in the EU, and especially those sold by actors established outside the EU and placed on the EU market, do not meet the legal requirements[13]. 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 achieve the objectives of consumer protection and protection of human health and of the environment, and to ensure compliance with the requirements of the CLP Regulation within the EU, the CLP Regulation will introduce a requirement that suppliers have to ensure that substances or mixtures, including those sold online via distance sales, meet the requirements of CLP, in particular on classification, labelling and packaging. In addition, online offers and advertisements often do not display hazard information, therefore, consumers may not be able to make informed choices at the moment of accepting the online offer or when following up on the advertised chemical. Chemicals' labelling information should be made available before placing on the market, regardless of the means of sale.

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10 Commission Staff Working Document – Impact Assessment Report Accompanying the document Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and of mixtures ('Impact Assessment Report'), (not yet published), p. 34.

11 2017 Special Eurobarometer 468.

12 Rate of non-compliance with CLP provisions was 75% of 2,752 inspected products in 29 EEA countries and 82.4% of 1,314 inspected products in 15 EU countries; Non-compliant with Article 48(2) on advertisement of mixtures, ECHA, Final report on the Forum Pilot Project on CLP focusing on control of internet sales, 2018.

13 KEMI, Increased e-commerce – increased chemicals risks? A mapping of the challenges of e-commerce and proposed measures. Report of a government assignment, 2021.

Another provision leading to legal ambiguities relates to the notifications that companies must submit to poison centres for emergency health response. It is essential that poison centres, when answering emergency calls, have all the necessary information on the composition of mixtures so they can provide clear advice to consumers or health professionals. While the CLP Regulation provides for the obligation for downstream users and importers to submit relevant information for emergency health response, it does not explicitly do so for distributors either supplying those mixtures across borders or rebranding or relabelling them. An explicit obligation to do so would close the loop of loss of information submitted to poison centres.

Conclusion

The three problems outlined above highlight why the current legislation fails to sufficiently protect humans and the environment from the hazards of chemicals moving freely within the EU single market and why modifications are needed to facilitate enforcement.

The CLP Regulation revision package therefore aims to:

(i) ensure that all hazardous chemicals, including those with ED, PBT, vPvB, PMT and vPvM properties, are classified adequately and uniformly throughout the EU;

(ii) improve the efficiency of hazard communication by making labels more accessible and understandable for users of chemicals, and provide companies with more flexibility, thereby reducing the administrative burden without lowering safety levels;

(iii) make sure that the rules on chemical hazard classification and communication are applied by all relevant actors in the supply chain.

- **Consistency with existing policy provisions in the policy area**

The delegated act referred to above complements the present proposal by introducing into Annex I to the CLP Regulation new hazard classes and corresponding classification criteria for substances and mixtures with ED properties for human health and for the environment, as well as PBT, vPvB, PMT and vPvM properties. The proposed provision in this proposal to prioritise the above-mentioned hazard classes for harmonised classification will help achieve the European Green Deal's vision of a toxic-free environment.

The Chemicals Strategy for Sustainability calls for the Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (REACH)[14] and the CLP Regulation to be reinforced as the cornerstones for regulating chemicals in the EU. They should also be complemented by coherent approaches to assess and manage chemicals in existing sectoral legislation, especially in relation to consumer products. The CLP Regulation focuses on classifying chemicals that are hazardous, i.e. which have adverse effects on human health or the environment or adverse physical effects, and on communicating them to users of chemicals and decision makers (consumers, industry and authorities).

[14] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

Under the CLP Regulation, the decision to classify a substance or a mixture for environmental and human health hazards is exclusively based on existing information. The need to generate any additional data requirements is regulated by REACH. As part of ongoing revision of REACH, a possible extension of data requirements for ED identification and for substances placed on the market in lower volumes is being assessed. These data would be made available for classification, thus further improving how these two regulations work together.

An extension of the generic approach to risk management – which relies on harmonised classification as a starting basis – is currently under review under REACH and product legislation (e.g. cosmetics, toys, food contact materials). Legislation based on pre-market authorisations[15], such as plant protection products[16] and biocides legislation[17], also relies on harmonised classification. Those revisions will very likely increase the reliance on harmonised classifications, so that appropriate risk management measures can be adopted.

Several other policy initiatives under the European Green Deal will ensure that consumers have access to updated information on the impact of consumer products on human health and/or the environment. The Ecodesign for Sustainable Products Regulation proposal[18] introduces provisions to regulate consumer products on several sustainability aspects. However, chemical safety is excluded from its scope. This revision proposal therefore complements the Ecodesign for Sustainable Products Regulation proposal in terms of consumer access to information on the dangers of chemicals present in products. The proposal also improves the provision of product information via digital tools, in particular a digital product passport that will gather data on a product and its value chain. This passport is particularly relevant for the introduction of digital labelling because it provides for the mandatory adoption of digital ways for communicating product information. However, the overarching principle that guides what information could be moved to an online label will be to ensure that any information directly linked to user safety and environment protection – and not somehow overlapping, redundant or of little added value – is kept on the physical label that is accessible under all circumstances.

- **Consistency with other Union policies**

The CLP Regulation plays a central role in hazard classification and communication.[19] Revising it also contributes to the realisation of the EU's zero pollution vision for 2050 by better managing chemicals' risks in products (including imports) and combination effects of different chemicals.

Furthermore, this proposal is fully aligned with the EU's climate objective to avoid and reduce greenhouse gas emissions. While relabelling (recalling chemicals in the supply chain to label and ship them again – cost that is tempered by the transitional provisions allowing

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15 Whereby placing on the EU market is conditional upon receiving authorisation to do so.

16 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

17 Regulation (EU) No 528/2012 of 22 May 2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products (OJ L 167 of 27.6.2012 p.1).

18 Proposal for a Regulation of the European Parliament and of the Council establishing a framework for setting ecodesign requirements for sustainable products and repealing Directive 2009/125/EC, COM(2022) 142 final.

19 Chemicals Strategy for Sustainability, Communication from the Commission, Brussels, 14.10.2020, p. 9 and 16, (COM(2020) 667 final).

substances and mixtures already placed on the market at the date of application not to be re-labelled) and the voluntary substitution of chemicals may generate some greenhouse gas emissions, the overall benefit of contributing to an environment more resilient to climate changes by identifying and reducing hazardous substances has a balancing effect[20].

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

• Legal basis

This proposal has as its legal basis Article 114 of the Treaty on the Functioning of the European Union.

• Subsidiarity (for non-exclusive competence)

In the same way as when the CLP Regulation was adopted, the objectives of this proposed Regulation cannot be sufficiently achieved at Member State level. Given the scale or effects of the proposed action, they can be better achieved at EU level. To solve the same problems, one action at EU level will be less costly and more efficient than 27 different actions.

Action at EU level is crucial to preserve the free movement of chemicals in the single market. Individual actions at national level would impose significant administrative burdens on companies seeking access to the market of more than one EU Member State. Furthermore, chemical pollution and its negative impacts are transboundary by nature. Citizens in one Member State would therefore be affected by the potential inaction in another Member State.

• Proportionality

The initiative does not go beyond what is necessary to achieve the objectives sought.

The supporting impact assessment[21] assesses the impacts of the proposed revision of the CLP Regulation. Both qualitative and quantitative assessment have been undertaken that show that the proposal is proportionate, i.e. that is that environmental and societal benefits are significantly higher than the costs incurred.

• Choice of the instrument

This proposal for revision is a legislative proposal. The CLP Regulation has been adopted by co-decision and therefore its revision needs to be adopted by ordinary legislative procedure. It maintains the choice of instrument as a directly applicable and binding EU Regulation. While the Annexes to the CLP Regulation have been amended several times before, this proposal is a targeted revision of the enacting terms and, where relevant, the related Annexes. Although the CLP Regulation has empowered the Commission to amend certain Articles of the CLP Regulation and the Annexes to adapt them to technical and scientific progress, a number of amendments to these Articles and Annexes are included in this legislative proposal to ease the adoption process as they are linked to the amended provisions which refer to them.

[20] Impact Assessment Report, p. 46; Annex to the Impact Assessment Report, p. 147.
[21] Impact Assessment Report; Executive Summary of the Impact Assessment Report

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- **Ex-post evaluations/fitness checks of existing legislation**

The CLP Regulation, together with other pieces of EU legislation, was evaluated in 2019[22]. The fitness check's overall conclusion was that EU chemicals legislation, including the CLP Regulation, meets the objectives. The added value of policy action at the EU level is high and remains relevant. Significant benefits in terms of avoided health and environmental impacts (healthcare costs, productivity losses, suffering and premature deaths, remediation costs, and degradation of environmental/eco-system services) were registered. At the same time, the fitness check identified some significant issues and weaknesses that hold the CLP Regulation back from delivering its full potential. The evaluation pinpointed potential areas of intervention:

- providing harmonised reference values in addition to harmonised classification;
- improving harmonised classification;
- improving and streamlining industry's classification;
- clarifying rules on hazard labelling;
- reviewing the exemption of certain chemical products from the CLP Regulation;
- addressing the low compliance rate with labelling requirements for the online selling of chemicals;
- closing notification gaps for poison centres;
- improving data quality in the European Chemicals Agency's ('the Agency') inventory.

- **Stakeholder consultations**

Initial feedback was provided on the **inception impact assessment** published on the Commission's 'Have Your Say' website[23]. The feedback period ran from 4 May 2021 to 1 June 2021, with 182 comments.

As part of the impact assessment, an **open public consultation** on the revision of the CLP Regulation ran for 14 weeks from 9 August 2021 to 15 November 2021[24]. The questionnaire was split into two sections, one containing 11 questions for the general public, and one containing 37 questions for experts. Both sections allowed respondents to provide position papers.

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22 Commission Staff Working Document, Fitness Check of the most relevant chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries, SWD(2019) 199.

23 European Commission, Revision of EU legislation on hazard classification, labelling and packaging of chemicals, available at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12975-Revision-of-EU-legislation-on-hazard-classification-labelling-and-packaging-of-chemicals/feedback_en?p_id=24338728.

24 European Commission, Revision of EU legislation on hazard classification, labelling and packaging of chemicals, available at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12975-Revision-of-EU-legislation-on-hazard-classification-labelling-and-packaging-of-chemicals/public-consultation_en.

The consultation was followed by a **targeted stakeholder survey.** The survey was open for 6 weeks (from 10 November to 22 December 2021). A stakeholder mapping exercise identified 548 stakeholders, to whom the survey was sent.

Furthermore, extensive discussions on specific issues of the revision of the CLP Regulation were held in three ad hoc meetings of the CARACAL expert group (Competent Authorities for REACH and CLP), with broad Member State and stakeholder participation:

- CARACAL meeting on poison centres and online sales (27 October 2021);
- CARACAL meeting on harmonised classification and labelling prioritisation, predicted no-effect concentration, derived no-effect level, derived minimal effect level and labelling (6 December 2021);
- CARACAL meeting on new hazard classes, more than one constituent substance and self-classification (14 December 2021).

Relevant discussions on specific topics covered by this proposal were also held in other CARACAL meetings.

In addition, **22 interviews** were conducted between December 2021 and February 2022 with public authorities, EU agencies, companies and business associations, non-governmental organisations and other organisations. The aim was to complement the findings of the open public consultation, the targeted stakeholder consultation and the views provided by CARACAL members and observers.

Another **open public consultation on simplification and digitalisation of labels on** chemicals was open for 12 weeks, from 24 November 2021 to 17 February 2022[25]. The launch of that consultation was complemented by a **stakeholder workshop** on simplification and digitalisation of labelling requirements for chemicals, held on 26 November 2021. Two **online surveys**, on policy options for digitalisation and for information from professionals and industry users, were also conducted.

Main input on the problems identified:

Harmonised classification and labelling: Most stakeholders welcomed the measures proposed to improve the number of harmonised classification and labelling dossiers, including prioritisation for developing harmonised classifications of substances raising a high level of concern. However, all stakeholders pointed out that those measures should not restrict the Member States' right of initiative.

Opinions about providing the Commission with the right to initiate harmonisation processes varied, with more respondents strongly agreeing than disagreeing. Civil society, public authorities and citizens were more likely to strongly agree with this than companies and business associations.

Classification: Consultees believe that the Agency should be able to remove incomplete, incorrect or obsolete notifications from the inventory after having informed the notifier. It is also important to improve the Agency's digital tools for classification and labelling

[25] European Commission, simplification and digitalisation of labelling requirements, available at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12992-Chemicals-simplification-and-digitalisation-of-labelling-requirements/public-consultation_en.

notification. 72% of respondents to the open public consultation believe that the obligation to agree on an inventory entry should be strengthened.

Labelling of chemical products provided in small packages: companies and business associations strongly supported derogations (exemptions) from labelling requirements for these products. They felt that labelling such products is beneficial only when the presence of a hazardous substance has a realistic chance of causing harm to users.

Interviewees consider it beneficial that the selling **of refill chemicals** is addressed specifically in the CLP Regulation, as this sales method is being used more and more. In the targeted stakeholder survey, companies expressed different opinions on the labelling of **chemicals sold in bulk to consumers.** Some stressed that hazards of chemicals sold in bulk to consumers (fuels in particular) are not communicated; others emphasised that fuels are sold to trained users who buy them repeatedly and they supported derogations from labelling requirements for substances and mixtures supplied in bulk to consumers. 38% of respondents – digitally connected to reply to the open public consultation that was conducted online – chose digital labels as the best option for receiving information on hazards and safety instructions when buying refill detergents.

Company representatives supported the broader use of **fold-out labels** as they allow the industry to take advantage of economies of scale, in particular when distributing a chemical in Member States with a low population. National authorities explained that featuring multiple languages makes labels hard to read at the expense of communicating important safety and hazard information. Consumer associations had similar views on this. They proposed adding languages only if there is enough space left on the label after essential safety and hazard information has been included in a readable manner.

Digital Labelling: concerns were expressed about not all product users having access to digital information. However, it was generally accepted that a limited set of information could be provided by digital means only, for example as a complementary hazard communication measure. Public authorities were the most likely to suggest that obligatory provision of information via digital labelling instead of the traditional label could have significant negative health, safety and environmental impacts. Representatives from all stakeholder groups considered that information that is instrumental for the protection of health and the environment must remain on the on-pack label. They especially indicated that the Unique Formula Identifier, the hazard statement, the signal word, and the hazard pictogram should remain **on the on-pack label**.

Strengthening the rules for **online sales** received strong and unanimous support from all categories of stakeholders. The overwhelming majority of respondents agree that the online selling of chemicals poses challenges and problems, in particular sales by non-EU traders directly to consumers in the EU. They believe that there is a great need to apply the same obligations under the CLP Regulation (for example labelling, classification and notifications to poison centres) to chemical products sold online, and that the CLP Regulation is not sufficiently adapted to technological progress and societal developments when it comes to online sales, advertising, offerings and distant contracting.

Poison centres: Stakeholders welcomed the clarification of obligations in Article 45 and recognised the problem of ambiguous obligations. Some stakeholders believed that the problem lies with the diverging interpretation of Article 45 by the Member States, leading to specific national requirements. Stakeholders also generally welcomed the clarification of the

rules for the obligation to notify poison centres of chemicals for some types of companies. On adding notifications of substances, most respondents think that it is not useful to submit poison centres notifications on substances as this information is already available to poison centres by other means.

- **Collection and use of expertise**

In analysing the results of the consultation activities in preparation of this proposal, including the open public consultation, targeted stakeholder consultation, interviews and workshops, the Commission has used the services of an external contractor. When assessing the range of issues with enforcement of the CLP Regulation's labelling provisions, the Commission also took reports by the Agency into account[26].

- **Impact assessment**

An impact assessment was carried out, which resulted in a positive opinion with reservations from the Regulatory Scrutiny Board[27]. The Board concluded that the report still contains shortcomings, in particular on the costs and benefits, the methodology used to derive them and the justification of the proportionality of the preferred option. The impact assessment has been revised to fully address the comments received.

Based on the evaluations of existing legislation and stakeholder input, a comprehensive list of potential measures has been drawn up. Following an initial screening, 22 measures have been retained for in-depth assessment. In the end, 17 retained measures have been bundled into three independent policy options, corresponding to each of the three identified problem areas that the revision of the CLP Regulation intends to address.

Regarding the first problem on the classification of chemicals hazards, 4 options were assessed regarding:

1.1. Inclusion of new hazard classes;

1.2. Consistent classification and improving transparency;

1.3. More and prioritised harmonised classification;

1.4. Complementing hazard identification with hazard quantification.

Three options were analysed with regards to the second problem on the communication of chemicals hazards:

1.5. New or revised guidance;

1.6. Improving labelling and packaging and making labelling more flexible;

1.7. Digital labelling.

Finally, three options were developed in response to the third problem on addressing main legal gaps and ambiguities:

1.8. Awareness campaigns;

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[26] ECHA, REF-6 project report - Classification and labelling of mixtures, 2019; ECHA REF-8 project report on enforcement of CLP, REACH and BPR duties related to substances, mixtures and articles sold online, 2021.

[27] Opinion of the Regulatory Scrutiny Board, May 11 2022 (Ref. Ares(2022)3650615 – 13/05/22).

1.9. Provisions and clear responsibilities for online sales and imports;

1.10. Clarifying provisions for notifications to poison centres.

The preferred policy option (combining options 1.1, 1.2, 1.3, 2.2, 2.3, 3.2 and 3.3) was chosen as it will generate significant and positive health and environmental impacts and incur limited negative economic impacts (considering all retained policy options).

Given the very cross-cutting nature of chemicals, which constitute the basic elements of virtually every material and product that we produce and use, the objectives of this initiative are closely linked to the other goals of the European Green Deal and the Chemicals Strategy for Sustainability, in particular climate neutrality, circularity, biodiversity protection and the green and digital transition of the EU industry. Those objectives also contribute to the achievement of the United Nations Sustainable Development Goals (SDGs), of which 4 are directly relevant for chemicals:

- SDG #3 Good health and well-being: Reduction of exposure of humans and the environment to hazardous substances as meeting one of the existing hazard classes (improvement of self and harmonised classifications) or new ones for EDs and PMT, vPvM, PBT and vPvB substances.
- SDG #6 Clean water and sanitation: Identification of PMT and vPvM substances, which are difficult to remove from waste waters will help to reducing the pollution of water bodies.
- SDG #9 Industry, innovation and infrastructure: Setting criteria to identify hazardous substances and improving both the self and harmonised classification processes will allow the European chemical industry to transition to more sustainable and future-proofed chemicals. Voluntary substitutions of substances classified as hazardous as such or in mixtures will also foster innovation in the chemical industry.
- SDG #12 Ensure sustainable consumption and production patterns: Information on chemical hazards will be improved so consumers and users of chemical can not only protect themselves better but also make informed choices. Self-refill chemicals will be better regulated to allow only refill of mildly hazardous substances. When it comes to online sales of chemicals, customers will have access to more comprehensive information on chemical hazards. Voluntary substitution of hazardous substances in mixtures will also help producing more sustainable chemical products.

• **Elements of the legislative proposal**

1. COMPREHENSIVE IDENTIFICATION AND CLASSIFICATION OF CHEMICAL HAZARDS

The first set of amendments consists of five measures aimed at ensuring the comprehensive identification and classification of chemical hazards.

First, to boost the efficiency and effectiveness of the harmonised classification process and complementary to the first measure, **harmonised classification for the new hazard classes to be introduced by delegated act will be prioritised.** This includes the development of prioritisation criteria to guide the submission of harmonised classification and labelling proposals.

A second measure that swiftly boosts the development of harmonised classifications is to **allow the Commission to initiate and fund more harmonised classification and labelling dossiers**, with the possibility to mandate the Agency or the European Food Safety Authority (the Authority) to develop a dossier.

Furthermore, companies' **classification of substances will be improved** as stronger incentives and provisions for companies to appropriately classify are being introduced through three measures. One of them involves making available the **reasons for diverging** notified classifications in the Agency's inventory, another one in making the **names of notifiers public**, while the last measure requires **updates of notifications** of classifications within a certain early stage deadline.

The transparency and predictability of the proposals that the Member States, the Commission, manufacturers, importers or downstream users intend to submit to the Agency will be improved through an obligation for them to communicate such intentions to the Agency. The Agency will also be obliged to publish information on such intentions and update information on the submitted proposal at each stage of the procedure for the harmonisation of classification and labelling of substances. For the same reason, a new obligation will be introduced for competent authorities to communicate to the Agency their decision to accept or refuse a proposal for revision of a harmonised classification and labelling submitted to it by a manufacturer, importer or downstream user. In the latter case, the Agency should share the information with other competent authorities.

2. IMPROVING HAZARD COMMUNICATION

The second set of amendments consists of **five complementary measures.**

First, minimum requirements for hazard communication will be strengthened by introducing **obligatory formatting rules**, such as minimum font size and colour, to increase the readability of labels.

Second, **selling chemicals in refillable containers has the potential to reduce packaging waste**. A framework of specific rules will ensure that this sales method does not lead to an increased risk. For this reason, this method will also be limited to chemicals with less severe hazards.

Third, the proposal introduces a general framework to allow for the voluntary digital **labelling** of chemicals. Moreover, the proposal provides that some information can be provided only on the digital label and no longer needs to be indicated on the on-pack label. As a rule, only information that is not instrumental in the protection of health and the environment should be moved to the digital label without it being on the on-pack label. In addition, information that is obligatory on the on-pack label in accordance with the UN Globally Harmonized System of Classification and Labelling of Chemicals will remain on it.

Fourth, **broader use of fold-out labels** will be allowed. Advantages in labelling technologies allow us to remove certain limitations, enabling companies to take advantage of economies of scale. This will also further facilitate the free movement of chemicals in the single market.

Additional derogations will also be introduced for **chemicals sold to consumers in bulk,** such as fuel, and in **very small packaging,** such as various writing instruments. In these cases, there is a limited risk of exposure, whereas adhering to the standard labelling rules is sometimes disproportionately expensive or even impossible in practice.

3. ADDRESSING LEGAL GAPS AND AMBIGUITIES OF CLP PROVISIONS

The third set of amendments consists of **three complementary measures** to address legal gaps and ambiguities in online sales and poison centre notifications.

First, provisions for distance sales, including online sales, and clear responsibilities for all relevant actors will be introduced. To this end, all online sales will require a supplier to ensure that a substance or a mixture placed on the EU market through distance sales meets the requirements of CLP, in particular on classification, labelling and packaging. The objective is to ensure a high level of protection of human health and environment, including by facilitating the enforcement of the legislative requirements.

Second, the Digital Services Act[28] ensures that the providers of online marketplaces design and organise their online interfaces in a way that enables suppliers to comply with their obligations regarding product safety information under applicable Union law. This is without prejudice to the Consumer Rights Directive[29].

Third, the provisions for **notifications to poison centres** will be clarified. All relevant actors, including distributors placing chemicals on the market across borders or rebranding/relabelling mixtures, will have to make sure that they notify poison centres across the EU about the relevant information, where necessary.

Health, environmental and economic impacts of the preferred option

The proposed amendments will generate significant and positive health and environmental impacts and will exert limited negative economic impacts. The benefits stem mainly from improvements to the protection of health and the environment, even if the impact assessment could not fully quantify them. The health benefits would result from a reduction in exposure of European citizens to harmful chemicals, as chemical manufacturers would voluntarily substitute some harmful substances. The reduced exposure would save a fraction of the annual costs to public health systems. More benefits will arise from the knock-on effect that the CLP Regulation revision will have on REACH and other downstream chemicals legislation (for example toys, cosmetics, plant protection products or biocides). The measures outlined above will also lead to improvements in the level of safety while reducing administrative burden.

As for human health, a reduced exposure of the environment to hazardous substances will also generate savings, in particular from depollution costs.

Appropriate and uniform hazard classification and communication will allow chemical suppliers and users, as well as public authorities, to take appropriate chemical risk management measures, while preserving integrity on the EU single market and levelling the playing field between companies operating in it.

Improved communication on the hazards of chemicals through better labelling is expected to strengthen consumers' understanding of the physical, health and environmental hazards of chemicals – and thus, to allow them to make more informed purchasing choices. Simplified labelling rules will also lead to a highly positive cost-benefit ratio for companies.

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[28] Proposal for a Regulation of the European Parliament and of the Council on a Single Market For Digital Services (Digital Services Act) and amending Directive 2000/31/EC, COM(2020) 825 final.

[29] OJ L 304, 22.11.2011, p. 64.

Prioritisation of the harmonised classification and labelling of substances meeting the criteria for the new hazard classes will allow for increased protection of human health and the environment.

In terms of economic impacts, investment predictability in the single market will be provided on which chemicals will undergo regulatory measures and when. This will offset the costs for industry associated with the addition of new hazard classes and voluntary substitution. The improvement of the classification process, the simplification and clarification of the labelling requirements, as well as stronger convergence of classifications by industry, will harmonise chemical safety assessments throughout the EU. This will lead to efficiency gains. Improving certain legal provisions and closing identified legal gaps will lead to better implementation and compliance, creating a more level playing field for the actors in the single market.

Quantitative estimates of cost and benefits

While it has not been possible to quantify and monetise all impacts, it is estimated that the set of measures enhancing the effectiveness of the Regulation enable direct and indirect savings, 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, of which the magnitude is confounded by a number of problems, including the possibility of estimating the attributable fraction of disease incidence, prevalence and mortality to certain chemical products. However, the human health and environmental benefits of the preferred option stem from a reduced exposure of humans and of the environment to hazardous substances. Savings to public health systems and depollution schemes could amount to a significant fraction of the costs of endocrine related pathologies, estimated to more than €300 million per year.

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 (€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).

The estimated savings offset the estimated direct and indirect administrative costs, leading to a final estimated surplus of €19.95 million per year for the next ten years. The positive ratio would however turn negative (-26.09 million euro per year for the next ten years) when adjustment costs are factored in. However, the overall cost/benefit ratio will be positive, considering the benefits of an increased protection of human health and of the environment.

- **Regulatory fitness and simplification**

In line with the Commission's commitment to better regulation, this proposal has been prepared inclusively, based on full transparency and continuous engagement with stakeholders, listening to external feedback and taking account of external scrutiny to ensure the proposal strikes the right balance.

Consistent classification of substances by companies and improved transparency will help reduce the burden and save costs for industry, as well create a stronger basis for Member States' enforcement authorities. These measures will contribute to a simplified and searchable inventory (savings estimated at slightly less than €9 million) that would mostly benefit to SMEs. On hazard communication, broader use of fold-out labels (estimated savings of up to

around €39.5 million for the detergent industry alone) and introducing exemptions to labelling requirements for some chemicals (savings amounting to more than €10 million) will also add up. The envisaged measures will therefore also contribute positively to the 'one in, one out' commitment of the Commission.

The initiative will entail costs for companies that place chemicals on the EU market – both direct costs for compliance with the new rules, and indirect costs for voluntary substitution. Costs for small and medium-sized enterprises (SMEs) will be higher in relative terms as they benefit less from economies of scale and have less capacity to absorb fixed costs. Clarification of the rules on responsibilities for economic actors involved in selling chemicals via distance sales (e.g. via online sales) to EU consumers will, however, improve application of the CLP for all substances and mixtures placed on the market.

The prioritisation of the new hazard classes (to be introduced via separate Delegated act (cf. above) for the harmonised classification and labelling will increase costs for certain companies placing chemicals on the EU market. At the same time, a coherent, EU-wide framework will prevent national initiatives putting at risk the internal market.

Finally, measures to ensure uniformity of classification of identical substances manufactured by different companies will enable SMEs to take advantage of classifications included in the inventory and not spend costs for classifying.

- **Fundamental rights**

The proposal respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union[30].

Under Article 52(1) of the Charter, any limitation on the exercise of the rights and freedoms recognised by this Charter must be provided for by law and respect the essence of those rights and freedoms. Subject to the principle of proportionality, limitations may be made only if they are necessary and if they genuinely meet objectives of general interest recognised by the Union or the need to protect the rights and freedoms of others.

This proposal strikes the right balance between the fundamental right of freedom to conduct a business and the fundamental right of property and other fundamental rights (environment, health, remedy). It has no impact on gender equality.

The limitation to the right of freedom to conduct a business and the right of property is limited to what is necessary to preserve the other above-mentioned fundamental rights and objectives of general interest in accordance with Article 52(1).

The proposal contributes to (i) the objective of a high level of environmental protection in accordance with the principle of sustainable development as laid down in Article 37 of the Charter; (ii) the right to life and the integrity of the person and its health as laid down in Articles 2, 3 and 35 of the Charter; and (iii) the right to consumer protection as laid down in Article 38.

It also contributes to the right to an effective remedy as laid down in Article 47, in relation to the protection of human health.

[30] OJ C 364, 18.12.2000, p. 1.

4. BUDGETARY IMPLICATIONS

This proposal does not have immediate budgetary implications. One of the retained measures needs to allocate 5 FTEs to the Agency. This will be considered in the on-going wider assessment on the reallocation of tasks to the Agency.

5. OTHER ELEMENTS

- **Procedure for adoption**

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[31].

While the Commission is empowered to adopt a delegated act for the aforementioned amendments, other measures that form part of the same set of amendments pertain to Articles for which the Commission is required to make a legislative proposal via the ordinary legislative procedure. The amendments to labelling provisions are a good example of this aspect. To ensure the coherence of these measures, the Commission has decided to introduce all measures in this legislative proposal, i.e. amendments of essential elements together with amendments of certain non-essential elements of the CLP Regulation. This will ensure a transparent and effective discussion of the policy package and enable the synergies between complementary measures to manifest. Moreover, bundling all amendment proposals together will facilitate legal clarity for all involved. However, this has no bearing on Commission empowerment under Article 53(1) of the CLP Regulation, which should be kept for future amendments.

On the other hand, the criteria for the new hazard classes ED, PBT, vPvB, PMT and vPvM can be introduced via a delegated act separately as they are self-standing. The timely adoption of the delegated act introducing new hazard classes will precede the negotiation process (and the final adoption of this proposal) and also facilitate the negotiation on introduction of these hazard classes into the UN Globally Harmonized System (GHS) of Classification and Labelling of Chemicals. The EU has submitted a proposal for new work on unaddressed hazard classes in the GHS work programme for 2023-2024[32]. This underlines the EU's role as global front runner in the environment and health protection. It contributes to the CLP Regulation's objective of protecting human health and the environment from the most hazardous substances, while also ensuring a well-functioning single market for chemicals. Lastly, adoption of the ED hazard classes by delegated act also responds to calls by the Council and the European Parliament for the Commission to take swift action on adopting criteria for endocrine disruptors. The European Parliament called on the Commission to '*swiftly take all necessary action*[33] *to ensure a high level of protection of human health and the environment against EDs*'[34]. In its conclusions of June 2019, the Council also called for

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31 Article 53(1) of Regulation (EC) No 1272/2008 empowers the Commission to amend Articles 6(5), 11(3), 12, 14, 18(3)(b), 23, 25 to 29 and 35(2) second and third subparagraph and Annexes I to VIII in order to adapt them to technical and scientific progress.

32 Proposal for new work on unaddressed hazard classes in the programme of work for the biennium 2023-2024 (European Union) |UNECE

33 European Parliament resolution of 18 April 2019 on a comprehensive European Union framework on endocrine disruptors (2019/2683(RSP)) (P8_TA(2019)0441).

urgent action[35]. Moreover, the Council Conclusions of 15 March 2021[36], which expressed explicit support for introducing the new hazard criteria, called for full implementation of the Chemicals Strategy for Sustainability 'without undue delay'.

- Implementation plans and monitoring, evaluation and reporting arrangements

To monitor and evaluate the effectiveness of this proposal, the Commission is currently developing a framework – due by 2024 – of indicators monitoring the drivers and impacts of chemical pollution and measuring the effectiveness of chemicals legislation. The development involves the expertise of all relevant agencies, in particular the European Environment Agency and the European Chemicals Agency. This framework will be fully aligned to and complement the monitoring and outlook framework of the EU zero pollution action plan and the monitoring framework of the 8th environment action programme to 2030.

- **Detailed explanation of the specific provisions of the proposal**

The amendment of Article 1(1) results into a clarification that the obligations under Article 45 to notify poison centres also cover certain distributors, i.e. relabellers, rebranders and distributors supplying in another Member State than the one in which the mixture was notified.

The amendment to Article 2 introduces a definition for multi-constituent substances and of acute toxicity estimates.

The amendment of Article 4(10) requires that there is a supplier established in the Union, which ensures that the substance or the mixture meets the requirements set out in the CLP Regulation when it is being placed on the market, including via distance sales. This provision will improve compliance with and enforcement of the CLP Regulation and will ensure a high level of protection of human health and the environment. In order to prevent situations where consumer becomes *de jure* and *de facto* an importer when buying the substance or the mixture via distance sales from the economic operators established outside the EU, the amendment of Article 4(10) specifies that the supplier in the EU which ensures that the substance or the mixture in question meets the requirements set out in the CLP Regulation acts in course of an industrial or professional activity.

The new Article 5(3) sets out that 'multi-constituent substances' shall, normally, be classified following the same classification, labelling, and packaging rules as mixtures and includes the identification and examination of available information on these 'multi-constituent substances'.

Article 6(3) and Article 6(4) are amended to extend to the new hazard classes regarding endocrine disruptors, PBT, vPvB, PMT and vPvM the classification provisions already in place for certain hazard classes, according to which the information on the substance included in the mixture is used to classify the mixture itself.

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34 'Towards a Sustainable Chemicals Policy Strategy of the Union-Council conclusions', 26 June 2019, https://data.consilium.europa.eu/doc/document/ST-10713-2019-INIT/en/pdf

35 //data.consilium.europa.eu/doc/document/ST-10713-2019-INIT/en/pdf, p.3

36 'Sustainable Chemicals Strategy of the Union: Time to Deliver-Council conclusions', 15 March 2021, https://www.consilium.europa.eu/media/48827/st06941-en21.pdf

Amendments to Article 9(3) and (4) clarify the use of bridging principles in order to classify a mixture or 'multi-constituent substance', simultaneously when applying the weight of evidence approach using expert judgement.

Amendments to Article 10 require manufacturers, importers and downstream users to establish acute toxicity estimates that allow for the calculation of thresholds at or above which a substance or mixture is to be classified as acutely toxic. Where specific acute toxicity estimates exist for those hazard classes for which substances have a harmonised classification and labelling (entries in Table 3 of Part 3 of Annex VI to the CLP Regulation), acute toxicity estimates must not be set by manufacturers, importers or downstream users. Furthermore, application rules for concentration limits are clarified for cases in which the presence of a hazardous substance as an identified impurity, additive or individual constituent leads to the classification of a mixture.

Amendments to Article 23 and Section 1.3. of Annex I provide derogations from some labelling obligations for certain ammunition that are not articles and set out specific rules for the labelling of certain ammunition shot through firearms.

Furthermore, the obligation under Article 32(6) to include label elements that are resulting from requirements provided for in other EU acts is moved to Article 25. The obligation to include supplemental information on certain mixtures that containing classified substances in Article 25(6) is extended to also cover also certain mixtures which that contain non-classified substances that share the properties set out in Part 2 of Annex II to the CLP Regulation.

The amendments to Article 29 and Section 1.5 of Annex I set out specific labelling provisions for substances and mixtures in very small containers; where the container is so small that these obligations cannot be met, a reduction in the label elements is allowed according to specific rules. It also sets out specific provisions for labelling of chemicals sold in bulk to consumers. Furthermore, ammunition used by the military in combat zones is exempted from labelling requirements under certain conditions.

The amendment to Article 30 clarifies the timeframe for the obligation to update the label by setting a fixed deadline and by clearly defining the start of the transition periods.

The amendments to Article 31(1) and (3) introduce obligatory formatting rules for labels, especially for fold-out labels.

Article 32(6) is deleted as the obligation to place label elements resulting from requirements provided for in other EU acts in the section for supplemental label information is moved to Article 25.

The newly introduced Articles 34a and 34b set out the rules on digital labelling. Only label elements that are not instrumental in protection of health and safety and the environment, and are not obligatory under GHS may be replaced by a digital label. The digital label must meet certain requirements. For example, it must be searchable, available in less than two clicks and not track any user data. The Commission should be empowered to adopt delegated acts in accordance with Article 53(1) in order to adapt the labelling elements that may be provided digitally only to technical and scientific progress as well as to digital readiness.

The amendment to Article 36 adds the new hazard classes to be adopted via the delegated act (ED, PBT, vPvB, PMT, vPvM) to the list of hazards that are normally subject to harmonised classification and labelling.

The amendment of Article 37 mandates the Commission to initiate the harmonised classification and labelling procedure in addition to the right currently conferred on Member States competent authorities and manufacturers, importers and downstream users. In such a

case, the dossiers would be developed either by the Agency or by the Authority. The possibility to initiate harmonised classification and labelling proposals for several substances at once is added by replacing the references to 'substance' by 'substances'. It is clarified that the harmonised classification and labelling procedure under Article 37 can include acute toxicity estimates where appropriate. Paragraphs 7 and 8 are added to Article 37 to insert an obligation on the Commission to adopt delegated acts to amend Annex VI in order to include in Table 3 of Part 3 of that Annex substances that have been included in the candidate list as ED, PBT or vPvB under the REACH Regulation, and those that have not been approved under the Plant Protection Products Regulation and the Biocidal Products Regulation or those that have been approved because they fulfilled the conditions for derogation.

Article 38 is amended to adjust to the newly defined acute toxicity estimates.

The amendment to Article 40(1) introduces and specifies the obligation to provide the Agency with the reasons for divergence from other classification entries for the same substance and to update notifications within 6 months after a decision to change the classification and labelling of a substance has been taken.

The amendment to Article 42(1) sets out that the identity of the notifier must be made publicly available, subject to duly motivated confidentiality requests. If there are group notifications, only the identity of the notifier acting on behalf of the group members needs to be made publicly available.

The amendment to Article 45 obliges certain distributors to notify information on emergency health responses to appointed bodies where the latter would not have all the information required to carry out the tasks for which they are responsible, in particular in case of distribution across borders, or re-branding or re-labelling. This information could now also be shared with the Commission and with the Agency upon request for the purpose of statistical analysis and evaluating the need for risk management measures.

The amendment to Article 48 makes a distinction between advertisements and distance sales offers linked to the marketing and sale of hazardous chemicals. It provides that advertisements of hazardous substances and certain mixtures should contain, in addition to the hazard class, the hazard pictogram, the signal word and the hazard statements. The newly introduced Article 48a provides for requirement for distance sales offers to indicate the applicable labelling information.

Amending Article 50 provides for the possibility of designating the Agency as the appointed body to receive relevant information for emergency health responses under Article 45. It further tasks the Agency with ensuring the availability of appropriate tools to share information with national appointed authorities so they fulfil their other obligations under Article 45. Furthermore, it clarifies the Agency's remit of providing competent authorities with tools to support CLP Regulation implementation and industry with tools to comply with the CLP Regulation.

Article 53 paragraph 1 is amended to empower the Commission to amend the new Article 34a on the content of digital labels by means of delegated acts. This is based on technical and scientific progress and the level of digital readiness among all population groups.It is further amended to oblige the Member States and the Commission to promote harmonisation of the criteria for classifying and labelling ED, PMT and vPvM substances at UN level, in the same way as their current obligation related to the criteria for classifying and labelling PBT and vPvB substances. The same obligation is introduced on the promotion of non-animal methods at the UN.

The amendment to Article 53c relates to the scope of the Commission's obligation to adopt separate delegated acts in respect of each power delegated to it under the CLP Regulation. It aims to allow for the adoption of one single delegated act when it amends Part 1 and Part 2 together with Part 3 of Annex VI to the CLP Regulation triggered by the harmonised classification procedure of a particular substance or group of substances.

Part 1 of Annex I is amended to provide that supplemental labelling information under Article 25(3) may be provided in a digital format only. It will introduce formatting requirements for labels, specific labelling requirements for bulk sales as well as an exemption from labelling requirements for certain mixtures in small packaging and for certain ammunitions. Moreover, it clarifies a provision on the weight of evidence determination. The amendment to Part 5 of Annex II specifies a labelling exemption for ready-mixed cement and concrete in the wet state and sets out an exemption from the labelling obligations for sales of chemicals in bulk to consumers. It also sets specific packaging requirements for bulk products for sale at refill stations.

Amendments to Part A and Part B of Annex VIII extend the obligation to submit information to certain other suppliers, in addition to downstream users and importers, where appointed bodies would not have sufficient information to provide an adequate emergency health response. The amendments also define the term 'composition conforming with a standard formula' in the context of certain submission requirements for gypsum, ready-mixed concrete and cement. They introduce the obligation to provide the name and product description of the standard formula for the fuel in the submission and provide in certain cases for the obligation to submit information on components even if they are not always present. Furthermore, they clarify when submission updates are required, as well as ways to identify the mixture, submitter and contact point by means of their product identifier.

2022/0432 (COD)

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

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114(1) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[1],

Acting in accordance with the ordinary legislative procedure[2],

Whereas:

(1) In order to keep pace with globalisation, technological development and new means of sale, such as online sales, it is necessary to adapt Regulation (EC) No 1272/2008 of the European Parliament and of the Council. While under that Regulation it is assumed that all responsible actors in the supply chain are established in the Union, practical experience has shown that economic operators established outside the Union sell chemicals online directly to the general public in the Union. Hence, enforcement authorities are unable to enforce Regulation (EC) No 1272/2008 against economic operators not established in the Union. It is therefore appropriate to require that there is a supplier established in the Union, which ensures that the substance or the mixture in question meets the requirements set out in that Regulation when it is being placed on the market, including via distance sales. This provision would improve compliance with and enforcement of the Regulation (EC) No 12727/2008 and thereby ensure a high level of protection of human health and the environment. In order to prevent situations where consumer becomes *de jure* and *de facto* an importer when buying the substance or the mixture via distance sales from the economic operators established outside the Union, it is necessary to specify that the supplier which ensures that the substance or the mixture in question meets the requirements set out in that Regulation acts in course of an industrial or professional activity.

(2) From a toxicological point of view, substances with more than one constituent ('multi-constituent substances') are no different from mixtures composed of two or more substances. In accordance with Article 13 of Regulation (EC) No 1907/2006 of the

[1] OJ C , , p. .

[2] Position of the European Parliament of xxx and decision of the Council of xxx.

European Parliament and of the Council[3], aimed to limit animal testing, data on multi-constituent substances is to be generated under the same conditions as data on any other substance, while data on individual constituents of a substance is normally not to be generated, except where individual constituents are also substances registered on their own. Where data on individual constituents is available, multi-constituent substances should be evaluated and classified following the same classification rules as mixtures, unless Annex I to Regulation (EC) No 1272/2008 provides for a specific provision for those multi-constituent substances.

(3) It is normally not possible to sufficiently assess the endocrine disrupting properties for human health and the environment and the persistent, bioaccumulative and mobile properties of a mixture or of a multi-constituent substance on the basis of data on that mixture or substance. The data for the individual substances of the mixture or for the individual constituents of the multi-constituent substance should therefore normally be used as the basis for hazard identification of those multi-constituent substances or mixtures. However, in certain cases, data on those multi-constituent substances themselves may also be relevant. This is the case in particular where that data demonstrates endocrine disrupting properties for human health and the environment, as well as persistent, bioaccumulative and mobile properties, or where it supports data on the individual constituents. Therefore, it is appropriate that data on multi-constituent substances are used in those cases.

(4) In order to improve legal certainty and implementation with regard to the evaluation of hazard information for mixtures where no or inadequate test data are available for the mixture itself, the interaction between the application of the bridging principles and a weight of evidence determination using expert judgement should be clarified. Such clarification should ensure that the weight of evidence determination complements but does not substitute the application of the bridging principles. It should also be clarified that if bridging principles cannot be applied to evaluate a mixture, manufacturers, importers and downstream users should use the calculation method or other methods described in Parts 3 and 4 of Annex I to Regulation (EC) No 1272/2008. It should also be clarified which criteria, when not met, determine when a weight of evidence determination using expert judgment is to be carried out.

(5) To avoid over-classification of mixtures which contain substances classified as hazardous solely due to the presence of an impurity, an additive or an individual constituent, and of mixtures which contain other mixtures with such substances, the classification should only be mandatory if such impurity, additive or individual constituent is contained in the mixture or in the final mixture at or above a certain concentration limit as referred to in Annex I to Regulation (EC) No 1272/2008.

(6) Acute toxicity estimates are mainly used to determine the classification for human health acute toxicity of mixtures containing substances classified for acute toxicity. Substances can be classified in one of four acute toxicity hazard categories based on the oral, dermal or inhalation exposure route according to certain numeric criteria. Acute toxicity values are expressed as (approximate) LD50 (oral, dermal) or LC50

[3] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

(inhalation) values or as acute toxicity estimates. It is appropriate to specify the meaning of, and further specify, acute toxicity estimates to increase their clarity and consistency. As acute toxicity estimates are part of the harmonised classification and labelling elements of substances classified for acute toxicity they should be included in the proposal, opinion and decision for harmonised classification of a substance for acute toxicity. In the same way as M-factors and concentration limits, acute toxicity estimates should, together with a justification, be notified to the Agency in view of their inclusion in the classification and labelling inventory.

(7) Ammunition qualifying as a substance or a mixture is to bear a label affixed to the surface of the packaging immediately containing the substance or the mixture (inner packaging), which is typically the ammunitions' cartridge. Affixing a label to the cartridge might however cause safety problems for the user, as the label could interfere with the correct functioning of the ammunition and could damage the firearm. Such ammunition should therefore be allowed to bear a label affixed to the next packaging layer instead of the inner packaging. In addition, labelled ammunition, which is exclusively used by national defence forces in combat zones, could, in specific cases, constitute an unacceptable safety or security risk for the cargo, soldiers and staff, if sufficient camouflaging cannot be ensured. For such cases, it is necessary to provide for an exemption from the labelling requirements and allow for alternative ways of communicating the hazard information.

(8) In order to enhance clarity, all supplemental labelling requirements should be placed together in one Article.

(9) Part 2 of Annex II to Regulation (EC) No 1272/2008 sets out rules for additional hazard statements to be included on the label of certain mixtures listed in Part 2 of that Annex. Given that those statements provide important additional information in specific cases, they should be applied to all mixtures referred to in Part 2 of Annex II, regardless of whether they are classified and whether they contain any classified substance.

(10) To increase enforceability of the obligation placed on suppliers to update their labels after a change in the classification and labelling of their substance or mixture, a deadline should be laid down as regards that obligation. A similar obligation placed on registrants is set out in Commission Implementing Regulation (EU) 2020/1435[4]. Where the new hazard class is additional to an existing hazard class or represents a more severe hazard class or category, or where new supplemental labelling elements are required under Article 25, the deadline to update the labelling information in the case of adaptation of the classification in accordance with the result of a new evaluation should be set at 6 months from the day on which the results of a new evaluation on the classification of that substance or that mixture were obtained. In case where a classification is updated to a less severe hazard class or category without triggering classification in an additional hazard class or new supplemental labelling requirements, the deadline for updating the labels should remain at 18 months from the day on which the results of a new evaluation on the classification of that substance or that mixture were obtained. It should also be clarified that, in cases of harmonised

[4] Commission Implementing Regulation (EU) 2020/1435 of 9 October 2020 on the duties placed on registrants to update their registrations under Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 331, 12.10.2020, p.24.)

classification and labelling, the deadlines to update the labelling information should be set at the date of application of the provisions setting out the new or amended classification and labelling of the substance concerned, which is usually 18 months from the date of entry into force of those provisions. The same applies in case of changes triggered by other delegated acts adopted in light of the adaptation to technical and scientific progress, for instance as a result of the implementation of new or amended provisions of the UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

(11) Regulation (EC) No 1272/2008 only allows for the use of fold-out labels if the general rules for the application of labels cannot be met due to the shape or form of the packaging or its small size, whilst it does not provide for a minimum font size of labels that would ensure readability. As a result of advancements in labelling technologies, more flexibility should be given to suppliers by providing for a broader use of fold-out labels, while readability of labels should be ensured by laying down minimum font size and formatting requirements.

(12) Regulation (EC) No 1272/2008 needs to be adjusted to technological and societal changes in the field of digitalisation and be prepared for future developments. Digital labelling could improve the efficiency of hazard communication, especially for vulnerable population groups and people who do not speak the national language of a Member State. Therefore, it is necessary to provide for voluntary digital labelling and to lay down technical requirements for such labelling. In order to provide for legal certainty, it is appropriate to specify the label elements that are allowed to be provided in a digital format only. That possibility should only exist for information which is not instrumental for the safety of the user or the protection of the environment.

(13) In order to adapt the label elements allowed to be provided only in a digital format to technical progress or to the level of digital readiness among all population groups in the Union, the Commission should be empowered to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union to amend the list of label elements allowed to be provided only in a digital format, taking into account societal needs and a high level of protection of human health and the environment.

(14) In order to adjust to technological changes and developments in the field of digitalisation, the Commission should be empowered to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union to supplement Regulation (EC) No 1272/2008 by further specifying the technical requirements for the digital labelling.

(15) Regulation (EC) No 1272/2008 currently does not lay down any specific rules for labelling and packaging of substances or mixtures supplied to the general public and professional users via refill stations. Considering the increasing trend of selling products, including certain chemicals such as detergents, without packaging to reduce waste and to facilitate more sustainable sales forms, it is appropriate to set out specific rules and conditions for such type of sales, and establish a list of hazard classes and categories prohibiting such refill station sales for substances of mixtures meeting the criteria for classification in those hazard classes and categories, in order to ensure safety and the protection of human health.

(16) Regulation (EC) No 1272/2008 does not lay down rules on the labelling of chemicals supplied to the general public without packaging except for ready mixed cement and concrete in a wet state. In order to enhance legal clarity and ensure a better protection

of citizens, it is appropriate to provide for the labelling elements of other chemicals, such as fuels supplied at filling stations and intended to be pumped into receptacles from where they are normally not intended to be removed.

(17) As the new hazard classes and criteria introduced by Commission Delegated Regulation[5] allow for the harmonised classification and labelling of substances of the highest concern with regard to health and environment, they should normally be subject to harmonised classification and labelling and added to the list of hazard classes which includes respiratory sensitisation, germ cell mutagenicity, carcinogenicity and reproductive toxicity. Sub-categorisation of the hazard class for respiratory sensitisation in sub-category 1A or 1B should be performed where sufficient information to classify in those hazard sub-categories is available, in order to avoid over- or under-classification. In view of the rapid development of scientific knowledge and the long-standing expertise of the European Chemicals Agency (the 'Agency') and the European Food Safety Authority (the 'Authority') on the one hand, and the limited resources of Member States' competent authorities to develop harmonised classification proposals on the other, the Commission should have the right to request the Agency and the Authority to develop a harmonised classification and labelling proposal.

(18) Harmonised classification and labelling proposals need not necessarily be limited to individual substances and could cover a group of similar substances, where such similarity allows for similar classification of all substances in the group. The purpose of such grouping is to alleviate the burden on manufacturers, importers or downstream users, the Agency and the Commission in the procedure for harmonisation of classification and labelling of substances. It also avoids testing of substances when similar substances can be classified as a group.

(19) To increase transparency and predictability of the proposals submitted to the Agency, the Member States' competent authorities, manufacturers, importers or downstream users should be required to notify the Agency of their intention to submit a proposal for harmonised classification and labelling, while the Commission should be required to notify the Agency of its request to the Agency or to the Authority to prepare such proposal. Furthermore, the Agency should be required to publish information on such intention or request and update the information regarding the submitted proposal at each stage of the procedure for the harmonised classification and labelling of substances. For the same reason, a competent authority that receives a proposal for revision of a harmonised classification and labelling submitted by a manufacturer, importer or downstream user should be required to communicate its decision to accept or refuse the proposal for revision to the Agency, which should share that information with the other competent authorities. receives a proposal for revision of a harmonised classification and labelling submitted by a manufacturer, importer or downstream user should be required to communicate its decision to accept or refuse the proposal for revision to the Agency, which should share that information with the other competent authorities.

(20) The criteria for inclusion of substances in the candidate list referred to in Article 59(1) of Regulation (EC) No 1907/2006 are equivalent to those of certain hazard classes and

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5 [Commission Delegated Regulation amending Regulation (EC) No 1272/2008 as regards hazard classes and criteria for the classification, labelling and packaging of substances and mixtures, OJ XX of XX p XX.]

categories included in Annex I to Regulation (EC) No 1272/2008. In view of the high level of evidence required for inclusion in the candidate list, the substances currently on that list should be included in Table 3 in Part 3 of Annex VI to Regulation (EC) No 1272/2008.

(21) As the criteria for substances to qualify as endocrine disruptor for human health or the environment included in sections 3.6.5. and 3.8.2. of Annex II to Regulation (EC) No 1107/2009 and in Commission Delegated Regulation (EU) 2017/2100, and those to qualify as endocrine disruptor for human health or the environment included in Annex I to Regulation (EC) No 1272/2008, are equivalent, substances which qualify as meeting the criteria for endocrine disruptor properties in accordance with Commission Regulation (EU) 2018/605 and Commission Delegated Regulation (EU) 2017/2100 should be included as endocrine disruptors category 1 for human health or endocrine disruptors category 1 for the environment in Table 3 in Part 3 of Annex VI to Regulation (EC) No 1272/2008.

(22) As Article 5(1), point (e), of Regulation (EU) No 528/2012[6] refers to the PBT and vPvB criteria included in Annex XIII to Regulation (EC) No 1907/2006 to identify the PBT and vPvB properties of active substances and as those criteria are equivalent to those included in Annex I to Regulation (EC) No 1272/2008, the active substances meeting the criteria to qualify as PBT and vPvB under Regulation (EU) No 528/2012 and under Annex XIII to Regulation (EC) No 1907/2006 should be included in Table 3 of Part 3 of Annex VI to Regulation (EC) No 1272/2008. As PBT and vPvB properties included in sections 3.7.2. and 3.7.3. of Annex II to Regulation (EC) No 1107/2009 of the European Parliament and of the Council[7] are equivalent to those included in Annex I to Regulation (EC) No 1272/2008, the active substances meeting the criteria to qualify as PBT and vPvB according to those criteria in sections 3.7.2. and 3.7.3. of Annex II to Regulation (EC) No 1107/2009 should be included in Table 3 in Part 3 of Annex VI to Regulation (EC) No 1272/2008.

(23) As the substances referred to in recitals 30 and 31 have already been assessed by the European Food Safety Authority or the Agency as well as the Commission which has decided upon by them, they should be included in Table 3 of Part 3 of Annex VI to Regulation (EC) No 1272/2008 by a delegated act, without prior consultation of the Agency as provided for in Article 37(4) of Regulation (EC) No 1272/2008.

(24) Manufacturers and importers often notify different information for the same substance to be included in the Agency's inventory for classification and labelling. In some cases, such divergences result from different impurities, physical states or other differentiations and may be justified. In other cases, the divergences are due to differences in data used for classification, or to disagreement between notifiers or registrants in the case of joint submission of data in accordance with Regulation (EC) No 1907/2006, or to obsolete classification entries. As a result, the classification and labelling inventory contains divergent classifications, which makes the inventory less effective as a hazard collection and communication tool and leads to incorrect

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[6] Regulation (EC) No 528/2012 of 22 May 2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products (OJ L 167 of 27.6.2012 p.1).

[7] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

classifications, ultimately hindering the ability of Regulation (EC) No 1272/2008 to protect human health and the environment. Therefore, the notifiers should be required to provide reasons for divergence from the most severe classification or for introducing a more severe classification per hazard class for the same substance to the Agency. To address divergences between more recent and obsolete classifications, notifiers should be required to update their notifications within 6 months after a decision to change the classification and labelling of a substance has been taken pursuant to a review in Article 15(1) of that Regulation.

(25) In order to enhance transparency of notifications as well as to facilitate the notifiers' duty to come to an agreed notification entry for the same substance, certain information notified to the Agency's classification and labelling inventory should be made publicly available, free of charge. Without prejudice to the protection of commercial interests, that information should include the identity of the notifiers as, knowing whom to contact, would facilitate the objective of coming to an agreed entry to be included in that classification and labelling inventory. In the case of notifications by a group of manufacturers or importers, it should suffice to make publicly available the identity of the notifier submitting the information on behalf of the other members of the group.

(26) Pursuant to Article 45(1) of Regulation (EC) No 1272/2008, appointed bodies in the Member States are to receive relevant information relating to emergency health response submitted by importers and downstream users placing on the market mixtures that are hazardous based on their health or physical effects. Distributors are not required to submit such information. In certain cases of distribution across borders from one Member State to another, or where distributors rebrand or relabel mixtures, the absence of such submission obligation causes information loss for the appointed bodies which may prevent them from providing adequate emergency health response. To address this situation, an obligation to submit information relating to emergency health response should also be introduced for distributors, where they further distribute hazardous mixtures in other Member States or where they rebrand or relabel hazardous mixtures.

(27) Pursuant to Article 45(3) of Regulation (EC) No 1272/2008, appointed bodies are to have all the required information available to provide adequate emergency health response. The Agency already set up and maintains a Union level Poison Centres Notification portal, and established, developed and maintains a database containing information relating to emergency health response to assist some Member States in complying with that Regulation. Therefore, the Agency would be in a position to fulfil the task of receiving that information. To reduce administrative burden for Member States and take advantage of economies of scale, Regulation (EC) No 1272/2008 should provide for the option of appointing the Agency as a body responsible for receiving the relevant information, should a Member State wish to do so.

(28) In addition to the Member States' appointed bodies, the Commission or the Agency should be able to use the information relating to emergency health responses for the purpose of carrying out statistical analysis. That would usefully complement information on the uses of substances submitted as part of registration under Regulation (EC) No 1907/2006, while enabling a better prioritisation of substances to be subject to harmonised classification and labelling under Regulation (EC) No 1272/2008 and feeding into the risk management processes under Regulation (EC) No 1907/2006, and potentially under other Union acts.

(29) Regulation (EC) No 1272/2008 regulates advertisement of hazardous substances and mixtures in a general manner and provides that an advertisement for a substance classified as hazardous is to mention the hazard classes or hazard categories concerned, and an advertisement for a mixture classified as hazardous or a mixture containing a classified substance is to mention the types of hazards indicated on the label where such advertisement allows concluding a contract for purchase without first having sight of the label. This obligation should be changed to ensure that the advertisement of hazardous substances and mixtures contains all the information which is most important in terms of safety and protection of the environment. Therefore, the advertisement should contain the hazard pictogram, the signal word, the hazard class and the hazard statements. The hazard category should not be provided, as it is reflected by the hazard statement.

(30) Regulation (EC) No 1272/2008 does not explicitly refer to offers, let alone to distance sales offers. Consequently, it does not address specific problems arising from distance sales, such as online sales. Whereas advertisements is understood as being at the pre-stage of offers, notably as information designed to promote messages of a natural or legal person, whether or not against remuneration, offers are understood as invitations by a natural or legal person to conclude a purchase contract. This differentiation should justify the requirement of providing more hazard information in offers than in advertisements. In order to keep pace with technological development and new means of sale, the compliance by design obligations laid down for providers of online marketplaces in Article 31 of Regulation (EU) 2022/2065 of the European Parliament and of the Council[8] should apply for the purpose of labelling information required by Article 17 of Regulation (EC) No 1272/2008. The enforcement of those obligations is subject to the rules laid down in Chapter IV of Regulation (EU) 2022/2065.

(31) Apart from providing industry with technical and scientific tools on how to comply with Regulation (EC) No 1272/2008, the Agency should also provide competent authorities with such tools, for example databases, in order to foster implementation. Regulation (EC) No 12727/2008 should more in detail set out the Agency's remit in this regard. Furthermore, the Agency, acting as a body appointed by a Member State competent authority for receiving information for emergency health response, should provide the relevant national appointed body of that Member State access to that information.

(32) After consultation of the Commission expert group of Competent Authorities for REACH[9] and CLP[10], the Commission regularly adapts the Annexes to Regulation (EC) No 1272/2008 to technical and scientific progress. According to Article 53c of

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8 Regulation (EU) 2022/2065 of the European Parliament and of the Council of 19 October 2022 on a Single Market For Digital Services and amending Directive 2000/31/EC (Digital Services Act) (OJ L 277, 27.10.2022, p. 1).

9 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

10 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 (OJ L 353, 31.12.2008, p. 1).

that Regulation, the Commission is to adopt a separate delegated act in respect of each power delegated to it. It has been difficult to apply that provision when amending different parts of Annex VI to Regulation (EC) No 1272/2008 that are subject to different empowerments. In particular in the case of simultaneous introduction of new notes into Part 1 of Annex VI to Regulation (EC) No 1272/2008 pertaining to new entries in Table 3 of Part 3 of Annex VI to Regulation (EC) No 1272/2008 and the introduction of new entries themselves in the same Annex, adoption of separated delegated acts has resulted in artificially separating intrinsically related provisions and thereby affecting coherence by requiring simultaneous adoption of two different but related delegated acts. In such cases, it should be possible to adopt a single delegated act in respect of different delegated powers.

(33) In accordance with Directive 2010/63/EU of the European Parliament and of the Council[11], it is necessary to replace, reduce or refine testing on animals. Implementation of Regulation (EC) No 1272/2008 should be based on the use of alternative test methods, suitable for the assessment of health and environmental classification of chemicals, wherever possible. In order to speed up the transition to non-animal methods, with the ultimate goal of fully replacing animal testing, as well as to improve the efficiency of chemical hazard assessments, innovation in the field of non-animal methods should be monitored and systematically evaluated, and the Commission and the Member States acting in the interest of the Union should promote the inclusion of harmonised criteria based on available alternative methods in UN GHS and subsequently include those criteria in Regulation (EC) No 1272/2008 without undue delay.

(34) Annex VIII to Regulation (EC) No 1272/2008 provides for harmonised information relating to emergency health response and preventative measures to be received by appointed bodies, and sets forth the general requirements, the information to be contained in a submission, the submission format and certain standard formulas. In order to provide legal certainty and clarity on the option for submission of information relating to standardised mixtures and fuels in the context of Annex VIII to Regulation (EC) No 1272/2008, that Regulation should define the term ‘composition conforming with a standard formula’, the obligation to provide the name and product description of the standard formula in the submission and of the fuel should be introduced, and the option to submit information on components even if they are not always present in certain cases should be provided for.

(35) In order to provide further legal certainty and clarity of Annex VIII to Regulation (EC) No 1272/2008, that Regulation should further specify when submission updates are required, as well as ways of identifying the mixture, submitter and contact point by means of their product identifier.

(36) Regulation (EC) No 1272/2008 should therefore be amended accordingly.

(37) To ensure that suppliers of substances and mixtures have time to adapt to rules on classification, labelling and packaging, the application of some provisions of this Regulation should be deferred. Substances and mixtures which are already placed on the market before the end of that deferral period, should be allowed to continue being placed on the market without being re-classified and re-labelled in accordance with this Regulation, to avoid additional burden on suppliers of substances and mixtures.

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[11] Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).

(38) In line with the transitional provisions of Regulation (EC) No 1272/2008 which allow the application of the new provisions at an earlier stage on a voluntary basis, suppliers should have the possibility of applying the new classification, labelling and packaging provisions on a voluntary basis before the date of deferred application of this Regulation.

(39) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States, because environmental pollution is transboundary and the citizens of the Union should benefit from an equal protection of their health and environment and because substances and mixtures should circulate freely on the Union market , but can rather, by reason of their scale, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives,

HAVE ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 1272/2008 is amended as follows:

(1) in Article 1(1), the following point (f) is added:

'(f) providing an obligation for downstream users, importers and distributors referred to in Article 45(1) to submit information relevant for providing an adequate emergency health response to appointed bodies in accordance with Annex VIII.';

(2) in Article 2, the following points 7a and 38 are added:

'7a. 'multi-constituent substance' means a substance that contains more than one constituent.

38. 'acute toxicity estimates' means numeric criteria according to which substances and mixtures are classified in one of four acute toxicity hazard categories based on the oral, dermal or inhalation exposure route.';

(3) in Article 4, paragraph 10 is replaced by the following:

'10. A substance or a mixture shall not be placed on the market unless a supplier has ensured in the course of an industrial or professional activity that the substance or the mixture fulfils the requirements set out in this Regulation.';

(4) in Article 5, the following paragraph 3 is added:

'3. A multi-constituent substance containing at least one constituent, in the form of an individual constituent, an identified impurity or an additive for which relevant information referred to in paragraph 1 is available, shall be examined in accordance with the criteria set out in this paragraph, using the available information on those constituents as well as on the substance, unless Annex I lays down a specific provision.

For the evaluation of multi-constituent substances pursuant to Chapter 2 in relation to the 'germ cell mutagenicity', 'carcinogenicity', 'reproductive toxicity', 'endocrine disrupting property for human health' and 'endocrine disrupting property for the environment' hazard classes referred to in sections 3.5.3.1, 3.6.3.1, 3.7.3.1, 3.11.3.1. and 4.2.3.1. of Annex I, the manufacturer, importer or downstream user shall use the

relevant available information referred to in paragraph 1 for each of the individual constituents in the substance.

Relevant available information on the multi-constituent substance itself shall be taken into account where one of the following conditions are met:

(a) the information demonstrates germ cell mutagenic, carcinogenic, or toxic to reproduction properties, or endocrine disrupting properties for human health or the environment;

(b) the information supports the conclusions based on the relevant available information on the constituents in the substance.

Relevant available information on the multi-constituent substance itself showing absence of certain properties or less severe properties shall not override the relevant available information on the constituents in the substance.

For the evaluation of multi-constituent substances pursuant to Chapter 2 in relation to the 'biodegradation, persistence, mobility and bioaccumulation' properties within the 'hazardous to the aquatic environment' 'persistent, bioaccumulative and toxic', 'very persistent and very bioaccumulative', 'persistent, mobile and toxic' and 'very persistent and very mobile' hazard classes referred to in sections 4.1.2.8 4.1.2.9, 4.3.2.3.1, 4.3.2.3.2, 4.4.2.3.1 and 4.4.2.3.2 of Annex I, the manufacturer, importer or downstream user shall use the relevant available information referred to in paragraph 1 for each of the individual constituents in the substance.

Relevant available information on the multi-constituent substance itself shall be taken into account where one of the following conditions are met:

(a) the information demonstrates biodegradation, persistence, mobility and bioaccumulation properties.

(b) the information supports the conclusions based on the relevant available information on the constituents in the substance.

Relevant available information on the multi-constituent substance itself showing absence of certain properties or less severe properties shall not override the relevant available information on the constituents in the substance.

(5) in Article 6, paragraphs 3 and 4 are replaced by the following:

'3. For the evaluation of mixtures pursuant to chapter 2 in relation to the 'germ cell mutagenicity', 'carcinogenicity', 'reproductive toxicity', 'endocrine disrupting property for human health' and 'endocrine disrupting property for the environment' hazard classes referred to in sections 3.5.3.1, 3.6.3.1, 3.7.3.1, 3.11.3.1 and 4.2.3.1 of Annex I, the manufacturer, importer or downstream user shall only use the relevant available information referred to in paragraph 1 for the substances in the mixture and not for the mixture itself .

However, where the available test data on the mixture itself demonstrates germ cell mutagenic, carcinogenic or toxic to reproduction properties, or endocrine disrupting properties for human health or the environment which have not been identified from the relevant available information on the individual substance referred to in the first subparagraph, that data shall also be taken into account for the purposes of the evaluation of the mixture referred to in the first subparagraph.

4. For the evaluation of mixtures pursuant to Chapter 2 in relation to the 'biodegradation, persistency, mobility and bioaccumulation' properties within the

'hazardous to the aquatic environment', 'persistent, bioaccumulative and toxic', 'very persistent and very bioaccumulative', 'persistent, mobile and toxic' and 'very persistent and very mobile' hazard classes referred to in sections 4.1.2.8, 4.1.2.9, 4.3.2.3.1, 4.3.2.3.2, 4.4.2.3.1 and 4.4.2.3.2 of Annex I, the manufacturer, importer or downstream user shall only use the relevant available information referred to in paragraph 1 for the substances in the mixture and not for the mixture itself ';

(6) in Article 9, paragraphs 3 and 4 are replaced by the following:

'3. Where the criteria referred to in paragraph 1 cannot be applied directly to available identified information, manufacturers, importers and downstream users shall carry out an evaluation by applying a weight of evidence determination using expert judgement in accordance with section 1.1.1 of Annex I to this Regulation, weighing all available information having a bearing on the determination of the hazards of the substance or the mixture, and in accordance with section 1.2 of Annex XI to Regulation (EC) No 1907/2006.

4. When evaluating hazard information for mixtures, manufacturers, importers and downstream users shall, where test data for the mixture itself are inadequate or unavailable, apply the bridging principles referred to in section 1.1.3. of Annex I and in each section of Parts 3 and 4 of that Annex for the purposes of the evaluation.

When applying the bridging principles, manufacturers, importers and downstream users may integrate a weight of evidence determination using expert judgement in accordance with section 1.1.1. of Annex I to this Regulation, weighing all available information having a bearing on the determination of the hazards of the mixture, and in accordance with section 1.2. of Annex XI to Regulation (EC) No 1907/2006. The rules on bridging principles in section 1.1.3 of Annex I shall remain applicable even in a weight of evidence determination.

When evaluating the hazard information for mixtures, manufacturers, importers and downstream users shall, where that information does not permit the application of the bridging principles in accordance with the first and second subparagraphs, evaluate the information by applying the other method or methods set out in Parts 3 and 4 of Annex I.';

(7) Article 10 is replaced by the following:

'Article 10

Concentration limits, M-factors and acute toxicity estimates for classification of substances and mixtures

1. Specific concentration limits and generic concentration limits are limits assigned to a substance indicating a threshold at or above which the presence of that substance in another substance or in a mixture as an identified impurity, additive or individual constituent leads to the classification of the substance or mixture as hazardous.

Specific concentration limits shall be set by the manufacturer, importer or downstream user where adequate and reliable scientific information shows that the hazard of a substance is evident when the substance is present at a level below the concentrations set for any hazard class in Part 2 of Annex I or below the generic concentration limits set for any hazard class in Parts 3, 4 and 5 of Annex I.

In exceptional circumstances specific concentration limits may be set by the manufacturer, importer or downstream user where that manufacturer, importer or downstream user has adequate, reliable and conclusive scientific information that a hazard of a substance classified as hazardous is not evident at a level above the concentrations set for the relevant hazard class in Part 2 of Annex I or above the generic concentration limits set for the relevant hazard class in Parts 3, 4 and 5 of that Annex.

2. M-factors for substances classified as hazardous to the aquatic environment, acute category 1 or chronic category 1, shall be established by manufacturers, importers and downstream users.

3. Acute toxicity estimates for substances classified as acutely toxic for human health shall be established by manufacturers, importers and downstream users.

4. By way of derogation from paragraph 1, specific concentration limits shall not be set for harmonised hazard classes or differentiations for substances included in Part 3 of Annex VI for which a specific concentration limit is given in that Part.

5. By way of derogation from paragraph 2, M-factors shall not be established for harmonised hazard classes or differentiations for substances included in Part 3 of Annex VI for which an M-factor is given in that Part.

6. By way of derogation from paragraph 3, acute toxicity estimates shall not be established for harmonised hazard classes or differentiations for substances included in Part 3 of Annex VI for which an acute toxicity estimate is given in that Part.

7. When setting the specific concentration limit, M-factor or acute toxicity estimate, manufacturers, importers and downstream users shall take into account any specific concentration limits, M-factors or acute toxicity estimate for that substance which have been included in the classification and labelling inventory.

   However, where an M-factor is not given in Part 3 of Annex VI for substances classified as hazardous to the aquatic environment, acute category 1 or chronic category 1, an M-factor based on available data for the substance shall be set by the manufacturer, importer or downstream user. When a mixture including the substance is classified by the manufacturer, importer or downstream user using the summation method, this M-factor shall be used.

8. Specific concentration limits set in accordance with paragraph 1 shall take precedence over the concentration limits set out in the relevant sections of Part 2 of Annex I or the generic concentration limits for classification set out in the relevant sections of Parts 3, 4 and 5 of that Annex.

9. The Agency shall provide further guidance for the application of paragraphs 1, 2 and 3.

10. Where a mixture contains a substance which is classified as hazardous solely due to the presence of an identified impurity, additive or individual constituent, the concentration limits referred to in paragraph 1 shall apply to the concentration of that identified impurity, additive or individual constituent in the mixture.

11. Where a mixture contains another mixture, the concentration limits referred to in paragraph 1 shall apply to the concentration of the identified impurity, additive or individual constituent referred to in paragraph 10 in the resulting final mixture.';

(8) in Article 23, the following point (g) is added:

'(g) ammunition as defined in Article 1(1), point (3), of Directive (EU) 2021/555 of the European Parliament and of the Council* unless it falls within the definition of an article in Article 2, point (9), of this Regulation.

* Directive (EU) 2021/555 of the European Parliament and of the Council of 24 March 2021 on control of the acquisition and possession of weapons (OJ L 115, 6.4.2021, p. 1).';

(9) Article 25 is amended as follows:

(a) in paragraph 6, the first subparagraph is replaced by the following:

(10) '6. The specific labelling rules set out in Part 2 of Annex II shall apply to mixtures containing substances referred to in that Annex.';

(a) the following paragraph 9 is added:

'9. Label elements resulting from requirements set out in other Union acts shall be placed in the section for supplemental information on the label.';

(11) Article 29 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. Where the packaging of a substance or a mixture is either in such a shape or form or is so small that it is impossible to meet the requirements laid down in Article 31 for a label or a fold-out label in the languages of the Member State in which the substance or mixture is placed on the market, the label elements set out in Article 17(1), shall be provided in accordance with sections 1.5.1.1. and 1.5.1.2. of Annex I.';

(b) paragraph 3 is replaced by the following:

'3. Where a hazardous substance or mixture referred to in Part 5 of Annex II is supplied to the general public without packaging, the labelling information shall be provided in accordance with the provision referring to that substance or mixture in that Part.';

(c) the following paragraphs 4b and 4c are inserted:

'4b. By derogation from Article 17(1), the labelling requirement set out in that Article shall not apply to packaging of ammunition that is used by defence forces in combat zones or shipped to such zones where labelling in accordance with that requirement would constitute an unacceptable security risk for the cargo, the soldiers and the staff, and sufficient camouflaging cannot be ensured.

4c. Where paragraph 4b applies, manufactures, importers or downstream users shall provide to the defence force the safety data sheet or a leaflet containing the information referred to in Article 17(1).';

(12) Article 30 is replaced by the following:

‘Article 30

Updating information on labels

1. In case of a change regarding the classification and labelling of a substance or a mixture, which results in the addition of a new hazard class or in a more severe classification, or which requires new supplemental information on the label in accordance with Article 25, the supplier shall ensure that the label is updated within 6 months after the results of the new evaluation referred to in Article 15(4) were obtained.

2. Where a change regarding the classification and labelling of a substance or a mixture is required other than that referred to in paragraph 1, the supplier shall ensure that the label is updated within 18 months after the results of the new evaluation referred to in Article 15(4) were obtained.

3. Paragraphs 1 and 2 shall not apply where a change regarding the classification and labelling of a substance or a mixture was triggered by a harmonised classification and labelling of a substance set out in a delegated act adopted pursuant to Article 37(5) or by a provision set out in a delegated act adopted pursuant to Article 53(1). In such cases, the supplier shall ensure that the label is updated by the date set out in the respective delegated act.

4. The supplier of a substance or mixture that falls within the scope of Regulation (EC) No 1107/2009 or Regulation (EU) No 528/2012 shall update the label in accordance with those Regulations’;

(13) in Article 31(3), the following sentence is added:

‘3. The label elements referred to in Article 17(1) shall be clearly and indelibly marked. They shall stand out clearly from the background and they shall be of such size and spacing as to be easily read. They shall be formatted in accordance with section 1.2.1 of Annex I.’;

(14) in Article 32, paragraph 6 is deleted;

(15) in Title III, the following Chapter 3 is added:

‘*CHAPTER 3*

Formats of the labelling

Article 34a

Physical and digital labelling

1. The label elements referred to in Article 17 shall be provided:

(a) on a label in a physical form (‘physical label’); or

(b) both on a physical label and on a label in a digital form (‘digital label’).

2. By way of derogation from paragraph 1, the suppliers may provide the label elements set out in section 1.6. of Annex I on a digital label only.

Article 34b

Requirements for digital labelling

1. The digital label for substances and mixtures shall satisfy the following general rules and technical requirements:

(a) all label elements referred to in Article 17(1) shall be provided in one place and separated from other information;

(b) the information on the digital label shall be searchable;

(c) the information on the digital label shall be accessible to all users in the Union,

(d) the digital label shall be accessible free of charge, without the need to register, download or install applications, or to provide a password;

(e) the information on the digital label shall be presented in a way that also addresses the needs of vulnerable groups and support, as relevant, the necessary adaptations to facilitate access to the information by those groups;

(f) the information on the digital label shall be accessible with no more than two clicks;

(g) the digital label shall be accessible through digital technologies widely used and compatible with all major operating systems and browsers;

(h) when the digital label is available in more than one language, the choice of language shall not be conditioned on the geographical location;

(i) the link to the digital label shall be printed or placed physically, visibly and legibly on the product in such a way that it can be processed automatically by digital devices widely used by consumers;

(j) the digital label shall remain available for a period of 10 years, including after an insolvency, a liquidation or a cessation of activity in the Union of the supplier that created it, or for such longer period required under other Union legislation covering the information that it contains.

2. Suppliers shall provide, on oral or written demand or when the digital label is temporarily unavailable at the time of purchase of the substance or mixture, the label elements provided on a digital label only in accordance with Article 34a(2) by alternative means. Suppliers shall provide those elements independently of a purchase and free of charge.

3. It is prohibited to track, analyse or use any usage information for purposes going beyond what is absolutely necessary for provision of digital labelling';

(16) in Article 35, the following paragraph 2a is added:

'2a. Hazardous substances or mixtures may be supplied to consumers and professional users via refill stations only if, in addition to the requirements set out in Titles III and IV, the conditions laid down in section 3.4 of Annex II are fulfilled.';

(17) in Article 36, paragraph 1 is amended as follows:

(a) point (a) is replaced by the following:

'(a) respiratory sensitisation, category 1, 1A or 1B (Annex I, section 3.4.)';

(b) the following points (e) to (j) are added:

'(e) endocrine disruption for human health, category 1 or 2 (Annex I, section 3.11.);

(f) endocrine disruption for the environment, category 1 or 2 (Annex I, section 4.2.);

(g) persistent, bioaccumulative and toxic (PBT) (Annex I, section 4.3.);

(h) very persistent, very bioaccumulative (vPvB) (Annex I, section 4.3.);

(i) persistent, mobile and toxic (PMT) (Annex I, section 4.4.);

(j) very persistent, very mobile (vPvM) (Annex I, section 4.4).';

(c) paragraph 2 is replaced by the following:

'2. Substances that are active substances falling within the scope of Regulation (EC) No 1107/2009 or Regulation (EU) 528/2012 shall be subject to harmonised classification and labelling. For such substances, the procedures set out in Article 37(1), (4), (5) and (6) shall apply.';

(18) Article 37 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. A competent authority may submit to the Agency a proposal for harmonised classification and labelling of substances and, where appropriate, specific concentration limits, M-factors or acute toxicity estimates, or a proposal for revision thereof.

The Commission may ask the Agency or the European Food Safety Authority established in accordance with Article 1(2) of Regulation (EC) No 178/2002* to prepare a proposal for harmonised classification and labelling of substances and, where appropriate, specific concentration limits, M-factors or acute toxicity estimates, or a proposal for revision thereof. The Commission may subsequently submit the proposal to the Agency.

The proposals referred to in the first and the second subparagraphs shall follow the format set out in Part 2 of Annex VI and contain the relevant information provided for in Part 1 of Annex VI.

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* Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p.1)';

(b) in paragraph 2, the first subparagraph is replaced by the following:

'2. Manufacturers, importers or downstream users of substances may submit to the Agency a proposal for harmonised classification and labelling of those substances and, where appropriate, specific concentration limits, M-factors or acute toxicity estimates, provided that there is no entry in Part 3 of Annex VI for such substances in relation to the hazard class or differentiation covered by that proposal.';

(c) the following paragraph 2a is inserted:

‘2a. Before submitting a proposal to the Agency, a competent authority, manufacturer, importer or downstream user shall notify the Agency of its intention to submit a proposal for harmonised classification and labelling and, in the case of the Commission, the request to the Agency or the European Food Safety Authority to prepare such proposal.

Within one week from receipt of the notification, the Agency shall publish the name and, where relevant, the EC and CAS numbers of the substance(s), the status of the proposal and the name of the submitter. The Agency shall update the information on the status of the proposal after completion of each stage of the process referred to in Article 37(4) and (5).

Where a competent authority receives a proposal in accordance with paragraph 6, it shall notify the Agency and provide any relevant information on its reason for accepting or refusing the proposal. The Agency shall share that information with the other competent authorities.’;

(d) paragraph 3 is replaced by the following:

‘3. Where the proposal of the manufacturer, importer or downstream user concerns the harmonised classification and labelling of substances in accordance with Article 36(3), it shall be accompanied by the fee determined by the Commission in accordance with the procedure referred to in Article 54(2).’;

(e) paragraphs 5 and 6 are replaced by the following:

‘5. The Commission shall adopt without undue delay, delegated acts in accordance with Article 53a to amend Annex VI by inclusion of substances together with the relevant classification and labelling elements and, where appropriate, the specific concentration limits, M-factors or acute toxicity estimates in Table 3 of Part 3 of Annex VI.

Where, in the case of harmonisation of classification and labelling of substances, imperative grounds of urgency so require, the procedure provided for in Article 53b shall apply to delegated acts adopted pursuant to this paragraph.

6. Manufacturers, importers and downstream users who have new information which may lead to a change of the harmonised classification and labelling elements of substances in Part 3 of Annex VI shall submit a proposal in accordance with paragraph 2, second subparagraph, to the competent authority in one of the Member States in which the substances are placed on the market.’;

(f) The following paragraphs 7 and 8 are inserted:

‘7. The Commission shall adopt delegated acts in accordance with Article 53a to amend Table 3 of Part 3 of Annex VI to this Regulation by inclusion of substances as endocrine disruptor category 1 for human health properties, endocrine disruptor category 1 for environment properties, as persistent, bioaccumulative and toxic or as very persistent and very bioaccumulative together with relevant classification and labelling elements where, on … [OP: please insert the date = the *date of entry into force of Commission Delegated Regulation (EU) ...i.e. delegated act on the new hazard classes - reference to be added once adopted*], those substances have been included in the candidate list referred to in Article 59(1) of Regulation (EC) No 1907/2006.

The inclusion of the substances, referred to in the first subparagraph, in Table 3 of Part 3 of Annex VI to this Regulation shall be carried out on the basis of the

respective criteria for which those substances have been included in the candidate list referred to in Article 59(1) of Regulation (EC) No 1907/2006.'

8. The Commission shall adopt delegated acts in accordance with Article 53a to amend Table 3 of Part 3 of Annex VI by inclusion of substances together with relevant classification and labelling elements where, on … [OP: please insert the date = *the date of entry into force of Commission Delegated Regulation (EU) ...i.e. the delegated act on the new hazard classes - reference to be added once adopted*] those substances have not been approved, under Regulation (EC) No 1107/2009 or Regulation (EU) No 528/2012 or have been approved with derogation in accordance with the relevant provisions of those Regulations, due to either of the following characteristics:

(a) endocrine disruptor in accordance with Section 3.6.5 or Section 3.8.2 of Annex II to Regulation (EC) No 1107/2009;

(b) persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with Section 3.7.2. or 3.7.3. of Annex II to Regulation (EC) No 1107/2009;

(c) endocrine disruptor for human health or for the environment in accordance with Article 1 of Commission Delegated Regulation (EU) 2017/2100*;

(d) persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with Article 5(1), point (e), of Regulation (EU) No 528/2012.

The inclusion of the substances, referred to in the first subparagraph, in Table 3 of Part 3 of Annex VI shall be carried out on the basis of the respective criteria that they meet in accordance with the acts referred to in that subparagraph, points (a) to (d).';

* Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council (OJ L 301 of 17.11.2017 p.1.';

(19) In Article 38(1), point (c) is replaced by the following:

'(c) the specific concentration limits, M-factors or acute toxicity estimates, where applicable;';

(20) Article 40 is amended as follows:

(a) paragraph 1, the first subparagraph is amended as follows:

(i) point (e) is replaced by the following:

'(e) specific concentration limits, M-factors or acute toxicity estimates, where applicable, in accordance with Article 10, together with a justification referred to in the relevant parts of sections 1, 2 and 3 of Annex I to Regulation (EC) No 1907/2006;'

(ii) points (g) and (h) are added:

‘(g) where applicable, the reason for divergence from the most severe classification per hazard class included in the inventory referred to in Article 42;

(h) where applicable, the reason for introducing a more severe classification per hazard class compared to those included in the inventory referred to in Article 42.’;

(b) paragraph 2 is replaced by the following:

‘2. The information listed in paragraph 1 shall be notified to the Agency by the notifier(s) concerned at the latest 6 months after a decision to change the classification and labelling of the substance has been taken pursuant to the review referred to in Article 15(1).’;

(21) in Article 42(1), the third subparagraph is replaced by the following:

‘3. The following information shall be made publicly available free of charge online:

(a) information referred to in Article 40(1), point (a), except where a notifier duly justifies why such publication is potentially harmful for its commercial interests or the commercial interests of any other concerned party;

(b) in the case of group notifications, the identity of the importer or manufacturer submitting the information on behalf of the other members of the group;

(c) information in the inventory which corresponds to the information referred to in Article 119(1) of Regulation (EC) No 1907/2006.

The Agency shall grant access to the information in the inventory that concerns a substance and is not referred to in the first subparagraph to other parties subject to Article 118 of Regulation (EC) No 1907/2006.’;

(22) Article 45 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. Member States shall appoint a body or bodies responsible for receiving the relevant harmonised information relating to emergency health response and preventative measures, in accordance with Annex VIII.’;

(b) the following paragraphs 1a, 1b and 1c are inserted:

‘1a. Member States may appoint the Agency as the body responsible for receiving information relating to emergency health response and preventative measures referred to in paragraph 1.’;

1b. Importers and downstream users placing on the market mixtures that are classified as hazardous on the basis of their health effects or physical effects, shall submit to the body or bodies appointed in accordance with paragraph 1 the harmonised information referred to in Part B of Annex VIII.

1c. Distributors placing on the market mixtures that are classified as hazardous on the basis of their health effects or physical effects, shall submit to the appointed body or bodies the harmonised information referred to in Part B of Annex VIII where they further distribute those mixtures in other Member States, or where they rebrand or relabel the mixtures. This obligation does not apply if the distributors can

demonstrate that the appointed body or bodies already received the same information from importers or downstream users.';

(c) in paragraph 2, point (b) is replaced by the following:

'(b) where requested by a Member State, the Commission or the Agency, to undertake a statistical analysis to identify where improved risk management measures may be needed.';

(d) paragraph 3 is replaced by the following:

'3. The appointed bodies shall have at their disposal all the information required from importers, downstream users and distributors referred to in paragraph 1c, to carry out the tasks for which they are responsible.';

(23) Article 48 is replaced by the following:

'*Article 48*

Advertisement

1. Any advertisement for a substance classified as hazardous shall indicate the relevant hazard pictogram, the signal word, the hazard class and the hazard statements.

2. Any advertisement for a mixture classified as hazardous or covered by Article 25(6) shall indicate the hazard pictogram, the signal word, the hazard class and the hazard statements.

(24) the following Article 48a is added:

'*Article 48a*

Distance sales offers

Suppliers placing substances or mixtures on the market through distance sales shall clearly indicate the label elements referred to in Article 17.';

(25) Article 50 is amended as follows:

(a) in paragraph 2, point (b) is replaced by the following:

'(b) provide competent authorities with technical and scientific guidance and tools on the operation and implementation of this Regulation and provide support to the helpdesks established by Member States under Article 44.';

(b) the following paragraph 3 is added:

'3. Where the Agency acts as an appointed body in accordance with Article 45(1a), it shall put in place the tools necessary to provide access to the information to the relevant appointed body or bodies of the appointing Member State to fulfil their tasks with regard to emergency health response and preventative measures.'

(26) Article 53 is amended as follows:

(a) the following paragraphs 1a to 1b are inserted:

'1a. The Commission is empowered to adopt delegated acts in accordance with Article 53a to amend section 1.6. of Annex I in order to adapt the label elements referred to in Article 34a(2) to technical progress or to the level of digital readiness among all population groups in the Union. When adopting those delegated acts, the

Commission shall take into account the societal needs and a high level of protection of human health and the environment;

1b. In order to adjust to technological changes and (future) developments in the field of digitalisation, the Commission is empowered to adopt delegated acts in accordance with Article 53a to supplement this Regulation by laying down further details on the requirements for the digital labelling referred to in Article 34b. Those requirements shall cover, in particular, the IT solutions which may be used, and the alternative means for providing the information. When adopting those delegated acts, the Commission shall:

(a) ensure coherence with other relevant Union acts;

(b) encourage innovation;

(c) ensure technological neutrality by applying no constraints or prescriptions on choices of technology or equipment, within the bounds of compatibility and interference avoidance;

(d) take into account the level of digital readiness among all population groups in the Union;

(e) ensure that digitalisation does not compromise the protection of human health and the environment.

(b) paragraph 2 is replaced by the following:

'2. The Commission or the Member States acting in the interest of the Union shall, in the manner appropriate to their role in the relevant UN fora, promote the harmonisation of the criteria for classification and labelling of endocrine disruptors for human health, endocrine disruptors 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) substances as well as alternative test methods at the level of the UN.';

(c) the following paragraph 3 is added:

3. The Commission shall regularly evaluate the development of alternative test methods referred to in Article 13(1) of Regulation (EC) No 1907/2006 for classification of substances and mixtures.

(27) Article 53a is amended as follows:

(a) in paragraph 2, the first sentence is replaced by the following:

'The power to adopt delegated acts referred to in Articles 37(5), 37(7), 37(8), 45(4) 53(1), 53(1a) and 53(1b) shall be conferred on the Commission for a period of five years from [OP please insert the date = the *date of entry into force of this Regulation]* ';

(b) in paragraph 3, the first sentence is replaced by the following:

'The delegation of power referred to in Articles 37(5), 37(7) and 37(8), 45(4), 53(1), 53(1a) and 53(1b), may be revoked at any time by the European Parliament or by the Council.';

(c) in paragraph 6, the first sentence is replaced by the following:

'A delegated act adopted pursuant to Articles 37(5), 37(7), 37(8), 45(4) 53(1), 53(1a) and 53(1b), shall enter into force only if no objection has been expressed

either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object.';

(28) Article 53c is replaced by the following:

'Article 53c

Separate delegated acts for different delegated powers

The Commission shall adopt a separate delegated act in respect of each power delegated to it pursuant to this Regulation, with the exception of amendments to Annex VI, where Parts 1 and 2 of that Annex may be amended together with Part 3 of that Annex in one single act.';

(29) Article 54 is replaced by the following:

'1.The Commission shall be assisted by the Committee established by Article 133 of Regulation (EC) No 1907/2006. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011*.';

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

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* Regulation (EU) 182/2011 …';

(30) in Article 61, the following paragraph 7 is added:

'7. Substances and mixtures which have been classified, labelled and packaged in accordance with Article 1(1), Article 4(10), Article 5, Article 6(3) and (4), Article 9(3) and (4), Article 25(6) and (9), Articles 29, 30 and 35, Article 40(1) and (2), Article 42(1), third sub-paragraph, Article 48, section 1.2.1. of Annex I, section 1.5.1.2 of Annex I, section 1.5.2.4.1 of Annex I, Parts 3 and 5 of Annex II, Part A, the first sub-paragraph of section 2.4, of Annex VIII, Part B, section 1, of Annex VIII, Part B, the third paragraph of section 3.1, of Annex VIII , Part B, section 3.6, of Annex VIII, Part B, the first row of Table 3 of Section 3.7, of Annex VIII, Part B, the first paragraph of Section 4.1, of Annex VIII, Part C, sections 1.2 and 1.4, of Annex VIII, and Part D, sections 1, 2 and 3, of Annex VIII as applicable on … [OP: please insert the date = the day before the entry into force of this Regulation] and which were placed on the market before [OP: please insert the date = the first day of the month following 18 months after the date of entry into force of this Regulation] are not required to be classified, labelled and packaged in accordance with this Regulation as amended by Regulation …/… of the European Parliament and of the Council* [OP: please complete the reference in the footnote – it should be the reference to this Regulation] until … [OP: please insert the date = the first day of the month following 42 months after the date of entry into force of this Regulation].

* Regulation (EU) .../... of the European Parliament and of the Council of ... on ... (OJ ...).';

(31) Annex I is amended as set out in Annex I to this Regulation;

(32) Annex II is amended as set out in Annex II to this Regulation;

(33) Annex VIII is amended as set out in Annex III to this Regulation.

ANNEX I

Part 1 of Annex I to Regulation (EC) No 1272/2008 is amended as follows:

(1) Section 1.1.1.3. is replaced by the following:

‘1.1.1.3. A weight of evidence determination means that all available information bearing on the determination of hazard is considered together, such as the results of suitable in vitro tests, relevant animal data, human experience such as occupational data and data from accident databases, epidemiological and clinical studies and well-documented case reports and observations. For substances, information from the application of the category approach (grouping, read-across) and (Q)SAR results are also considered. The quality and consistency of the data shall be given appropriate weight. Information on substances related to the substance being classified shall be considered, as appropriate. Information on substances or mixtures related to the mixture being classified shall be considered in accordance with Article 9(4). Information on the site of action and the mechanism or mode of action study results shall also be considered. Both positive and negative results shall be assembled together in a single weight of evidence determination.’;

(2) Section 1.2.1.4. is replaced by the following:

‘1.2.1.4. The dimensions of the label and of each pictogram, and the font size of letters shall be as follows:

Table 1.3

Minimum dimensions of labels, pictograms and font size

Capacity of the package	Dimensions of the label (in millimetres) for the information required by Article 17	Dimensions of each pictogram (in millimetres)	Minimum font-size
Not exceeding 3 litres:	If possible, at least 52x74	Not smaller than 10x10 If possible, at least 16x16	8pt
Greater than 3 litres but not exceeding 50 litres:	At least 74x105	At least 23x23	12pt
Greater than 50 litres but not exceeding 500 litres:	At least 105x148	At least 32x32	16pt
Greater than 500 litres:	At least 148x210	At least 46x46	20pt’;

(3) the following Section 1.2.1.5. is added:

‘1.2.1.5. The text on the label shall have the following characteristics:

(a) the background of the label shall be white;

(b) the distance between two lines shall be equal or above 120 % of the font size;

(c) a single font shall be used that is easily legible and without serifs;

(d) the letter spacing shall be appropriate for the selected font to be comfortably legible.

For the labelling of inner packaging where the contents do not exceed 10 ml, the font size may be smaller than indicated in Table 1.3, as long as it remains legible for a person with average eyesight, where itis deemed important to place the most critical hazard statement and where the outer packaging meets the requirements of Article 17.’

(4) the following Section 1.3.7. is added:

‘1.3.7. ***Ammunition***

In the case of ammunition that qualifies as a substance or mixture and that is shot through a firearm, the labelling elements may be provided on the intermediate packaging instead of on the inner packaging, or, if there is no intermediate packaging, on the outer packaging.’;

(5) the heading of Section 1.5.1. is replaced by the following:

‘1.5.1. Exemptions from Article 31 in accordance with Article 29(1)’

(6) Section 1.5.1.1. is replaced by the following:

‘1.5.1.1. Where Article 29(1) applies, the label elements referred to in Article 17 may be provided on a tie-on tag or on an outer packaging.’;

(7) Section 1.5.1.2. is replaced by the following:

‘1.5.1.2. Where section 1.5.1.1. applies, the label on any inner packaging shall contain at least hazard pictograms, the signal word, the trade name or the designation of the mixture referred to in Article 18(3), point (a), and the name and telephone number of the suppliers of the substance or mixture.’;

(8) the heading of Section 1.5.2 is replaced by the following:

‘1.5.2. ***Exemptions from Article 17 in accordance with Article 29(2)’;***

(9) Section 1.5.2.4.1 is replaced by the following:

‘1.5.2.4.1 The label elements required by Article 17 may be omitted from the inner packaging where the contents of the inner packaging do not exceed 10 ml and either of the following applies:

(a) the substance or mixture is placed on the market for supply to a distributor or downstream user for scientific research and development or quality control analysis and the inner packaging is contained within outer packaging that meets the requirements set out in Article 17;

(b) the substance or mixture does not require labelling in accordance with Part 1, 2 or 4 of Annex II and is not classified in any of the following hazard classes and categories:

(i) Acute toxicity, categories 1 to 4;

(ii) Specific target organ toxicity – Single exposure, categories 1 and 2;

(iii) Specific target organ toxicity – repeated exposure, categories 1 and 2;

(iv) Skin corrosion/irritation, category 1 (sub-categories 1A, 1B and 1C);

(v) Respiratory sensitisation, category 1 (sub-categories 1A and 1B);

(vi) Aspiration hazard;

(vii)Germ cell mutagenicity, any category;

(viii)Carcinogenity, any category;

(ix) Reproductive toxicity, any category;

(x) Flammable solids, categories 1 and 2.;

(xi) Endocrine disruptors for human health, any category;

(c) the substance or mixture requires labelling in accordance with Part 1, 2 or 4 of Annex II but is not classified in any of the hazard classes and categories referred to in point (b) and has an inner packaging that is contained within outer packaging that meets the requirements set out in Article 17.';

(10) the following Section 1.6. is added:

'1.6. **Label elements that may be provided on a digital label only**

(a) Supplemental information referred to in Article 25(3)';

ANNEX II

Annex II to Regulation (EC) No 1272/2008 is amended as follows:

(1) in Part 3, the following Section 3.4. is added:

'3.4. **Refill stations**

Hazardous substances or mixtures referred to in Article 35(2a), shall meet the following conditions:

(a) the labelling and packaging requirements applicable at the date of placing on the market of the hazardous substance or mixture are fulfilled for every refill station;

(b) a label is firmly affixed on a visible place of the refill station and with a font size that is easily legible and without serifs;

(c) substances and mixtures are only refilled in suitable and clean packaging without any visible residues, which are cleaned before reuse in case of suspected microbiological or other invisible contamination;

(d) the buttons to operate the refill station are out of reach of children and the refill station is not designed in a way to attract the curiosity of children;

(e) overfilling packaging is technically prevented;

(f) filling a substance or mixture into unsuitable packaging is technically prevented;

(g) at the moment of refill, the supplier is reachable for immediate assistance;

(h) refill stations are not operated outdoors and outside business hours where immediate assistance cannot be provided;

(i) the substances or mixtures provided through a refill station do not react with each other in a way that could endanger clients or staff;

(j) staff of the supplier are appropriately trained to minimise safety risks to consumers, professional users and themselves, and follow the necessary hygiene and cleaning protocols;

(k) no substance or mixture provided through a refill station meets the criteria for classification in any of the following hazard classes:

(i) Acute toxicity, categories 1 – 4;

(ii) Specific target organ toxicity – Single exposure, categories 1, 2 and 3;

(iii) Specific target organ toxicity – repeated exposure, categories 1 and 2;

(iv) Skin corrosion/irritation, category 1 (sub-categories 1A, 1B and 1C);

(v) Respiratory sensitisation, category 1 (sub-categories 1A and 1B);

(vi) Aspiration hazard;

(vii) Germ cell mutagenicity, any category;

(viii) Carcinogenicity, any category;

(ix) Reproductive toxicity, any category;

(x) Flammable gases, categories 1 and 2;

(xi) Flammable liquids, categories 1 and 2;

(xii) Flammable solids, categories 1 and 2.

(xiii) [insert: Endocrine disruptor for human health, categories 1 and 2].';

(xiv) [insert: Endocrine disruptor for the environment, category 1 and 2];

(xv) [insert: Persistent, bioaccumulative and toxic (PBT)];

(xvi) [insert: Very persistent and very bioaccumulative (vPvB)];

(xvii) [insert: Persistent, mobile and toxic (PMT)];

(xviii) [insert Very persistent and very mobile (vPvM)].

By way of derogation from point (b), a single label on the refill station may be used for several substances or mixtures for which the label elements referred to in Article

17(1) are identical, provided that the label clearly indicates the name of each substance or mixture that it applies to.';

(2) Part 5 is replaced by the following:

'PART 5: HAZARDOUS SUBSTANCES AND MIXTURES TO WHICH ARTICLE 29(3) APPLIES

Ready mixed cement and concrete in the wet state shall be accompanied by a copy of the label elements in accordance with Article 17.

For a substance or a mixture supplied at a filling station and directly pumped into a receptacle that forms an integral part of a vehicle and from where the substance or mixture is normally not intended to be removed, the label elements referred to in Article 17 shall be provided on the respective pump.';

ANNEX III

Annex VIII to Regulation (EC) No 1272/2008 is amended as follows:

(1) Part A is amended as follows:

(a) Section 1 is replaced by the following:

'1. Application

1.1 Importers, downstream users and distributors referred to in Article 45(1c) placing on the market mixtures for consumer use, within the meaning of Section 2.4 of Part A of this Annex, shall comply with this Annex from 1 January 2021.

1.2. Importers, downstream users and distributors referred to in Article 45(1c) placing on the market mixtures for professional use, within the meaning of Section 2.4 of Part A of this Annex, shall comply with this Annex from 1 January 2021.

1.3. Importers, downstream users and distributors referred to in Article 45(1c) placing on the market mixtures for industrial use or mixtures with an end use not subject to notification within the meaning of Section 2.4 of Part A of this Annex, shall comply with this Annex from 1 January 2024.

1.4. Importers, downstream users and distributors referred to in Article 45(1c) having submitted information relating to hazardous mixtures to a body appointed in accordance with Article 45(1) before the dates of applicability mentioned in Sections 1.1, 1.2 and 1.3 and which are not in accordance with this Annex, shall for those mixtures not be required to comply with this Annex until 1 January 2025.

1.5. By way of derogation from Section 1.4, if one of the changes described in Section 4.1 of Part B of this Annex occurs before 1 January 2025, importers, downstream users and distributors referred to in Article 45(1c) shall comply with this Annex before placing that mixture, as changed, on the market.';

(b) Section 2.1 is replaced by the following:

'2.1 This Annex sets out the requirements that importers, downstream users and distributors referred to in Article 45(1c) ('submitters') placing mixtures on the market shall fulfil in respect of the submission of information so that appointed bodies have at their disposal the information required to carry out the tasks for which they are responsible under Article 45.';

(c) in Section 2.4., first subparagraph, the following point (6) is added:

‘(6) ‘composition conforming with a standard formula specified in Part D’ means a composition which includes all the components listed in one of the standard formulas referred to in Part D of this Annex, where those components are present in the mixture in concentrations within the ranges specified in that standard formula.’;

(2) Part B is amended as follows:

(a) the following Section 1.1a. is inserted:

‘1.1a. Name and product description of standard formula or name of fuel

For mixtures with a composition conforming with a standard formula specified in Part D, the name and product description of the relevant standard formula as indicated in that Part shall be included in the submission.

For fuels listed in Table 3, the name of the fuel shall be provided as indicated in that table.’;

(b) in Section 3.1, the third paragraph is replaced by the following:

‘Components which are not present in a mixture shall not be notified. However, if the components are notified as part of an interchangeable component group in accordance with Section 3.5. or their concentration has been submitted as a range of percentages in accordance with Sections 3.6. or 3.7, they may be notified if it is certain that they will be present in the mixture at some point in time. In addition, for mixtures with a composition conforming with a standard formula specified in Part D for which the composition is notified in accordance with Section 3.6, first indent, components listed in the relevant standard formula shall be notified even if the component is potentially not, or not permanently, present in cases where the indicated concentration range in Part D includes 0 %.’;

(c) the title of Section 3.6. is replaced by the following:

‘3.6. Mixtures with a composition conforming with a standard formula’;

(d) in Section 3.7., the first row of Table 3 is replaced by the following:

‘Fuel name	Product description’;

(e) in Section 4.1, the first paragraph, the following indent is added; :

‘- when there are other changes to a mixture placed on the market which are relevant for the emergency health response referred to in Article 45’;

(3) Part C is amended as follows:

(a) Section 1.2. is replaced by the following:

‘**1.2 Identification of the mixture, submitter and contact point**

Product identifier

– Complete trade name(s) of the product including, where relevant, brand name(s), name of the product and variant names as they appear on the label, without

abbreviations or non-alphanumerical symbols and enabling specific identification of the product.

– Unique Formula Identifier(s) (UFI)

– Other identifiers (authorisation number, company product codes)

– In case of group submission, all product identifiers shall be listed.

Name and product description of standard formula or name of fuel

– Standard formula name and product description as specified in Part D (where applicable)

– Fuel name as specified in Table 3 of Part B (where applicable)

Contact details of the submitter and contact point

– Name

– Full address

– Telephone number

– E-mail address

Contact details for rapid access to additional product information (24 hours/7 days). Only for limited submission.

– Name

– Telephone number (accessible 24 hours per day, 7 days per week)

– E-mail address';

(b) Section 1.4. is replaced by the following:

'1.4. **Information on the mixture components and interchangeable component groups**

Identification of the mixture components

— Chemical/trade name of the components

— CAS number (where applicable)

— EC number (where applicable)

— UFI (where applicable)

— Standard formula name and product description (where applicable)

– Fuel name (where applicable)';

Name of interchangeable component groups (where applicable)

Concentration and concentration ranges of the mixture components

— Exact concentration or concentration range

Classification of mixture components

— Hazard classification (where applicable)

— Additional identifiers (where applicable and relevant for health response)

List according to Part B, Section 3.1, fifth subparagraph (where applicable) ';

(4) Part D is amended as follows:

(a) In section 1, the first row of the tables with standard formulas for cement are replaced by the following:

'Standard formula name	**Cement Standard Formula 1**'

'Standard formula name	**Cement Standard Formula 2**'

'Standard formula name	**Cement Standard Formula 3**'

'Standard formula name	**Cement Standard Formula 4**'

'Standard formula name	**Cement Standard Formula 5**'

'Standard formula name	**Cement Standard Formula 6**'

'Standard formula name	**Cement Standard Formula 7**'

'Standard formula name	**Cement Standard Formula 8**'

'Standard formula name	**Cement Standard Formula 9**'

'Standard formula name	**Cement Standard Formula 10**'

'Standard formula name	**Cement Standard Formula 11**'

‘Standard formula name	**Cement Standard Formula 12**’;

‘Standard formula name	**Cement Standard Formula 13**’

‘Standard formula name	**Cement Standard Formula 14**’

‘Standard formula name	**Cement Standard Formula 15**’

‘Standard formula name	**Cement Standard Formula 16**’

‘Standard formula name	**Cement Standard Formula 17**’

‘Standard formula name	**Cement Standard Formula 18**’

‘Standard formula name	**Cement Standard Formula 19**’

‘Standard formula name	**Cement Standard Formula 20**’;

(b) In section 2, the two first rows of the table with standard formula for gypsum is replaced by the following:

‘Standard formula name	– **Gypsum binder Standard Formula**
Product description	Gypsum binder’;

(c) In section 3, the two first rows of the tables with standard formulas for ready mixed concrete are replaced by the following:

‘Standard formula name	– **Ready mixed concrete Standard Formula 1**
Product description	– Ready mixed concrete with concrete strength classes C8/10, C12/15, C16/20, C20/25,

	C25/30, C28/35, C32/40, C35/45, C40/50, C45/55, C50/60, LC8/9, LC12/13, LC16/18, LC20/22, LC25/28, LC30/33, LC35/38, LC40/44, LC45/50, LC50/55, LC55/60’;

‘Standard formula name	– **Ready mixed concrete Standard Formula 2**
Product description	– Ready mixed concrete with concrete strength classes C55/67, C60/75, C70/85, C80/95, C90/105, C100/105, LC 60/66, LC70/77, LC80/88’.

Article 2

1. This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

2. The following provisions shall apply from [OP: please insert the date = the first day of the month following 18 months after the date of entry into force of this Regulation]:

   (a) Article 1, points (1), (4), (5), (6), (7), (10), (11), (12), (15), (16), (20), (21), (23) and (24);

   (b) points (2), (3), (7), (9) and (10) of Annex I;

   (c) Annex II;

   (d) points (1)(c), (2), (3) and (4) of Annex III.

3. By way of derogation from Article 1(1), Article 4(10), Article 5, Article 6(3) and (4), Article 9(3) and (4), Article 25(6) and (9), Articles 29, 30 and 35, Article 40(1) and (2), Article 42(1), third sub-paragraph, Article 48, section 1.2.1. of Annex I, section 1.5.1.2 of Annex I, section 1.5.2.4.1 of Annex I, Parts 3 and 5 of Annex II, Part A, the first sub-paragraph of section 2.4, of Annex VIII, Part B, section 1, of Annex VIII, Part B, the third paragraph of section 3.1, of Annex VIII , Part B, section 3.6, of Annex VIII, Part B, the first row of Table 3 of Section 3.7, of Annex VIII, Part B, the first paragraph of Section 4.1, of Annex VIII, Part C, sections 1.2 and 1.4, of Annex VIII, and Part D, sections 1, 2 and 3, of Annex VIII to Regulation (EC) No 1272/2008 as applicable on [OP: please insert the date = the day before the date of entry into force of this Regulation], substances and mixtures may until … [OP: please insert the date = the last day of the month following 17 months after the date of entry into force of this Regulation] be classified, labelled and packaged in accordance with Regulation (EC) No 1272/2008 as amended by the following provisions of this Regulation:

   (a) Article 1, points (1), (4), (5), (6), (7), (10), (11), (12), (16), (20), (21) and (23);

   (b) points (2), (3), (7) and (9) of Annex I;

   (c) Annex II;

   (d) points (1)(c), (2), (3) and (4) of Annex III.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*