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WORKING DOCUMENT

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To:	Working Party on Technical Harmonisation (Dangerous Substances - Chemicals)
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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) - Non-Paper: Considerations by the Commission on the improvement of CLP bridging principles

Delegations will find in the Annex a non-paper by the Commission with regard to the present Proposal, in order to clarify the rules for mixture classification **on when and how the bridging principles shall apply** and how and where they interplay with the principles of weight of evidence and expert judgement.

The non-paper is for reference at the discussion during the Working Party meeting on Technical Harmonisation (Dangerous Substances - Chemicals) on 2 May 2023.

Considerations for the improvement of CLP bridging principles

1. Introduction

Following feedback from MS' enforcement authorities, the Commission, with support from ECHA, proposes in their Legislative Proposal to clarify the rules for mixture classification on when and how the bridging principles shall apply and how and where they interplay with the principles of weight of evidence with expert judgement.

2. Current situation

Enforcement authorities have noted there have been cases where companies have used the room left for interpretation in CLP for their benefit to (not) classify mixtures using the weight-of-evidence determination using expert judgement (WoE/EJ) and all available data including data on similar tested mixtures but without applying the bridging principles (BPs). The issue concerns all hazard classes but mostly skin corrosion/irritation and serious eye damage/eye irritation. In the past, there were only animal tests available for these hazard classes. However, currently, there are validated non-animal testing strategies for both of these hazard classes that are appropriate for classification, and thus, testing of the mixture itself, or sufficiently similar mixtures using bridging principles has become easier. Due to inconsistencies in the legal text, the enforcement authorities have considered it impossible to take an enforcement action on cases where companies have used data on other mixtures for classification without being able to apply bridging principles (see further clarification in this document below where the reasons for ECHA's initial proposal to revise the CLP legal text are presented).

The general tiered¹ hierarchy for mixture classification, considering also WoE/EJ, based on the CLP legal text is the following:

1. Use reliable test data on the mixture itself and the same classification criteria as for substances, as outlined in parts 2 to 5 of Annex I (Arts. 9(1), 6(1) and 6(2)).
2. When the data on the tested mixture itself does not allow direct application of the criteria, use weight-of-evidence determination using expert judgement for all available data on the mixture itself (Article 9(3)).
3. Where test data are not available for the mixture itself, use data on related / similar mixtures, by applying bridging principles (recital 23, Art. 6(5), Art. 9(4)), which should be applied as referred to in section 1.1.3 and in each section of Parts 3 and 4 of Annex I.) A weight-of-evidence determination using expert judgement can also be applied within this tier, as long as the rules of bridging principles are followed.
4. Use another method or methods, as described in each of the sections of Parts 3 and 4 of Annex I (Art 9(4)), in particular calculation methods based on concentrations of constituents (including e.g., the additivity approach).

¹ In this context the word "tier" refers to each step in the 4-step hierarchy described below.

This approach is also supported by ECHA guidance and GHS. In this approach, the Commission, ECHA and the enforcement authorities consider that the regulation clearly describes how using these four tiers a mixture can be classified, and that these tiers should not be mixed together in a weight of evidence assessment. In the third tier above, the seven bridging principles described in Annex I, 1.1.3 are the only way that data on similar mixtures can be used for classification of the untested mixture. When none of these principles are applicable, the only possibility is to move to the fourth and last tier above, and classify based on the concentration of constituents, applying either the concentration limits or the calculation methods.

However, the approach presented in the current CLP Regulation on expert judgement and WoE is not fully consistent regarding:

- whether weight-of-evidence determination using expert judgement can be applied in the context of having test data on the mixture itself (tier 2. above) but not in the context of applying the BPs (tier 3. above);
- how data on similar mixtures shall be considered in classification of mixtures (tier 3. above)

(See references to legal text and ECHA guidance Annex 1 of this document).

In particular, section 1.1.1.3 of Annex I of the CLP Regulation (referred to in Article 9(3) and Article 9(4)) and generally defining the WoE approach under the CLP Regulation) appears to be unclear and contradictory to Articles 6(5) and 9(4). This is because in section 1.1.1.3 of Annex I, grouping and read-across and information on substances/mixtures related to the mixture being classified are referred to, among the information to be considered in the WoE determination.

In the Commission's view, the WoE approach on mixtures, as laid down in the current legal text, does not include information on similar mixtures but only on the mixture itself, although this may be misinterpreted when reading the second paragraph of current Article 9(4). Instead, the bridging principles (as referred to in Article 9(4) and Annex I 1.1.3) are the only method to be used when considering data on similar/related mixtures in mixture classification.

3. Proposed changes

The Commission proposes to amend paragraph 4 of Article 9 to clarify the tiered hierarchy for mixture classification, according to the diagram below, as follows:

- In case of inadequate or unavailable data on the mixture itself to be classified, manufacturers, importers and downstream users should apply the bridging principles.
 - When applying the bridging principles, manufacturers, importers and downstream users may need to apply the weight of evidence approach by expert judgement on the data on other relevant mixtures. In practice, this means selecting the most appropriate mixture(s) to which the bridging principles would apply.
- If the dataset does not allow the application of the bridging principles, manufacturers, importers and downstream users should then apply any other method referred to in Parts 1, 3 or 4 of Annex I to CLP.

