Council of the
European Union

Brussels, 30 June 2023
(OR. en)

11332/23

Interinstitutional File:
2022/0432(COD)

ENT 154
MI 585
CHIMIE 67
COMPET 718
IND 360
ENV 796
SAN 444
CONSOM 260
CODEC 1257

OUTCOME OF PROCEEDINGS

From:	General Secretariat of the Council
To:	Delegations
No. prev. doc.:	ST 10912/23
No. Cion doc.:	ST 16258/22 + ADD 1 - 8 - COM (2022) 748 final
Subject:	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 - Mandate for Negotiations with the European Parliament - Outcome of Proceedings

Delegations will find in the ANNEX the above Presidency Compromise text of a mandate to start negotiations with the European Parliament, which was approved at the Coreper meeting on 30 June 2023.

ANNEX

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],

[1] OJ C , , p. .

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

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, such as via online market places. This provision, together with requirements in Regulation (EU) 2023/988 of the European Parliament and of the Council on General Product Safety, Regulation (EU) 2022/2065 of the European Parliament and of the Council on a Single Market For Digital Services and Regulation (EU) 2019/1020 of the European Parliament and of the Council on Market Surveillance and Compliance of Products, would improve compliance with and enforcement of the Regulation (EC) No 1272~~/~~2008 and thereby ensure a high level of protection of human health and the environment. In order to ~~prevent~~ avoid 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 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.

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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).

(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 (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.

(6a) In general, substances and mixtures should be classified for any form or physical state. When the available scientific evidence warrants a different classification linked to a specific form or physical state, it should nevertheless be possible for manufacturers, importers, and downstream users in the self-classification process to classify differently depending on the form or physical state. However, if a substance is subject to harmonised classification without being limited to a specific form or physical state, this harmonised classification should apply to all its forms and physical states. If a substance is subject to harmonised classification only for a specific form of that substance, it should be clarified that the classification of the substance for the other forms or physical states is still subject to self-classification.

(7) While the majority of ammunition is usually considered as an article, ~~Ammunition qualifying as~~ in some cases, it may be a substance or a mixture. Where ammunition is determined to be a substance or a mixture, it 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 that~~e cartridge~~ inner packaging 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~~ that is intended for ~~exclusively~~ use~~d~~ by national defence forces ~~in combat zones~~, could, in specific cases, constitute an unacceptable ~~safety or~~ security risk for the cargo, soldiers ~~and~~ or 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~~ or 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 for a supplier 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 by, or communicated to, that supplier. 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 by, or communicated to, that supplier. To ensure that the results of reviewed classifications of substances and mixtures are communicated throughout the whole supply chain, suppliers shall cooperate in order to reduce the overall time needed to effectuate any necessary changes in classification, labelling or packaging.

It should also be clarified that, in cases of harmonised 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).

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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.)

(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~~ possibility to use ~~of~~ fold-out labels on a regular basis.~~,~~ It is therefore appropriate to allow labels to be presented in a form of fold-out labels, applying the general rules on application and formatting to ensure ~~while~~ readability and specific requirements for form and design of the front page ~~of labels should be ensured by laying down minimum font size and formatting requirements~~.

(11a) In order to ensure a high level of protection for human health and the environment it is necessary that labels on substances and mixtures are legible. Minimum requirements on important parameters such as font size, distance and colour should therefore be laid down. A flexible approach should however be taken in respect to nuances of those colours so as not to hamper the strive for a circular economy through the use of recycled materials for packaging material.

(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, such as people with visual impairments, and for 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 that the supplier who places a data carrier linking to ~~for~~ such a label~~ling~~ must satisfy. These technical requirements on the digital label should however not affect the responsibilities of all suppliers to ensure that labelling requirements are fulfilled when placing a substance or mixture on the market. In order to keep pace with digitalisation ~~provide for legal certainty,~~ it is appropriate to allow certain ~~specify the~~ label elements required under this Regulation ~~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, while not affecting the labelling requirements or possibilities for digital labelling laid down in other Union legislation.

(13) In order to adapt the label elements allowed to be provided only in a digital format to developments in GHS ~~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~~ put on a digital ~~format~~ label only, provided that the GHS does not require such labelling elements to be put on the physical label, and 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. Risk mitigation measures should be in place to ensure that refill can be performed safely, for example by preventing overfilling, contamination and operation by children as well as avoiding reaction between substances and mixtures provided through the station, or with residues in refilled packages.

(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, AdBlue and wind screen fluids, supplied at filling stations and intended to be pumped into receptacles from where they are normally not intended to be removed. For the same reason, when it comes to filling vehicle fuels in portable receptacles, there is a need to ensure that labelling information is provided to be available for the user during storage and use.

(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.

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.]

(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 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. Substances included in the candidate list as having endocrine disrupting properties should be included as endocrine disruption for human health category 1 or endocrine disruption for the environment category 1 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 disruption~~ors category 1~~ for human health category 1 or endocrine disruption~~ors category 1~~ for the environment category 1 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 20, 21 ~~30~~ and 22 ~~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.

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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).

To avoid duplication of ongoing work by authorities under Regulation (EC) No 1272/2008 and Regulation (EC) 1907/2006, Regulation (EC) 1107/2009 and Regulation (EU) 528/2012, delegated acts should also be adopted within an adequate deadline for substances which are foreseen to be added to the candidate list under Article 59 of Regulation (EC) No 1907/2006; substances for which applications for approval or renewal of approval have been submitted in accordance with the relevant provisions of Regulation (EC) No 1107/2009; substances for which the evaluating competent authority has submitted its draft assessment report on the approval or renewal of approval to the Agency in accordance with Regulation (EU) No 528/2012, or substances for which the application was submitted for the purpose of Directive 98/8/EC and the Member State's evaluation in accordance with that Directive has been completed by 1 September 2013 but no decision on the approval was adopted before that date, or substances for which the Agency has submitted to the Commission an opinion pursuant to Article 75(1)(g) of Regulation (EU) No 528/2012 concluding that they meet those criteria.

Furthermore, in order to ensure that new dossiers or on-going dossiers still at an early stage of the assessment contain a dossier for harmonised classification and labelling, the transitional provisions should apply for a limited time period.

(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 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~~ statistical information relating to emergency health responses for the purpose of ~~carrying out statistical analysis~~ identifying where improved risk management measures may be needed. 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 human health and the environment. Therefore, the advertisement should contain the hazard pictogram, the signal word~~, the hazard class and~~ the hazard statements and supplemental EUH statements, with derogations for non-visual advertisement. 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, it is necessary to require the labelling elements to be indicated in case of distance sales, including via online market places, in order for 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~~ to apply ~~for the purpose of~~ in relation to such 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.

[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).

(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 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.

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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).

(32a) It is important that the introduction, adjustment, or clarification of the criteria for the classification and labelling of endocrine disruptors for human health, endocrine disruptors for the environment, persistent, bioaccumulative and toxic (PTB), very persistent and very bioaccumulative (vPvB), persistent, mobile and toxic (PMT) and very persistent and very mobile (vPvM) substances is promoted in the relevant UN fora. When attending international meetings, the Commission and Member States should cooperate efficiently and be in line with Union positions in accordance with the Treaties.

(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 cooperate efficiently and be in line with Union positions in accordance with the Treaties to 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.

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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).

(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.

(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(1b) and 45(1c) 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 to 41 are added:

‘~~7a. ‘multi-constituent substance’ means a substance that contains more than one constituent.~~

38. ‘acute toxicity estimates’ means numeric values which are used to classify ~~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.~~’~~;

39. ‘data carrier’ means a linear bar code symbol, a two-dimensional symbol or other automatic identification data capture medium that can be read by a device;

40. ‘refill’ means an operation by which a consumer or a professional user fills a packaging with a hazardous substance or mixture offered by a supplier in the course of a commercial activity, whether in return for payment or free of charge;

41. ‘refill station’ means a place where a supplier offers to consumers or professional users hazardous substances or mixtures that can be acquired through refill, either manually or through automatic or semi-automatic equipment.’;

(3) ~~in~~ Article 4 is amended as follows:

(a) paragraph 3 is replaced by the following:

‘3. If a substance is subject to harmonised classification and labelling in accordance with Title V, through an entry in part 3 of Annex VI, that substance shall be classified in accordance with that entry, and a classification of that substance in accordance with Title II shall not be performed for the hazard classes, differentiations and forms or physical states covered by that entry.

The harmonised classification of that substance shall apply to all its forms and physical states unless an entry in Part 3 of Annex VI specifies that a harmonised classification applies to a specific form and physical state of that substance.

However, where the substance also falls within one or more hazard classes or differentiations or it is in a form or physical state not covered by an entry in Part 3 of Annex VI, classification under Title II shall be carried out for those hazard classes or, differentiations and forms or physical states.’

(b) ~~, paragraph 10 is replaced by~~ the following paragraph 11 is added:

‘~~10. A substance or a mixture shall not be placed on the market unless~~

11. A natural or legal person established outside the Community can place substances and mixtures on the market only if it ensures that a supplier established in the Community, who shall be indicated on the label, ~~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 with regard to the substances and mixtures in question.’;

(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 Cchapter 2 of this Title in relation to the ‘germ cell mutagenicity’, ‘carcinogenicity’, ‘reproductive toxicity’, ‘endocrine disruptiong ~~property~~ for human health’ and ‘endocrine disruptiong ~~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, w~~Where the available test data on the mixture itself demonstrates germ cell mutagenic, carcinogenic or toxic to reproduction properties, or endocrine disruptiong ~~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 of this Title in relation to the ‘biodegradation, persistency, mobility and bioaccumulation’ properties within the ‘hazardous to the aquatic environment’, ‘persistent, bioaccumulative and toxic’~~,~~ or ‘~~very~~ persistent and very bioaccumulative properties’, ‘persistent, mobile and toxic’ ~~and~~or ‘~~very~~ persistent and very mobile properties’ 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.’;

(5a) in Article 8, the following paragraph 7 is added:

‘7. 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.’

(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. If more than one similar tested mixture is available ~~W~~when applying the bridging principles, manufacturers, importers and downstream users ~~may~~ shall ~~integrate~~ apply 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 to select the most suitable similar tested mixtures according to Article 6(5) for decision on classification. ~~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~~ such a 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.

Manufacturers, importer or downstream users may set a specific concentration limit of a substance ~~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 shows that ~~a~~ the 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. Manufacturers, importers and downstream users shall establish 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, second and third subparagraph, 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.

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.

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, second and third subparagraph, 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, second and third subparagraph, 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, second and third subparagraph, shall apply to the concentration of the identified impurity, additive or individual constituent referred to in paragraph 10 in the resulting final mixture.';

(7a) Article 13 is replaced by the following:

Article 13

Decision to classify substances and mixtures

If the evaluation undertaken pursuant to Article 9 and Article 12 shows that the hazards associated with the substance or mixture meet the criteria for classification in one or more hazard classes or differentiations in Parts 2 to 5 of Annex I, manufacturers, importers and downstream users shall classify the substance or mixture or, if scientifically justified, specific forms or physical states thereof, in relation to the relevant hazard class or classes or differentiations by assigning the following:

(a) one or more hazard categories for each relevant hazard class or differentiation;

(b) subject to Article 21, one or more hazard statements corresponding to each hazard category assigned in accordance with (a).

(7b) in Article 18(3), point (b) is replaced by the following:

‘(b) the identity of all substances in the mixture that contribute to the classification of the mixture as regards acute toxicity, skin corrosion or serious eye damage, germ cell mutagenicity, carcinogenicity, reproductive toxicity, respiratory or skin sensitisation, specific target organ toxicity (STOT), aspiration hazard, or endocrine disruption for human health.'

(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[12] unless it is an article according to ~~falls within~~ the definition ~~of an article~~ in Article 2, point (9) and~~,~~ that falls within the scope of Article 4(8) of this Regulation.

[12] 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).’

(8a) In Article 24(2), the second subparagraph is replaced by the following:

'The level of the fees shall be determined by the Commission by means of implementing act in accordance with the examination procedure referred to in Article 54(2) of this Regulation.'

(9) Article 25 is amended as follows:

(x) paragraph 3 is replaced by the following:

3. 'The supplier may include supplemental information in the section for supplemental information on the label other than that referred to in paragraphs 1, 2 and 6 to 9, provided that that information does not make it more difficult to identify the label elements referred to in Article 17(1) (a) to (g) and that it provides further details and does not contradict or cast doubt on the validity of the information specified by those elements.';

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

~~(10)~~

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

(~~a~~b) 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 section~~s~~ 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 paragraph~~s~~ 4b ~~and 4c are~~ is 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 intended for use~~d~~ 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~~ or the staff, and sufficient camouflaging cannot be ensured.

~~4c.~~ ~~Where paragraph 4b applies~~ In this case, manufacturers, importers or downstream users shall provide to the defence force the safety data sheet or, if no safety data sheet is required, a ~~leaflet containing~~ copy of the label elements ~~information referred to~~ in accordance with 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~~ or 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 of that substance or that mixture shall ensure that the label is updated without undue delay and no later than ~~within~~ 6 months after the results of the new evaluation referred to in Article 15(4) were obtained by, or communicated to, that supplier.

2. Where a change regarding the classification ~~and~~ or labelling of a substance or a mixture is required other than that referred to in paragraph 1, the supplier of that substance or that mixture shall ensure that the label is updated without undue delay and no later than ~~within~~ 18 months after the results of the new evaluation referred to in Article 15(4) were obtained by, or communicated to, that supplier.

2a. Suppliers shall cooperate in accordance with Article 4(9) to ensure that the results of the new evaluations referred to in Article 15(4) are communicated throughout the supply chain without undue delay in order to fulfil the obligations in paragraphs 1 and 2.

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 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. Labels shall be firmly affixed to one or more surfaces of the packaging immediately containing the substance or mixture and shall be readable horizontally when the package is set down normally. The label may be presented in the form of a fold-out-label.'

(b) the following paragraph 1a is inserted:

‘1a. Where a digital label pursuant to Article 34a(1) is used, a data carrier to that digital label shall be firmly affixed or printed on the physical label or on the packaging next to the label in such a way that it can be processed automatically by digital devices that are widely used.

Where label elements pursuant to Article 34a(2) are provided on a digital label only, the data carrier shall be accompanied by the statement ”More hazard information available online” or by a similar indication.’

(c) paragraph ~~(~~3~~),~~ is replaced by 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*

Labelling ~~F~~formats ~~of the labelling~~

Article 34a

Physical and digital labelling

1. The label elements for substances and mixtures referred to in Article 17 shall be provided~~:(a)~~ on a label in a physical form (‘physical label’)~~.; or (b) both on a~~ In addition to the physical label~~, and on a~~ the label elements referred to in Article 17 may be provided 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.

   Where those label elements are provided on a digital label only, suppliers shall, upon oral or written request or when the digital label is temporarily unavailable at the time of purchase of the substance or mixture, provide those label elements by alternative means. Suppliers shall provide those elements independently of a purchase and free of charge.

3. Where the information is provided through a digital label, the requirements for digital labels set out in Article 34b shall apply.

Article 34b

Requirements for digital label~~s ling~~

1. The supplier who pursuant to Article 31(1a) places a data carrier linking to a digital label ~~for substances and mixtures~~ shall ensure that the digital label satisfies~~y~~ the following general rules and technical requirements:

   (a) all label elements referred to in Article 17(1) shall be provided together 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 and shall remain accessible for a period of at least 10 years or for a longer period where required by other Union legislation;

(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 information on the digital label is ~~available~~ accessible in more than one language, the choice of language shall not be conditioned ~~on~~ by the geographical location when accessed;

~~(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.

This paragraph shall not apply to hazardous substances or mixtures supplied to the general public without packaging in accordance with Article 29(3).’;

(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~~ request the Agency or the European Food Safety Authority established in accordance with Article 1(2) of Regulation (EC) No 178/2002[13] 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.’

(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.’;

[13] 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);

(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 t~~The Commission shall also notify to the Agency of its~~, 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, the proposed classification 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 by means of implementing act in accordance with the examination 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, where it finds that the harmonisation of the classification and labelling of the substance concerned is appropriate, 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 is inserted:

‘7. In order to avoid duplication of assessment of hazardous properties of substances, The Commission is empowered to shall adopt delegated acts in accordance with Article 53a to amend Table 3 of Part 3 of Annex VI to this Regulation to:

- by include sion of substances by [OP, please insert the date: 24 months after the entry into force of this Regulation] in Table 3 of Part 3 of Annex VI as endocrine disruption or category 1 for human health category 1 properties, endocrine disruption or category 1 for the environment category 1 properties, as persistent, bioaccumulative and toxic, or as very persistent, and very bioaccumulative, together with relevant classification and labelling elements on the basis of respective criteria where, on … [OP: please insert the date = the date of 6 months after entry into force of Commission Delegated this Regulation *(EU) …i.e. delegated act on the new hazard classes – reference to be added once adopted*], those substances:

  (a) have been included in the candidate list referred to in Article 59(1) of Regulation (EC) No 1907/2006 as having endocrine disrupting properties for human health or the environment, as persistent, bioaccumulative and toxic or as very persistent and very bioaccumulative,

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]~~

(b) have been identified as having endocrine disrupting properties in accordance with Section 3.6.5 or Section 3.8.2 of Annex II to Regulation (EC) No 1107/2009, or 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 and a decision on the application for approval or the renewal of approval of those substances has~~ve not~~ been adopted ~~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[14];~~

~~(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.~~

[14] 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.';

~~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).';~~

(c) have been identified as having endocrine disrupting properties in accordance with Article 1 of Commission Delegated Regulation (EU) 2017/2100, or persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with Article 5(1), point (e), of Regulation (EU) No 528/2012 and a decision on the application for approval or renewal of approval of those substances has been adopted under Regulation (EU) No 528/2012.

– include substances in Table 3 of Part 3 of Annex VI as endocrine disruption for human health category 1, endocrine disruption for the environment category 1 as persistent, bioaccumulative and toxic, or as very persistent, very bioaccumulative, together with relevant classification and labelling elements on the basis of respective criteria where:

(a) those substances have been included in the candidate list referred to in Article 59 of Regulation (EC) No 1907/2006 before [OP, please insert date – 18 months after the entry into force of this Regulation] as having one of the properties mentioned above and for which a dossier according to Annex XV of Regulation (EC) No 1907/2006 was under assessment by [OP, please insert date – 6 months after entry into force of this Regulation]

(b) a decision on the application for approval or the renewal of approval of those substances identified as having one of the properties mentioned above has been adopted under Regulation (EC) No 1107/2009 before [OP, please insert date – 7 years + 6 months after the entry into force of this Regulation] and an application for approval or renewal of approval of those substances in accordance with the relevant provisions of Regulation (EC) No 1107/2009 was submitted before [OP, please insert date – 6 months after entry into force of this Regulation]

(c) a decision on the application for approval or the renewal of approval of those substances identified as having one of the properties mentioned above has been adopted under Regulation (EU) 528/2012 before [OP, please insert date – 5 years + 6 months after the entry into force of this Regulation] and where, by the date of [OP: please insert the date – 6 months after the entry into force of this Regulation]:

i. the evaluating competent authority has submitted its draft assessment report on the application for approval or renewal of approval to the Agency in accordance with the relevant provisions of Regulation (EU) No 528/2012, or

ii. the application was submitted for the purpose of Directive 98/8/EC and the Member State's evaluation in accordance with that Directive has been completed by 1 September 2013, but no decision on the application for approval or renewal of approval was adopted before that date, or

iii. the Agency has submitted to the Commission an opinion pursuant to Article 75(1)(g) of Regulation (EU) No 528/2012 following a request to establish whether the respective criteria are met.

(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.’;

(iii) subparagraph 2 is replaced by the following:

The information referred to in (a) to (h) shall not be notified, if it has been submitted to the Agency as part of a registration pursuant to Regulation (EC) No 1907/2006, or if it has already been notified by that notifier.

(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~~.~~;

(d) the date of the latest update of the classification and labelling.

~~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.~~

Information referred to in Article 40(1)(a) shall not be made publicly available where a notifier duly justifies why publication of such information is potentially harmful for its commercial interests or the commercial interests of any other concerned party.’;

(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 appointed in accordance with paragraph 1 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 athe 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 in accordance with paragraph 1.’;

(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 pictograms, ~~the~~ signal word, ~~the hazard class and the~~ hazard statements and supplemental EUH statements set out in Annex II.

2. Any advertisement for a mixture classified as hazardous or covered by Article 25(6) shall indicate the hazard pictograms, ~~the~~ signal word, ~~the hazard class and the~~ hazard statements and supplemental EUH statements set out in Annex II.

3. By way of derogation from paragraph 1 and 2, the hazard pictograms and signal word may be omitted where the advertisement is non-visual.**’;**

(24) the following Article 48a is added:

‘*Article 48a*

Distance sales offers

~~Suppliers placing~~ When substances or mixtures are placed on the market through distance sales, the offer shall clearly and visibly 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.’

(25a) In Article 52, paragraph 2 is replaced by the following:

‘2. Within 60 days of receipt of the information from the Member State, the Commission shall adopt implementing acts in accordance with the examination procedure referred to in Article 54(2) either to authorise the provisional measure for a time period defined in the decision or to require the Member State to revoke the provisional measure.’

(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 include the label elements that may be put on a digital label only, provided that GHS does not require such labelling elements to appear on the physical label ~~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 Articles 34a and 34b. Those requirements shall cover, in particular, the IT solutions which may be used, and the alternative means for providing the information. When adopting such ~~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 deleted ~~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[15].’;

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

[15] Regulation (EU) 182/2011 …

(29a) the following Article 54a is added:

'Article 54a

Review

By *[insert date four years after the date of entry into force of this Regulation*], the Commission shall present a report to the European Parliament and the Council on the applicable articles regarding classification of substances containing more than one constituent. The report may be accompanied by an appropriate legislative proposal.'

(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[16] [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].

[16] 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.

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

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 (x-height in millimeters)
Not exceeding 3 litres:	If possible, at least 52x74	Not smaller than 10x10 If possible, at least 16x16	~~8pt~~ 1,4
Greater than 3 litres but not exceeding 50 litres:	At least 74x105	At least 23x23	~~12pt~~ 1,8
Greater than 50 litres but not exceeding 500 litres:	At least 105x148	At least 32x32	~~16pt~~ 2,0
Greater than 500 litres:	At least 148x210	At least 46x46	~~20pt~~ 2,0’;

(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) printed in black on a white ~~the~~ background ~~of the label shall be white~~;

(b) the distance between two lines shall be appropriate for the selected ~~equal or above 120 % of the~~ font size to be easily legible;

(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~~ easily 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 it is deemed important to place the most critical ~~hazard~~ statement, such as hazard statement or EUH statement, and where the outer packaging meets the requirements of Article 17.’

(3a) the following Section 1.2.1.6. is added:

1.2.1.6. The front page of the fold-out label shall include at least the following elements:

i. name, address and phone number of supplier(s);

ii. nominal quantity of the substance or mixture in the package made available to the general public, unless this quantity is specified elsewhere on the package;

iii. the product identifiers in accordance with Article 18(2) for substances and Article18(3)(a) for mixtures in all languages of the label that are used in the inside pages;

iv. where applicable, hazard pictograms;

v. where applicable, signal words in all languages of the label that are used in the inside pages;

vi. where applicable, the unique formula identifier, unless printed or affixed on the inner packaging in accordance with point 5.3, Part A in Annex VIII of this Regulation;

vii. a reference to the full safety information inside the fold-out label in all languages of the label or a symbol to inform a user that the label can be opened and to illustrate that additional information is available on inside pages;

viii. an abbreviation of the language (country code or language code) for all the languages that are used in the inside pages.

(4) the following Section 1.3.7. is added:

‘1.3.7. ***Ammunition***

In the case of ammunition that ~~qualifies as~~is 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 product identifier referred to in Article 18(2) for substances or the trade name or ~~the~~ designation ~~of the mixture~~ referred to in Article 18(3), point (a) for mixtures, 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~~ any 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~~,~~ or 2 ~~or 4~~ of Annex II and is not classified in any of the following hazard classes and categories:

(i) Acute toxicity, any category~~ies 1 to 4~~;

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

(iii) Specific target organ toxicity – repeated exposure, any category~~ies 1 and 2~~;

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

(iv1) Serious Eye Damage, category 1;

(iv2) Skin Sensitisation, any category;

(v) Respiratory sensitisation, any 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 disruption~~ors~~ for human health, any category;

(c) the substance or mixture requires labelling in accordance with Part 1~~,~~ or 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. Supply via ~~R~~r**efill stations**

When ~~H~~hazardous substances or mixtures are supplied ~~referred to~~ in accordance with Article 35(2a), the supplier shall ensure that ~~meet~~ the following conditions are met:

(a) the refill station shall carry ~~the~~ label~~s~~~~ling~~ corresponding to the labels for each ~~and packaging requirements applicable at the date of placing on the market of the~~ hazardous substance or mixture supplied at the ~~are fulfilled for every refill~~ station;

(b) ~~a~~ the ~~label~~ labels on the refill station shall be ~~is~~ firmly affixed horizontally on a visible place ~~of the refill station~~ and fulfil the requirements in Article 31 paragraphs 2 to 4 mutatis mutandis ~~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;~~

(f1) risk mitigation measures are applied to ensure that exposure of humans, especially of children, and the environment is avoided as far as possible;

(g) at the moment of refill, the supplier is ~~reachable~~ available on site for maintenance and immediate assistance, including emergency 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;~~

(j1) for every refilled package, the requirements on hazard communication in the form of labelling set out in Title III of this Regulation are fulfilled;

(j2) for every refilled package the requirements on packaging set out in Title IV of this Regulation are fulfilled;

(k) hazardous ~~no~~ substances or mixtures shall not be provided at ~~through~~ a refill station if ~~meets~~ the criteria for classification in any of the following hazard classes or differentiations are met:

(i) Acute toxicity, any category~~ies 1 – 4~~;

(ii) Specific target organ toxicity – Single exposure, any category~~ies 1, 2 and 3~~;

(iii) Specific target organ toxicity – repeated exposure, any category~~ies 1 and 2~~;

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

(iv1) Serious eye damage, category 1;

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

(v1) Skin sensitisation, any category;

(vi) Aspiration hazard;

(vii) Germ cell mutagenicity, any category;

(viii) Carcinogenicity, any category;

(ix) Reproductive toxicity, any category;

(x) Flammable gases, any category~~ies 1 and 2~~;

(xi) Flammable liquids, categories 1 and 2;

(xii) Flammable solids, any category~~ies 1 and 2.~~**;**

(xiii) ~~[insert:~~ Endocrine disruption~~or~~ for human health, any category~~ies 1 and 2].~~’;

(xiv) ~~[insert:~~ Endocrine disruption~~or~~ for the environment, any category~~ 1 and 2]~~;

(xv) ~~[insert:~~ Persistent, B~~b~~ioaccumulative and T~~t~~oxic ~~(PBT)]~~;

(xvi) ~~[insert:~~ Very P~~p~~ersistent and V~~v~~ery B~~b~~ioaccumulative ~~(vPvB)]~~;

(xvii) ~~[insert:~~ Persistent, M~~m~~obile and T~~t~~oxic ~~(PMT)]~~;

(xviii) ~~[insert~~ Very P~~p~~ersistent and V~~v~~ery M~~m~~obile ~~(vPvM)]~~.

By way of derogation from point (a~~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 a visible place on the respective pump. When vehicle fuels are supplied at a filling station through pumping into portable receptacles designed to be used for fuels, a physical copy of the label elements referred to in Article 17 shall, in addition to the visible place on the pump, also be provided to be attached on the receptacle.’;

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(1b) and (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(1b) and (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(1b) and (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(1b) and (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(1b) and (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 those 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, as defined in section 2.1 of Part A of this Annex, *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 row~~s~~ of the table with standard formula for gypsum is replaced by the following two rows:

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

(a) (c) In section 3, the ~~two~~ first row~~s~~ 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’.