



POSITION PAPER

THE CLASSIFICATION OF 'MORE THAN ONE CONSTITUENT SUBSTANCES' (MOCS) UNDER THE CLP REGULATION

This paper addresses the issue of the classification of "more than one constituent substances" (MOCS) as proposed by the European Commission and ECHA in its "Thought starter for discussion on the application of mixture rules for substances containing more than one constituent (including impurities) and potential impacts for REACH dossier evaluation process" (CA/74/2020) (the "CARACAL Paper").

This paper only addresses the classification of MOCS (Section 3 of the Caracal Paper). The undersigned will come back with their comments on the other parts of the Caracal Paper in due course.

On the basis of the legal analysis conducted by the law firm Mayer Brown, attached hereto, the undersigned consider that the position developed in Section 3 of the Caracal paper is contrary to the CLP Regulation and would require an amendment of the text of the CLP Regulation. They also consider that such amendment is not warranted.

Indeed, as fully demonstrated in the attached legal opinion:

- The concept of MOCS is a pure creation, outside of any legal basis under REACH, CLP or other EU legislation. It encompasses and would affect virtually all chemical substances produced, imported and placed on the market in the EU.
- The CLP provides specific rules for substances and mixtures and there is no rationale, nor reasonable interpretation of the CLP Regulation that could lead to subjecting substances to the rules applicable to mixtures where the CLP Regulation specifies different rules for substances and mixtures. This would not only be an unlawful interpretation of the CLP but an abuse of power if applied by authorities.
- In particular, Article 6(3) of the CLP which provides an exemption to the general rule of the precedence of data on the mixture itself, for CMR endpoints, unquestionably only applies to mixtures, not to substances. There is no interpretation issue at stake in this respect. This is confirmed by the wording of the preamble of the CLP.
- ECHA justifies its interpretation that a similar classification approach should apply for mixtures and MOCs as regards CMR endpoints, with reference to Articles 10(1), 11(1) and Section 1.1.2.2.(a) (iv) of Annex I of the CLP. However, the only rational interpretation of these provisions is that they specify how the GCL, SCL and cut-off values need to be applied to substances and mixtures, but not when or in which conditions they need to be applied.
- While the rules applicable prior to the adoption of REACH and the CLP Regulation were modified in 2001 to assimilate substances containing impurities, additives or individual constituents to mixtures for classification purposes for all endpoints, these provisions have not been carried over in the CLP. As the CLP no longer assimilates those substances now defined as MOCS to mixtures, this means that the legislator has chosen another



approach, and thus that there is no legal basis to extend Article 6.3 to MOCS under the CLP Regulation.

- This is in line with the GHS, which the CLP is implementing at the EU level, which consecrates the primacy of data on mixtures and the subordinated role of the calculation method. Under the GHS, the use of the calculation method for CMR endpoints (1) is limited to mixtures, (2) is not absolute and (3) is justified by the anticipated lack of data on the mixtures themselves.



Susanne Zänker



Alain Aubanel



E.F.E.O.

European Federation of Essential oils

Elisabeth Vossen



effa

Alexander Mohr



John Chave



THE INTERNATIONAL FRAGRANCE ASSOCIATION

Martina Bianchini



Mark Smith