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NOTE

From:	Greek Delegation
To:	Working Party on Technical Harmonisation (Dangerous Substances - Chemicals)
N° prev. doc.:	ST 8697/23, CM 2899/23
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: Position by Greece on the Considerations by the Commission on the improvement of the CLP bridging principles



Hellenic Republic



ΑΑΔΕ

Independent Authority
for Public Revenue (IAPR)

Independent Authority for Public Revenue
Directorate General
General Chemical State Laboratory
Directorate of Energy, Industrial and Chemical Products

Athens 01.05.2023

EL CA position on doc : Non-Paper: Considerations by the Commission on the improvement of CLP bridging principles

As many times we have expressed our view “on when and how the bridging principles shall apply”, we would like to mention the following :

The “bridging principles” are applied according to the concrete rules described in 1.1.3 of Annex I. The rules cannot be applied in a weight of evidence approach, because they are either met or not met. However, according to the last compromised Presidency document, the question is placed, when we have more than one similar mixtures. Therefore, as far as the “proposed changes” in section 3 of the non-paper is concerned, we disagree with the following phrase in first sub-bullet:

“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”.

We propose the replacement of the above mentioned text with the following text, included also in the relevant compromise document of the Presidency, with our addition of the text in bold:

*“When applying the bridging principles, if more than one similar tested mixture is available, manufacturers, importers and downstream users may a weight of evidence determination using expert judgement, to select the most suitable similar tested mixture for decision on classification **which leads to the most protective scenario for human health and the environment**”.*

We consider that, this addition is absolutely necessary in order to be clear what prevails, if the application of a bridging principle in different similar mixtures leads to a different classification. This may lead to a confusion on the determination of the hazards of the mixture, unless if it is clarified in the legal text that the “worst case scenario” should be considered for the evaluation of the classification of the mixture.

As far as the text in section 2 of the non-paper is concerned: *“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", we would like to mention that some validated in vitro tests are not suitable for all mixtures as the validated in vitro methods themselves have limitations in their applications. (e.g. "Isolated Chicken Eye (ICE), (B.48 of the Testing Methods Regulation) for the classification of substances and mixtures as "corrosive cat. 1 irreversible eye effects" may be applied under specific conditions and restrictions. The restrictions mainly relate to false negative results for solids and surfactants (point 6 of B.48)).

Finally, we have an observation in the middle zone of the diagram (within the light blue color): A green arrow is missing between the box "Is there sufficient data to apply BPs?" and the box "Classify using bridging principles". Furthermore, we propose the replacement of the box "Even considering WoE/EJ?" (for bridging principles), with the following two boxes: "Are there more than one similar mixtures?" and "Select the most suitable similar mixture using WoE/EJ".