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NOTE

From: To:	Presidency Working Party on Technical Harmonisation (Dangerous Substances - Chemicals)
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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 Discussion Paper

PRESIDENCY DISCUSSION PAPER

CLP Regulation

29 November 2023

1. APPLICATION OF THE PROVISIONS ON MOCS

Following the latest technical input received, new compromise texts regarding the rules of MOCS have been put forward to be assessed by the Council (**see the Annex to this steering note**).

Compared to the previous compromise text, where a targeted derogation was set for 'substances of renewable botanical origin', this term has been replaced by '**substances containing more than one constituent which are extracted from plants or plant parts**' with the aim of specifying the scope of the derogation. A definition of 'plants' has also been added for further clarification.

We have come to the present choice on the basis of the EP's wish to subject petro-chemicals to proper scrutiny and classification, and also to acknowledge the special case of essential oils as different from MOCS. In order to codify their difference and explain the way to do it, the COM sent the documents included in WK 15547/2023.

In addition to this compromise text (**option A**), an alternative simplified proposal (**option B**) has been suggested, including the natural extracts in the list of exemptions in Annex I to the CLP, while keeping the review clause.

Q1: ***Which of the following two options do you prefer on MOCS? If no clear answer is given at the WP level, this topic will be discussed at COREPER on 1/12.***

2. OTHER COMPROMISE PROPOSALS

Delegations will find below additional proposals suggested in technical meetings with the European Parliament:

A) <u>Row 340b</u>: Deletion

'(iv2) Skin Sensitisation, any category'

According to technical input provided during the meetings with the European Parliament, skin sensitisation is a minor hazard class, and imposing a labelling requirement on it for small packages could be disproportionate.

The input was positively accepted by the European Parliament, who suggested, as a compromise, to delete rows 340b (Council amendment) and 341a (EP amendment), while keeping row 372a, related to refilled packages as a condition to accept the Council position on rows 359-362a; and 364-366.

Q2: *Could delegations agree to accept this trade-off, in the spirit of a compromise?*

B) <u>Row 242</u>: Insertion of the following text:

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, ***<u>cooperate to</u>*** 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 ***<u>the adaptation of criteria for</u>*** alternative ***<u>methods, in particular non-animal</u>*** test methods***<u>, and the assessment</u>*** ~~*at the level*~~ of the ~~*UN*~~***<u>need for new criteria for immunotoxic and neurotoxic substances</u>***.***<u>'</u>***;

The Council deleted the original text from the Commission proposal and moved the ideas to recitals 32a and 33, following the advice from the Council Legal Service.

The rationale for this deletion was that Member States act in their own national interest in international fora and cannot promote the harmonisation of criteria, as this entails a policy choice that has to be adopted in the Council before the UN meeting.

According to the legal service, if there is an EU position, MS cannot go against it, but if there is not, nothing prevents MS from expressing their national views at international fora. As the Commission acts "on behalf" of the Union, the article should refer only to cooperation between the Commission andMS at international fora and not to promoting any particular policy.

Nevertheless, this formulation already exists in Article 53(2) of the current CLP. Both the Commission and the European Parliament insist on keeping it. The European Parliament offered to drop their amendment in row 244a if the Council accepts the wording suggested in row 242.

Q3: *Could delegations agree the text suggested for row 242, provided that the EP amendment in row 244a is deleted?*

C) <u>Fold-out labels</u> (rows 319b-j)

In its mandate, the Council included specific elements on the front page of the fold-out labels. Although the European Parliament can accept the Council text, elements for the inner pages and the back-page of the fold-out labels are missing.

Q4: *Which of the following options would delegations consider more appropriate:*

1) Deleting rows 319b-j, as the elements to be included on the different pages of the fold-out labels are already in the ECHA guidelines, or

2) Keeping rows 319b-j and, in addition, copying from the ECHA guidelines the elements corresponding to inner pages and to the back page?

ANNEX: PROPOSALS ON MOCS

OPTION A: Derogation for substances containing more than one constituent extracted from plants or plant parts, in the ARTICLES

Recitals

11	(2) *Substances containing more than one constituent are complex substances.*-From a toxicological point of view, substances containing more than one constituent 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[1], aimed to minimise animal testing, data on substances containing more than one constituent 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 are available, substances containing more than one constituent should be evaluated and classified following the same classification rules as mixtures. _____ 1. [1] 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).

11a	(2a) Scientific evidence on some substances containing more than one constituent extracted from plants and other organisms shows that specific constituents considered in an isolated way can have hazard properties that might not be expressed in the substance as a whole. Therefore, these substances should be exempted from the rules on classification of multi-constituent substances containing more than one constituent. However, this exemption does not prevent manufacturers, producers or importers to continue to apply these classification rules to their substances extracted from plants when no relevant information is available on the substance itself in order to maintain the current level of protection and the existing good practice. The Commission should review the identification and examination of these substances within five years from the entry into force of this Regulation.
12	(3) Under the current state of science, it is difficult 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 substance containing more than one constituent 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 substance containing more than one constituent should therefore normally be used as the basis for hazard identification of those substances containing more than one constituent or mixtures. However, in certain cases, data on those substances containing more than one constituent 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.
14	(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.

Provisions

61	(4) in Article 5, the following paragraphs 3 to 8 are added:
62	3. A substance containing 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 evaluated, using the available information on those known constituents as well as on the substance itself.
63	4. For the evaluation of substances containing more than one constituent pursuant to Chapter 2 in relation to the 'germ cell mutagenicity', 'carcinogenicity', 'reproductive toxicity', 'endocrine disruption for human health' and 'endocrine disruption for the environment' hazard classes referred to in sections 3.5., 3.6., 3.7., 3.11. and 4.2. of Annex I, the manufacturer, importer or downstream user shall use the relevant available information referred to in paragraph 1 for each of the known constituents.
64	Relevant available information on the substance containing more than one constituent itself shall be taken into account where one of the following conditions are met:
65	(a) the information demonstrates germ cell mutagenic, carcinogenic, or toxic to reproduction properties, or endocrine disruption for human health or the environment;
66	(b) the information supports the conclusions based on the relevant available information on the constituents in the substance.

67	Relevant available information on the substance containing more than one constituent itself showing absence of the properties referred to in point (a) or less severe properties shall not override the relevant available information on the constituents in the substance.
68	5. For the evaluation of 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', '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 known constituents in the substance.
69	Relevant available information on the substance containing more than one constituent itself shall be taken into account where one of the following conditions are met:
70	(a) the information demonstrates persistence, mobility and bioaccumulation properties or lack of degradation.
71	(b) the information supports the conclusions based on the relevant available information on the constituents in the substance.
72	Relevant available information on the substance containing more than one constituent itself showing absence of the properties referred to in point (a) or less severe properties shall not override the relevant available information on the constituents in the substance.
72a	6. Paragraphs 3, 4 and 5 shall not apply to substances containing more than one constituent which are extracted from plants or plant parts and which are not chemically modified according to Article 3 (40) of Regulation (EC) No 1907/2006.

	7. For the purpose of paragraph 6, 'plants' refers to living or dead organisms from the kingdoms Plantae and Fungi. It includes algae, lichens and yeasts. 8. For certain substances containing more than one constituent that are not covered by paragraphs 6 [and 7], where the Commission receives evidence that the criteria set out in paragraphs 4 or 5 may not be suitable for certain substances containing more than one constituent, the Commission may request the Agency to evaluate the available data. The Commission is empowered to adopt delegated acts in accordance with Article 53a to amend Annex I providing for derogations from paragraphs 4 or 5 on classification of substances containing more than one constituent, taking into account the opinion of the Agency when available and the scientific justification to appropriately classify substances containing more than one constituent.

Provisions on the review clause

259a	(29a) the following Article 54a is added: 'Article 54a Review By [insert date five years after the date of entry into force of this Regulation], the Commission shall present a scientific report to the European Parliament and the Council regarding classification of extracted from plants or plant parts containing more than one constituent referred to in [Article 5(6)]. [The report may be accompanied by an appropriate legislative proposal]

OPTION B: New simplified proposal for a derogation for natural extracts in Annex I to CLP

The changes are introduced in the text currently in the 4-column. **Changes appear in bold and green font. Deletions are struck through.**

Row 11	No changes
Row 11a	***(2a) Scientific evidence on some substances containing more than one constituent extracted from plants [and other organisms] shows that specific constituents considered in an isolated way can have hazard properties that might not be expressed in the substance as a whole. Therefore, these substances should be exempted from the rules on classification of*** ~~**multi-constituent**~~ ***substances containing more than one constituent. However, this exemption does not prevent manufacturers, importers or downstream users to continue to apply these classification rules to their substances extracted from plants when no relevant information is available on the substance itself in order to maintain the current level of protection*** **of human health and the environment** ***and the existing good practice. The Commission should review the*** ~~**rules**~~ **provisions** ***applicable to the*** ~~**identification and**~~ ***examination of the information on these substances within five years from the entry into force of this Regulation.***
Row 61	(4) in Article 5, the following paragraph**s** 3 ***to 6*** ~~***8 is***~~ **are** added:
Row 62	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*~~***evaluated***, **in accordance with the provisions set out in this paragraph and in paragraphs 4 and 5,** using the available information on those ***known*** constituents as well as on the substance~~*, unless Annex I lays down a specific provision*~~ ***itself,*** **except where Section 1.1.4 of Annex I lays down a specific provision**.

Row 63	***4.*** For the evaluation of ~~*multi-constituent substances*~~***substances containing more than one constituent*** pursuant to Chapter 2 in relation to the 'germ cell mutagenicity', 'carcinogenicity', 'reproductive toxicity', 'endocrine ~~*disrupting property*~~***disruption*** for human health' and 'endocrine ~~*disrupting property*~~***disruption*** 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*~~***3.5., 3.6., 3.7., 3.11. and 4.2***. 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*~~***known*** constituents ~~*in the substance*~~.
Rows 64 to 72	No changes
Row 72a	~~**6. Paragraphs 3, 4 and 5 shall not apply to substances containing more than one constituent which are extracted [A1] from plants or plant parts [A2] and which are not chemically modified[A3] according to Article 3 (40) of Regulation (EC) No 1907/2006.[A4]**~~ ~~**7. For the purpose of paragraph 6, 'plants' refers to living or dead organisms from the kingdoms Plantae and Fungi. It includes algae, lichens and yeasts. [A5]**~~ **6.** ~~**For certain substances containing more than one constituent that are not covered by paragraphs 6 [and 7],**~~W~~w~~***here the Commission receives evidence that the* ~~*criteria*~~ provisions ***set out in paragraphs 4 or 5 may not be suitable for certain substances containing more than one constituent*** that are not yet subject to section 1.1.4 of Annex I, ~~**the Commission**~~ it ***may request the Agency to evaluate*** that evidence ~~**the available data.**~~ ***The Commission is empowered to adopt delegated acts in accordance with Article 53a to amend Annex I providing for derogations from paragraphs 4 or 5 on classification of substances containing more than one constituent, taking into account the opinion of the Agency when available and the scientific justification to appropriately classify substances containing more than one constituent.***

Row 259a	*(29a) the following Article 54a is added:* *'Article 54a* *Review* *By [insert date five years after the date of entry into force of this Regulation], the Commission shall present a scientific report to the European Parliament and the Council regarding ~~classification~~* the examination of the information on substances containing more than one constituent *~~of~~ extracted from plants or plant parts containing more than one constituent referred to in* section 1.1.4 of Annex I*. ~~[The report may be accompanied by an appropriate legislative proposal]'~~*
New row 287a	(1a) the following Section 1.1.4. is added: **'1.1.4. examination of the information on of substances containing more than one constituent** **Articles 5(3) to 5(5) shall not apply to:** **- substances containing more than one constituent which are extracted from plants or plant parts and which are not chemically modified according to Article 3 (40) of Regulation (EC) No 1907/2006.** **For the purpose of this section, the following definition shall apply: 'Plants' are living or dead organisms from the kingdoms Plantae and Fungi. They include algae, lichens and yeasts.'**