

**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
(Seventh session, 14-16 July 2004,
agenda item 6)

COORDINATION AND WORK PROGRAMME

**REVISED DRAFT SUMMARY RECORD OF THE 13TH MEETING OF THE TASK FORCE ON
HARMONISATION OF CLASSIFICATION AND LABELLING
(Paris, 3-5 May)[?]**

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

This Draft Summary Record has been revised on 22/06/04. It will be finally approved at the 14th meeting of the Task Force. Any amendments made to the record at that time and agreed will be noted in the draft summary record of that meeting.

AGENDA ITEM 1: Opening of the Meeting

1. The Chair, Ms Anna-Liisa Sundquist from Finland, opened the Meeting and welcomed the Task Force members. She invited all participants to introduce themselves. The list of participants is added to this report as Annex 1.

AGENDA ITEM 2: Approval of the Agenda

2. As a background to the Agenda, the Secretariat introduced Document INF 5, which summarizes the status and the priorities of the OECD work, in relation to the mandate given by the UN Sub-Committee of Experts on the GHS (UN SCEGHS). The Agenda [ENV/JM/HCL/A(2004)2] was adopted. It is added to this report as Annex 2.

AGENDA ITEM 3: Confirmation of approval of the Report of the 12th Meeting of the Task Force

3. Draft Summary Record, revised on 27th August 2003, was approved without any further changes.

AGENDA ITEM 4: General Information by the Secretariat

4. The Secretariat reported on the discussions related to the OECD work at the two UN SCEGHS meetings that were held in July and December 2003. It referred to Paragraphs 18-24 of Document INF 1 and Paragraphs 12-21 and 60-66 of Document INF 2. It pointed out that the Sub-Committee did not agree on the proposal for classification criteria for substances and mixtures, which in contact with water, release toxic gases and that further work on this proposal was assigned to a "Correspondence group" of the UN SCEGHS.

[?] This document includes the core part of the draft report and Annexes 1 and 2 only.

5. The Secretariat also drew the attention of the Task Force to Document INF 2, Paragraph 61 that makes it clear that the OECD proposals, in the framework of the UN SCEGHS mandate, should not include changes, aiming at simplifying the GHS or facilitating its understanding and implementation, that would not be within the mandate.

6. Ms Catherine Masson, representing the UN SCEGHS secretariat informed the Task Force on the status of the work of the Sub-Committee and its Correspondence Groups. A meeting on Substances and mixtures, which in contact with water, release toxic gases was planned on 7th May 2004; no new GHS element was already agreed thus far but it was expected that some would be shortly adopted. A new proposal regarding Safety Data Sheets was posted on the UNECE website in the previous week (Australia leadership); a nearly final revision of GHS Annex 3 on Precautionary Statements (Germany leadership) is also available. A revision of part of Annex 6 (USA leadership) was adopted in December 2003 but more guidance is needed for small packages. Work is going on regarding toxic gases mixtures and physical hazards.

7. The UN SCEGHS will pursue cooperation with the Basel Convention secretariat. The work of the Correspondence Group on Ozone depleting substances and cooperation with the Montreal Protocol secretariat are also going on. Furthermore, in addition to the English and French versions, GHS translations are now available in Russian and Spanish. Chinese and Arabic translations should be available by the end of 2004.

8. The OECD secretariat then drew the attention of the participants to Paragraphs 81-116 of document ENV/JM(2004)5 that was prepared for the Joint Meeting held on 4-6 February 2004. It reported on the Joint Meeting conclusions regarding collaboration of OECD with the UN SCEGHS; the Joint Meeting agreed on the three following proposals made by the Secretariat and Austria in order to improve exchange of information with the UN SCEGHS and the UN Sub-Committee of Experts on the Transport of Dangerous Goods (UN SCETDG):

- (i) To invite all the members of the UN SCEGHS and the UN SCETDG to the Task Force meetings on HCL;
- (ii) To post all draft proposals on the protected website and give the URL, Username and Password to the UN SCEGHS and UN SCETDG secretariats for circulation to the members of the two Sub-Committees;
- (iii) When submitting a proposal to the Task Force, to also submit it to the UN SCEGHS and UN SCETDG secretariats for circulation to the two Sub-Committees with the same commenting deadline.

The Secretariat observed that this new arrangement means that those who are members of the Task Force on HCL and also members or observers of the UN SCEGHS represent both organizations.

9. Because carcinogen potency was not an item on the Agenda, the Secretariat shortly introduced Document INF 4, which is the Draft Summary Record of the conference call held on 22 April on carcinogen potency. It pointed out that a sub-Group will start listing the methods for potency estimation and report to the Expert Group on 5 July 2004. The second step will be to evaluate the usefulness of these methods with respect to the classification for mixtures.

AGENDA ITEM 5: Revision of Chapter 3.1

10. The Chair introduced the issue and observed that most part of Document ENV/JM/HCL(2004)7 was already agreed at the last Task Force meeting; agreement was still requested on definitions of “dust”, “mist” and “vapour”. The secretariat then explained that the proposal was added to the Agenda due to comments received after it was circulated to the Task Force, the UN SCEGHS and the UN SCETDG. The US and Canada proposed two different definitions for “vapour”. BIAC sent several comments on the definitions,

requested a revision of Paragraph 3.1.2.6.5 and proposed to revise Chapter 3.1 to make clear how legacy range data should be handled in classification for acute toxicity (Document INF 3).

11. Regarding the definitions, there was a discussion on whether “normal temperature and pressure” should be added to each definition to take into account the inhalation tests conditions. As there was no consensus on this point, it was agreed to delete “in relation to toxicity testing” in Note (d) to Table 3.1.1. The Task Force also agreed on the definition for “vapour” proposed by Canada. It was observed that BIAC proposal to exclude “fume” from the definition of “dust” and to include a specific definition for “fume” was neither requested by the Sub-Committee nor needed insofar as reaction products are not to be labelled. BIAC proposal to add “aerodynamic diameter” to precise size ranges was considered too technical and complicated. Finally, BIAC agreed to withdraw its proposals related to definitions.

12. BIAC explained its proposal for revision of Paragraph 3.1.2.6.5 related to corrosivity. The Task Force discussed this proposal but there was no agreement on revising a paragraph that already was the result of a compromise. Finally, because BIAC proposal related to legacy range data was outside the mandate given by the UN SCE GHS, it could not be considered for inclusion in the proposal for revision of Chapter 3.1. The Chair concluded that the proposal for revision of Chapter 3.1, as presented in Annex 3 was approved and will be submitted to the Joint Meeting for declassification.

Agenda ITEM 6: Revision of Chapter 3.4 on Sensitization: Issue of Elicitation and Induction

13. The Chair introduced the two options included in Document ENV/JM/HCL(2004)1, and invited the Task Force to first discuss the text in Section 3.4.1 on general considerations, then to focus on labelling and finally to consider the classification. The Secretariat indicated that Document ENV/JM/HCL/M(2004)1, which is the Summary Report of the Expert Group Meeting that was held in Paris on 15-16 December 2003, was provided for information only. It made it clear that the proposal on elicitation should be ready in this biennium while the proposal on potency is requested later. This means that the two issues are to be dealt with separately.

14. With respect to Section 3.4.1, the proposal to add “for cell mediated allergy” after “predictive tests” and “cell-mediated” before “skin sensitization” in the same paragraph was not supported. The text proposed in Document ENV/JM/HCL(2004)1 related to general consideration was agreed. The Task Force also agreed to add the name of sensitizing substances on the label of the mixtures containing these substances at or above a cut-off value yet to be agreed. It also agreed to insert the word “Guinea pig” in the second line of Paragraph 3.4.2.2.4.1.

15. Regarding the proposed cut-off values, the Chair observed that it would be easier for the discussion to use percentages (10 ppm = 0.001% and 1000 ppm = 0.1%). The Secretariat noted that the Expert Group proposal was not restricted to these two values. The European Commission explained that the value of 0.001% was proposed by the European Expert Group as the most appropriate to protect already sensitized individuals, although even lower values would be needed in some cases.

16. There was a long discussion on the cut-off value. It was recognized that relationship between induction and elicitation is unclear and that elicitation depends on individuals and other conditions. Some experts expressed the view that the rationale for the value of 0.001% is not clear and that GHS Section 1.3.3.2 provides enough flexibility to lower the cut-off value of 0.1% as appropriate. A sentence to be included in Chapter 3.4 was proposed along this line by Ca. It was observed that the cut-off value for carcinogens classification was only 0.1%, that 0.001% was close to impurity range and detection limits, and that no impact analysis was available for the cut-off value of 0.001%.

17. Considering that lower levels are necessary for elicitation than are required for induction as agreed in Section 3.4.1, some other experts supported the value of 0.001% for adding the name of the sensitizers on the mixtures labels. It was also observed that this cut-off value does not take the worse case into account and that

Health Insurance companies would support the value of 0.001% and that this cut-off value would not trigger any other measures than naming the substance on the label as does the cut-off value for carcinogens. The Chair suggested that if there was no way out, optional provisions should be considered. It was agreed to set up a small group that would further discuss this issue and report to the Task Force on the following day. She observed that the final decision will be an administrative one, taking scientific knowledge into account.

18. The Chair then invited the Task Force to comment on whether or not there should be a classification for elicitation. She observed that unlike classification for other endpoints, a classification for elicitation would only refer to mixtures and not to substances. Mixed views were expressed on this issue. Some experts had the opinion that there should be a classification. Some could accept a classification if they were sure that the only consequence of the classification is the addition of the name of the sensitizers on the mixtures labels. Some other experts considered that it was not reasonable to classify with the consequence of only adding the name of the sensitizers on the mixtures labels. It was observed that classification may have consequence for bulk liquid transport and that a double classification would be misleading. The issue of mixtures that have been tested out was raised. It was observed that no test method for mixture elicitation is available. It was however also observed that the GHS already provides for classification without test in some cases.

19. The Chair invited the small group (Ca, EC, Ge, US, Sw, and BIAC) to also consider the issue of classification. The small group met after the first day meeting; on the basis of its discussion, the Secretariat prepared a compromise that was shortly discussed by some experts and revised. In Paragraph 3.4.3.4, the table with cut-off values for classification of mixtures was replaced by a sentence reflecting GHS Section 1.3.3.2 and optional classification of mixtures if they contain 0.001% or more of a skin or respiratory sensitizer. Ms Kim Headrick presented to the Task Force the compromise based on option 1 (including classification). This proposal was not unanimously accepted and more time was requested to reflect on it. Whether Paragraph 3.4.3.4 was creating a new category for elicitation was not completely clear. Some changes were proposed to improve the wording of the proposal. Revised Paragraphs 3.4.3.4 and 3.4.4 are attached to this report as Annex 4.

20. It was proposed to link the issue of elicitation with the issue of strong and weak sensitizers. Concern was expressed with respect to this proposal which would delay the work for a number of years. The Chair concluded that there was an agreement on the three paragraphs in the general considerations and the addition of "Guinea pig", but more time was needed to consider the cut-off value and the concept of classification. A conference call is planned on 18 June 2004 to try and agree on a compromise.

Agenda ITEM 7: Guidance document on Carcinogenicity: Guidance for the Use of Additional factors in Carcinogenicity

21. The Chair invited the Secretariat to introduce Document INF 9, which is the result of the discussions at a conference call with the Expert Group, held on 29 April 2004. The Secretariat explained that the Expert Group started working separately on each additional factor and then decided that a sub-group would produce a document integrating all the expert's contributions. This document should be read in conjunction with GHS Chapter 3.6, and in particular with Paragraph 3.6.5.3. The Secretariat informed the Task Force that the Background Guidance in Paragraph 3.6.5.3 was in fact a quotation of IARC Guidance and not of OECD Guidance as mentioned in that paragraph. The Secretariat noted that some bracketed texts in Document INF 9 need more discussion.

22. It was observed that conference calls so close to Task Force meetings should be avoided as it was difficult for experts to have internal consultations in a short time. Some experts observed that there was overlapping and inconsistency in the proposed guidance. It was also pointed out that the basic criteria should not be changed and that only Paragraphs 914 are relevant with respect to the mandate. Some experts questioned the splitting in Category 1A and 1B given that the criteria for both categories are not split in the

GHS. There was also some support for the proposal which reflects very technical discussions and for a clear distinction of Category 1A and 1B.

23. Acknowledging that the guidance content would depend on its place in the GHS, the Task Force discussed where the guidance should be placed. Because the proposed guidance is very short, some experts were in favour of placing the existing Background Guidance and the new guidance together, at the end of Chapter 3.6. Some experts preferred to have it as a GHS annex. Some other experts suggested including new paragraphs that would be guidance in nature, after Paragraph 3.6.2.5.2. It was also observed that the structure of Chapter 3.6 was confusing with reference to a WHO/IPCS workshop in Paragraph 3.6.2.7, in addition to the Background Guidance in Section 3.6.5.3.

24. The Chair concluded that developing a good guidance was not easy and that it was better not to hurry too much and develop good guidance. She suggested that the Expert Group could further consider the issue and draft a new proposal, keeping in mind that the structure of Chapter 3.6 may change. She requested that a small group prepares, in the margin of the meeting, recommendations for the Expert Group further work. Experts from Be, Ca, NL, No, Sw, UK, US and BIAC volunteered to be in the small group.

25. The small group met on the day after, just before the Task Force meeting. Ms Kim Headrick reported on the conclusions of the small group the day after. She explained that guidance proposed by the Expert Group goes beyond the mandate. As a consequence, the Expert Group should refocus on Paragraph 3.6.2.5.2 and propose additional guidance on how the different factors should be integrated to the evaluation process. The different factors should not be considered one at a time and be assigned to a specific category. Guidance should only be proposed on how they increase or reduce the strength of evidence. Background Document from IPCS and IARC should be used to develop useful examples to describe how to take into account the different factors. Whether Guidance will be part of the main text or placed at the end of Chapter 3.6 will depend on the content of the proposal.

26. The Task Force agreed that the US will propose a Guidance first draft to the Expert Group and that the Expert Group will be co-chaired by the US and No. The Expert Group should try to finish its work by end of September 2004. The proposal would then be circulated to the Task Force. At the July meeting of the UN SCEGHS, the Secretariat will only report on the work progress.

Agenda ITEM 9: Issue Paper on Terrestrial Environment

27. The Chair observed that the Issue Paper [ENV/JM/HCL(2004)3] was unanimously accepted by the Expert Group, and that the purpose of this discussion by the Task Force is to approve the document, but not to decide to start the activities on terrestrial hazard classification. She invited Dr. Jose Tarazona, in his capacity of Chair of the Expert Group established to develop the Issue Paper, to report on the work. After the presentation of the Issue Paper by Dr. Jose Tarazona, the Secretariat explained that Rob Visser had sent a letter requesting comments on the Issue Paper to the Working Group of National Co-coordinators of the Test Guidelines Programme, the Pesticide Working Group, the Task Force on Existing Chemicals and the Task Force on Biocides. Comments were received from the Netherlands (Document INF 6), Germany (Document INF 7), Sweden (Document INF 8) and BIAC (Documents 10 and 11) in response to that letter. As most of these comments were not proposals for technical rewording, the Secretariat considered that, if the Task Force cannot agree on the Issue Paper, the only possible solution might be to note in the document that a few countries did not support the Issue Paper.

28. Several experts supported the Issue Paper. In response to the concern expressed by the Netherlands, Sweden and Germany, Dr. Jose Tarazona explained other tests methods could be added to the document, that the number of chemicals with available data on terrestrial effects had significantly increased in the recent years and that the additional preliminary work would anyway be provided. In response to a question from Sweden, the US confirmed that they do use a hazard based classification. Dr. Jose Tarazona added that individual EU Member States may also use hazard based classification. The Chair pointed out that because

the decision to start developing a classification scheme will be taken by the UN SCEGHS, political comments on this decision should be made at the Sub-Committee Meeting. The UK informed the Task Force that they will shortly provide the results of a survey of a UK database; they will show that very few chemicals would be classified for terrestrial effects only.

29. The Task Force reviewed the Issue Paper page by page, and particularly discussed the final conclusion (Paragraph 24). This conclusion was revised so that it would reflect all positions. The Task Force agreed that the first sentence of Paragraph 24 could be changed to a technical statement and moved after the conclusion on the feasibility of developing criteria. It was further agreed to delete part of the text in Paragraph 3 of Annex II that referred to the percentage (about 10%) of the chemicals not classified as hazardous for aquatic systems that would require a classification as hazardous for terrestrial systems. There was concern that this percentage, which depends on the classification criteria for Terrestrial Effects, would be misinterpreted by the UN SCEGHS. The chair concluded that the Issue Paper with the agreed changes is adopted for submission to the Joint Meeting. The agreed changes to the Issue Paper are provided as [Annex 5](#) to this report.

Agenda ITEM 10: Progress with the Work on Aquatic Environment

30. The Chair observed that the Task Force was invited to (i) take note of the Expert Meeting Report and of the progress made and (ii) request that the Expert Group continues developing and refining its proposals. She added that this work was not expected to be finalized by 2004 but that a proposal on how to continue the work and within which time frame should however be prepared for the UN SCEGHS. She then invited Dr. Jose Tarazona, in his capacity of Chair of the Expert Group for the scientific discussion, to introduce Document ENV/JM/HCL(2004)8.

31. Dr. Jose Tarazona explained that different databases were used to propose Acute/Chronic ratios. The Expert Group had identified two important issues: different options for cut-off values and the issue of NOEC of 1mg/l as the upper limit for classification. He added that it should be possible to further work on the different approaches and afterwards find an option that may combine these different approaches. The Chair and other experts expressed support for the ongoing work, and appreciated the start of the discussion based on real data. It was observed that toxicity may differ by several orders of magnitude for the most toxic chemicals. Different views were expressed with respect to the mandate and the upper limit of 1 mg/l. Some stressed that the limit of 1 mg/l was already agreed and should not be reopened. On the other hand, it was observed that the mandate from the UN SCEGHS can be interpreted in a way that would allow the establishment of a new upper limit.

32. Dr. Thomas Höfer, as a member of the GESAMP (Joint Group of Experts on the Scientific Aspects of Maritime Environmental Protection) Working Group on the Evaluation of the hazards on Harmful Substances Carried by Ships reported about the outcome of a meeting two weeks ago at the International Maritime Organization. After discussing the OECD's Expert Meeting Report, the GESAMP group asked him to explain at the OECD level the already existing guidelines and regulations introduced by IMO and GESAMP. The criteria used are based on the existing GHS cut-off value using bands of factor 10. A decision by the Task Force on any other factor than 10 would create disharmony with existing IMO instruments under the Annex II of the MARPOL Convention. Mr. Sergio Benassai, in his capacity of Chair of the UN SCETDG recommended proposing a user-friendly system; otherwise implementation might be postponed as it happened for land transport in the EU.

33. The Chair concluded that the Expert Group should (i) continue working on a proposal, (ii) focus on the scientific side and on the analysis of databases (iii) further discuss the issue of the upper limit and (iv) keep in mind the work of other organizations such as the Maritime Organization.

Agenda ITEM 11: Validation of the Transformation/Dissolution Protocol: Progress Report on Phase 1 and Discussion on Phase 2

34. The Chair observed that the validation of the Transformation/Dissolution Protocol (T/D Protocol, GHS Annex 9) is supposed to be finalized by 2004 and that the work is already a little bit behind in this respect since the experimental results of Phase 1 focusing on the reliability of the Protocol are only expected in August. The Secretariat introduced Document ENV/JM/HCL(2004)4. It explained the progress of Phase 1, including the issues of pH and alloys that were raised at the 12th Task Force meeting. With regard to the plan for Phase 2 focusing on the relevance of the protocol, it pointed out the lack of representation of the Validation Management Group (VMG) in the teleconferences and the disagreements between the two participating members of the VMG at the last conference call. It explained that Document ENV/JM/HCL(2004)4 is a Secretariat paper to reflect the discussions. It added that guidance was needed on validation Phase 2 and referred to Paragraph 19. Finally, it proposed two options as mentioned in Paragraph 32.

35. Canada expressed satisfaction that Phase 1 will be completed by September and regretted that progress is hampered by lack of participation. It urged the Task Force to encourage the VMG members to participate in the work. It recommended that the Secretariat prepares a paper on the feasibility of (i) evaluating the existing transformation/dissolution test data and (ii) comparing these and other relevant data with a view to setting up an ad-hoc Expert Group to undertake such work, and that, after taking that decision, and after Phase 1 is concluded, the Task Force should terminate the Validation Management Group. It also recommended that transformation/dissolution data available to the European Commission should be made available to the ad-hoc Expert Group.

36. US observed that the T/D Protocol would not be an internationally agreed document until it is validated and that GHS Section A8.7 (metals and metal compounds) depends on this protocol. Sweden observed that in the GHS, the T/D Protocol is only mentioned as a way to get information.

37. The Chair summarized the issues to be debated by the Task Force as follows:

- ⌘ the scope of Phase 2
- ⌘ the timing for Phase 2
- ⌘ which kind of Expert Group should do the work, and
- ⌘ what the Expert Group should discuss.

38. With regard to the scope of the phase 2, different views were expressed. The arguments made by the Task Force members include the following:

- ⌘ the first bullet of Paragraph 20 could apply to any test Guideline and should include the issue of the pH,
- ⌘ the third bullet of Paragraph 20 would be difficult to evaluate,
- ⌘ some questions described in Paragraphs 22-28 are issues on classification strategy rather than on the Protocol itself,
- ⌘ the issue on surface area approach is dealt with in the Guidance Document on Aquatic Hazard Classification.

It was noted that these points could not be considered fully and that written comments will be submitted later.

39. With respect to the timing, some experts expressed the view that work on Phase 2 should start only when work on Phase 1 is finished. However, it was pointed out that reconvening/establishing an Expert Group would take time, that a proposal on further work should be ready as soon as possible for the UN SCE GHS, and that the Expert Group could start the discussion and then take into account the Phase 1 results in the course of discussion.

40. Regarding the Expert Group membership, options included the following:
- ⌞ to reconvene the old ad-hoc Expert Group on Aquatic Hazards and the metals Working Group (merged in 2000 as the Extended Expert group on Aquatic Hazards),
 - ⌞ to use the new Expert Group on Chronic Toxicity,
 - ⌞ to establish a new Expert Group.

It was observed that the views of the member countries should be represented in the Expert Group. Noting that having conference calls with too many experts is difficult, and that furthermore, the old Expert Groups would require some changes in the membership anyway, the Secretariat proposed to establish a new Expert Group. It was agreed that the Expert Group should include the VMG members.

41. With respect to what the Expert Group should discuss, the Task Force agreed that it should first develop the terms of reference for its work. It was noted that if issues on classification strategy are to be reopened, long discussions would be repeated. The Secretariat observed that the validation report might include proposals for changes to the Protocol.

42. The following technical comments were also made:
- ⌞ in the second bullet, “one factor” should be replaced by “factors”
 - ⌞ in the same bullet, “metal elements” should be replaced by “metal species” and “ions”. In response to this, it was explained that the word “elements” was more appropriate since it covers metal forms and ion species.

Furthermore, the US informed the Task Force that they may provide a paper on the notion of “loading added” as mentioned in the GHS Guidance.

43. The Task force agreed that the Secretariat will shortly send a letter requesting nomination of members for an Expert Group and ask whether any country is interested in chairing this Expert Group. This Expert Group will include the members of the VMG. It will formulate and submit to the Task Force the terms of reference for its work which should focus on the validation of the relevance of the protocol itself and not deal with other issues. It will not close the discussion on the terms of reference before the results of Phase 1 are available; however, while drafting the terms of reference, it will identify what can be discussed with and without the results of Phase 1. The Expert Group will take into account, amongst other issues, the three topics identified in Document ENV/JM/HCL(2004)4 Paragraph 20. Adoption by the Task Force of the terms of reference will be requested by written procedure.

Agenda ITEM 12: Proposal related to Effects on or via lactation

44. The Secretariat introduced Document ENV/JM/HCL(2004)5 and indicated that a first draft of this document was provided by UK. It pointed out the rationale supporting the proposed concentration limits, i.e.: toxicity in breast feeding infants resulting from effects on or via lactation can be regarded as an adverse effect of equivalent seriousness to effects on fertility or developmental toxicity.

45. BIAC did not support the proposed concentration limits for the classification of mixtures. It argued that the proposal goes beyond the current systems and that there is no scientific basis for the proposed concentration limits. It considered that 3% would be more appropriate. The Task Force otherwise agreed on the submission of the proposal to the Joint Meeting for declassification, subject to the deletion of Paragraph 3 and Table 1 from the rationale. The revised rationale is included as [Annex 6](#) to this report.

Agenda ITEM 14: Reproductive Toxicity – Issue Paper on Potency

46. The Chair observed that the Expert Group on Reproductive Toxicity / Potency was still at an early stage in its work. The Secretariat introduced document ENV/JM/HCL(2004)6 and explained that BIAC proposal on this issue was very helpful to start the work and to trigger the comments and questions that have been summarized in the document. It pointed out the options mentioned under “Mandate, definition and

general considerations". It added that the late US/Ca contribution in the annex to the document should also be considered with respect to these options.

47. Diverse views were expressed regarding the work on potency. Some experts considered that the high complexity of the reproductive toxicity does not allow for using potency for classification and that it should only be used for risk assessment. They also pointed out that reproductive toxicity should not be compared to TOST and that GHS Paragraph 1.3.3.2.1 already allows for changes to the default cut-off values for mixtures classification. The US indicated that it was already agreed at an Expert Meeting that was held in Berlin that potency should not be used for classification of substances. Canada clearly stated that it would not use mixture classification based on potency and that any proposal could only be optional; it would however take part in the work.

48. Some other experts thought that exploring the issue was worthwhile and that it would be useful to have an insight on how many substances are strong versus weak reproductive toxicants. It was observed that because science related to potency is still a little immature, gathering of information and examples would be useful. BIAC informed the Task Force that the very first draft of Chapter 3.7 included potency but it was then decided that potency would be considered at a later stage. The Netherlands informed the Task Force that a project was ongoing to get more data on potency.

49. The Chair concluded that the Expert Group (i) should not reopen the adopted criteria (ii) should only consider potency for mixtures (other than default cut-off values on a case by case basis), not for substances (iii) should try to analyze available data / information (e.g. the ILSI database) in order to identify the factors that should be taken into consideration and to evaluate the consequences of cut-off limits (iv) could seek clarification on the mandate once it gets a more precise view on the issue.

Agenda ITEM 16: Date of the 14th Meeting of the Task Force on HCL and any other business:

50. The Chair summarized the status of the various proposals discussed at the meeting and the processes for their submission to the UN SCEGHS. The three proposals below have been adopted:

- ☒ The Issue Paper on Terrestrial Environmental Hazards
- ☒ The proposal related to lactation
- ☒ The proposal for revision of Chapter 3.1.

51. These proposals will be shortly submitted to the Joint Meeting for declassification by written procedure. If they are declassified after the six weeks commenting period, they will be presented to the UN SCEGHS as Information Documents. If they are not declassified, the Secretariat will inform the UN Sub-Committees secretariats that the documents are available on the HCL website.

52. With respect to the four other proposals below, the Secretariat will provide a report on the work progress at the GHS Sub-Committee meeting in July:

- ☒ Proposal on Aquatic Chronic toxicity
- ☒ Proposal on Sensitization/Elicitation
- ☒ Proposal for Guidance for the use of additional factors in carcinogenicity classification
- ☒ Proposal on Reproductive Toxicity/Potency.

53. The tentative date for the next Task Force Meeting is 15-17 February 2005.

54. The Chair thanked the Meeting participants. She announced that although she will continue participating in the Task Force meetings, she will no longer chair the meeting due to an increasing work load. She was warmly thanked for her very good chairmanship, in particular when difficult issues such as mixture classification were raised. All appreciated her efforts to facilitate Task Force achievements.

55. Regarding the organization of the Task Force work, some experts requested the Secretariat to arrange Expert Group meetings shortly after the first conference calls on a new issue.

Annex 1
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3 May 2004 - 5 May 2004

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Annex 2

Draft Agenda of the 13th Meeting of the Task Force on Harmonization of Classification and Labelling (TF-HCL) Paris, 3-5 May 2004

Monday 3rd May		
09h30	1	Opening of the Meeting, Introduction of Participants
		The Meeting will be opened by the Chair, Ms Anna Liisa Sundquist. Participants will be invited to introduce themselves unless there are no new faces.
09h45	2	Approval of the Draft Agenda
		ENV/JM/HCL/A(2004)2 INF. 5
09H55	3	Confirmation of the Approval of the Report of the 12th Meeting of the TF-HCL
		ENV/JM/HCL/M(2003)1
		This draft summary record has been revised on 27/8/2003. All comments received were considered in the revised version of the Report. Any amendments made to the record at this meeting and agreed by the group will be noted in the draft summary record of this meeting.
10H00	4	General Information by the Secretariat
		ENV/JM(2004)5 INF. 1 INF. 4 INF. 2
		The Secretariat will report on the July and December Meetings on the UN Sub-Committee of Experts on the GHS (INF.1 and INF.2). It will also briefly introduce the Progress Report of the HCL Programme in ENV/JM(2004)5, pages 17-23.
10H15	5	Revision of Chapter 3.1: Approval of the proposal for revision
		ENV/JM/HCL(2004)7 INF. 3
		The TF will be invited to (i) agree on a definition for “vapour”, (ii) discuss the comments from BIAC and (iii) agree on the submission of the proposal, revised as appropriate, to the Joint Meeting in view of its submission to the UN Sub Committee of Experts on the GHS.
11h00		Coffee Break
11h45	6	Sensitization: Approval of a proposal related to elicitation
		ENV/JM/HCL/M(2004)1/REV ENV/JM/HCL(2004)1
		The document ENV/JM/HCL(2004)1 includes two options for elicitation: (i) classification and indication of the name of the sensitizer (ii) no classification, indication of the name of the sensitizer. The TF will be invited to (i) agree on option 1 or option 2, (ii) agree on a default concentration value for having the names of the sensitizers on the labels of mixtures when present at this concentration and (iii) approve the submission of the proposal including a rationale, revised as appropriate, to the Joint Meeting in view of its subsequent submission to the UN Sub-Committee of Experts on the GHS.
12h45		Lunch Break

14h00	7	Carcinogenicity: Approval of a guidance document	ENV/JM/HCL(2004)2 INF. 9
		The TF will be invited to (i) discuss and comment the proposed document, (ii) agree on pending issues, (iii) approve the submission of the proposed document, revised as appropriate, to the Joint Meeting in view of its submission to the UN Sub-Committee of Experts on the GHS and (iv) recommend where the document should be placed in the GHS.	
16h00		Coffee Break	
16h30	8	Any remaining issue on Item 5, 6 or 7	
18h		Meeting adjourns for the day	
Tuesday 4TH May			
9h30	9	Terrestrial environment: Approval of an Issue Paper	ENV/JM/HCL(2004)3 INF. 6, INF. 7, INF. 8, INF. 10, INF. 11
		The TF will be invited to (i) review and discuss the proposed paper and (ii) approve the submission of the proposed paper, revised as appropriate, to the Joint Meeting in view of its subsequent submission to the UN Sub-Committee of Experts on the GHS.	
11h00		Coffee Break	
11h15	10	Aquatic Environment: Progress with the work	ENV/JM/HCL(2004)8
		The Task Force is invited to (i) take note of the Expert Meeting that was held in Madrid, (ii) request that the Expert Group continues developing its proposal.	
12h30		Lunch Break	
14h00	11	Validation of the Transformation/Dissolution Protocol: Progress report on phase 1 and discussion on phase 2	ENV/JM/HCL(2004)4
		The Task Force is invited to (i) take note of the progress, (ii) consider what aspects should be covered in the second-phase validation with regard to the relevance of the Protocol and (iii) discuss and decide on the options for future work.	
15H30		Coffee Break	
16h00	12	Reproductive toxicity: Approval of a proposal related to Effects on or via Lactation	ENV/JM/HCL(2004)5
		The Task Force is invited to approve the submission of the proposal including the rationale, revised as appropriate, to the Joint Meeting in view of its subsequent submission to the UN Sub-Committee of Experts on the GHS.	
17h00	13	Any remaining issue on item 9, 10, 11 or 12	
18h00		Meeting adjourns for the day	

Wednesday 5th May			
9h30	14	Reproductive Toxicity: Issue Paper on Potency	ENV/JM/HCL(2004)6
		The Task Force is invited to take note and comment on the Issue Paper.	
11h00		Coffee Break	
11h15	15	Any remaining issue, for which approval is requested	
12h15	16	Date of the 14th Meeting of the Task Force on HCL and any other business	
12h30		Meeting adjourns	

OVERVIEW OF MEETING DOCUMENTS

ENV/JM(2004)5	Highlights and Progress of the Environment, Health and Safety Programme
ENV/JM/HCL/M(2003)1	Report of the 12 th Meeting of the TF-HCL
ENV/JM/HCL/M(2004)1	Summary Report of the Expert Group Meeting on Sensitization (Paris, 15-16 December 2003)
ENV/JM/HCL(2004)1	Proposal related to elicitation
ENV/JM/HCL(2004)2	Proposal for a Guidance Document related to Carcinogenicity
ENV/JM/HCL(2004)3	Proposal for an Issue Paper related to classification for Terrestrial Environment Hazards
ENV/JM/HCL(2004)4	Proposal for Validation of the Transformation/Dissolution Protocol: Progress and Future Plan
ENV/JM/HCL(2004)5	Proposal related to Effects on or via Lactation
ENV/JM/HCL(2004)6	Reproductive Toxicity: Issue Paper on Potency
ENV/JM/HCL(2004)7	Revision of Chapter 3.1: Approval for revision
ENV/JM/HCL(2004)8	Aquatic Environment: Progress Report including the Summary Report of the Expert Group Meeting on Aquatic Environment Hazards (25-26 March 2004)

- Information Document No. 1 (INF.1): ST/SG/AC.10/C.4/10: Report of the UN Sub-Committee of Experts
- Information Document No. 2 (INF.2): ST/SG/AC.10/C.4/12: Report of the UN Sub-Committee of Experts - 6th Session
- Information Document No. 3 (INF 3): Proposal for revision of Chapter 3.1: BIAC Comments and lists of proposed definitions for "dust", "mist" and "vapour"
- Information Document No.4 (INF 4): Carcinogenicity/Potency- Draft Summary Record of the conference call, 22 April 2004
- Information Document No.5 (INF 5): Task Force Meeting- About the Process
- Information Document No. 6 (INF 6): NL comments on the OECD paper on the development of the classification and labelling for Terrestrial Environment
- Information Document No. 7 (INF 7): Germany- comments on ENV/JM/HCL(2004)3- 'Issues to be addressed to develop the classification and labelling for terrestrial environment hazards'
- Information Document No. 8 (INF 8): Swedish comments on ENV/JM/HCL(2004)3- 'Issues to be addressed to develop the classification and labelling for terrestrial environment hazards'
- Information Document No. 9 (INF 9): Proposal for Guidance for the use of additional factors in carcinogenicity classification
- Information Document No. 10 (INF 10): Concawe- comments on the paper 'Issues to be addressed to develop the classification and labeling for terrestrial environmental hazards' (ENV/JM/HCL(2004)3)
- Information Document No. 11 (INF 11): Crop Life-comments on the paper 'Issues to be addressed to develop the classification and labeling for terrestrial environmental hazards' (ENV/JM/HCL(2004)3)
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