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MEMORANDUM

Legal opinion on "The Classification of MOCS under the CLP Regulation"

This memorandum analyses the legality of the classification of "more than one constituent substances" (MOCS), as proposed by the European Commission and ECHA, under Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures ("the CLP Regulation" or "the CLP")

In Section 3 of their "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"), the European Commission and ECHA seek to justify that, as regards CMR endpoints, MOCS should be classified according to the rules applicable to mixtures, and in particular Article 6.3 of the CLP.

In summary, as discussed below, the CLP Regulation provides specific rules for substances and mixtures, does not refer to the concept of MOCS, and there is no rationale, nor reasonable interpretation of the CLP that could lead to subjecting almost all substances (MOCS) 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 could constitute an abuse of power if applied by authorities.

1. Context

The Caracal paper creates a new acronym, that of "more than one constituent substances" or "MOCS", to designate "UVCBs", "mono-constituents containing impurities" and "multi-constituent substances". There is no trace of the concept of MOCS anywhere in REACH, the CLP or EU legislation. It is a pure creation of ECHA/the Commission.

REACH and the CLP define and distinguish substances and mixtures. They also refer to UVCBs as a category of substances. REACH defines a substance as including any additive or impurity deriving from the process used. The distinction between mono and multi-constituent substances was introduced by ECHA in its Guidance on substance identity. Mono-constituents are substance which are at least 80% pure with up to the remaining 20% considered as impurities.

Considering that there is almost no mono-constituent substance that is 100% pure, this means that, in practice, virtually all substances will qualify as MOCS. This also means that the new rules proposed for MOCS will affect virtually all chemical substances produced, imported and placed on the market in the EU.

2. Classification of Substances and Mixtures under the CLP

The CLP Regulation provides rules for the classification and labelling of substances and mixtures as defined under REACH. Some of these rules apply to both substances and mixtures; other apply only to substances or mixtures, as provided for by the legislator.

For the purpose of classification of substances and mixtures, articles 5 and 6 of the CLP, respectively, lay out lists of relevant sources of information, starting with data generated in accordance with any of the methods referred to in Article 8(3) which allows generating new information for substances and mixtures.

The CLP establishes a clear hierarchy among those sources for mixtures, as specified in Article 6(2) which confirms the supremacy of data on the mixture itself.

This is less clear for substances, as there is no equivalent to Article 6(2) for substances. However, the same hierarchy applies. This results indirectly from a comparison of Articles 5(1)(a) and 6)(1)(a) of the CLP. While Article 6(1)(a) for mixtures refers to "data generated in accordance with any of the methods referred to in Article 8(3) on the mixture itself or the substances contained in it", Article 5(1)(a) simply refers to "data generated in accordance with any of the methods referred to in Article 8(3)", thus implying data on the substance itself. There is no reference in this article to data being generated on additives, constituents or impurities.

When for mixtures, data on the substances in the mixtures are used, this is generally referred to as the "conventional method", the "calculation method" or the "summation method".

3. Classification of MOCS for CMR properties

The first objective of the Caracal Paper is to "*clarify(…) the interpretation of mixture classification rules under CLP to MOCS for CMR properties*". In Section 3 of the Paper, the authors consider that "*MOCS, while being substances, are similar to mixtures in so far as they contain more than one component/constituent*" and that "*from this perspective, one could argue that a similar classification approach for mixtures and MOCS should be applied*".

This disregards the fact, as developed above, that the CLP provides specific rules for substances and mixtures, does not refer to the concept of MOCS, and that there is no rationale, nor reasonable interpretation of the CLP Regulation that could lead to subjecting almost all substances to the rules applicable to mixtures where the CLP Regulation specifies different rules for substances and mixtures. This would be not only an unlawful interpretation of the CLP but could constitute an abuse of power if applied by authorities.

Article 6.3 only applies to mixtures

As regards mixtures, as outlined in the Caracal Paper itself, Article 6(3) provides that, as an exemption to the general rule of the prominence of test data on the mixture itself, for CMR endpoints, "*the classification of mixtures shall be based on the CMR classification of the constituents, applying the relevant generic or specific concentration limits (GCL/SCL), in accordance with Articles 10 and 11*".

In the Caracal Paper, ECHA specifies that "*for the classification of MOCS, for CMR endpoints, the CLP legal text seems to have been subject to different interpretations*". This may be the case but article 6(3) 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 recital 22 in the preamble to the CLP which clearly applies only to mixtures as opposed to substances:

"(*22) To facilitate hazard identification for mixture, manufacturers, importers and downstream users should base this identification on data for the mixture itself, where available, except for mixtures with carcinogenic, gem cell mutagenic or reproductive toxic substances, or where the biodegradation or bioaccumulation properties in the hazard class hazardous to the aquatic environment are evaluated. In those cases, as the hazards of the mixture cannot be sufficiently assessed in a manner that is based on the mixture itself, the data for the individual substances of the mixture should normally be used as a basis for the hazard identification of the mixture (emphasis added).*"

Although we could not find a rationale or scientific justification supporting the statement that " *hazards of the mixture cannot be sufficiently assessed in a manner that is based on the mixture itself*", this recital shows that the legislator only intended article 6.3 to apply to mixtures.

Articles 10(1), 11(1) and Section 1.1.2.2.2.(a) (iv) of Annex I of the CLP cannot be interpreted to specify when the "calculation" method must be applied

The Caracal paper then 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 1.1.2.2.2.(a) (iv) of Annex I of the CLP.

This interpretation is however legally flawed and indefensible. Indeed, these Articles can only be interpreted to explain the conditions that apply when a substance or a mixture is to be classified on the basis of its constituents under the so-called "calculation method", not when such method needs to be used, which is a question regulated by Article 6 of the CLP Regulation.

Article 11(1) specified that "*Where a substance contains another substance, itself classified as hazardous, whether in the form of an identified impurity, additive or individual constituent, this shall be taken into account for the purposes of classification, if the concentration of the identified impurity, additive or individual constituent is equal to, or greater than, the applicable cutoff value in accordance with paragraph 3*".

The Caracal paper seems to considers that the fact Article 11(1) requires ("shall") one to take account of the classification of impurities, additives or individual constituents of such substance, if above the cut-off limits, justifies to treat MOCS as mixtures and therefore, it would require these substances to be classified on the basis of data on the substance itself, except for CMR properties, where the calculation method should be used.

However, this Article does not differentiate between CMRs and other endpoints and there is no rationale for considering that this rule would apply only to the CMR endpoints, as there is no reference to Article 6(3) in either Article 11(1) or Article 11(2) which is a mirror paragraph for mixtures.

Also, Article 11(1) and (2) could not be interpreted as requiring the use of the calculation method for all endpoints when a substance or mixture contains a hazardous constituent, impurity or substance (for mixtures). Indeed, this would be contrary to the hierarchy applicable for substances and mixtures as discussed above.

To conclude, the only rationale interpretation of articles 10(1) and 11(1) of the CLP 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.

4. The Dangerous Substances and Preparations Directives

A review of the classification provisions under EU Law as applicable prior to the adoption of the REACH and CLP Regulation, show that these rules evolved over time and that the CLP legislator adopted different rules for the classification and labelling of substances and mixtures containing CMR constituents, and departing from the previously applicable rules.

Classification rules for substances were introduced by the Sixth Amendment to the Dangerous Substances Directive 67/548/EEC (the "DSD") (Directive 79/831/EEC). Annex VI of the DSD has been modified several times, making some references to the rules applicable to mixtures under the Dangerous Preparation Directive 88/379/EEC and then 1999/45/EC. Annex VI was modified in particular by Directive 91/325/EEC of 1 March 1991 and Directive 2001/59/EC of 6 August 2001.

In its latest version, Section 1.7.2.1 of Annex VI specified that the "classification of substances containing impurities, additives or individual constituents" of concentration greater than or equal to the limits specified "should be carried out according to the requirements of Article 5, 6 and 7 of Council Directive 1999/45/EC", which include the predecessor of Article 6.3 of the CLP. Therefore, under the DSD as modified, the classification of substances containing impurities, additives or individual

constituents of concentration greater than or equal to the limits specified, for CMR endpoints, was to be made on the basis of the conventional method using data on these constituents, as opposed to data on the substance itself.

However, and most importantly, these provisions have not been carried over in the CLP. Rather Article 6.3 of the CLP, clearly refers only to mixtures, not substances. If the EU legislator had intended to subject MOCS to the same rules as substances for CMR properties in continuation of the rules of the DSD, as modified by Directive 2001/59/EC, it would have carried section 1.7.2.1 of Annex VI of the DSD into the CLP or specified in recital 22 and/or in Article 6(3) that the rules applicable to mixtures also apply to MOCS.

By contrast, the CLP no longer assimilates MOCS to mixtures. This means that the legislator has chosen another approach, in line with the GHS, as described below, and thus that there is no legal basis to extend Article 6.3 to mixtures under the CLP Regulation.

5. The CLP implements the GHS which also discriminates between the classification of mixtures and substances for CMR endpoints

Section 1.3.3.1.3 of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) states that "*where impurities, additives or individual constituents of a substance or mixture have been identified and are themselves classified, they should be taken into account during classification if they exceed the cut-off value/concentration limit for a given hazard class*". This is the origin of similar language in Article 11(1) and (2) of the CLP. However, under the GHS as under the CLP, this does not mean that for all or for some endpoints, substances with impurities, additives or individual constituents should be treated as mixtures:

First, Section 1.3.3.2, which follows Section 1.3.3.1.3 mentioned above, refers to cut-off values and concentration limits and specifies clearly that "*when classifying an untested mixture based on the hazards of its ingredients, generic cut-off values or concentration limits for the classified ingredients or the mixtures are used for several hazard classes in the GHS*". Unlike Articles 11(1) and (2) of the CLP, this section specifies the "when" such values and limit must be used and that is "*when classifying an untested mixture based on the hazards of its ingredients".* This shows the subordinated role of the calculation method under the GHS.

This is confirmed by Section 1.3.2.3.1 of the GHS, which consecrates the primacy of data on the complete mixture, followed by bridging principles, and then only other methods.

In Section 1.3.2.3.2, the GHS specifies that for germ cell mutagenicity, carcinogenicity and productive toxicity "*mixture will generally be classified based on the available information for the individual ingredients in the mixtures, using the cut-off values/concentration limit methods in each chapter*". Importantly, it also specifies that this is due to the fact that "*in most cases, it is not anticipated that reliable data for complex mixtures are available* (for these endpoints)". Thus under the GHS, 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.

Also, each of the specific chapters of the GHS on "Germ Cell Mutagenicity" (Chapter 3.5), "Carcinogenicity" (Chapter 3.6), and "Reproductive Toxicity" (Chapter 3.7), clearly distinguish the classification criteria applicable to mixtures from those applicable to substances. Points 3.5.3.1 (for mutagenicity), 3.6.3.1 (for carcinogenicity) and 3.7.3.1(for reproductive toxicity) establish when the classification of mixtures should be based on data of the individual ingredients. There is no corresponding principle for substances in these chapters.

Lastly, while in Annex 9, paragraph A9.3.5 on "difficult to test substances", the GHS refers to "complex substances" such as "petroleum distillate fractions, polymers, substances with significant levels of impurities, etc." which "are in fact mixtures", the GHS does not call for these substances - which also

do not coincide with the concept of MOCS - to be treated as mixtures for purposes of classification and labelling. Also, this is only for classification for aquatic toxicity, not for CMRs.

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18 December 2020