

## **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**

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Item 7 of the provisional agenda

**Programme of work for the biennium 2023–2024**

### **Comments on ST/SG/AC.10/C.4/2022/18: Proposal for new work on unaddressed hazard classes in the programme of work for the biennium 2023-2024**

#### **Transmitted by the International Council of Chemical Associations (ICCA)**

1. This document provides commentary from the International Council of Chemical Associations (ICCA) on the European Union's Proposal for new work on unaddressed hazard classes in the programme of work for the biennium 2023-2024 (ST/SG/AC.10/C.4/2022/18)

#### **Background**

2. In our review of ST/SG/AC.10/C.4/2022/18, ICCA had concerns regarding the suggested scope of work relating to the proposed new hazard classes and would like to offer our constructive comments and proposals to the Sub-Committee at large.

3. ICCA remains committed to supporting the implementation of GHS globally. We believe that all stakeholders within the GHS Sub-Committee should focus on maintaining the core procedural functions of GHS, promoting its implementation worldwide, and providing additional guidance as needs arise. This should all be done in conjunction with ongoing efforts to foster the stability and consistency across countries of the harmonized system to encourage its adoption and implementation, especially in developing countries.

4. ICCA supports GHS developments that enable communication of relevant intrinsic hazards, with hazard classes that are based on scientifically sound and clear criteria that are suitable to identify the specific intrinsic properties. To achieve these objectives, relevant, validated methods and result interpretation frameworks must be in place, allowing for accurate assessments.

#### **Analysis**

5. ICCA is concerned that the proposed new hazard classes (EDs, PMT/vPvM, PBTs/vPvB) may be brought to the Sub-Committee in the latest stage of their development, i.e., once they have already been finalized for adoption within the European Union. We believe that this is contrary to the consensus-based nature of the Sub-Committee, where members and observers identify a specific protection objective or concern, and then work jointly to develop hazard classes and endpoints to meet that established goal. As a result of this process, the proposed new hazard classes would be developed by global consensus, and thus lend themselves to stronger individual commitments from countries to follow through and adopt the proposed changes via implementation in their own national-level regulations.

6. In our review, we see a lack of a well-established, consensus-based, and globally recognized assessment criteria and guidance for two of the identified endpoints (PMT/vPvM and EDs), rather than just the one identified in the paper (EDs). It is imperative that the Sub-Committee consider the lack of a globally harmonized results interpretation framework when evaluating the proposal. Furthermore, to achieve the intended protection goal, the technical criteria must be defined accordingly, and be applicable to all regions. Only by having adequately defined technical criteria and results interpretation frameworks can a correct and consistent application be achieved, and the principal goals of GHS accomplished.

7. The criteria for PBT/vPvB were not established for the purpose of deriving a hazard class. Instead, they were specifically created for the purpose of risk characterization and assessment under different chemicals management frameworks (e.g.: EU REACH, China, Japan, Korea, US, Canada and Australia). Moreover, it must be taken into consideration that the screening criteria for Persistence (P), Bioaccumulation (B) and Toxicity (T) all have a number of regional differences in thresholds and cut-offs, differences that are justified by the risk management approach implemented in each respective country<sup>1</sup>

8. We would like to note that there was also a previous discussion in 2009 regarding addition of PBTs to the GHS (INF.4, 18<sup>th</sup> session). We also noticed that in this document it is stated that *“the term ‘hazard classification’ is used to identify the intrinsic hazardous properties of a substance or mixture. It means intrinsic hazards are intended to identify the nature of the physical, health or environmental hazard and to determine the appropriate hazard class, e.g., flammable solids, carcinogens, acute and chronic aquatic hazards. Such combinations of properties are used to trigger specific actions in terms of risk assessment and risk management.”* The meeting concluded that the Sub-Committee was not in a position to take a view on the issue and welcomed receiving any further information on this issue in the future (refer to the report of the Sub-Committee on its 18th session, 9 – 11 December 2009).<sup>2</sup> ICCA does not believe that that there have been any other notable scientific developments that would cause the Sub-Committee to change their view on this topic.

9. Using that same line of reasoning, PMT/vPvM should not be considered an intrinsic hazard. Instead, it is a contributing environmental fate factor to effects that a hazardous chemical may have within an environment. The ability for a trait to be mobile can potentially be identified by measuring leachability or adsorption, but both test methods merely indicate the ability for a substance to be mobile, rather than identify it as a specific concern.

10. In our view the currently proposed timeline is unrealistic, and we agree with the statement made in ST/SG/AC.10/C.4/2022/18 that the task will most likely go into the next biennium or beyond.

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<sup>1</sup> We can look at bioaccumulation as an example. For Tier I, if you look at Kow, a value of > 4.5 screens a substance in as a potential B/vB in EU. Comparatively, the cut-off for this value is 4.2 in Australia, in Japan “In vivo” testing is required if greater than or equal to 3.5. When looking at As for “In vivo” study BCF cut-offs – there are also disparities between regions – in EU the BCF for B is > 2000, vB > 5000 L/kg; USA B > 1000 L/kg and in Australia there is just one threshold which is at a BCF of 5000 L/kg. Each country might have a reason to establish their own threshold under their risk-based approach as part of their regulatory system.

<sup>2</sup> Some experts considered that it would be premature for the Sub-Committee to start addressing this matter and said that it would be preferable to await the outcome of the work related to these substances which was being carried out internationally. A few others on the contrary felt that there was a need to address the classification and labelling of PBT and vPvB substances from the point of view of their intrinsic hazards and suggested that work in this direction could start by compiling information about the current practices for the classification and labelling of PBT and vPvB substances. 58. Noting that it was not in a position to take a view on this issue, the Sub-Committee welcomed receiving any further information on this issue in the future (Report of the Sub-Committee on its 18<sup>th</sup> session, document ST/SG/AC.10/C.4/36, available from <https://unece.org/DAM/trans/doc/2009/ac10c4/ST-SG-AC10-C4-36e.pdf>).

## Proposal

11. ICCA proposes that the Sub-Committee hold a discussion to evaluate the appropriateness of including the proposed hazard classes into the GHS based on considerations of whether these constitute intrinsic properties. This discussion would determine if there are solid scientific arguments that the adoption of the proposed hazard classes would increase protection of human health and the environment, and thus justify their inclusion into the GHS.
  12. Any working group developed to address the proposed hazard classes should consider the principles of equitable geographical representation and gender balance.
  13. We propose that the working group identified to work on the proposed work stream develop a more robust and concise terms of reference, including a description of the protection goals and how intrinsic substance properties can purposefully be applied to achieve the goals. The terms of reference should also establish a structured work plan for review during the next biennium and beyond.
  14. We propose that all regions and countries be involved from an early stage in the discussions of a scientific assessment on immunotoxic, neurotoxic effects and terrestrial ecotoxicity. If these are to be future proposed hazard classes, it is imperative that the underlying scientific assessment be globally relevant and appropriate.
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