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Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals

Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals **6 December 2016**

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Proposal to consider additivity for classification of mixtures and multi-constituent substances on a case-by-case basis, for any human health hazard class

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Introduction and background

1. For several hazard classes in GHS, additivity should be considered in the classification of mixtures when the classification is based on ingredients which contribute to the hazardous property of the mixture. The additivity approach is explicitly mentioned in some chapters and should be used in the evaluation of the classification of mixtures for acute toxicity, skin corrosion/irritation (except in certain cases), serious eye damage/irritation (except in certain cases), respiratory irritation and narcotic effects (STOT SE category 3), aspiration hazard, and for short- and long-term aquatic toxicity.

2. However, in certain cases additivity may be scientifically justified and could reasonably be assumed also for other health hazard classes. This could e.g. be the case when the mode of action (MoA) of a substance or mixture containing two substances is the same. Examples currently discussed in the EU where additivity is considered are the reproductive toxicity of anti-coagulant rodenticides (a group of substances affecting the same enzyme in the same way), reproductive toxicity of mixtures containing substances releasing boron ions, skin sensitisation by mixtures containing substances releasing nickel ions, and carcinogenicity and mutagenicity of mixtures containing formaldehyde releasers. For the latter group of substances, in the EU, the sum of the levels of releasable formaldehyde from the different components in a mixture is used to derive the classification of the mixture.

3. Even if the MoA of substances in a mixture is different, there may be some cases where it is deemed appropriate to assume additive (or synergistic) effects. In other cases, additivity may not be justified. Additivity may also be assumed in specific cases for specific target organ toxicity for substances with the same target organ, especially if the MoAs are similar.

4. Clearly, expert judgement is needed in all of these cases.

5. Currently, the evaluator must take into account any relevant information about the potential synergistic effects among ingredients in a mixture according to 1.3.3.3, for any hazard. Likewise, potential additive effects should also be considered for any hazard.

Proposal

6. The Sub-Committee is invited to consider the scope of applicability of additivity, including its limitations, and to explore whether it should be possible to apply additivity also to other human health hazard classes, for which additivity is currently not explicitly mentioned, and if so, whether such a provision should be included in the introductory part of GHS (e.g. in 1.3.3.2).