Council of the European Union
General Secretariat

Interinstitutional files:
2022/0432 (COD)

Brussels, 14 November 2023

WK 14925/2023 INIT

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NOTE

From: To:	Presidency Working Party on Technical Harmonisation (Dangerous Substances - Chemicals)
N° prev. doc.: N° Cion doc.:	CM 5319/23 ST 16258 2022 ADD 1 - 8
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

17 November 2023

1. APPLICATION OF THE RULE OF MOCS TO ESSENTIAL OILS

The 2017 ECHA guidance on the Application of the CLP Criteria[1] specifies that for substances containing impurities, additives or other constituents, the classification should preferably be based on data on the whole substance. For CMRs or when evaluating the bioaccumulation and degradation properties, the guidance specifies that it is "strongly recommended" (but not obligatory) to use the mixtures rule.

The new article 5.3 of the Commission proposal on CLP including the mixture rule for substances containing more than one constituent, would lead to a significant change, as it would make the use of the mixture rule mandatory, therefore leading, in some cases to a different classification.

It should be noted that at international level (the United Nations Global Harmonized System / GHS), in point 1.3.2.3.2, for mixtures, it states:

"1.3.2.3.2 In most cases, it is not anticipated that reliable data for complete mixtures will be available for germ cell mutagenicity, carcinogenicity, and reproductive toxicity hazard classes. Therefore, for these hazard classes, mixtures will generally be classified based on the available information for the individual ingredients of the mixtures, using the cut-off values/ concentration limit methods in each chapter. The classification may be modified on a case-by-case basis based on available test data for the complete mixture, if such data are conclusive as described in each chapter."

This case-by-case assessment offers the opportunity for the evaluators to determine the most relevant approach for the classification of substances containing more than one constituent.

[1] https://echa.europa.eu/documents/10162/2324906/clp_en.pdf/58b5dc6d-ac2a-4910-9702-e9e1f5051cc5?t=1499091929578

Regarding essential oils, today, the classification criteria used for Natural Complex Substances (NCS) are those based on scientific data showing effects or absence of effects like for any other substance.

The revision of the CLP proposes for CMR, endocrine disruptors, PBTs, vPvBs, PMTs, and vPvMs to take into account information on the individual constituents, while the data on the NCS itself may not be used if it contradicts or leads to a less severe classification than that obtained from the information on the constituents. This may lead to a different classification from that based on the calculation rules for mixtures. Many voices have been raised expressing the inappropriateness of this approach to essential oils. Firstly, these essential oils are composed by hundreds of different constituents, which can vary depending on the type, crop conditions, or time of harvesting. Data on the individual constituents is not always available, and there would be the need for testing these constituents, contrary to the purpose of the CLP, where the classification shall be based on available data.

Secondly, due to the chemical structure of their constituents, they can give raise to antagonistic effects. In this cases, antagonistic effects should also be considered, as stated in article 12 of the CLP Regulation.

Lastly, for many essential oils, the data on the REACH Registration dossiers confirms that an essential oil tested as a whole, and on the basis of existing OECD guidelines, often gives a different result to those of its constituents.

These elements once again raise the question of the irrelevance of ignoring data of the whole substance in the evolution of CLP regulations.

For example, the **para-cymene**, a substance proposed for classification as a CMR Reproductive toxicant (Reprotox.) Category 1B. This substance is **naturally present in hundreds of NCS**, as neroli oil, thyme oil, lemon oil, cumin oil, etc. and naturally present in foods as these NCS are commonly used in foodstuffs. If this classification as Reprotox. Category 1B is adopted for para-cymene, applying the mixture rules under the new CLP proposal, **this will automatically lead to the classification of hundreds of natural substances (neroli oil, thyme oil, lemon oil, cumin oil)** as Reprotox. Category 1B – as the para-cymene is naturally present in these oils above the legal classification limit (0,3%).

Below, you will find other examples provided by industry associations:

- **Threshold for classification :**

CLASSIFICATION CONSTITUANT		THRESHOLD FOR CLASSIFICATION (%)	CLASSIFICATION ESSENTIAL OIL (HE)
Carcinogenic Mutagenic	1A, 1B	≥ 0,1	HE classée CM 1A, 1B
	2	≥ 1	HE classée CM 2
Reprotoxic	1A, 1B	≥ 0,3	HE classée Repr. 1A, 1B
	2	≥ 3	HE classée Repr. 2
Endocrine disruptor	1A, 1B	≥ 0,1	HE classée PE 1A, 1B
	2	≥ 1	HE classée PE 2
PBT – vPvB PMT - vPvM		≥ 0,1	HE classée PBT, vPvB, PMT, vPvM

COMPARISON CONSTITUANT VS ESSENTIAL OIL :

CONSTITUANT	EUCALYPTUS ESSENTIAL OIL
p-cymene	2% ≤ p-cymene ≤ 10%
Effects on fertility of mice (OCDE 422)	No effects on fertility of mice (OCDE 422)
Proposal CMR1B	
P-cymène REACH registration dossier	*Eucalyptus. REACH registration dossier*

COMPARISON CONSTITUANT VS ESSENTIAL OIL :

CONSTITUANT	YLANG YLANG ESSENTIAL OIL
P-methyl anisole	6 ≤ P-methyl anisole ≤ 10%
Effects on fertility of mice	No effects on fertility of mice (OCDE 422)
(P-methyl anisole REACH registration dossier)	*Ylang ylang ext. REACH registration dossier*

COMPARISON CONSTITUANT VS ESSENTIAL OIL:

CONSTITUANT	ROSE ESSENTIAL OIL
Methyleugenol	≤ 3 % Methyleugenol
Potential genotoxic effect (OCDE 489)	No genotoxic effect (OCDE 471, OCDE 487)
(Methyl eugenol ECHA Registration dossier)	*(Rosol et al, 2023 ; Gateva et al 2020 ; CIR 2022 ; Données RIFM non publiées)*

COMPARISON CONSTITUANT VS ESSENTIAL OIL:

CONSTITUANT	ANISE ESSENTIAL OIL
Estragole	Between 0,5 and 4% Estragole
Mutagenic effect	No mutagenic effect OCDE 471/487
(EMA, 2021; Suzuki et al, 2012; Martins et al, 2012)	*(Anis ext. REACH registration dossier)*

COMPARAISON CONSTITUANT VS HE :

ESSENTIAL OIL	NON EASILY BIODEGRADABLE CONSTITUANT (28 j) OCDE 301		BIODEGRADABILITY ESSENTIAL OIL OCDE 301
	Gamma-terpinène	Camphène	
Thyme	8,08%	0,57%	Easily biodegradable
Bergamote	6,3%	-	
Lemon	8,82%	-	
Green lemon	10,86%	0,55%	
Tea tree	20,5%	-	
Small Mandarin Grain	24,64%	-	
Siberian pine	0,1%	21%	
Spanish sage	0,4%	6,9%	

LES HUILES ESSENTIELLES CONTENANT DU GAMMA-TERPINÈNE OU DU CAMPHENE SERAIENT CONSIDEREES NON-BIODEGRADABLES, ALORS QUE LES DONNEES (test OCDE) MONTRENT UNE BONNE BIODEGRADABILITE

During the negotiations in trilogues, the European Parliament showed no margin of flexibility to move towards the Council position on the application of the rule of MOCS. The EP argued that the deletion of the text could lead to certain hazardous substances, such as petrochemicals, being exempted from the mandatory requirement to apply the rule, while, contrary to the essential oils, there is no scientific evidence that a classification based on the rule of mixtures would be inappropriate.

Therefore, the EP put forward possible suggestions for a compromise with the Council, keeping a targeted derogation for essential oils:

In line with the above-mentioned reasoning, and taking into account the need for further assessments regarding the appropriateness of the mixture rule for the classification of Natural Complex Mixtures, a possible compromise solution would be to have a time-limited derogation for these type of substances. No later than five years the Commission shall present a report on the classification approach for these substances together with a legislative proposal, if considered necessary. In the meantime they should continue to be classified as today.

This new proposal will still allow for other MOCS to be correctly classified based on their individual constituents for the above-mentioned hazard classes.

Compromise proposals presented in trilogues:

Article 1, first paragraph, point (4), amending provision, numbered paragraph (3), seventh subparagraph a:

"***in Article 5, the following paragraph is added:***

"3a. Paragraph 3 shall not apply to substances containing more than one constituent of renewable botanical origin that are not chemically modified."

Article 1, first paragraph, point (29a)

(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 report to the European Parliament and the Council regarding classification of substances [of renewable botanical origin] containing more than one constituent. The report shall indicate scientific evidence and may be accompanied by an appropriate legislative proposal.'

Q1: *Could delegations give flexibility to the Presidency to accept the above-mentioned compromise proposals if this was necessary to reach an agreement with the European Parliament?*

2. MINIMUM FONT SIZES

Industry has to work with balancing the requirement for readability with the ever-increasing pressure to include additional information on labels (e.g. relating to the presence of specific substances such as biocides, isocyanates), as well as meeting specific market and design requirements (especially the inclusion of several languages).

In particular, companies from the Paint, Printing Ink, and Artist's Colours sectors are typically using somewhere between 5-point fonts (estimated as 0,9-1,0 mm x-height) and 6-point (1,2mm) formats for their labels, to minimise resource use, optimise logistics and maximise information provision in a readable manner. In this regard, they have voiced their concerns, that the implementation of the current Council or Parliament proposals will result in the 'CLP box' on labels increasing in size (they estimate by a multiple of between 2,5 to 3 times, depending on the amount of text in the box).

They argue that, apart from the negative economic impact on the industry, there will be other negative consequences, such as the increased use of resources, and an increase in waste generation. In addition, the increased dimensions of labels would result in labels exceeding the surface area available on the package.

One example of this would be the labelling of IBCs (Intermediate Bulk Containers for 1000 litre quantities etc.). The current metal plates fixed on the containers during manufacture are designed to hold A5 labels, but the proposed format requirements would result in the obligatory use of A4-

size labels that would no longer fit the plates which are an inherent part of the structure. Finally, many labelling software programmes used will automatically adjust font size printed in the CLP box according to the amount of information that is required to be included on the label, so setting a minimum font size will require a complete review of all label designs and associated text to determine whether the label will meet the new requirements or not.

In addition, the new proposals could lead to the loss of at least half the current languages included on the label (e.g. reduced from 4 to 2 languages, 6 to 3 etc.). This would then require companies to either have at least 2 new labels to replace the existing label (introducing double the number of existing Stock Keeping Units (SKUs) in their systems), or to resort to fold-out labels.

Operators with insufficient space on labels (to accommodate new minimum requirements) will be required to switch to fold-out labels, this requiring the use of additional resources (paper, adhesive, print) as well as the installation of new equipment on filling lines. In this regard, industry claims that fold-outs are unlikely to reach a paper recycling waste stream as they will remain attached to the packaging and will be removed or incinerated during the plastic or metal recycling processes. Additionally, operators will normally buy in fold-outs from external suppliers so there will be a loss of control on label production, resulting in a (possibly significant) time delay to revising labels when changes to labels are required e.g. due to new substance classifications, and extended delivery times (3-4 weeks) to meet customer orders. They also question whether the fold-out suppliers could meet the market demand to supply a large number of additional fold-out labels if a mass transition to this format is required in the very short timescales proposed.

Therefore setting inappropriately high minimum font sizes will cause very extensive disruption to production processes and supply chains, will be costly and time-consuming, and will lead to greater resource use and waste generation.

As a result of the above-mentioned concerns raised by the industry, the European Parliament and the Presidency have asked the Commission for a technical opinion of the input provided by the industry, in order to determine whether the figures in Annex I should be revised.

Q2: ***In case the demands from industry prove to be legitimate, can delegations accept to deviate from the Council mandate in Annex I, third paragraph, amending provision, first paragraph, Table 1, Column 4, in order to set minimum font size requirements that accommodate the concerns raised by stakeholders?***

3. COMPROMISE PROPOSALS ON OTHER PARTS OF THE TEXT

Delegations will find below additional compromise proposals suggested in trilogues.

Q3: ***Can delegations agree in accepting the compromise proposals presented below?***

Recital 18

(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 ***based on scientific justification,*** allows for similar classification of all substances in the group. The ***grouping process should be scientifically robust, coherent and transparent for all stakeholders. 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 ***Where it is scientifically justified and possible, proposals for classification should prioritise groups of substances rather than individual substances. In the event of a proposal for harmonised classification and labelling of a group of substances, those substances should be grouped together based on clear scientific criteria, including structural similarity and similar evidence-based hazard profiles***.

Recital 24

(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 ***, without needing to acquire new data or new studies being necessary,*** 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. ***Moreover, the Agency should be able to request the notifier to correct incomplete, incorrect or obsolete notifications in the inventory.***

Article 1, first paragraph, point (4), amending provision, numbered paragraph (3), sixth subparagraph, point (a) (row 70)

(a) the information demonstrates ~~*biodegradation*~~, persistence, mobility and bioaccumulation properties ***or lack of degradation or biodegradation***.

Article 1, first paragraph, point (18)(a), amending provision, numbered paragraph (1), second subparagraph (row 165)

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 ~~**1*~~ to prepare a proposal for harmonised classification and labelling of ***a substance or a group 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 Agency and the Authority may, on their own initiative, provide scientific advice to the Commission and Member States on substances or a group of substances where a harmonised classification could be necessary to protect human and animal health and the environment.***

Article 1, first paragraph, point (18)(a), amending provision, numbered paragraph (1a) (row 166a)

1a. 'Whenever considered scientifically justified and possible by a competent authority or the Commission, proposals for harmonised classification and labelling shall aim toprioritise groups of substances rather than individual substances.'

Article 1, first paragraph, point (20)(ba) (row 200a)

(20a) Article 41 is replaced by the following:

"Article 41

Agreed entries

Where the notification in Article 40(1) results in different entries on the inventory referred to in Article 42 for the same substance, the notifiers and registrants shall make every effort to come to an agreed entry to be included in the inventory. The notifiers shall inform the Agency accordingly.'"