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WORKING DOCUMENT

From:	General Secretariat of the Council
To:	Delegations
N° prev. doc.:	CM 2899/23 - Agenda of the meeting ST 9689/23 - Presidency Compromise text
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) - Compromise proposal from the Presidency - Non-Paper by Bulgaria on Essential Oils

Delegations will find in the Annex a Non-Paper by Bulgaria on the subject of essential oils in the Compromise Proposal by the Presidency, as set out in document ST 9689/23, examined at the Working Party meeting on 31 May 2023.

Non-paper by Bulgaria

on the revision of the CLP Regulation and the issue of essential oils

Bulgaria fully shares the need to ensure **high level of protection of human health and the environment** by proper identification and classification of chemical hazards. Reasonable approach must be undertaken also in light of preserving EU production capacity of natural renewable substances of biological origin and protecting the freedom of consumer to choose qualitative products of natural, organic and bio-origin. We consider that complies with the priorities of the Green Deal and Chemicals Strategy for Sustainability.

From that perspective and for the following reasons, we have serious concerns about the approach proposed by the European Commission to address the multi-constituent substances (MCS) in the current CLP revision, in particular the repercussions such an approach will have for the production and usage of essential oils:

I. The scientific rationale for the MCS concept applicable for UVCB is questionable, and it is unclear how it takes into account the specificity of essential oils as UVCB substances.

Bulgaria firmly supports all substances, including MCS, to be classified and labelled using **relevant, reliable, and robust scientific data**, prior to this information being communicated down to the supply chain and to the consumers.

UVCB substances of biological origin are difficult to test because of lack of knowledge of the precise composition which varies according to many factors (harvesting location, harvest year, climatic conditions, source, manufacturing process, cultural practices, harvesting and storage/drying conditions, extraction conditions, etc).

Collecting data on each individual constituent of the substance will require new testing, including animal testing, which is not in line with the objective of avoiding unnecessary testing, according to Article 25 of the REACH Regulation. Moreover, there is no clear methodology how to select the appropriate constituents for testing.

As a general principle, substances are classified based on their hazardous properties and REACH requests information to be provided on a substance level. In that respect there is no justification about the **need for additional testing of constituents when information on the whole substance is already available**.

II. There is no evidence supporting the presumption that if one of UVCB constituents possesses certain properties, then the whole substance also possesses them.

In the case of UVCB substances of biological origin, such as all essential oils, we should consider **existing scientific evidence** that the test results related to hazards often differ from those obtained when testing the individual constituents.

An essential oil is not the sum of its chemical constituents and displays properties that are a function of its overall composition. The constituents of essential oils have specific **stereochemical properties** that could change the toxicity, whereas many other MCS (e.g. petrochemicals) do not have these properties.

In accordance with UN GHS (chapter 1.3.3.3.) and CLP (Art. 12c) requirements, when performing an assessment, the evaluator must take into account all available information regarding the potential **occurrence of synergistic or antagonistic effects** among the different ingredients of the mixture. If we apply this to substances, only the test results on the substance itself allow taking into account the interactions between all its constituents.

III. The current CLP draft amendment (Art.5.3) states that negative test results obtained on 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.

It must also be taken into account that the consumer is exposed to the effect of the substance as a whole not to its constituents separately and creating over- or under-classification has a potential to seriously mislead the consumer and undermine the trust in the EU law and the Internal Market.

IV. We also have serious doubts regarding the feasibility of the envisaged derogation under Annex I.

The proposed derogation under Annex I is very uncertain and unclear, without a defined procedure and criteria for determining the exclusions. What **criteria can be defined** for granting such derogation? Furthermore, it is not clear **how the substances will be classified during the period until the granting of a derogation,** which may take a significant amount of time (at least 3 years). And **what kind of evidence** is expected to be provided by the industry?

V. The current CLP draft amendment is not matching the UN GHS (Globally Harmonized System of Classification and Labelling of Chemicals).

That creates legal uncertainty and confusion on how to explain the different interpretation of the intrinsic properties (hazards) of essential oils across the global regions.

VI. The consequences of applying the mixture principle to essential oils, and how will this affect the European industry?

The classification of substances **is not an end in itself**, and we cannot ignore the practical consequences if an essential oil is classified in certain hazard classes, without sufficient scientific grounds.

With such burdensome provisions without impact assessment or strong justification for introducing it, lack of criteria and procedure, uncertainty about the number of tests and usefulness of the results, necessity to avoid animal testing, lack of clarity for the real added value, possibility to mislead the consumer or reduce their choices (as the consumer demand for natural, bio- and organic products is increasing), the EU legislation will create a regulatory environment where it will be impossible for small producer of biological renewable substances to produce them in Europe. In our understanding that is the purpose of neither the Green Deal/Chemical Strategy, nor of the EC/MSs**.** Our firm position is that, together with preserving the highest health and environment protection standards, we **have to protect, as well, the EU market and consumers from synthetic substitutes of the EU natural products coming from third countries.**

<u>Proposed way forward:</u>

We propose the exclusion from the MCS concept of the essential oils so they continue to be classified according to the current rules for substances, not as mixtures:

Our concrete proposal is that in Article 5, the following paragraph 4 be added:

"Paragraph 3 shall not apply to UVCB substances of biological origin."

We remain constructive and ready to consider alternative formulations, as far as they allow for the exclusion of the essential oils from the MCS concept.