Comments by Potugal

***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?*

Although we would strongly support maintaining the Council's approach, we may accept EP's proposal in case that's absolutely necessary to achieve a compromise.

***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?*

In our opinion, the Council's approach is a delicate balance. We are, however, solidary with the concerns expressed by the industry, and can consider deviating from the Council's mandate, if the deviated minimum font sizes would still guarantee improvement of readability of labels. We consider, in this regard, that the proposal included in the non-paper from the Commission (WK 15264/2023 INIT) is a good starting point.

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

Recital 24

Although we can agree with this proposal, we consider that the last sentence introduced («Moreover, the Agency should be able to request the notifier to correct incomplete, incorrect or obsolete notifications in the inventory») is not aligned with the respective proposed legal text in paragraph 3a of article 42 (row 206a: «3a. Where the Agency considers that an entry is incomplete, incorrect or obsolete it shall delete the corresponding entry from the inventory after having informed the notifier»).

Additional resources for ECHA

We can agree as a compromise proposal, having in mind that this proposal should not result in an increase in the fees paid by the industry. However, we agree with other

Member States that maybe the CLP Regulation is not the most adequate file to regulate this and should be considered under ECHA´s Standalone Founding Regulation.

Remaining proposals

In general, we are flexible regarding the remaining compromise proposals presented in Q3.

Council of the European Union
General Secretariat

Interinstitutional files:
2022/0432 (COD)

Brussels, 27 November 2023

WK 15808/2023 INIT

LIMITE

ENT
MI
IND
ENV
SAN
CHIMIE
CONSOM
CODEC

This is a paper intended for a specific community of recipients. Handling and further distribution are under the sole responsibility of community members.

NOTE

From: To:	General Secretariat of the Council Working Party on Technical Harmonisation (Dangerous Substances - Chemicals)
N° prev. doc.: N° Cion doc.:	ST 14625/2/2023 REV 2 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) - Comments by DK, EL, IT, NL, PT, SE on the proposed amendments by the European Parliament

Delegations will find in the Annexes the comments by Member States on MOCS and on the full text of the proposed amendments by the European Parliament on the CLP revision, as set out in document ST 14625/2/2023 REV 2, following the Working Party meeting on 23 November 2023.

APPLICATION OF THE RULE OF MOCS TO ESSENTIAL OILS

One of the core principles in the CLP Regulation is that the classification should be based on relevant and scientific data. Sweden considers it crucial that this principle is upheld in order to ensure that the purpose of the Regulation is not undermined.

Sweden cannot support a general derogation made for substances of renewable botanical origin where there is no scientific data available to justify a general exemption for this entire group of MOCS. If we start compromising with the scientific basis, the CLP Regulation is at risk of impairing its credibility as the central piece of hazard classification in the EU chemicals legislation.

Current test methods are not sensitive enough (for statistical reasons) to identify e.g. CMR-properties of MOCS (or mixtures) and therefore not appropriate to use as a basis for classification when the test results are negative.

There is no legal basis for considering socioeconomic impacts of classifications within the context of the Regulation. Socio economic impacts are taken into account under other relevant sector regulations where appropriate amendment can be made, for example in the Cosmetics Regulation.

MINIMUM FONT SIZES

Sweden can support the proposal in the non-paper by the Commission to reduce the minimum font size to 1,2 mm for packages not exceeding 0,5 litres. Sweden does not see the need for a longer transitional period, but we can be flexible in this matter.

Based on experience from market surveillance and also the Commissions impact assement, Sweden considers there is need to regulate parameters such as font size, contrast and spacing in order to ensure readability. Good readability is a necessity in order to achieve one of the main purposes of the CLP, which is to effectively inform the relevant actors about the hazardous properties of chemicals products and how to handle them to protect oneself and the environment.

COMPROMISE PROPOSALS ON OTHER PARTS OF THE TEXT

Recital 18

Sweden supports that grouping should be based on scientific criteria (e.g in line with section 1.5 of annex XI of the REACH Regulation) but we think the end of the sentence *"including structural similarity and similar evidence-based hazard profiles"* should be deleted as it is too limiting. Alternatively, the sentence could be amended to clarify that these are examples: *"**such as** structural similarity and similar evidence-based hazard profiles"*

Recital 24

Sweden is flexible.

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

The word "degradation" should be deleted. It should only say "lack of biodegradation".

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

We think the addition is not needed but we can be flexible. ECHA can already give support to COM and MS.

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

It is important that the right to decide on the scope of the classification proposal lies with the MS putting forward the proposal. But as long as this is made clear we are flexible to adding a general sentence like this.

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

Sweden support this. This text is already present in the current CLP.

ADDITIONAL RESOURCES FOR ECHA, Recital (36a) (row 45a) and Article 1, first paragraph, point (25)(ba) (row 231a)

Sweden are against including wordings on ensuring resources for ECHA in the articles but we are flexible when it comes to the addition in the recital. Discussions about the future financing of ECHA should be held when the upcoming basic regulation for ECHA is negotiated. Budgetary decisions should not be preceded by inserting wordings in the articles of CLP.

ENVIRONMENTAL CLAIMS (row 222a)

Sweden is flexible to the addition but prefer it to be placed in article 48. You may also wish to consider the possibility to refer to the consumer empowerment legislation in a recital.

Swedish comments on posts highlighted in green in the four-column document (14625/2/23 REV 2)

Regarding **row 60** on Article 4(10) Sweden considers that it can lead to ambiguities when there is no reference to the actor outside the Union and considers a reference to that actor is necessary. Sweden also has concerns about the phrase 'who shall be identified on the label' as its meaning is unclear in relation to the labelling requirement in Article 17(1)(a). The wording in Article 4(10) could be interpreted as meaning that only one supplier must be indicated on the label and not, if relevant, all the suppliers.

In **row 181** Sweden consider it to be necessary for the Commission to have at least 18 months to adopt delegated acts to amend Table 3 of Part 3 of Annex VI to the CLP Regulation, since the obligation regards substances for which a decision has been adopted within 6 months from the entry into force of the new CLP Regulation. For the Commission to have 18 months, the deadline must be 24 months in accordance with the Council mandate.

Sweden notes that **row 183** should be placed after row 181 and begin with a 'b)' instead of '8' in order to make sense.

In **row 239** Sweden consider that the concept of 'digital readiness' includes the possibility of having access to the necessary wireless and other technological infrastructure, therefore the amendment is not necessary.

In **row 101b** the references in Article 25(3) should be amended and list paragraph 1, 2 and *6 to 9* in accordance with the Council mandate in row 102b, and not only to paragraph 1, 2 and 7.

In **row 113** the initial '4c' should be removed since the paragraph is a subparagraph to 4b.

In **row 510** the initial 'c' should be removed since this is not text that is intended to be included in the Regulation.

There are some **rows (76a, 98b and 385)** highlighted in green that lack a proposal in the column 'Draft Agreement'. If the EP Mandate are the compromised text, Sweden would like to comment on these amendments.

ΕΛΛΗΝΙΚΗ ΔΗΜΟΚΡΑΤΙΑ

Hellenic Republic

ΑΑΔΕ
Independent Authority for Public Revenue (IAPR)

Independent Authority for Public Revenue
Directorate General
General Chemical State Laboratory
Directorate of Energy, Industrial and Chemical Products

Athens, 24.11.2023

Comments by Greece with regard to the compromise proposal and the Presidency's proposal presented on 17th November

The compromise proposal put forward in the Presidency's discussion paper "WK 14925/2023 REV 1», includes an exemption for MOCS of renewable botanical origin.

- The term "renewable", is neither justified nor defined in document WK 15547/2023 INIT. It does not seem to be related to "Natural Complex Substances" used in fragrances, for which industry claims, that there are scientific reasons justifying an exemption from the general classification rules for MOCS. Furthermore, the term 'renewable' implies that there are "substances" of botanical origin that are not renewable.

- We also understand from the WK 15547/2023 INIT document, that IFRA and Cosmetics Europe support the use of the term 'substances of renewable botanical origin' because, as they explain, this term would cover the 206 NCS used in fragrances. However, it is not reasonable to ask for the exemption of a huge and undefined category of "substances" for the sole purpose of exempting 206 "substances" belonging to it. 'Substances of renewable botanical origin' is an undefined and incredibly diverse group, which for these reasons is not even possible to be studied. The terms used in legislation must be well defined and precise in order to enable proper implementation and enforcement.

- We are also concerned that the proposed for exemption "substances" might contain residues from the manufacturing process or impurities of concern.

- In addition, the general category of "substances" obtained from living plant, algae and fungi organisms, includes plant toxins and fungal toxins, which are extremely hazardous to health.

- Finally, we would like to draw your attention to the fact that the industry's disagreement mainly relates to the application of rules for the classification of MOCS containing constituents classified as CMR or others of high risk. Describing the above category of "substances" with a broad in scope, ambitious term, in our opinion, has no added value and could in some cases lead to underestimation of the hazards and creates problems in implementation. For these reasons, we suggest using precise terms and limiting the scope of any exceptions requested to the minimum possible.

In addition, we would like to note that in document wk15547.en23 (Supporting documents by the Commission on Essential Oils and the CLP), it is stated that: *"We have several examples of REACH dossiers in which the classification of these NCS has been made based on data available on the whole substance (e.g., genotoxicity on the whole substance)".*

However, the registration and the notification information on ECHA's website show that a large number of stakeholders already classify their products (MOCS, UVCBs) based on the relevant available information for each of the known individual constituents according to Article 6(3) of the current CLP legal text. These rules are now specifically described for MOCS in the proposed Article 5(3) of the revised legal text.

Below there are some examples of registration dossiers submitted by industry, for some of the Natural Complex Substances listed in the document WK 15547/2023, such as the NCS (Rosa Damascena (Concrete-CAS no 90106-38-0) and Myrtle oil (CAS no 84082-67-7)), where the decision on the CMR classification was based on the relevant available information of the individual substances. Although these NCS contain a carcinogenic and mutagenic constituent, are not classified as CMRs as this ingredient is below the generic concentration limit for the respected category. **These examples show that the rule of the proposed article 5(3) is already used and respected by a large part of the industry, as MOCS are toxicologically considered as mixtures and classified accordingly.**

The following two paragraphs appear in the registration dossiers of the above mentioned NCSs showing that they are classified according to CLP criteria for mixtures containing CMR substances :

- "***The NCS*** *is composed of several identified constituents and in that, it* ***can be considered as a mixture according to the definition of the CLP Regulation***. ***The decision logic for classification of mixtures from the ECHA Guidance on the Application of the CLP Criteria (2017) was used to determine the mutagenic potential of the registered substance***. ***The registered substance has not been tested itself*** *in appropriate in vitro or in vivo tests* ***but one of its constituents is*** *classified as mutagenic Cat. 2 (methyl eugenol) and strictly present* ***below the CLP generic concentration limit of 1% that triggers classification of the mixture***. *As none of the other constituents of the registered substance are classified for mutagenicity, the registered substance is not classified for mutagenicity, without further testing according to the Regulation (EC) No 1272/2008" (*https://echa.europa.eu/el/registration-dossier/-/registered-dossier/21771/7/7/1).
- "***The typical composition*** *provided by the Lead Registrant* ***contains less than 1% of constituents classified for mutagenicity and carcinogenicity*** *(i.e., Methyl eugenol < 1%),* ***therefore according to the Regulation (EC) 1272/2008*** *and the Directive 1999/45/EEC,* ***Myrtle oil does not require classification for mutagenicity and carcinogenicity"*** (https://echa.europa.eu/el/registration-dossier/-/registered-dossier/17467/7/7/1).

Another example is Laurel leaf oil with CAS no 84603-73-6 (included in the list of NCS of document WK 15547/2023). It **is classified according to the CLP criteria for mixtures containing CMR substances** [which are also specified in the proposed Article 5(3)], based on the **classification of the individual constituents**. The vast majority of the notifiers (99,8%) classify it as muta. 2 and carc. 2. In the registration dossier of the same product, as well as in the registration dossiers of other NCSs, it is indicated that the abovementioned general rule for classification of MOCs is respected:
*(«**All Laurel leaf oils should be classified having more than the generic concentration limit of the constituents 1% of Methyl eugenol as mutagenic and carcinogenic**. Based on the typical composition provided by the Lead Registrant, Laurel Leaf oil should be classified as mutagen and carcinogen: Germ cell mutagen Category 2 (H341: Suspected of causing genetic defects) and Carcinogen Category 2 (H351: Suspected of causing cancer) according to the Regulation (EC) No. 1272/2008 (CLP)…»* (*https://echa.europa.eu/el/registration-dossier/-/registered-dossier/17161/7/7/1*).

To our understanding, the major concern of fragrance industry is that producers of natural complex "substances" containing methyl-eugenol (CAS no: 93-15-2) at a concentration equal to or above 1% or p-cymene at a concentration > 0,3% (in case that a repro. 1B harmonized classification will be decided after about 2 years), will have to classify their products accordingly, as muta. 2 and carc. 2 in the first case (when the concentration of methyl-eugenol > 1%) or repro. 1B when the concentration of p-cymene > 0,3% in the essential oil. Producers of NCS fear that their products, their essential oils will not be used by the fragrance sector because of the CMR classification they will have to put on the label.

This is not true. There are several examples of compounds classified according to CLP criteria as CMR that are used by the cosmetics industry below the concentration limits set in the Cosmetics Regulation (1223/2009/EC). According to article 15(1) of the Cosmetics regulation, a CMR substance classified in category 2 may be used in cosmetic products where the substance has been evaluated by the SCCS and found safe for use in cosmetic products.

A very familiar to the cosmetics industry example is methyl-eugenol. Methyl eugenol is included with reference number 102 in annex III of cosmetics Regulation, meaning the list of substances which cosmetic products must not contain, except subject to the restrictions laid down. According to the aforementioned Regulation, the highest concentration of methyl eugenol in the finished products must not exceed 0.01 % in fine fragrance, 0.004 % in eau de toilette, 0.002 % in a fragrance cream, 0.0002 % in other leave-on products and in oral hygiene products, and 0.001% in rinse-off products.

These maximum concentrations were set following the Opinion concerning Methyl eugenol adopted by the SCCNFP during the 14th plenary meeting of 24 October 2000 (https://ec.europa.eu/health/scientific_committees/consumer_safety/opinions/sccnfp_opinions_97_04/sccp_out126_en.htm). Evaluation of genotoxicity, (in vitro/ in vivo) and carcinogenicity have shown that methyl eugenol can only be safely used under the conditions stated in the Opinion.

The Opinion concludes that "Methyl eugenol should not be intentionally added as a cosmetic ingredient. However, when fragrance compounds containing methyl eugenol naturally present in essential oils are used as components in cosmetic products, the highest concentration of methyl eugenol in the finished products must not exceed 0.01 % in fine fragrance, 0.004 % in eau de toilette, 0.002 % in a fragrance cream, 0.0002 % in other leave-on products and in oral hygiene products, and 0.001% in rinse-off products".

Has the cosmetics industry stopped using essential oils containing methyl eugenol? To our knowledge NO. Are there any data proving the opposite? No such data has been provided.

In the document wk14925.en23 (Presidency Discussion Paper) it is mentioned that: "*p-cymene 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%)".*

To this we would like to note the following: Even if all the NCS containing > 0,3% p-cymene will be exempted from the CLP mixture classification, alone the existence of a repro. 1B substance (when decided for p-cymene), excludes, according to article 15(2) of cosmetics regulation, the use of those NCS in cosmetics unless specific exemptions are allowed, when all of the following conditions are fulfilled:

1. Compliance with the European Food Regulation 178/2008 (and amendments)

2. No suitable alternative substances exist
3. Use for a specific purpose with a known exposure 0
4. Approval by the Scientific Committee on Consumer Safety (SCCS) for a determined exposure.

Such an example where exemption has been granted is Cinnamon bark oil (NCS, CAS no 84649-98-9). In the registration dossier it is stated: *"Cinnamon leaf oil contains the constituent safrole, which is considered to be a carcinogen category 1B (may cause cancer). Based on the presence of safrole in cinnamon leaf oil in a typical concentration of 1.2%, cinnamon leaf oil is classified as carcinogenic in accordance with the classification criteria in Annex I of the CLP Regulation" (https://echa.europa.eu/el/registration-dossier/-/registered-dossier/15259/7/8)*.
According to cosmetics regulation, safrole, as a CMR cat. 1 substance, is prohibited in cosmetic products, except for normal content in the natural essences used and provided the concentration does not exceed: 100 ppm in the finished product, 50 ppm in products for dental and oral hygiene, and provided that Safrole is not present in toothpastes intended specifically for children.

Furthermore, according to REACH Annex VI, 4.1, the hazard classification of the substance(s) by the registrants should be a result from the application of Title I and II of CLP for all hazard classes and categories in that Regulation. The classification appearing in the dossier or the notification should be applied by the registrant, the notifier and all those to whom the compound has been supplied.

It is a breach of REACH regulation not to use the classification appearing in the registration dossier. According to article 22 of REACH, following the registration, a registrant shall be responsible on his own initiative for updating his registration without undue delay with relevant new information and submitting it to the Agency which according to REACH have to be submitted in the registration dossier to update it accordingly in the case of any change in the classification and labelling of the substance.

By moving to exemptions in Article 5(3), are we taking a step back from CLP classification of "substances" already classified by industry (registrants and notifiers) in one or more CMR categories, without having evidence to justify this exemption. We are ignoring the main objective of both the CLP and REACH regulations, which is to protect human health. What are the arguments for cancelling CMR risk categories in NCS already classified as CMR by industry itself? We consider that any exemption from the CLP classification rules, especially in the case of CMRs, constitutes a significant breach of the regulation with potentially serious health impacts on citizens, adults and vulnerable groups, while the use of these products is not essential, according to the definition outlined in the Chemicals Strategy for Sustainability. It is our duty and responsibility to protect their health and to base our decisions on scientifically based data.

The time-limited exemption of the proposal we submit jointly with other Member States, corresponds better to the Presidency's comments on the time-limited derogation, than the wording of Article 5 (3a) proposed by the EP. (In document WK 14925/2023 REV 1, the Presidency states that: *« a possible compromise solution would be to have a **time-limited derogation** for these type of substances*»).

Written comments of the Netherlands following the Working Party Meeting on 17 November 2023

Presidency Paper Q1 – substances with more than one constituent

Please see the Non-paper on substances containing more than one constituent which puts forward an alternative compromise proposal.

Presidency Paper Q2 – In case demands from industry on minimum font sizes prove to be legitimate, can delegates accept to deviate from the Council mandate in order to set minimum font size requirements that accommodate the concerns raised by stakeholders?

The Netherlands has previously raised concerns about the new minimum font sizes and we support the demands by industry as summarised in the paper by the Presidency. We would like to propose, again, to codify the current guidance, which sets out a minimum font size of 1,2 mm X-height. We would be able to support the proposal by the Commission as included in their Non-Paper on Label Formatting in CLP by way of compromise.

Presidency Paper Q3 Compromise proposals on other parts of the text

Recital 18 - grouping

We support the slight adjustment in recital 18 regarding the prioritisation of the grouping of substances - as we understand, the addition of the word "possible" in recital 18 would mean that it takes into account the capacity and resources of the Competent Authorities and the Commission to submit a CLH for a group of substances.

However, the wording in Article 1, first paragraph, point (18)(a), amending provision, numbered paragraph (1a) (row 166a), which reads "considered scientifically justified and *possible by Competent Authorities and the Commission*" is in our opinion clearer and we would like to suggest to change recital 18 accordingly.

Regarding the last part of the last sentence in recital 18, we would like to see this part of the sentence deleted: "*including structural similarity and similar evidence-based hazard profiles",* meaning we would propose to end the last sentence after "based on clear scientific criteria". We find the sentence to be too limiting and would rather not specify the underlying criteria for grouping in the provisions or recitals. If it is decided upon to keep the sentence, we would propose to change "*including*" to "such as", to have more emphasis on the fact that these are examples.

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

We support the compromise text, if it is confirmed that the compromise text, which added "possible", means that it is up to the judgment of the Competent Authority or the Commission to decide when to target groups instead of individual substances.

Environmental claims (row 222a)

We support the new proposal to prohibit statements that are not allowed on the label or packaging in accordance with Article 25(4), in advertisements.

In addition, we would like to reiterate our support for the amendment by the EP on the prohibition of environmental claims for substances and mixtures classified as CMR, ED, PBT/vPvB/PMT/vPvM. An option would be to amend Article 25(4) to include the prohibition of statements for substances and mixtures that are classified in aforementioned hazard classes, and additionally, clarifying that specific

environmental claims, e.g. about the production of a product, are still allowed if they are not contradictory to the classification of the substance or mixture.

<u>Other topics not specifically mentioned in the Working Party Meeting on 17/11 that have a draft text in the draft agreement column in the Four Column Table</u>

<u>Refill stations: rows 371a 372 in the Four Column Table</u> (also included in our previous written comments)

We would like to suggest to not include eye irritation category 2 and skin sensitisation category 1 to the exclusion list for refill sales.

We believe that refill has the potential to reduce packaging waste and find it important that a right balance should be made between facilitating more sustainable sales forms and the protection of the consumer.

Considering the fact that refill will often be used for cleaning products that contain biocides that will meet the criteria under eye irritation cat 2 and skin sensitisation cat 1, we believe we should look at the risks involved by allowing substances classified as skin sensitisation and eye irritation to be supplied by refill stations – and we think this small risk can be accepted in light of the purpose of the circular economy and supplying chemicals through refill.

We believe it would be a considerable limitation for refill stations if skin sensitisation and eye irritation is excluded. Consumers will be informed of the hazards by the label on the refill station and on the container. Some consumers will already be aware of their sensitivity to certain substances, and skin sensitisation is normally an effect that disappears when there's no more exposure. Regarding eye irritation category 2, a lot of consumers will be aware of this property and exposure would result in reversible effects where in most cases washing the eye thoroughly is sufficient to prevent further irritation.

As a compromise, we would support the Compromise Proposal and would prefer to have this put forward over the amendment by the EP.

Ministry of Environment
of Denmark
Department

Drinking Water and Chemicals
Case No 2023-11300
Ref. MICGH/LIHAS
November 22 2023

Comments from Denmark on the revision of the CLP Regulation following WP THC November 17th 2023

Denmark thanks the Presidency for providing the opportunity to submit written comments from Member States in advance of the Trilogues. Our written comments to the compromise proposals and discussion regarding the meeting on November 17 in WP THC are set below. We have taken the liberty to include comments on other areas of the proposals. Denmark reserves the right to submit further comments at a later stage in the Trilogues.

The comments are structured after the blocks assigned by the Presidency before the meeting in WP THC on October 23rd 2023. Some topics were discussed on the meeting in WP THC on November 17th 2023. We have added additional points to Block 8 (miscellaneous).

Block 1) MOCS and essential oils

A compromise proposal regarding this topic was discussed on November 17th 2023 but was not found acceptable by Denmark. The compromise proposal put forward in the Presidency's discussion paper includes a permanent exemption for MOCS of renewable botanical origin, such as essential oils. Parliament justifies this exemption with reference to the argument that for MOCS of renewable botanical origin, due to the chemical structure of their constituents, they can give rise to antagonistic effects. Therefore, in these cases, the antagonistic effects should also be considered, as stated in Article 12 of the CLP Regulation. Furthermore, Parliament argues that data in 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. We are not aware of scientific data that supports the concerns relating to antagonistic effects put forward by Parliament, but recognise the fact that this is a complicated and technical issue, and respect that there are diverging views on the science within the Council Working Party.

We are not convinced that the term "renewable botanical origin" is sufficiently well-defined to be the basis for determining which group of MOCS should fall within the scope of the exemption.
To reach a compromise on this issue, which respects the Parliament's desire to introduce a new general rule on the classification of MOCS with alternative classification rules for certain groups of MOCS, such as essential oils or *naturally complex mixtures*, we have proposed the following along with other Member States:

- Adopting the general rule for MOCS in Article 5(3), though deferring the entry into force of this rule until five years after adoption of the revised CLP Regulation.
- A review clause, with a view to establishing whether certain groups of MOCS – such as essential oils – ought to be subject to a different procedure to the general rule proposed under Article 5(3).
    - The review shall be conducted by ECHA with industry, academia and Competent Authorities invited to participate in the review process.

    - The review should also take into account relevant processes set out in other regulations, such as the Pesticides Regulation and the Biocides Regulation.
    - The review is to be completed before the entry in to force of the new general rule on MOCS in Article 5(3).
- A commitment to enacting legislation, if ECHA's review concludes that there is a scientific basis for using an alternative procedure to the general rule set out in Article 5(3) for certain groups of MOCS, which shall enter into force simultaneously with the general rule at the end of the 5 year transitional period.

We have set out a potential reformulation to recital 2a in an appendix to the joint non paper, along with suggested formulations for Article 54a.

Denmark also notes that the Parliament's proposal in amendment 3 / Recital 2a puts forward socio-economic concerns. However, social and economic factors should not be considered when assessing the inherent hazardous properties of a substance that could lead to a classification. A classification is based on relevant and scientific data alone.

Block 2) Procedure for harmonisation and notification

As expressed at the working party Denmark remains flexible with regard to the points whereby proposals for classification should prioritise groups of substances rather than individual substances (amendment 9, 52 and 101) and the timelines for the adoption of delegated acts (amendment 55).

Denmark remains in favour of the compromise text suggested in the revised discussion paper before the working party on November 17th, regarding the wording for the compromise in row 200a in the four column document.

Block 3) Right to request action and access to justice

As stated in our previous comments, Denmark welcomes efforts to improve transparency in the classification of hazardous chemicals, but has serious reservations about Parliament's proposal. Denmark still cannot support Parliament's proposal, which would represent a significant interference with the day-to-day operations of our authorities.

The CLP Regulation does not prevent interested parties from bringing issues relevant for classification and risk management to the attention of the authorities. The proposal may even prove counterproductive as rigidly defined approaches to transparency could lead to problems with regard to self-incrimination, as this may discourage suppliers from engaging in early dialogue with authorities. It is also unclear what the reporting obligations set out in amendment 64 point 7 would entail for Member States.

The proposals on access to justice will also potentially lead to a significant increase in administrative costs for authorities. Decisions on the best process for addressing classification of substances should not be determined by concerns over litigation. Denmark is worried that the use of litigation could be abused and lead to backlogs in the classification process and an approach to classification guided by the fear of litigation instead of evaluation of scientific arguments.

Block 4) Environmental claims

Denmark can support the suggested approach on environmental claims as set out in the discussion paper presented at the WP THC November 17th 2023. However, we suggest a slightly different wording, which we believe will more clearly specify the responsibility with regard to advertisements:

"Statements such as ‘non-toxic’, ‘non-harmful’, ‘non-polluting’, ‘ecological’ or any other statements indicating that the substance or mixture is not hazardous or any other statements that are inconsistent with the classification of that substance or mixture shall not appear on any advertisement for that substance or mixture."

If, however, the rationale for the link to Article 25(4) is to ensure a consistent approach between the two provisions, we can be flexible on the wording of the provision.

Block 5) Child-resistant fastenings

As stated in our previous comments, Denmark has sympathy for Parliament's proposal, which is designed to improve child safety. Initial feedback from our industry actors suggests that a significant number of daily household products will be affected by this proposal, necessitating new packaging. It is also unclear whether the proposed changes will have a positive or negative effect upon consumer behaviour, as complicated packaging may simply lead to products being transferred to alternative containers.

Parliament's proposal relates to a provision in Annex II, part 3. Article 53(1) empowers the Commission to adopt delegated acts amending the criteria for child-resistant packaging. Denmark suggests that the negotiating parties work towards a solution, whereby instead of adopting the Parliament's proposal, the Commission and Member States agree to examine this proposal within the CARACAL forum.

Block 6) Labelling obligations + Minimum dimension of labels, pictograms and font size

Denmark still favours the Council's negotiating position on the regulation of fold-out labels, which codifies ECHA's guidelines on front pages. Ensuring the most important information is readily available on the front page of a fold-out label will improve consumer safety. Council's proposal ensured that this was the case, whereas the proposal put forward by Parliament will mean that important information such as hazard pictograms and product identifiers can be placed on the inner pages of a fold-out label. Parliament's proposal on fold-out labels would codify rules on fold-out labels that are weaker than the ECHA guidelines. Denmark is flexible with regard to rules on the inner pages of fold-out labels, but prefers the position adopted in Council, as the logical ordering of labels is best dealt with via guidelines, where for instance linguistic concerns are easier to address.

Denmark welcomes the flexible approach shown by the negotiating parties with regard to font sizes. The costs cited by the Presidency in the discussion paper correspond to findings from our own dialogue with industry. We support the decision to improve the flexibility regarding font sizes, but at the same time it is important to consider readability and that the rules are still clear as to how to correctly perform labelling. Our market surveillance authority informs us that it is more straightforward to enforce a distance between two lines measured in percent than one estimated on a case by case basis (row 316 in st 14625/2/23, rev. 2). With regard to the font sizes set out in the Commission's non-paper WK 15264/2023 INIT, Denmark supports the introduction of the lower font sizes set out in column 4, which more closely correspond to the Council's negotiating position. For the two larger categories of packaging, we therefore support using a x-height size of 2,0 mm. We also support the introduction of differentiated rules for packaging up to 0,5 l with a font size of 1,2 mm.

Block 7) Refill stations

Denmark remains in favour of the positions adopted by Council on refill sales, including the hazard classes determining which substances and mixtures may not be sold via refill. Council's position reflected lengthy discussions on this topic, resulting in a nuanced compromise that creates a workable system for refill sales. Labelling was a key issue in this regard, and Denmark regards it as important, that the revised CLP clearly states that labels must be made available for consumers at refill stations, as set out in Council's negotiating position (row 358a).

Denmark has been made aware by the industry that adding eye irritation category 2 to the list of hazard classes that cannot be sold via refill, as EP suggests, would cause significant problems for the sale of detergents via refill stations.

In addition to this, we have also been alerted by industry actors about an emerging area of the refill market where the consumer buys a small container with a concentrated product to later dilute in a container at home. The concentrated products could be household detergents, cleaning products such as glass spray and dishwashing liquid. This form of refill could be affected by the rules for refill stations when the consumer needs to refill the small container with the concentrated product again. The concentrated product could possibly be excluded from refill stations as the mixture in the product is classified with one or more of the hazard classes mentioned in Annex II, part 3.

Denmark prefers the definitions for refill set out in the Council Negotiation mandate (Article 3, (38, 40 and 41)) and the rows relating to these seem now reflect the Council Mandate in the Draft Agreement in the revised four column document (st 14625/2/23, rev. 2). Our reading of this is that the definition of refill only covers instances where the consumer or the professional user fills a packaging. It does not seem to cover situations where the supplier performs the act of filling the packaging for the consumer or professional user. As such, suppliers may refill packaging provided by a consumer or professional user with substances which are classified with the hazard classes otherwise prohibited from selling via refill stations as suggested in Annex II (rows 367-385 in st 14625/2/23, rev. 2).

Block 8) Other amendments

Online sales

Denmark notes that it appears that the negotiating parties have departed from the position adopted in Council relating to the liability of third country sellers. We will send further comments on this point based upon the response we receive to our questions.

Resources for ECHA

Denmark can support the proposed amendment to recital 36a with a slight amendment, as we favor addressing the funding of ECHA under the ECHA founding Regulation, however we are not aware how far along this is. We would suggest that the funding of ECHA's extended workload after the revision of the CLP Regulation should be financed via a similar mechanism to that agreed in the Batteries Regulation.

Denmark is also of the opinion that all tasks performed by ECHA on behalf of the industry should be chargeable by industry paying a fee for the service ECHA provide.

Non-Animal Methods (NAM) / Alternative methods

Denmark understands that the changes put forward by Parliament on non-animal methods, will not lead to a material change in the law as it stands today. As such, Denmark does not object to the proposals put forward by Parliament. However, if the proposals on animal testing will lead to a

material effect upon the effectiveness of the classification system as non-animal methods are introduced, it is be necessary to assess the safety implications of the change. Non-animal methods must provide the same level of safety as animal testing. The issue of non-animal methods has not been considered in the impact assessment.

Timelines under Article 37

With regards to the suggested draft amendments in row 28 and 177 for recital 19 and article 37(5), respectively in the revised four column document (st 14625/2/23, rev. 2), the suggested changes state that the Commission must adopt delegated acts 'without undue delay' or at the latest by the end of the calendar year. This is, if anything, even more pressed for time than the 12 months proposed by Parliament. Denmark is against the suggested draft amendments and strongly recommends to revert to the text from the Council Mandate.

At the Working Party meeting of the 21st June 2023, Denmark raised a practical issue relating to timeframes in Article 37(7) in the Council's negotiation proposal, regarding the transfer of substances that have been included in the candidate list referred to in Article 59(1) of REACH for certain hazard classes to CLP annex VI. The Commission stated at the meeting that it would look into this issue, which we are now taking the opportunity to follow up on.

Our Competent Authority informs us that it is currently only possible to submit dossiers regarding SVHC twice a year to ECHA. As such, we believe that the 6 month period after entry into force is too short, if all possible submissions are to be registered. Therefore, we suggest that the submission period is extended from 6 months to 12 months, unless the process for submission according to REACH is not altered, so as to avoid the duplication of assessment of hazardous substances. Similarly the 24-month period in Article 37(7) should be extended to 30 months and the 18-month period in Article 37(7a) should be extended to 24 months to take account of the extended submission periods. A similar update will also be necessary for paragraph 8, which we would also support.

[Background: As the classification guidance for the new hazard classes is not expected to be finalized before Q2 2024, it would be difficult for member states to submit CLH classification proposal before the new guidance is available. The SVHC process takes place twice a year (normally around February and August). The submission deadlines exist due to the need to connect the legal timelines prescribed in Article 59 of REACH (*Identification of substances referred to in Article 57*) with a meeting of the Member State Committee (MSC), should a case need to be referred to the MSC to strike an agreement, as happens quite often in the SVHC process. Without this connection, it could result in the legal timelines be exceeded in some SVHC cases, thereby leaving them open to legal challenge on a purely procedural matter. We refer to the following guide on the ECHA homepage for more information: https://echa.europa.eu/da/support/authorisation/substances-of-very-high-concern-identification]

Ministry of Environment
of Denmark
Department

Non paper on the classification of substances with more than one constituent or MOCS under the CLP Regulation.

The CLP Regulation is one of the cornerstones of chemicals legislation in the European Union. It is built upon the principle that classification of a substance or mixture should be based upon scientific evidence and the inherent properties of chemicals.

The amendments suggested by EP and put forward by the Presidency include the proposal from the Commission where new text was brought into play in article 5(3) to better accommodate the need for a clear approach to the classification of multi-constituent substances or MOCS. This is very positive as there really is a need to strengthen the classification of MOCS. However, the EP compromise suggest a permanent exemption for substances of 'renewable botanical origin', such as essential oils, from this very article. With respect to social and economic impacts, EP suggests that these impacts should be considered when a substance is classified.

One of the core principles of the CLP Regulation is that classification is based on scientific data and when the criteria for classification is met, a hazard class and a category is assigned to the substance. Social and economic factors are not to be considered when assessing the inherent hazardous properties of a substance. Any social and economic impacts as a consequence of a substance or a group of substances meeting the criteria for classification as hazardous, should be dealt with under the relevant sector legislation.

With respect to the wish to exempt all MOCS of 'renewable botanical origin' there is no relevant or scientific data yet presented that could lead to an exemption for the entire undefined and incredibly diverse group of substances. Classification based on tests on a MOCS will be less sensitive for statistical reasons, than classification based on the individual constituents and the purpose of classification is to identify the inherent properties of the substance.

It has also been suggested that codified rules for MOCS would result in more tests being required. However, it does not follow from the new rules on MOCS that there is an obligation for suppliers to generate new data. CLP is not a data generating regulation and the proposed rules on MOCS do not change that. We would therefore support clarification of this point in either the recitals or the articles, which we hope will allay some of these legitimate concerns.

Ministry of Environment • Frederiksholms Kanal 26 • 1220 Copenhagen K Denmark
Phone +45 38 14 21 42 • CVR 12854358 • EAN 5798000862005 • mim@mim.dk • www.mim.dk

For both suggested changes by the EP, the permanent exemption for MOCS of 'renewable botanical origin' and the inclusion of social and economic impacts in hazard evaluation, these suggestions – if implemented – would lead to insufficient classification and improper and potentially dangerous use of chemicals. These suggested changes are unacceptable as the level of protection would drop significantly and the consequences would result in long term devastating impacts on health and environment.

MOCS: *stand by*.

Font size

The proposal modification of the first packaging category to 1 litre instead of 0.5 litre would let more flexibility for producers as the most involved products are detergent products and biocides for which the label needs to include the additional statutory information requirements in compliance with the sectorial legislation, so many combined information have to reported on their packaging.
In addition, as shown by the study, commissioned by CEPE, carried out by global experts in the field of vision science about, there is no difference in the legibility of font sizes between 1,2mm and 1,4mm at 30cm https://www.cepe.org/wp-content/uploads//2023/09/CEPE-Study-Testing-legibility-at-1.2-and-1.4mm-3.pdf). This statement is evident for those products (< 1L) that can be approached to the consumer in order to reduce the viewing distance (i.e. 30 cm).

Increasing font size would also reduce the space available with implications that may impact other European policy objectives:
-manufacturers would need to use larger labels;
- and in some cases, use larger rather than smaller packaging formats, contradicting the objective of Packaging and Packaging Waste Regulation (PPWR) adressed to minimise packaging.

Moreover, in some Member States multi-lingual labels are a legal requirement, for example Belgium (French, Dutch & German), and they enable manufacturers to optimise sales and distribution, including catering to smaller markets which might otherwise not be economically viable. With fewer opportunities for multi-lingual labels, the number of Stock Keeping Units (SKUs) could increase, leading to more packaging and more energy used in production, storage and transportation and the destruction of obsolete products. This will hit small and medium sized companies in the professional sector particularly hard as they have more specialty products but with lower volumes.

At the end we would like underline that other legislations request other mandatory information in the labelling and this could be satisfied if the font size was maintened as proposing in the following table:

dimension	size
<1L	1,2mm
1L-3L	1,4mm
3L – 50L	1,8mm
50-500L	2,0mm
>500L	2,0mm

Funding for the Agency (recital 36a, lines 45a and line 231a)

We substain stable funding for the Agency but a specific revision under CLP regulation does not appear appropriate. We are in favour of other solution that the legal service of the Counsilium will individuate.

Environmental Claims

In the revision of CLP Regulation it is not necessary introduce other provisions related to the use of enviromental claims versus those are already present in the Art. 25(4) of the CLP, as the Proposal for a Directive amending Directives 2005/29/EC and 2011/83/EU as regards empowering consumers for the green transition through better protection against

unfair practices and better information already includes specific provisions for the 'environmental claim on the basis of the following definitions:

- "'**environmental claim**" means any message or representation which is not mandatory under Union law or national law, including text, pictorial, graphic or symbolic representation, **in any form,** including labels, brand names, company names or product names, in the context of a commercial communication, and which states or implies that a product, product category, brand or trader has a positive or no impact on the environment or is less damaging to the environment than other products, brands or traders, respectively, or has improved their impact over time;
- "'**generic environmental claim'** means any "*environmental claim made in written form or orally, including through audiovisual media, not contained in a sustainability label, where the specification of the claim is not provided in clear and prominent terms on the same medium;"*

Furthermore another Proposal Directive on substantiation and communication of explicit environmental claims (Green Claims Directive) is currently under discussion that applies to **explicit environmental claims** made by traders about products or traders in business-to-consumer commercial practices" on the basis of the following definition: "'**explicit environmental claim'** means an environmental claim that is in textual form or contained in an environmental label".

Transition period (for your convenience we repeat the position already sent on the transition period, not yet discussed)

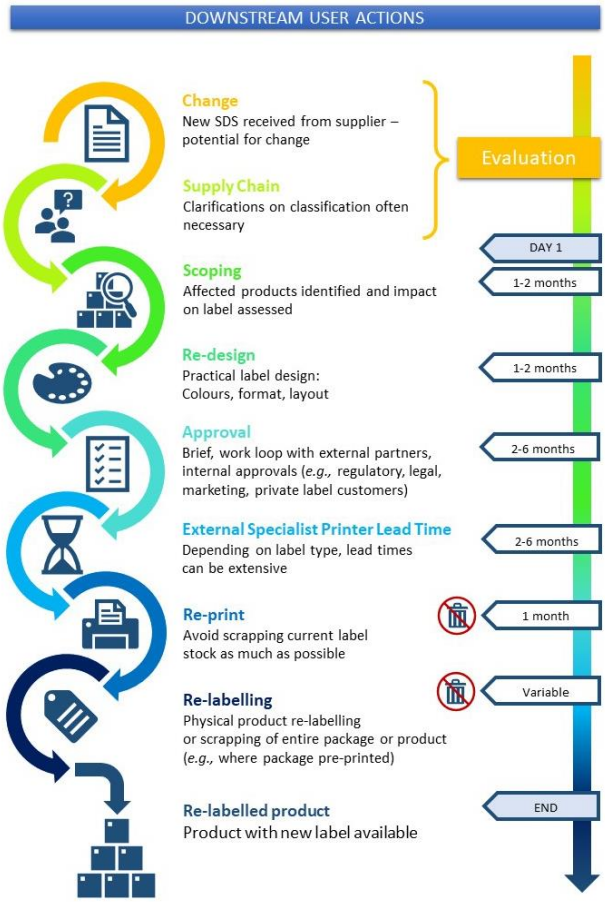
On other Amendements of PE

- AM82 an AM83 EP on **transition period** of article 61 of the CLP. We support the opinion of EP to distinguish the application date of the CLP new rules for substance and mixture. So, for this aspect, we support AMs EP. Anyway, we let's seize the opportunity to request again more time especially for the mixtures. Please, remember that it is in parallel the updating of the labelling as consequence of the 2023/707 regulation (new criteria Eds HH/ENV, PBT vPvB PMT vPvM). In the table below we try to summarize the situation and the Italian proposal.

		Substance	*Substance already on the market*	*mixtures*	*Mixture already on the market*
Article 61	Comm/ Consilium	18months	42 months	18 months	42 months
	PE	18 months	42 months	24 months	48 months
	IT proposal	**24** months	**42** months	**36** months	**60** months

- At the end, even if the EP does not propose Amendments on the "**Updating information on labels**" set up in the **article 30 paragraph 1**, we continue to receive from companies' side concerning analysis on the feasibility of the timing proposal especially for the mixtures. So, we need to continue putting under your attention the enterprise's difficulties. Please, see the fig.1 that shows the necessary time to update a label (especially for formulators of several mixtures when receive a communication of an updated label from its supplier).

  Fig.1 timing need to modify a label, after the evaluation



In the following table, in yellow, we would like to propose a Italian amendment:

COMM	EP	Consilium	**IT proposal**

1. In case of a change regarding the classification and labelling of a substance or a mixture, which results in the addition of a new hazard class or in a more severe classification, or which requires new supplemental information on the label in accordance with Article 25, the supplier shall ensure that the label is updated within 6 months after the results of the new evaluation referred to in Article 15(4) were obtained.		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 ~~within~~ **without undue delay and no later than** 6 months after the results of the new evaluation referred to in Article 15(4) were obtained **by, or communicated to, that supplier**.	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:** **i) substance** ~~**or that mixture**~~ shall ensure that the label is updated ~~within~~ **without undue delay and no later than** 6 months after the results of the new evaluation referred to in Article 15(4) were obtained **by, or communicated to, that supplier;** ii) **that mixture shall ensure that the label is updated without undue delay and no later than 9 months after the results of the new evaluation referred to in Article 15(4) were obtained by, or communicated to, that supplier.**