

Background Information to the Documents in ANNEX

1. Delegations will find in the Annex two supporting documents sent by the Commission, concerning essential oils.

The information in the documents originates from the fragrance and cosmetics industry sectors in their portfolio of registered substances under REACH. In their view, the information provided defines the meaning of what are the “substances of renewable botanical origin”.

The replies to the Commission's questions are the following:

Question on the way Natural Complex Substances (NCS) are registered under REACH:

In accordance with REACH requirements, this is done depending on the substances:

Whether the substance is a mono-constituent

Whether the substance is a multi-constituent

Whether the substance is a UVCB

UVCBs represent the most important category in which NCSs used in fragrances are registered. According to the registration rules for UVCBs, NCSs included in the same registration dossier must come from the same source, and the main steps in the obtaining process must be similar. Regarding composition, given that this category of substances has a variable composition, a certain tolerance is accepted. For example, lavandin essential oil is the subject of a different registration dossier to lavandin concrete, because the obtaining processes are different. The same applies to styrax essential oil and styrax resinoid.

You will find more information in the attached excel table with the number of registrations of NCSs (source: ECHA website).

206 NCSs have been registered, split as follows:

88 essential oils (Eos)

14 absolutes

15 concretes

20 resinoids

9 oils

39 extracts

21 other (multi, powder, etc).

This is why IFRA and Cosmetics Europe support the use of the term “substances of renewable botanical origin” as this term would cover all these NCS.

The registrant then shall classify the substance depending on the available data. This will be done based on all available (toxicity) data. This data could be on the data on individual constituents (or based on the data available on the (whole) substance if this data is available). 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).

Question on the ‘scientific rationale’ for maintaining similar classification rules for all natural ingredients used in cosmetics and perfumery (and not only for essential oils) – i.e., using all available data for classifying the substance (data on constituents & data on the (whole) substance):

Since the finalization of EFEO-IFRA guidelines on substance identification and sameness of NCS under REACH and CLP (SEE HERE) in 2015, these substances were treated the same way and defined under the same ‘umbrella’ (natural complex substances), without ‘creating differentiation’ depending of their extraction techniques (same specific characteristics of the natural substances, made up of hundreds of constituents, etc.).

On the ‘similarity’ of composition between extracts obtained by different processes, you will find attached an example showing the typical composition of the main constituents of a rose essential oil & a rose absolute. It can be seen that the main constituents are present in both extracts, albeit in different proportions. Consequently, the same "reasoning" can be applied to potentially different results between constituent and (whole) substance data.

Question on the scope of NCS, including the use of ‘funghi’:F

Our sector uses funghis/ mushrooms or algae as fragrance or cosmetic ingredients. Some examples:

- Our sector uses funghis/ mushrooms or algae as fragrance or cosmetic ingredients.

Some examples:

- Oleoresin Botelus: cèpe - <https://www.biolandes.com/produit/cepe-2/>
- Truffle extracts in final products:
<https://www.esteelauder.fr/products/13797/catalogue-produit/re-nutriv/collections/ultimate-diamond>; <https://www.loreal.com/fr/loreal-luxe/yuesai/>
- <https://www.fragrenza.com/blogs/notes-in-perfumery/algae-in-perfumery>

For further information:

All these ingredients are obtained through **simple extraction techniques**, derived from plants (physical extraction/ no chemical modification). To name a few: lemon, lavender, rose essential oil; rose absolute; oakmoss, etc. Some plants are only subject to certain extraction techniques for perfumery, due to their fragility. This is particularly **the case with jasmine: the flowers are very fragile and cannot withstand steam distillation**, a technique for obtaining essential oils. Other extraction processes at room temperature are therefore used **for jasmine (flowers): a first extraction to obtain a jasmine concrete, then a second extraction of the concrete to obtain a jasmine absolute**. Hence, **there is no such thing as "jasmine essential oil" – because jasmine flowers are too fragile to be subjected to distillation**. This explains why jasmine produces ingredients such as jasmine absolute (but not essential oil).

2. Delegations will find below the publicly available hyperlink related to the study which the Commission used for their Impact Assessment. Annex 10 is the one related to Neurotoxicity and Immunotoxicity:

[Chemicals policy - Library \(europa.eu\)](#)



Council of the European Union
General Secretariat

Brussels, 21 November 2023

Interinstitutional files:
2022/0432 (COD)

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WORKING DOCUMENT

From:	General Secretariat of the Council
To:	Working Party on Technical Harmonisation (Dangerous Substances - Chemicals)
N° prev. doc.:	ST 14625/1/23 REV 1 CM 5319/23
N° Cion doc.:	ST 16258 2022 ADD 1- ADD 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) - Supporting documents by the Commission on Essential Oils and the CLP Revision

<i>Comparaison compositions des substances volatils dans une absolue de Rose vs Huile essentielle de rose (Rosa damascena)</i>		
Main constituents contained in the volatile part from 0,1%	Rose Essential Oil	Rose Absolute
	Typical %	Typical %
Bulnesene alpha	0.2	0.1
Caryophyllene beta (E)	0.8	0.16
Citronellol-levo	35	11.4
Citronellyl acetate	0.6	0.4
Eicosane	1.06	0.32
Eugenol	1.8	0.9
Farnesol-trans-trans	1	0.2
Geranial	0.7	0.26
Geraniol	13.75	4.9
Geranyl acetate	1.5	0.45
Guaiene alpha	0.3	0.15
Heneicosane	3.1	0.76
Heptadecane	2.1	1
Humulene alpha	0.2	0.1
Methyl eugenol	2.8	0.54
Mint Sulfur	0.1	0.1
Neral	0.2	0.15
Nerol	9	0.1
Nonadecane	7.8	5
Nonadecene-9 (Z)	1.9	2.2
Phenylethyl acetate	0.2	0.39
Phenylethyl alcool	2.5	41
Rose oxide-cis	0.7	0.27
Rose oxide-trans	0.2	0.1

