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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Geneva, 7–9 December 2010 Item 2 (d) of the provisional agenda Updating of the third revised edition of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) – Annexes

Aligning the metals section (Annex 9, section 9.7) to the generic environmental hazard guidance

Transmitted by the International Council on Mining and Metals (ICMM)

Introduction

- 1. The third revised edition of the Global Harmonised System published in 2009 introduced the long-term aquatic hazard assessment scheme by amending Part 4 on *Environmental hazards* and Annex 9, *Guidance on hazards to the aquatic environment*.
- 2. However, as raised at the 19th session of the Sub-Committee, the minerals and metals sector has noted that Annex 9, section 9.7 (Classification of metals and metal compounds) and Annex 10 (Guidance on Transformation/Dissolution of metals and metal compounds in aquatic media) of this update have not yet been adapted to include the long-term aquatic hazard assessment scheme.

Background

Long-term aquatic hazard assessment for metals and metal compounds

- 3. During the previous biennium of the GHS review, a validation study of the Transformation Dissolution Protocol (T/Dp) as included in Annex 10 of the GHS was conducted by a Validation Management Group (VMG). The Transformation Dissolution Protocol was designed to measure the rate and extent to which metals and poorly soluble metal compounds release metal ions, a key trigger in the classification strategy and scheme for metals and poorly soluble metal compounds (see Fig. A9.7.1 in the annex to this document).
- 4. The Validation Management Group presented its report at the 16th session of the Sub-Committee, including minor suggestions to amend Annex 10. The report, as well as the proposed changes in Annex 10, was adopted and the updated Annex 10 was included in the third revised edition of the GHS.
- 5. In parallel with the VMG activities, the Sub-Committee revised Part 4 and Annex 9 of the GHS introducing the long-term aquatic hazard assessment scheme. As a consequence of the parallel timing of the work of the VMG and the Sub-Committee, neither section A9.7



on the Classification of metals and metal compounds, nor Annex 10 could be amended for the third revised edition to include this new long-term aquatic hazard classification strategy. Consequently, section A9.7 and Annex 10 are presently in conflict with part 4 and the remaining sections of Annex 9, in that they do not include a long-term aquatic hazard classification strategy and guidance, or recommendations on how to measure this.

- 6. The drafting of the European Union (EU) Classification, Labelling and Packaging Regulation's guidance on metals, metal compounds and poorly soluble metal compounds anticipated the introduction of the third revised edition of the GHS in the EU and demonstrated the clear need to change the strategy presented in Figure A9.7.1 (see annex) and the associated guidance in order to align the GHS metals section with the changes implemented by the long-term aquatic hazard assessment of its third revised edition.
- 7. Given that many countries are presently implementing or are planning to implement the third revised edition of the GHS, Industry is of the opinion that section A9.7 of Annex 9 on the *Classification of metals and metals compounds* and to a lesser extent Annex 10 should be updated as soon as possible to ensure alignment with part 4 and the remainder of Annex 9.
- 8. The issue was introduced as an INF paper by ICMM at the 19th session of the Sub-Committee. The Sub-Committee recognised the need for alignment and requested ICMM to propose a potential way forward (see below).

Hazard assessment of special inorganic matrix type mixtures

- 9. While several jurisdictions are introducing the hazard assessment rulings for substances, the application of the GHS hazard assessment system for mixtures is only now gaining momentum. The inorganic sector raised some years ago the special situation of matrix type substances, such as alloys, for which the hazards of the mixture do not correspond to those of the constituent elements. In some cases these hazards can be very different. Without a suitable solution at hand, the EU recognised the issue when adopting the CLP Regulation and provided matrix type inorganic mixtures the status of "special preparations" for which specific guidance to reflect the hazard properties shall be developed in the near future. The mining and metals sector has accordingly developed initial concepts based on Transformation Dissolution (for the environmental endpoints) and Bio-elution (for given Health endpoints).
- 10. It is therefore suggested that the progress made with the assessment of special inorganic matrix type mixtures like alloys and comparable materials could be reviewed in order to develop a specific assessment scheme in line with the GHS mixture ruling and guidance which could better reflect the hazard properties of these substances.

Potential way forward

Long-term hazard assessment for metals and metal compounds

11. Amending the strategy for metals and metal compounds to include the long-term aquatic assessment is feasible, technical in nature and not overly complex given that chronic toxicity data are typically abundantly available for metals and that the Transformation/Dissolution tool (T/Dp Protocol) can be applied in the same way as it is for the acute hazard assessment. No new concepts or principles are needed to implement this update in section A9.7 of Annex 9 and Annex 10 as parallel application to the acute environmental hazard assessment can be drawn. It is therefore suggested that a specific

technical correspondence group could develop the update and guidance accordingly based on the experience in the EU.

- 12. Indeed industry, in cooperation with the European Chemicals Agency (ECHA), has almost completed a redrafting of the EU guidance for the introduction of the third revised edition of the GHS under the CLP Regulation, which includes an updated classification strategy, scheme and guidance for metals and metal compounds. It is expected that the proposed update of the CLP guidance will be approved in the first semester of 2011. It is well recognised that the EU GHS introduction for the environmental hazard endpoints is not identical to the original third revised edition of the GHS given that hazard categories Acute 2 and 3 are not existing in the EU. This however does not hamper the review suggested here since it is focussed on the long-term hazard assessment exclusively and in the EU this is identical to the GHS.
- 13. Industry would therefore be pleased to provide the Sub-Committee, by late spring 2011, a suggestion for updating section A9.7 of Annex 9 as well as Annex 10 for review by a technical correspondence group.

Hazard assessment of special inorganic matrix type mixtures

- 14. The hazard assessment of special inorganic matrix type mixtures and in particular alloys has already been investigated during the VMG on the validation of the Transformation Dissolution protocol for the Environmental assessment of metals and metal compounds. Based on this experience, industry developed subsequently a hazard assessment strategy scheme under the MERAG program¹ demonstrating how such "special inorganic matrix type mixtures" could be assessed under GHS for the environmental endpoint. However, unlike the long-term hazard update of section A9.7 of Annex 9 and Annex 10 or the environmental hazard classification scheme for alloys, the development of a health assessment scheme would require significant technical discussion given the complexity of endpoints and the use of bio-elution tests. Industry has advanced well with internal validation of a draft health assessment strategy for alloys and aims to finalise this evaluation in 2011 (under HERAG²).
- 15. ICMM would therefore suggest that the Sub-Committee considers providing a mandate to the OECD to develop specific guidance for the *hazard assessment of special inorganic matrix type mixtures* based on the experience with alloys and the commitment of industry to provide a proposal for the environment before summer 2011 and one on health in 2012.

Recommendation

- 16. In summary, ICMM would like to recommend the Sub-Committee to:
 - Establish a specific "technical correspondence group" to review Section A9.7 of Annex 9 on the classification of metals and metal compounds as well as Annex 10 on the Transformation/Dissolution of metals and metal compounds in aqueous media for inclusion under the next revised edition of the GHS. This would ensure the classification strategy, guidance and tools on metals and metal compounds are in line with the long-term aquatic classification scheme introduced by the third revised

¹ MERAG: Metals Environmental Risk Assessment Guidance including a special draft fact sheet on alloys environmental hazard assessment (www.icmm.com)

² HERAG : Health Risk Assessment Guidance for metals (www.icmm.com)

- edition revision. The metals sector would provide a draft for consideration by the correspondence group in spring 2011.
- Prepare a mandate for OECD to develop an environmental and health hazard assessment strategy, scheme and technical guidance for special inorganic matrix type mixtures based on the experience with alloys, for inclusion under the next revised edition of the GHS. This would ensure that the GHS hazard assessment strategy and guidance provides adequate identification of the hazards of these materials which are in most cases clearly different from their constituents. In order to facilitate the OECD review, the metals sector would be prepared to provide a draft for review before the summer of 2011 for the environmental section and early 2012 for the health section.
- 17. The Mining and Metals sector would be pleased if the Sub-Committee could consider these proposals in order to ensure consistency in respect to the long-term environmental hazard evaluation of metals and metal compounds and to develop a hazard assessment scheme for *special inorganic matrix type mixtures* that would properly and efficiently assess the effective hazards of these materials.

Annex

Figure A9.7.1 (GHS Rev.3): Classification strategy for metals and metal compounds

