

**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**

Ninth session, 11-13 July 2005
Item 2 (d) of the provisional agenda

**UPDATING OF THE GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION
AND LABELLING OF CHEMICALS S(GHS)**

Note by the secretariat

The secretariat reproduces hereafter the draft summary record of the 14th Meeting of the OECD Task Force on Harmonization of Classification and Labelling (Paris, 14-15 February 2005).

ENV/JM/HCL/M(2005)3**Draft Summary Record of the 14th Meeting of the Task Force on Harmonization of Classification and Labelling
(Paris, 14-15 February 2005)**

This Draft Summary Record will be finally approved at the 15th Meeting of the Task Force. Any amendments made to the record at that time will be noted in the Draft Summary Record of that meeting.

I. Opening of the meeting

1. Anna-Liisa Sundquist, previous chair of the Task Force, had sent her apologies for not being able to attend the first day of the Task Force Meeting. On her behalf the Secretariat welcomed the participants and invited the Task Force members to propose names for the new Chairperson and for the members of the ad-hoc Bureau of the Task Force.

2. Kim Headrick proposed Gregory Moore as the new Chair of the Task Force and Solvår Hardeng proposed the following membership for the ad-hoc Bureau: Gregory Moore, Amy Rispin, Kim Headrick and Elisabet Breggren. The Task Force agreed on these proposals.

3. The Chair invited participants to introduce themselves (See Annex I for the Participants List).

2. Adoption of the Agenda

4. The Draft Agenda was approved without modification. The Chair noted that he would follow the Agenda with some flexibility so that some issues could be revisited in order to finally reach consensus. The Secretariat noted that the last document that was posted on the Website is Document ENV/JM/HCL(2005)7 that relates to (Q)SARs.

3. Confirmation of the approval of the Draft Summary Record of the 13TH Meeting of the TF-HCL

5. The Secretariat reported that comments on the Draft Summary Record were sent by Anna-Liisa Sundquist, Henk Roelfzema and Thomas Hofer. The Draft Summary Record was revised on 22 June 2004, and posted on the UN Sub-Committee website with Annex 1 and Annex 2. Approval of the Draft Summary Record was confirmed.

4. General Information by the Secretariat

6. The Secretariat introduced Documents INF 1, INF 2 and INF 3.

7. Document INF 1 is the report on the Session of the UN Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals (SCEGHS) held in July 2004. The Secretariat referred to paragraphs [19-42] and Annex 1. At that meeting, the proposals related to aspiration hazards, respiratory tract irritation, narcotic effects and reproductive toxicity terminology were adopted with slight or no modification. The Sub-Committee also requested at that meeting that OECD initiate work on Toxic Gas Mixtures.

8. Document INF 2 is the report on the Session of the UN SCEGHS held in December 2004. The Secretariat referred to paragraphs [19-29] [59-71] and Annexes 2 and 3. At that Meeting, the proposal related to acute toxicity and the proposal related to lactation were adopted with slight or no modification. The Sub-Committee also adopted its programme of work for the biennium 2005-2006, which includes the work plan for the OECD. Scientific issue papers are expected to be completed in 2005 for four work activities. With respect to the document *Issues to be addressed to develop the classification and labelling for terrestrial environmental hazards*, the Sub-Committee agreed not to include terrestrial classification in the OECD work plan for the next biennium. On the other hand, it agreed to include in the OECD work plan the development of a detailed comparison of classification systems for ozone depleting substances.

9. Document INF 3 prepared by the Secretariat includes a status report on the work that was requested by the UN SCEGHS for the biennium 2003-2004, and a table with all issues that require to be addressed in the biennium 2005-2006. The Secretariat explained that in order to submit scientific issue papers to the UN SCEGHS by mid-October for the December 2005 Session, the Expert group draft papers should be available and circulated in the beginning of June 2005 to the Task Force and Sub-Committees for comments. By end of June, the revised draft papers should be sent to the Task Force for agreement by end of August. Then, the Task Force draft papers should be submitted to the Joint Meeting for declassification in the very beginning of September.

5. Sensitization/Elicitation

10. The Secretariat introduced Document ENV/JM/HCL(2005)1 including a report on the discussions since the last Task Force Meeting and the Expert Group proposal, which was submitted to the Task Force for approval. This proposal allowed certain authorities to require that if the classifier has information that an elicitation response for an ingredient in a mixture will be evident below the cut-offs provided in Table 3.4.1, the mixture should be supplementary labelled by giving the name of the sensitizer(s) on the label.

11. Following a comment on issues already agreed at the last Task Force Meeting, the Chair made it clear that the Task Force would not reopen these issues and would focus on Paragraph 3.4.4.1. It was observed that this paragraph does not provide full harmonization; it was also pointed out that the proposal is not assumed to cover what is already included in the notes to Table 3.4.1. of Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

12. The Chair invited a small group to propose a revised paragraph. The group considered several possible versions and finally proposed after long discussions Paragraph 3.4.4.1 as included in document ENV/JM/HCL(2005)1 with the replacement of “will” with “may” as follows:

“3.4.4.2 Certain authorities may require that if the classifier has information that an elicitation response for an ingredient in a mixture **may** be evident below the cut-offs provided in Table 3.4.1, the mixture should be supplementary labelled by giving the name of the sensitizer(s) on the label.”

13. The Task Force agreed on this proposal.

6. Guidance for Use of Important Factors in Classification of Carcinogenicity

14. The Secretariat introduced Document ENV/JM/HCL(2005)2 including an introduction and a draft proposal, which were submitted to the Task Force for adoption. Clear references to the work carried out by IPCS, IARC and ILSI are inserted in the proposal for guidance, which is not intended to provide strict rules.

15. There were different views on whether the document was sufficiently detailed to provide real guidance and remove uncertainty, and on the need for an extended mandate for developing more guidance.

16. The Chair invited two small groups to discuss Paragraphs 3.6.5.3.2.2 and 3.6.5.3.2.3, on which comments had been made; these two groups however finally proposed not to change the wording of the two paragraphs.

17. Finally, the Task Force agreed on the proposal as included in document ENV/JM/HCL(2005)2 with the following change: (i) the title “Guidance for Use of Important Factors in Classification of Carcinogenicity” is replaced with “Guidance on how to consider Important Factors in Classification of Carcinogenicity”, (ii) in Paragraph 2 of the introduction “is considering” is replaced with “considered” and in Paragraph 3.6.5.3.2.2 of the proposal “all the factors listed above” is replaced with “all the factors listed in Paragraph 3.6.2.5.2.”

7. Aquatic Environment

18. The chair invited José Tarazona, in his capacity of Chair of the Expert Group on Chronic Aquatic Toxicity to inform the meeting on the results of the Expert Group Meeting that was held on 10-11 February

2005 and circulated an Expert Group draft working proposal (See Annex 2). This proposal amends the classification scheme to add two “Long Term” categories and two “Chronic” categories in GHS Table 3.10.1, and amends the label elements accordingly. The Expert Group first evaluated the information provided by the analysis of the databases conducted by Sweden, Germany, the US and Spain on the Acute/Chronic ratio, then assessed how this information can be used for accommodating classifications based on chronic NOECs in the current system.

19. The Task Force welcomed the work progress achieved by the Expert Group and stressed the importance of the draft working proposal. It was observed that with respect to hazard communication, there may be a need to limit the information on the label by means of information prioritisation in some systems.

20. The Task Force recognized that it will be necessary to also amend Chapter 3.10 and agreed that this issue should be discussed at the next Task Force Meeting rather than approved by written procedure.

8. Validation of the Transformation/Dissolution Protocol: Phase 1 and Phase 2

21. The Secretariat (Kotaro Yoshida) introduced Document ENV/JM/HCL(2005)5, which includes a short status report on the work since the last Task Force meeting, and provides some initial considerations on how to deal with the phase 2 validation on relevance of the protocol.

22. The need for the Transformation/Dissolution (T/D) Protocol validation and the priority of the phase 1 validation on reliability were stressed; the results of the T/D Protocol test were expected to be submitted by the end of February 2005 due to a technical delay. It was commented that the T/D Protocol should be validated according to the process described in chapter 4 of the OECD draft Guidance Document 34 and that independent statisticians should evaluate a report for phase 1 validation provided by the laboratories before they are submitted to the Validation Management Group (VMG). It was noted that the VMG was initially set up for the phase 1 validation; however, there was no agreement on this point.

23. With respect to the pH values used for the T/D protocol, although technical difficulties were recognized, the deviation from the recently revised OECD TG 111 for hydrolysis test was pointed out (the hydrolysis test covers the pH range 4-9, while the T/D Protocol only covers the pH range 5.5-8.5).

24. It was commented that:

- the results obtained by using the T/D Protocol, as described in GHS Annex 9 is part of a classification strategy and that the strategy is included in an agreed guidance for interpretation of data for use in applying the classification criteria (described in GHS Annex 8);
- the validation (reliability and relevance) should only cover the protocol as described in GHS Annex 9, and that the question of regulatory acceptance of the classification strategy, as proposed by some members of the Expert Group, goes beyond the mandate given by the UN SCEGHS;
- the whole strategy for classification of metals may require re-examination at a latter date; however, this would first require more tests on transformation/dissolution being conducted for various metals and metal compounds.

25. It was also commented that:

- the extended Expert Group established in 2004, which includes experts who have a good understanding of classification, should assess the relevance of the T/D Protocol in accordance with OECD draft Guidance Document 34;
- all countries should nominate additional members of the Expert Group.

26. The Secretariat observed that for the discussion on phase 2 validation of relevance, the Task Force had been invited to nominate members representing the national position in addition to the members of the VMG.

27. In order to promote the report of new test results, it was emphasised that priority should be given to first complete the validation according to phase 1 on reliability before deciding on how to proceed with phase 2 on relevance and/or a possible discussion on the regulatory acceptance of the classification strategy.

28. The Task Force agreed on (i) the need for an independent and high quality validation, (ii) requesting independent statistical experts to analyse the results of the T/D Protocol tests before providing the final draft report to the VMG, and (iii) waiting for the summary report of the VMG before deciding on how to deal with a phase 2 validation on relevance for classification purposes and/or discussion on the regulatory acceptance of the classification strategy.

29. The Secretariat invited the Task Force members to nominate statisticians for the phase 1 validation.

9. Sensitization: strong vs. weak sensitizers

30. The Secretariat introduced the report of the Expert Group Meeting that was held on 5-6 May 2004, back to back with the Task Force Meeting, as well as a progress report since the last Task Force Meeting. It added that the UN SCEGHS has requested a draft scientific issue paper by the end of 2005, which means an agreement by the Expert Group in early June. Any proposal to revise the GHS Chapter 3.4 should then be submitted by the end of 2006.

31. The Task Force agreed on the US proposal for developing the first draft scientific issue paper at the latest by 15 March 2005. Relevant information contained in the Summary reports of the Expert Groups meetings held in December 2003 and May 2004, as well as in document ENV/JM/HCL(2005)6 will be used to develop the scientific issue paper.

32. The US informed the Task Force that the public meeting, to be organized by US Consumer Products Safety Commission on the issue of strong vs. weak sensitizers, should be announced by the end of the summer. The Expert Group Meeting was expected to be held back to back with the public meeting.

10. Draft List of Carcinogenicity Potency Estimation Methods

33. The Secretariat introduced Document ENV/JM/HCL(2005)3, which includes, as an annex, a draft list of potency estimation methods initially developed by Norway, and observed that the first paragraph of this list was not agreed. Two versions of the first paragraph were provided, one by Norway and the other by the US. The Secretariat also questioned about whether and which additional information was needed to finalize the scientific issue paper.

34. Norway commented that it was very difficult to get other countries involved and provide input. There was no agreement on using the methods to derive specific concentration limits for certain carcinogenic mixtures. The UK explained that they currently use these methods for ranking and prioritisation on the basis of hazard.

35. It was stressed that more work is needed to describe the strengths and weaknesses, domain of applicability, and the type of expertise required to use the methods. There was no agreement on submitting a paper with the description of the methods as included in document ENV/JM/HCL(2005)3 to the UNSCEGHS.

36. After some discussions on the first paragraph, the Chair invited a small group to try and find an agreement. The Task Force agreed on the proposal made by this small group, with some editorial changes (See the new first paragraph in Annex 3).

37. The Task Force also agreed on providing the UN SCEGHS, at its July Meeting, with a status report including the new first paragraph and, as included in the annex to document ENV/JM/HCL(2005)3, the second paragraph, the list of estimation methods but without their descriptions and addition of a reference list. This status report will be submitted as an information document.

38. Norway agreed to further develop the list of potency estimation methods. Written comments will be requested through the Secretariat.

11. Reproductive Toxicity Potency

39. The Secretariat introduced document ENV/JM/HCL(2005)4 that includes a short draft scientific issue paper. It was explained that the remaining important issue concerns whether it is or is not possible to develop a short guidance on appropriate parameters to be considered to apply to Paragraph 1.3.3.2 of GHS.

40. There was support for the draft scientific issue paper and one comment suggesting delaying its adoption. The European Commission reported that there will be an EU expert meeting on this issue in April 2005. It proposed to add some text in order to allow a new discussion if considered appropriate at a later date.

41. Finally, the Task Force agreed on the draft scientific issue paper as included in document ENV/JM/HCL(2005)4 with the following changes: in Paragraphs 4 the bracketed text is deleted and in Paragraph 5 "at the present stage of scientific knowledge" is added at the end of the first sentence. The Task Force did not recommend further work on this issue at the present stage.

12. Toxic Gas mixtures

42. The Secretariat presented a short status report on the work that had recently been started. An Expert group Meeting was to be held on 17-18 February 2005.

13. (Q)SARs

41. The Secretariat (Drew Wagner) explained the history of the OECD work on (Q)SARs and pointed out that the last Joint Meeting decided to focus the work on regulatory acceptance of (Q)SARs. The input of the different OECD groups and Task Forces is necessary to ensure that the toolbox will meet all the needs. It was made clear that document ENV/JM/HCL(2005)7 was submitted for initiating discussion and that the use of (Q)SAR should be understood as including use of qualitative structure activity/property, read across, analogues and chemical categories.

42. The Task Force supported the OECD work on this issue. It recommended a wide scope toolbox including all alternative methods, and stressed the importance of these methods with respect to animal welfare and cost saving.

43. The current uses of approaches based on chemical structure similarities in countries, regions and in the transport sector were mentioned. The need for validated methods was stressed as well as the need to ensure consistency of various OECD programmes. In particular, it was observed that existing chemical hazard profiles provide the basis for classification; therefore, the concept of chemical categories could be used for classification purposes. It was discussed that OECD may propose at a later stage a general sentence to be included in the GHS in relation to the use of SARs.

44. With respect to document ENV/JM/HCL(2005)7, it was proposed to replace "99% probability" with "very high probability" in Paragraph 7.

45. The Chair invited the Task Force to send written general comments on the use of alternative approaches and/or comments on document ENV/JM/HCL(2005)7 by 15 March 2006 or to inform the Secretariat if an extension of the commenting period is needed. The Secretariat will then circulate all comments. The comments of all OECD groups will be given to the Expert Group on (Q)SAR that should have a meeting in the second half of 2005, and a report will be submitted to the November Joint Meeting. This issue will be on the Agenda of the next Task Force Meeting.

14. Other issues

46. Amy Rispin informed the Task Force of the work carried out under the test guideline programme in relation to inhalation toxicity and to the definitions of "dust", "mist" and "vapour"; she pointed out the need to ensure consistency with the work done on this issue under the HCL Programme, through national coordination.

47. The 15th Task Force Meeting will be held on **15-16 March 2006**. The 16th Task Force Meeting will be held in the United States in February 2007. The Secretariat invited the Task Force participants to consider the possibility to send a national expert to support the Secretariat with its work on Harmonization on Classification and Labelling.

**Annex 1
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