

Amendment 104**Pietro Fiocchi**

on behalf of the ECR Group

Report**A9-0271/2023****Maria Spyra**Classification, labelling and packaging of substances and mixtures
(COM(2022)0748 – C9-0433/2022 – 2022/0432(COD))**Proposal for a regulation****Recital 4***Text proposed by the Commission**Amendment*

(4) In order to improve legal certainty and implementation with regard to the evaluation of hazard information for mixtures where no or inadequate test data are available for the mixture itself, the interaction between the application of the bridging principles and a weight of evidence determination using expert judgement should be clarified. Such clarification should ensure that the weight of evidence determination complements but does not substitute the application of the bridging principles. It should also be clarified that if bridging principles cannot be applied to evaluate a mixture, manufacturers, importers and downstream users should use the calculation method or other methods described in Parts 3 and 4 of Annex I to Regulation (EC) No 1272/2008. It should also be clarified which criteria, when not met, determine when a weight of evidence determination using expert judgment is to be carried out.

(4) In order to improve legal certainty and implementation with regard to the evaluation of hazard information for mixtures where no or inadequate test data are available for the mixture itself, the interaction between the application of the bridging principles and a weight of evidence determination using expert judgement should be clarified. Such clarification should ensure that the weight of evidence determination complements but does not substitute the application of the bridging principles. It should also be clarified that if bridging principles cannot be applied to evaluate a mixture, manufacturers, importers and downstream users should use the calculation method or other methods described in Parts 3 and 4 of Annex I to Regulation (EC) No 1272/2008. It should also be clarified which criteria, when not met, determine when a weight of evidence determination using expert judgment is to be carried out. ***Recognising that the application of criteria for information on the different hazard classes is not always straightforward and simple, and bearing in mind that a specific hazard class may be defined by multiple criteria, manufacturers, importers and downstream users should apply, as above, weight of evidence determinations involving expert judgement to arrive at adequate results. The weight of evidence should give due***

consideration to all available information, irrespective of the possibilities for direct comparison with the criteria; it does not mean averaging results, nor does it involve a worst-case approach. For hazard classes defined by multiple criteria, a single weight of evidence determination should take into account the individual assessments with regard to each of the criteria as well as any interdependencies between the properties defined by those criteria. Where the criteria cannot be applied directly to available identified information, manufacturers, importers and downstream users should carry out an evaluation by applying a weight of evidence determination using expert judgement in accordance with section 1.1.1 of Annex I to Regulation (EC) No 1272/2008, weighing all available information having a bearing on the determination of the hazards of the substance or the mixture, and in accordance with section 1.2 of Annex XI to Regulation (EC) No 1907/2006.

Or. en

Justification

Building an assessment on all available data is a fundamental scientific practice, for some hazard classes a classification can only be decided on a Weight of Evidence basis, as clearly stated in UN GHS section 1.3.2.4.9.

Especially where a hazard classification will be based on the evaluation of several criteria as in PBT/vPvB (persistent, bioaccumulative and toxic) and PMT/vPvM (persistent, mobile and toxic) assessment, it is crucial to consider all available information to assess if a classification is really warranted.

In order to ensure the robustness and alignment of all classifications contained in CLP annex

VI, to consider all additional information now available and not previously taken into account and to allow the possibility of a harmonized categorisation, substances should be reviewed by ECHA Risk Assessment Committee (RAC) before their inclusion in CLP annex VI.

In particular, for active substances in plant protection products, there is a risk that new data might be available after the decision made by EFSA, which would need to be taken into account to ensure the harmonized classification according to CLP principles is granted during this transfer of regulatory decisions across regulations.

Amendment 105**Pietro Fiocchi**

on behalf of the ECR Group

Report**A9-0271/2023****Maria Spyraiki**Classification, labelling and packaging of substances and mixtures
(COM(2022)0748 – C9-0433/2022 – 2022/0432(COD))**Proposal for a regulation****Article 1 – paragraph 1 – point 6**

Regulation (EC) No 1272/2008

Article 9 – paragraph 3

*Text proposed by the Commission**Amendment*

3. Where the criteria referred to in paragraph 1 cannot be applied directly to available identified information, manufacturers, importers and downstream users shall carry out an evaluation by applying a weight of evidence determination using expert judgement in accordance with section 1.1.1 of Annex I to this Regulation, weighing all available information having a bearing on the determination of the hazards of the substance or the mixture, and in accordance with section 1.2 of Annex XI to Regulation (EC) No 1907/2006.

3. Where the criteria referred to in paragraph 1 cannot be applied directly to **all** available identified information, **or where hazards are defused by multiple criteria**, manufacturers, importers and downstream users shall carry out an evaluation by applying a weight of evidence determination using expert judgement in accordance with section 1.1.1 of Annex I to this Regulation, weighing all available information **across all individual and relevant criteria**, having a bearing on the determination of the hazards of the substance or the mixture, and in accordance with section 1.2 of Annex XI to Regulation (EC) No 1907/2006.

Or. en

Justification

Building an assessment on all available data is a fundamental scientific practice, for some hazard classes a classification can only be decided on a Weight of Evidence basis, as clearly stated in UN GHS section 1.3.2.4.9.

Especially where a hazard classification will be based on the evaluation of several criteria as in PBT/vPvB (persistent, bioaccumulative and toxic) and PMT/vPvM (persistent, mobile and toxic) assessment, it is crucial to consider all available information to assess if a classification is really warranted. In order to ensure the robustness and alignment of all classifications contained in CLP annex VI, to consider all additional information now available and not previously taken into account and to allow the possibility of a harmonized categorisation, substances should be reviewed by ECHA Risk Assessment Committee (RAC)

before their inclusion in CLP annex VI. In particular, for active substances in plant protection products, there is a risk that new data might be available after the decision made by EFSA, which would need to be taken into account to ensure the harmonized classification according to CLP principles is granted during this transfer of regulatory decisions across regulations.