

ICADA suggestion for the application of Article 15(2) to NCS

31.01.2025

Dear Sylwia and Rizos-Georgios

Please find the suggestion of ICADA members for the application of Article 15(2) to NCS

NCS are complex substances which vary depending on the part of the plant, the geographical origin of the plant, the season and climate conditions, the method of extraction, etc. but deliver the benefit of a unique aroma signature of the specific natural ingredient. The regulatory consequences of CMR classifications under Article 15.2 of the CPR were designed for single substances that are used as such as they are. No consideration was given to NCS and the impact that the classification of a substance could have on the wide range of NCSs that naturally contain it as a constituent. Also from a toxicological point of view it has been shown, that a natural complex substance tested as a whole may show different results than one or more of its constituents when tested as single chemicals.

As a consequence ICADA suggest for the application of Article 15(2) to NCS substances is therefore to initially recognise that the first two conditions of Article 15(2) to be fulfilled, namely

- a) compliance with food safety requirements and
 - b) no suitable alternatives are available
- are considered to be fulfilled for the NCS.

Regarding the criterion of compliance with food safety requirements, it should be noted that NCS are usually found as components of plants and spices. Therefore, the criterion should be met if individual/few examples of the natural occurrence of the ingredient in food are detected.

Regarding the criterion of no suitable alternatives, it is not possible with NCS to replace a natural ingredient with another ingredient without changing the properties of the complex mixture. Replacing an ingredient in an NCS inevitably results in a different substance that not only has different properties but may also no longer be classified as an NCS. The widespread natural occurrence of the ingredient in hundreds of very different NCS from different botanical families would require an unmanageable number of assessments of alternatives to be carried out. The unavailability of suitable alternatives should therefore be the standard conclusion for ingredients of NCS.

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The last two conditions, c) application for a specific use with known exposure and d) safe evaluation by the SCCS, should also be met for the CMR-classified ingredients of an NCS.

There are already examples of this in the CPR, namely methyl eugenol (Annex III CPR) as a component of essential oils and an exception for safrole (Annex II) as a normal content in natural essences.

Since perfume oils are often involved, it should be noted that the maximum concentrations specified in the CPR refer to the application concentrations of the cosmetic products. An example of this is bath salts, which are very diluted in the bath water and can therefore contain higher concentrations in the undiluted product.

Similarly to the “Practical guidelines on the procedural steps to enforce the ban or possible exemptions to the ban of CMR substances in cosmetic products (February 2020) (Working document of the Working Group on Cosmetic Products)”, ICADA suggests to create a guideline for the application of the Article 15.2 of CPR. The guideline should lay down the responsibilities and deadlines for both industry and Member States. This will provide transparency on the decision-making process and consequently legal clarity and certainty for all stakeholders not only for constituents of NCS but for any substance subjected to the CMR Cat 1 derogation process.

Kind regards,

Beate

A handwritten signature in blue ink, appearing to read "Dr. B. Pfundstein".

Dr. Beate Pfundstein

ICADA e.V.