# UN/SCEGHS/14/INF.8

# 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

Fourteenth session Geneva, 12(p.m.)-14 December 2007 Item 7 of the provisional agenda

#### OTHER BUSINESS

<u>Draft Summary Record of the 16<sup>th</sup> Meeting of the Task Force on Harmonisation</u> of Classification and Labelling Bern (Switzerland), 4-5 July 2007

Transmitted by the Organization for Economic Co-operation and Development (OECD)

The Summary Record will be finally approved at the 17<sup>th</sup> meeting of the Task Force. Any amendments made to the record at the 16<sup>th</sup> meeting will be noted in the Draft Summary Record of the 17<sup>th</sup> meeting.

## Agenda Item 1: Opening of the meeting and adoption of the draft Agenda

1. The Chair of the Task Force, Gregory Moore (Sweden) opened the meeting and invited the participants to present themselves. The Participant's List is attached as <u>Annex 1</u>. The draft Agenda [ENV/JM/HCL/A(2007)2] was adopted, with the addition under Agenda Item 3 of (i) the consideration of a recent document submitted by the US and Canada (INF. 9) and (ii) a short presentation on promoting use of alternatives for classification and labelling, by the Netherlands. The Task Force agreed to defer the main part of Agenda Item 3 after Agenda Item 6.

# Agenda Item 2: Confirmation of approval of the draft Summary Record of the 15<sup>th</sup> Meeting of the Task Force

2. Approval of the draft summary record [ENV/JM/HCL/M(2006)4] was confirmed.

# Agenda Item 3: Issues related to the organization of the work on Harmonization of Classification and Labelling (HCL)

- 3. The issue was initially on the Task Force draft Agenda given the decrease of proposals to be discussed or approved. However, several aspects of the work on HCL were discussed. The lists of Task Force's members (INF. 3) and expert groups' members (INF. 8) were circulated during the meeting for updating. The Heads of delegation were invited to further update the lists within one month.
- 4. The Secretariat made a presentation, which is available on the meeting website, to clarify the role of the Joint Meeting, Task Force, expert groups/validation management group and Bureau of the Task Force. The Task Force discussed the thought starter (INF. 9) prepared by Amy Rispin (United States) and Kim Headrick (Canada). Initial comments were made on face to face meetings, use of written procedure and need for consensus. The proposed recommendations were generally welcomed; however, it was noted that some countries have difficulties to attend too many meetings, the proposal related to the use of written proposals should be softened, and the needs of the UN SCEGHS should be kept in mind.
- 5. Given the request from several participants to have more time to comment on the thought starter, it was agreed that comments should be sent to Kim Headrick, Amy Rispin and the Secretariat by the end of August. A draft schedule of activities was attached to the thought starter. A revised version discussed during the Task Force meeting is attached as <u>Annex 2</u>. The date proposed by the Bureau for the next Task Force meeting (24-25 April 2008) was agreed. The Task Force meeting will be at OECD Headquarters in Paris.
- 6. The Task Force was informed that Gregory Moore was requested to take new time consuming responsibilities in Sweden, and therefore, a new Chair had to be elected. Gregory Moore was greatly appreciated for his very good chairmanship of three Task Force meetings from 2005 to 2007. At the end of the meeting, the Task Force elected Thomas Gebel (Germany) as the new Chair.
- 7. Henk Roelfzema (Netherlands) referred to the draft summary of the Joint Meeting discussions [INF 6] and made a presentation of the outline of a discussion document on use of alternatives as a basis for classification and labelling. He clarified that alternative methods include in vivo test methods, (Q)SARs, read across, and grouping of chemicals. The presentation will be made available to the Task Force. Task Force members, who would like to contribute to the preparation of the discussion document, should inform Henk Roelfzema and the Secretariat within 3 months.

#### **Agenda Item 4: Aquatic Hazards**

- 8. The proposal for revision of Chapter 4.1 in order to accommodate chronic toxicity to aquatic organisms for assigning a chronic hazard category had been revised twice after it had been circulated for the first time in November 2006. The Task Force was requested to address remaining issues related to two definitions and to the safety net [ENV/JM/HCL(2007)2].
- 9. The Task Force agreed on the following revised definition of "Acute (short term) hazard" proposed by the US: "For classification purposes, **Acute (short term) hazard** is the hazard of a chemical caused by its acute toxicity to an organism during short-term aquatic exposure to that organism". The Task Force agreed on the text proposed into brackets for the definition of "Long-term hazard".
- 10. The Task Force discussed the issue of the safety net. Canada raised some concern about the safety net and asked to send the matter back to the expert group. The Task Force requested that a small group make a proposal. The Task Force considered the small group proposal and agreed on the following:

- In Paragraph 4.1.2.2, "organic" is deleted in the third sentence and the last sentence is replaced with "The need for this classification can be negated by demonstrating that the substance does not require classification for aquatic long-term hazards."
- In Table 4.1.1, Category: Chronic 4, "a" is deleted before "chronic toxicity NOECs >1 mg/l".
- In Figure 4.1.1, first box: "Note 6 to Table 4.1.1" is replaced with "Note 2 to Table 4.1.2" [there was no note 6 in Table 4.1.1.1.].
- In Table 4.1.2, box for Category: Chronic 4: "unless NOECs >1 mg/l" is added and the text of Note 5 to Table 4.1.2 is replaced with "For poorly water soluble substances for which no acute toxicity has been demonstrated at the solubility limit, and are both not rapidly degraded and have a potential to bioaccumulate, this category should apply unless it can be demonstrated that the substance does not require classification for aquatic long-term hazards."
- 11. The decision logic of document ENV/JM/HCL(2007)2 was presented in a format compatible with the GHS and circulated for comments. The Task Force agreed on the decision logics for long term aquatic hazard classification and noted that two arrows should be added and "No classification" should be replaced with "Not classified for long term hazard". The Task Force agreed not to change away from the original decision logic for acute (short-term) aquatic hazard classification. The US noted several discrepancies in this regard and planned to send a mark up of the acute sections.
- 12. The Task Force agreed on the proposal for revision of Annex 9 (A9.1-A9.3 and Appendix VI) as a consequence of proposed changes to Chapter 4.1 [ENV/JM/HCL(2007)3] with a correction of the first sentence of the second paragraph of Section A9.3.2.7.1 to accommodate chronic toxicity to aquatic organisms (deletion of "only the acute  $EC_{50}$  is used for classification in the harmonized system").
- 13. The Task Force had no comment on the explanatory notes to the proposal for the revision of GHS Chapter 4.1, Annex 9.1-9.3 and Appendix VI as included in document ENV/JM/HCL(2007)4. This document will be reviewed by the Secretariat to ensure consistency with the most recent Task Force agreements, and submitted to the Joint Meeting and to the UN Sub-Committee of Experts on the GHS (UN SCEGHS) for information.
- 14. The Task Force agreed on consequential changes in other parts of the GHS [ENV/JM/HCL(2007)9] and had no comment on corrections to the text of Chapter 4.1 submitted by the UNECE (INF. 5). These corrections were either already adopted by the UN Sub-Committee of Experts on the GHS (UN SCEGHS) or editorial corrections.
- 15. The proposals for revision of Chapter 4.1 and Annex 9, with agreed corrections (see above) were then approved. The proposals will be corrected accordingly and submitted to the Joint Meeting for endorsement and declassification, and to the UN SCEGHS for adoption.

# **Agenda Item 5: Draft Proposal on Ozone Depleting Chemicals**

16. The Task Force considered first Section 4.2.1 related to definitions and general considerations and Section 4.2.2 related to classification criteria [Annex 2 of document ENV/JM/HCL(2007)6]. The Task Force agreed on the definitions and classification criteria for substances and mixtures. It discussed the text of Paragraph 4.2.1.2 on general considerations. Some experts were in favour of deleting the paragraph. The Task Force agreed that as the substance of the paragraph is already described in the scope of the GHS, it would better fit as a footnote to the title *Classification criteria* of Section 4.2.2. The Task Force discussed at length the text to be used for the footnote. A small group proposed the following: "The

criteria in this chapter are intended to be applied to chemicals and not to equipment, articles or appliances (e.g. refrigeration equipment, fire extinguishers). Consistent with 1.1.2.5a (iii) regarding pharmaceutical products, GHS [classification and] labelling does not apply to medical inhalers at the point of intentional intake".

- 17. The word "classification" was placed into square brackets because Paragraph 1.1.2.5a (iii) refers to labelling only. The US proposed to delete the examples in round brackets. However, the UNECE observed that there was no definition of "equipment", "article" and "appliances" in the GHS; therefore examples would be useful. As the US was not in a position to accept the suggestion to delete the full first sentence at the meeting, the Task Force agreed that the footnote should be placed into square brackets until a compromise is found.
- 18. The Task Force then considered Section 4.2.3 on hazard communication. With respect to the hazard statement, there were various views concerning the hazard statement proposed by the expert group: "Harms public health and the environment by destroying ozone in the upper atmosphere". A majority of countries were in favour of a shorter statement, but some countries could accept either a shorter or a longer statement. Spain proposed the following compromise: "Harms human health and the environment by destroying the ozone layer". The US could not agree on the Spanish proposal at the meeting. Regarding the symbol, countries initially expressed diverse views: (i) use no symbol, (ii) use the "Fish and tree" symbol, and (iii) use the exclamation mark symbol. After some discussion, the Task Force agreed that the proposal to be submitted to the Joint Meeting should include the exclamation mark. However, the US requested that the symbol be placed into square brackets until US agreement can be confirmed. Norway and Sweden expressed that the use of the symbol should be considered as part of a "packaged deal". The Task Force decided to place the whole of section 4.2.3 on hazard communication into square brackets until US agreement can be confirmed.
- 19. Depending on information received from the US regarding the footnote and the communication elements within one month, the proposal will be either submitted to the Joint Meeting by written procedure or submitted at the February 2008 Joint Meeting. The Task Force may be consulted about a slightly revised proposal from the US. If there is no agreement of all other countries on the US revised proposal, the current brackets will stay in the proposal to be submitted to the Joint Meeting in February 2008.

#### Agenda Item 6: Validation of the Transformation/Dissolution Protocol

20. The Secretariat reported progress on the work. The Task Force took note of the report [ENV/JM/HCL(2007)7 and INF. 7]; the US commented that they don't agree on the elements, listed in Paragraph 5, to be included in the phase 2 report. The Task Force endorsed the proposal for an extended VMG meeting on 25-26 October 2007 to agree on the content of the Phase 2 report, and a following meeting in February or March 2008. It was agreed that the Summary Record of the October meeting will be circulated to the Task Force before finalization of the report.

## Agenda Item 7: Draft proposal on strong versus weak sensitizers

21. The Secretariat reported progress on the work at and after the expert group meeting held in the US. The Task Force took note of the report [ENV/JM/HCL(2007)8]. It endorsed the proposed time schedule for developing a proposal for the UN SCEGHS (see Annex 2).

### **Agenda Item 8: Work on terrestrial hazards**

22. José Tarazona, Chair of the expert group, reported progress of the work [ENV/JM/HCL(2007)10]. The Task Force took note of the progress and endorsed the expert group meeting that was planned on 24-25 October 2007 in the US [after the Task Force meeting, the US proposed to host the meeting on 23-24 October 2007].

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**ANNEX 2: Proposed Timelines for Task Force Activities** 

Harmonization of Classification and Labelling Next Task Force Meeting: 24-25 April 2008			
SUBJECT Transformation/Dissolution Protocol Validation	<b>ACTIVITY</b> Extended VMG meeting to address report of Phase I experiments and	TIMING 25-26 October 2007	
	organize Phase 2 Task Force approval of the experiments performed in Phase 1 Extended VMG Meeting to finalize	2007-2008	
	Phase 2 report Task Force approval of Phase 2 report	February or March 2008	
Sensitization: strong vs.	Work will continue depending on	April 2008 17-18 October 2006	
weak sensitizers	the results of the October IPCS meeting on skin sensitization in chemicals risk assessment.  Expert Group meeting in Bethesda (US)	2007-2008	
	Impact Analysis Expert Group meets to review impact analysis, ICCVAM results	April 2008	
	and finalize the Expert Group Proposal (back to back with the ICCVAM Peer Panel Meeting) If needed, expert meeting, immediately before the Took Force	April 2008 April 2008	
	immediately before the Task Force meeting Task Force approval		

Aquatic chronic hazards	Third expert group meeting (Washington) Approval of a scientific issue paper and of the broad outlines of a proposal at the next Task Force Meeting	
	Submission of a first proposal and of revised versions to the Task Force by written procedure	End 2006 – early 2007
	Submission of revised proposal for approval at the Task Force meeting	July 2007
Ozone Depleting	Submission of the expert group proposal and options for Task Force comments	·
Chemicals	Submission of a proposal for approval at the Task Force meeting	July 2007
Terrestrial Hazards	Re-start of the work	January 2007
	Status Report to Task Force	July 2007
	Expert group meeting – develop work plan	23-24 October 2007