Council of the European Union

Brussels, 26 April 2023
(OR. en)

8697/23

Interinstitutional File: 2022/0432(COD)

LIMITE

ENT 80
MI 322
CHIMIE 37
COMPET 354
IND 186
SAN 208
ENV 404
CODEC 697

NOTE

From:	General Secretariat of the Council
To:	Delegations
No. prev. doc.:	ST 7616/23 ST 8705/23
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 on Classification, Labelling and Packaging of Substances and mixtures (CLP Revision) - Presidency Compromise Proposal on Sub-Groups A3 and A4, Cluster B, and Sub-Groups C1 and C3

Delegations will find in the Annex the second partial Presidency Compromise proposal for the revision of the CLP Regulation. The new compromise text includes:

- sub-groups A 3 and A 4 of Cluster A: Labelling and Sales;
- Cluster B: Classification;
- sub-groups C 1 and C 3 of Cluster C: Regulatory Procedures.

The changes from the Commission Proposal are marked in **bold underlined** for additions and ~~strikethrough~~ for deletions. The grey sections in this document indicate text which is not part of the given cluster heading.

ANNEX

Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of Substances and mixtures (CLP Revision)

Presidency Compromise Proposal on Sub-Groups A3 and A4,
Cluster B, and Sub-Groups C1 and C3

Cluster A – Labelling and sales

Subgroup A3. Refill sales

Articles in A3

(2c) in Article 2, the following points *[7a and 38]* **to 41** are added:

[…]

40. 'refill' means an operation by which a consumer or a professional user fills its own container, which fulfils the packaging function, with a hazardous substance or mixture offered by a supplier in the context of a commercial transaction.

41. 'refill station' means a place where a supplier offers to consumers or professional users hazardous substances or mixtures that can be purchased through refill.';

(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).';

Changes to Annex II in A3

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

'3.4. **Supply via ~~R~~refill stations**

When h~~H~~azardous 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 a** ~~the~~ label~~ling~~ **corresponding to the label 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 **or labels on the refill station shall be**~~is~~ firmly affixed on a visible place ~~of the refill station~~ and **fulfil the requirements in Article 31** ~~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, is avoided or, if not possible, minimized;

(g) at the moment of refill, the supplier is ~~reachable~~**available on site** for immediate **routine and 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) the requirements on hazard communication in the form of labelling set out in Title III are fulfilled for every refilled package;

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

(k) **hazardous** ~~no~~ substance**s** or mixture**s may not be** provided **at** ~~through~~ a refill station **if** ~~meets~~ the criteria for classification in any of the following hazard classes **are met**:

(i) Acute toxicity, categories 1 – 4;

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

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

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

(iv-bis) Serious eye damage category 1;

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

(v-bis) Skin sensitisation category 1 (sub-categories 1A, 1B);

(vi) Aspiration hazard;

(vii) Germ cell mutagenicity, any category;

(viii) Carcinogenicity, any category;

(ix) Reproductive toxicity, any category;

(x) Flammable gases, categories 1**A, 1B** and 2;

(xi) Flammable liquids, categories 1 and 2;

(xii) Flammable solids, categories 1 and 2.~~;~~

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

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

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

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

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

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

By way of derogation from point (**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.';

Recitals relating to A3:

(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 and operation by children as well as avoiding reaction between substances and mixtures provided through the station, or with residues in refilled packages.**

Subgroup A4. Online sales

Articles in A4

(3) in Article 4, ~~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 **in the Community** ~~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**.';

(23) Article 48 is replaced by the following:

'*Article 48*

Advertisement

1. Any advertisement for a substance classified as hazardous shall indicate the relevant hazard pictogram**s**, 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 **relevant** hazard pictogram**s**, 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 substances or mixtures on the market through distance sales shall**, within the offer,** clearly **and visibly** indicate the label elements referred to in Article 17.';

Recitals relating to A4

(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 [Proposal for a Regulation 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~~7~~/2008 and thereby ensure a high level of protection of human health and the environment. In order to prevent situations where consumer becomes *de jure* and *de facto* an importer when buying the substance or the mixture via distance sales from the economic operators established outside the Union, it is necessary to specify that the supplier which ensures that the substance or the mixture in question meets the requirements set out in that Regulation acts in course of an industrial or professional activity.

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

(30) Regulation (EC) No 1272/2008 does not explicitly refer to offers, let alone to distance sales offers. Consequently, it does not address specific problems arising from distance sales, such as online sales. Whereas advertisements is understood as being at the pre-stage of offers, notably as information designed to promote messages of a natural or legal person, whether or not against remuneration, offers are understood as invitations by a natural or legal person to conclude a purchase contract. This differentiation should justify the requirement of providing more hazard information in offers than in advertisements. In order to keep pace with technological development and new means of sale, **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[1] ~~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.

[1] 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).

Subgroup B1. Rules on Classification

Articles in B1

(2b) in Article 2, the following points ~~*[7a and]*~~ 38 *[to 41]* are added:

[…]

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.';

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

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

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

4. For the evaluation of mixtures pursuant to Chapter 2 **of this Title** in relation to the 'biodegradation, persistency, mobility and bioaccumulation' properties within the 'hazardous to the aquatic environment', 'persistent, bioaccumulative and toxic~~²~~, **or** ~~'~~very persistent and very bioaccumulative **properties**', 'persistent, mobile and toxic~~²~~ ~~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**.**';

(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~~**w**hen applying the bridging principles, manufacturers, importers and downstream users may ~~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 mixture for decision on classification**. The rules on bridging principles in section 1.1.3 of Annex I shall **in this case** remain applicable even in a weight of evidence determination.

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

(7) Article 10 is replaced by the following:

'*Article 10*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(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;';

Changes to Annex I in B1

(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.';

Recitals relating to B1

(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.

Subgroup B2. MOCS

Articles in B2 (for Article 5(3), please see the Presidency's proposed alternatives in the separate annotation document)

(2a) 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.~~

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

'3. A ~~multi-constituent~~ substance containing ~~at least~~**more than** 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 **containing more than one constituent** pursuant to Chapter 2 **of this Title** in relation to the 'germ cell mutagenicity', 'carcinogenicity', 'reproductive toxicity', 'endocrine disrupti**o**n~~g property~~ for human health' and 'endocrine disrupti**o**n~~g 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 disrupti**o**n~~g 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~~ **the** properties **referred to in (a)** or less severe properties shall not override the relevant available information on the constituents in the substance.

For the evaluation of ~~multi-constituent~~ substances **containing more than one constituent** pursuant to Chapter 2 **of this Title** in relation to the 'biodegradation, persistence, mobility and bioaccumulation' properties within the 'hazardous to the aquatic environment'**,** 'persistent, bioaccumulative and toxic'~~,~~ **or** '~~-~~very persistent and very bioaccumulative', 'persistent, mobile and toxic'~~-~~ ~~and~~ **or** '~~-~~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 **and lack of biodegradation**.

(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~~ **the** properties **referred to in (a)** or less severe properties shall not override the relevant available information on the constituents in the substance.**';**

Recitals relating to B2 (to be updated in line with discussion on articles):

(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[2], 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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2 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).

Subgroup C1. New Hazard Classes

Articles in C1

(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.’;

(18f) Article 37 is amended as follows:

[…]

(f) the following paragraphs ~~7 and 8~~ are inserted:

‘7. **By 1 January 2026,** ~~T~~**t**he Commission shall adopt delegated acts in accordance with Article 53a to amend Table 3 of Part 3 of Annex VI to this Regulation by inclusion of substances as endocrine disrupt**ion**~~or~~ category 1 for human health ~~properties~~, endocrine disrupt**ion**~~or~~ category 1 for environment ~~properties~~, as persistent, bioaccumulative and toxic or as very persistent and very bioaccumulative together with relevant classification and labelling elements where, on ~~…~~ [~~OP: please insert the date = the *date of entry into force of Commission Delegated Regulation (EU) …i.e. delegated act on the new hazard classes - reference to be added once adopted*~~ **1 January 2025**~~]~~, those substances have been included in the candidate list referred to in Article 59(1) of Regulation (EC) No 1907/2006.

The inclusion of the substances, referred to in the first subparagraph, in Table 3 of Part 3 of Annex VI to this Regulation shall be carried out on the basis of the respective criteria for which those substances have been included in the candidate list referred to in Article 59(1) of Regulation (EC) No 1907/2006.~~²~~

8. **By 1 January 2026,** ~~T~~**t**he 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*~~ **1 January 2025**~~]~~ those substances have not been approved, under Regulation (EC) No 1107/2009 or Regulation (EU) No 528/2012 or have been approved ~~with derogation~~ in accordance with the relevant provisions of those Regulations, due to either of the following characteristics:

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

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

(c) endocrine disruptor for human health or for the environment in accordance with Article 1 of Commission Delegated Regulation (EU) 2017/2100[3];

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

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

Recitals relating to C1

(17a) As the new hazard classes and criteria introduced by Commission Delegated Regulation[4] 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.

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[3] 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.';

[4] [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.]

[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.]

(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.

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

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

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

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5 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).

6 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).

Subgroup C3. Procedure for Harmonised Classification

Articles in C3

(18a-e) Article 37 is amended as follows:

(a) paragraph 1 is replaced by the following:

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

The Commission may ask the Agency or the European Food Safety Authority established in accordance with Article 1(2) of Regulation (EC) No 178/2002[7] 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.';

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7 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 the Commission, the request to the Agency or the European Food Safety Authority to prepare such proposal.

Within one week from receipt of the notification, the Agency shall publish the name and, where relevant, the EC and CAS numbers of the substance(s), the status of the proposal**, 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 in accordance with the procedure referred to in Article 54(2).';

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

'5. The Commission shall adopt without undue delay, delegated acts in accordance with Article 53a**, 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.';

[...]

Recitals relating to C3

(17b) *[As the new hazard classes and criteria introduced by Commission Delegated Regulation[8] 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.

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8 [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.