

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

30 June 2016

Thirty-first session

Geneva, 5-8 July 2016

Item 5 (a) of the provisional agenda

Implementation of the GHS:

Development of a list of chemicals classified in accordance with the GHS

Assessing the potential development of a global list of classified chemicals

Transmitted by the expert from the United States of America on behalf of the
informal correspondence group

Purpose

1. The purpose of this document is to provide an update on the work undertaken by the informal correspondence group assessing the potential development of a global list of classified chemicals, and an agenda for the group's meeting at the 31st session.

Background and update

2. During the 28th session, the Sub-Committee agreed to a plan of work in the pilot classification project, the three chemicals that would be evaluated in the pilot, and a provisional timeline for the project (ST/SG/AC.10/C.4/56, paragraphs 50-53; INF. 22, 28th session).

3. The OECD agreed to coordinate the development of draft classifications and data assessments in the pilot project. Under the agreed procedures, each sponsor country developed an initial draft data assessment and classification which was posted on a dedicated website. Any interested party was provided access to the website. Interested parties provided written comments and sponsors provided responses and revisions in response. This was followed by teleconferences to resolve remaining issues. Participants were asked to prepare forms tracking the resources used to participate in the process.

4. The OECD's work is almost complete. Attached as Annex 1 is a draft report presented to the OECD Task Force on Hazard Assessment. Although the OECD's work will not be completed for the 31st session of the Sub-Committee, it is expected to be completed soon thereafter.

5. An overview of the project to date is as follows:

- (a) The three pilot chemicals were selected in October 2014 and a work plan was agreed by the Sub-Committee in December 2014. The three chemicals are:
 - (i) Dimethyltin dichloride, CAS No. 753-73-1 (DMTC) (Nominated by the European Chemicals Agency)

- (ii) Dicyclopentadiene, CAS No. 77-73-6 (DCPD) (Nominated by the Russian Federation)
- (iii) Di-n-butyl phthalate, CAS No. 84-74-2 (DBP) (Nominated by the United States of America)
- (b) The sponsor countries agreed on an initial reporting format in October 2014, which was refined throughout the drafting process.
- (c) The sponsor countries completed their draft classification and labelling reports July-August, 2015 and they were provided to reviewers on 2 September 2015 for a 6-week review period.
- (d) Comments were received from approximately 10 countries and organizations, and the comments were all uploaded to the OECD site by 5 November 2015.
- (e) The OECD prepared comments summaries for each chemical. They show that 6 commenters provided a total of 217 discrete comments on the DCPD draft assessment; 7 commenters provided a total of 118 comments on the DBP draft assessment; and 5 commenters provided a total of 38 comments on DMTC.
- (f) The chemical sponsors updated their reports based on comments received and provided written responses to comments.
- (g) For DMTC, the sponsor (ECHA) provided a written response to comments and a revised report on 15 December 2015. On 22 January, a teleconference call with was held with interested parties. Based on further feedback received on the call the report was revised, and an additional teleconference was held on 7 April at which time the report was agreed. A finalized report was received by the OECD on 29 April, 2016.
- (h) For DCPD, the sponsor (Russian Federation) provided a written response to comments and revised report on 9 March and a teleconference was held 13 April with interested parties. Based on further feedback received during the call, a revised report was received 13 May and commented on by written procedure. In response to additional comments Russia provided another revised report on 15 June.
- (i) For DBP, the sponsor (United States of America) provided written responses to the comments and a revised report on 7 March and 26 February respectively, and a teleconference was held 7 April with interested parties. Based on further feedback received during a revised report was received 26 May and discussed during a teleconference on 8 June. Final comments received on the call were with respect to clarification of a few aspects of the report. A revised version was received by the OECD on 9 June.

6. Though the draft report shows several specific learnings, in general, the pilot to date has shown that it was possible to reach agreed nonbinding classifications through the process. Although resources expended to date have not yet been tabulated by the OECD, it is expected that they will be substantial.

Meeting agenda

7. Interested persons are invited to attend the meeting of the correspondence group in the plenary room during a break in the 31st session of the Sub-Committee on the afternoon of 7 July 2016. A proposed agenda follows:

- (a) Pilot project to date and draft OECD report.

- (b) Planning the final phase of the pilot project regarding reception and evaluation of the final OECD report and draft classifications. (See Annex 2, Thought Starter 1)
- (c) Consideration of how classifications adopted as a part of a Global List might impact the Model Regulations. (See Annex 2, Thought Starter 2)
- (d) Next steps, including possible list comparison exercise. (See Annex 2, Thought Starter 3 and Annex 3).

Annexes

8. Three annexes are attached to this document as follows:
- Annex I: Draft OECD report (see INF.21/Add.1)
 - Annex II: Thought starters
 - Annex III: European Union-Japan list comparison (see INF.21/Add.2)

ANNEX II

Thought starters

Thought starter 1: Final steps of the pilot project

The purpose of the classification pilot project is to obtain information on the process and resources needed if the Sub-Committee were to adopt harmonized classifications rather than actually obtain harmonized classifications of the selected chemicals. Thus, although it is not within the scope of the pilot for the Sub-committee to adopt classifications for DMTC, DCPD, and DBP based on the OECD's report, it is proposed that the pilot should consider what process and resources would be involved if the Sub-Committee were to consider adopting classifications for those chemicals.

One way to do this is to conduct a mock exercise modelling the decision making necessary if the Sub-committee were to consider and adopt harmonized classifications for DMTC, DCPD, and DBP based on the OECD report. Again, the Sub-Committee would not actually adopt classifications, but such an exercise would allow the Sub-Committee to examine the process and track resources that would be involved in adopting a harmonized classification for these chemicals.

Among the issues to be considered in this phase of the process:

1. Should the Sub-Committee provide any additional notice to member states and stakeholders that the Sub-committee is considering adopting a harmonized classification? If so, what form should that take?
2. Are the normal Sub-Committee procedures, including informal documents, working papers, and working groups adequate to provide avenues for comment on the OECD draft assessments? Would it be an adequate process to attach the draft assessment to a working document, so that it may be considered first by a working group and then by the full Sub-committee?
3. Would the harmonized list be a part of the Purple Book, or its own stand-alone list, perhaps published on the UNECE website?
4. Are there any other procedural steps to be considered in this process?
5. How should the resources used be tracked?

Thought Starter 2: Implications for the Model Regulations

It is possible that harmonized classifications adopted by the Sub-Committee might have impacts on the way those chemicals are treated under the Model Regulations for the Transport of Dangerous Goods. For example, the Secretariat noted that the draft classification reached in the OECD process for DCPD classified the chemical as Acute Toxicity, category 2, which would require packing group II under the Model Regulations. Currently, DCPD is assigned packing group III.

- In adopting a harmonized classification, how should potential impacts on the Model Regulations be considered?
- Should the TDG Sub-Committee be involved in the classification process in some fashion? If so, how and when?
- Are there other ways to address potential conflicts between harmonized classifications and TDG classifications?

Thought starter 3: Next steps

Though the pilot exercise is not yet complete, this thought starter proposes that the working group begin consideration of the next steps the Sub-committee should take in the investigation of the possibility of developing a global list. This consideration will hopefully facilitate developing a scope of work for the next biennium.

In the past, there had been interest in comparing national classification lists for common classifications. As background for considering these next steps, a comparison of classifications between two lists was prepared. These are classification opinions prepared by the ECHA Committee on Risk Assessment (RAC) under the harmonized classification process in the EU CLP Directive, and the list of classifications prepared by the Japanese National Institute of Technology and Evaluation.

These lists were chosen because, though they do not completely conform to the guiding principles, they comply with them in part. Both lists are supported by explanations of the classification determinations and references to the data relied on, though often the sources cited in the Japanese list are not readily accessible. The CLP harmonized classification process also provides opportunities for public comment. The RAC opinions do not necessarily consider all endpoints, but it appears that the Japanese list does.

The ECHA RAC Opinions may be found at the following link:
<http://echa.europa.eu/web/guest/opinions-of-the-committee-for-risk-assessment-on-proposals-for-harmonised-classification-and-labelling>

The Japanese classification list may be found at the following link:
http://www.safe.nite.go.jp/english/ghs/ghs_download.html

Annex 3 to this informal paper contains a side-by-side comparison of the 89 chemicals appearing on both lists. The classifications appearing under the EU column include both the RAC classification opinions and, for other endpoints not considered by the RAC, historical classifications from Annex VI of the CLP, where they appear. The RAC classifications are in **red bold font**.

Time did not allow for any further analysis of the Annex, but causal inspection shows some overlap, both in classification endpoint and category. It does not appear that there is any chemical classified identically in the two lists.

Topics for conversation:

- The comparison might generate ideas for next steps in the global list project.
 - For example, it might be possible to identify chemicals through such a comparison that warrant further consideration by the Sub-Committee for inclusion on a list of harmonized classifications. Do you agree? If so, how might the list be used in this way?
 - What further analysis of the list comparison should be done? Is there additional information about the chemicals listed there that should be gathered?
 - Are there other national lists that should be considered in a list comparison exercise? Last session, Canada noted that it may soon issue a list of GHS classifications (INF.18, 30th session). Should it be included in a list comparison? What criteria should be used to identify lists to include?
- Once the pilot project is concluded, will we be ready to consider the selection of chemicals for a harmonized classification list? If not, what additional information or analysis would be useful evaluating next steps?
- Are there other considerations that should be involved in the selection of chemicals for inclusion on a list of harmonized classifications? If so, what might they be?