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NOTE

From:	Bulgarian Delegation
To:	Delegations
N° Cion doc.:	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) - Bulgarian proposal for addressing the issue with essential oils in the revision of the CLP regulation

Delegations will find in the Annex a document from the Bulgarian delegation on essential oils for the meeting of Coreper on 30 June 2023.

BULGARIAN PROPOSAL

FOR ADDRESSING THE ISSUE WITH ESSENTIAL OILS IN THE REVISION OF THE CLP REGULATION

In order to classify the essential oils in a scientifically justifiable, predictable and clear way, providing optimal balance between high level of protection of human health and environment, and economic and social considerations, Bulgaria is proposing the following amendments to Art.5.3 in the latest Presidency compromise (highlighted in **grey/bold/underlined**):

(4) in Article 5, the following paragraphs 3 to 3c are added:

‘3. A ~~multi-constituent~~ substance containing at least more than one constituent, in the form of an individual constituent, an identified impurity or an additive for which relevant information referred to in paragraph 1 is available, shall be examined ~~in accordance with the criteria set out in this paragraph~~, using the available information on those known constituents as well as on the substance itself, ~~unless Annex I lays down a specific provision~~.

3a. By derogation to paragraph 3, ~~F~~for the evaluation of ~~multi-constituent~~ substances containing more than one constituent pursuant to Chapter 2 of this Title in relation to the ‘germ cell mutagenicity’, ‘carcinogenicity’, ‘reproductive toxicity’, ‘endocrine disruption~~g~~ ~~property~~ for human health’ and ‘endocrine disruption~~g~~ ~~property~~ for the environment’ hazard classes referred to in sections 3.5.3.1, 3.6.3.1, 3.7.3.1, 3.11.3.1. and 4.2.3.1. of Annex I, the manufacturer, importer or downstream user shall use the relevant available information referred to in paragraph 1 for each of the individual known constituents in the substance.

Relevant available information on the ~~multi-constituent~~ substance itself shall be taken into account where one of the following conditions are met:

- (a) the information demonstrates germ cell mutagenic, carcinogenic, or toxic to reproduction properties, or endocrine disruption~~g~~ ~~properties~~ for human health or the environment;
- (b) the information supports the conclusions based on the relevant available information on the constituents in the substance;

“(c) the substance is of renewable biological origin.”

In cases other than those referred to in (c), relevant available information on the ~~multi-constituent~~ substance itself showing absence of ~~certain~~ the properties referred to in (a) or less severe properties shall not override the relevant available information on the constituents in the substance.

This paragraph applies unless there is a specific provision in the section in Annex I created in accordance with paragraph 3c.

3b. By derogation to paragraph 3, ~~F~~for the evaluation of ~~multi-constituent~~ substances containing more than one constituent pursuant to Chapter 2 of this Title in relation to the ‘biodegradation, persistence, mobility and bioaccumulation’ properties within the ‘hazardous to the aquatic environment’, ‘persistent, bioaccumulative and toxic’, or ‘very persistent and very bioaccumulative’, ‘persistent, mobile and toxic’ ~~and or~~ ‘very persistent and very mobile’ hazard classes referred to in sections 4.1.2.8, 4.1.2.9, 4.3.2.3.1, 4.3.2.3.2, 4.4.2.3.1 and 4.4.2.3.2 of Annex I, the manufacturer, importer or downstream user shall use the relevant available information referred to in paragraph 1 for each of the individual known constituents in the substance.

Relevant available information on the ~~multi-constituent~~ substance itself shall be taken into account where one of the following conditions are met:

- (a) the information demonstrates ~~biodegradation~~, persistence, mobility, and bioaccumulation properties or lack of (rapid) biodegradation.
- (b) the information supports the conclusions based on the relevant available information on the constituents in the substance.

“(c) the substance is of renewable biological origin.”

In cases other than those referred to in (c), relevant available information on the ~~multi-constituent~~ substance itself showing absence of ~~certain~~ the properties referred to in (a) or less severe properties shall not override the relevant available information on the constituents in the substance.

This paragraph applies unless there is a specific provision in the section in Annex I created in accordance with paragraph 3c.

JUSTIFICATION:

All substances, including substances containing more than one constituent (MOCS) should be classified and labelled using relevant, reliable, and robust scientific data, prior to communicate this information down to the supply chain and to the consumers. There is sufficient scientifically substantiated data that justify the exclusion from the constituents’ approach of the substances of renewable biological origin.

Reliable scientific evidence shows that an essential oil is not the sum of its chemical constituents and displays properties that are a function of its overall composition. Unlike many other MOCS (e.g. petrochemicals), the constituents of essential oils have specific stereochemical properties that could neutralise toxicity. Thus, test results related to hazards of the oil (to which as a whole the consumer is exposed to), often differ from those obtained when testing the individual constituents it contains.

According to UN GHS and CLP the evaluator of the mixture must take into account all available information regarding the potential occurrence of synergistic or antagonistic effects among the different ingredients. If we apply this to substances, only the test results on the substance itself allow taking into account the interactions between all its constituents.

Also, contrary to mixtures which are intentionally mixed with known constituents, the composition of essential oils as natural complex substances may vary depending on harvesting location, harvest year, climatic conditions, source, manufacturing process, extraction conditions, etc. Essential oils could contain hundreds of natural constituents with unknown or variable composition and there is no clear methodology on the selection of the appropriate constituents for testing.

There are also arguments relating to legal stability, regulatory predictability and consistency.

As a general principle, substances are classified based on their hazardous properties and the REACH Regulation requests information to be provided on a substance level. In that respect, difference in the approach will be established between the two building blocks of one single system.

Derogation under Annex I still remain uncertain and burdensome for the sector (consisted mainly of SMEs), without a defined procedure and criteria for determining the exclusions.

The amended Art.5(3) states that negative test results obtained on the substance itself shall not override information on the hazard of its constituents. Such provision completely disregards the relevant information on the substance itself and does not allow all available and scientifically justified data to be used for the classification of essential oil.

The discrepancy between the EU and the UN GHS creates legal uncertainty and confusion in the context of the global value chain (trade with essential oils) where producers outside of the EU will have different interpretation of the hazards of essential oils.