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 **28 November 2012**

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Programme of work for the biennium 2013–2014

Comments on document ST/SG/AC.10/C.4/2012/30: How appropriate guidance in the GHS should ensure harmonised hazard communication of nanomaterials

Transmitted by the expert from Australia

I. Introduction

1. The expert from France proposes to include the following new item in the program of work for the biennium 2013-2014:

"improve technical guidance on the classification and hazard communication of nanomaterials in the GHS".

2. If the Sub-Committee agrees to this proposal, the expert from France, with the possible contribution of an informal working group, proposes to prepare a formal document for the next session that will consider the main issues relating to nanomaterials in the GHS and the possible ways for further work on hazard communication for hazardous nanomaterials.

II. Classification of nanomaterials

3. INF.11 describes the work to produce a recommended classification of carbon nanotubes in Australia. Australia's National Industrial Chemical Notification and Assessment Scheme (NICNAS) has used the same classification approach that is used for chemicals generally to classify for each health endpoint. This illustrates that the existing classification criteria can be used for both the bulk and nanoforms of materials. However, this work has raised some issues.

(a) Applying a precautionary approach

4. Technical guidance could be provided on how to apply a precautionary approach and where it is necessary and appropriate. NICNAS commented, in relation to classification for specific target organ toxicity repeated exposure:

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Although there are no supportive data for SWCNTs[1], given the adverse effects have been postulated due to lung overloading, SWCNTs are not expected to behave differently to MWCNTs[1]. Therefore, the report recommends that the above classification should also be applied on a precautionary basis to SWCNTs until data to the contrary become available, particularly as the applicability of the pathogenic fibre hypothesis to granuloma and fibrosis induction is not clear.

5. NICNAS further recommended a case-by-case assessment when specific toxicity data become available. From the report:

The report noted that the toxicological properties of CNTs may vary due to a number of factors; impurities and their concentrations, dimensions, state (agglomerated/aggregated or dispersed) and surface functionality. It recommends that when specific toxicity data are available, a case-by-case hazard assessment of CNTs is undertaken.

(b) Application of classification cut-offs

6. A technical issue is whether the cut offs/concentration limits that trigger the classification of a mixture are appropriate for nanomaterials. Nanomaterials are generally more hazardous than the larger sized particle ranges of the chemical, e.g. due to high surface area per unit mass. Advice could be developed in the GHS text on this aspect in relation to nanomaterials.

7. Relating to this issue, section 1.3.3.2.2 of the GHS states:

Normally, the generic cut-off values/concentration limits adopted in the GHS should be applied uniformly in all jurisdictions and for all sectors. However, if the classifier has information that the hazard of an ingredient will be evident below the generic cut-off values/concentration limits, the mixture containing the ingredient should be classified accordingly.

III. Hazard communication for nanomaterials

8. There are number of initiatives and developments that can inform the proposed guidance.

9. Safe Work Australia has published Codes of Practice for:

(a) the preparation of Safety Data Sheets (SDS) for hazardous chemicals, and

(b) Labelling of workplace hazardous chemicals.

These are in GHS format and include recommendations and information relating to nanomaterials.

10. The Codes recommend that SDS and workplace labels should be provided for engineered or manufactured nanomaterials unless there is evidence they are not hazardous:

[1] Note by the secretariat: SWCNTs and MWCNTs stand for "Single walled carbon nanotubes" and "multi walled carbon nanotubes" respectively.

(a) From the labelling code: 3.10 Products containing nanomaterials

For engineered or manufactured nanomaterials or chemicals containing engineered or manufactured nanomaterials, it is recommended that labels be prepared in accordance with this Code unless there is evidence that the nanomaterials are not hazardous. The following label statements are recommended for products containing nanomaterials when the hazards are not fully characterised:

- *Contains engineered/manufactured nanomaterials. Caution: Hazards unknown.*
- *Contains engineered/manufactured nanomaterials. Caution: Hazards not fully characterised.*

These phrases are for use on an interim basis, as the manufacturer/importer has a duty to correctly classify the chemical and include information on known hazards on the label in accordance with the WHS Regulations.

(b) From the SDS code: 1.4 Products containing nanomaterials

For engineered or manufactured nanomaterials or chemicals containing engineered or manufactured nanomaterials, an SDS should be provided unless there is evidence that the nanomaterials are not hazardous.

11. In Australia, additional parameters are recommended in the physical and chemical properties part of Safety Data Sheets and the following guidance has been provided:

In addition to those listed above, other physical or chemical parameters relevant to health and safety should be included in this section of the SDS. This includes parameters which, in addition to chemistry, can significantly influence the properties of chemicals, for example size or surface area in the case of engineered nanomaterials. Examples of parameters which may be included are:

- *Particle size (average and range)*
- *Size distribution*
- *Shape and aspect ratio*
- *Crystallinity*
- *Dustiness*
- *Surface area*
- *Degree of aggregation or agglomeration, and dispersibility*
- *Redox potential*
- *Biodurability or biopersistence*
- *Surface coating or chemistry (if different to rest of particle).*

(These are the additional parameters that are specifically relevant to nanomaterials)

12. The correspondence group on the revision of Section 9 of the SDS, led by Germany, has considered the Australian proposal to add extra parameters to Section 9 for nanomaterials. While the work of the group is yet to be finalised and approved, the group supports the addition of the parameter *particle characteristics* to the list of parameters in Section 9, with the addition of the following text:

- *applicable to solids only*

- *indicate the particle size (median and range)*
- *if available, further properties may be indicated in addition:*
    - *size distribution*
    - *shape and aspect ratio*
    - *crystallinity*
    - *dustiness*
    - *specific surface area*
    - *degree of aggregation or agglomeration, and dispersibility*

13. The International Organization for Standardization's Technical Committee on nanotechnologies (ISO TC 229) has developed a technical report entitled *Nanotechnologies — Safety Data Sheet (SDS) preparation for manufactured nanomaterials*. The project was led by the Republic of Korea. This technical report provides guidance on the development of SDS for manufactured nanomaterials (and materials or products that contain manufactured nanomaterials), and provides additional information on safety issues associated with manufactured nanomaterials. The document takes into account the GHS, including Annex 4 (SDS). The technical report is currently being prepared for publication.

IV. Summary

14. Australia supports the proposal by the expert from France and would welcome the opportunity to contribute to the work of a correspondence working group if established.

15. The same overall approach that is used for chemicals generally can be used to classify nanomaterials and provide hazard information.

16. However, in regard to classification and hazard communication there are some nanomaterial-specific issues. Thus, Australia considers that guidance specifically on nanomaterials or general guidance that covers nanomaterial issues should be included in the GHS text.

17. Issues to be considered may include clarifying the extent to which a precautionary approach can be used to contribute to classification where necessary and also whether current concentration cut-offs are appropriate for nanomaterials.

18. This guidance can build on previous or current work, as described in this paper. The work of Correspondence Group for revision of Section 9 of Annex 4 (SDS) is contributing towards this outcome.