



Secretariat

Distr.
GENERAL

ST/SG/AC.10/C.4/2008/22
23 September 2008

Original: ENGLISH

**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

Sixteenth session
Geneva, 10-12 (a.m) December 2008
Item 5 (c) of the provisional agenda

OTHER IMPLEMENTATION ISSUES

Proposals from the informal working group on GHS implementation issues

Transmitted by the expert from Australia on behalf of the informal working group¹

Background

1. At the fourteenth session of the Sub-Committee, it was agreed to establish an informal working group on GHS implementation, in accordance with the programme of work of the Sub-Committee for 2007-2008 approved by the Committee at its third session (refer to ST/SG/AC.10/C.4/24, Annex 2 and ST/SG/AC.10/34, para. 14). At the fifteenth session of the Sub-Committee, it was agreed that the work of the informal group should proceed as proposed in paragraph 15 of UN/SCEGHS/15/INF.25.

2. The informal group met immediately after the fifteenth session of the Sub-Committee in July 2008, and discussed the implementation issues summarised in UN/SCEGHS/15/INF.25. The

¹ In accordance with the programme of work of the Sub-Committee for 2007-2008 approved by the Committee at its third session (refer to ST/SG/AC.10/C.4/24, Annex 2 and ST/SG/AC.10/34, para. 14).

group agreed that a working paper should be developed for the sixteenth session of the Sub-Committee, to assist the Sub-Committee in deciding how to address some or all of the issues identified in UN/SCEGHS/15/INF.25, as well as any additional issues, and whether projects should be added to the next biennium work plan to help address these issues. Members of the informal working group were requested to provide comments on the issues described in Annex B of UN/SCEGHS/15/INF.25 during July and August 2008, to inform the proposal to the Sub-Committee in this paper.

3. The issues discussed by the informal group, many of which were identified in earlier Sub-Committee documents², included:

- (a) text or editorial issues in the GHS, where changes to the existing text, or the development of guidance material, might be necessary to clarify the intent of the document and/or to correct some of the terminology used in the document;
- (b) issues to do with the classification of mixtures;
- (c) classification and hazard communication issues within specific hazard classes; and
- (d) other issues, that could be broadly defined as general or 'policy' issues.

Proposals

4. The details of the issues discussed by the informal working group on GHS implementation were provided in UN/SCEGHS/15/INF.25. Listed below is the suggested handling for each issue, for discussion and proposals for agreement by the Sub-Committee.

4.1 *Issues relating to terminology*

Issue 1.1: The informal group proposes that this issue does not require Sub-Committee attention at this time, given that the terms "cut-off values" and "concentration limits" are intended to be used interchangeably, and are equivalent in the GHS;

Issue 1.2: The informal group considered that the term "chemical" refers to "substance(s)" or "mixture(s)" throughout the GHS. To remove any ambiguity on the use of this term, the informal group proposes that the definition of "chemical" be clarified in the GHS to identify that "chemical(s)" means "substance(s)" or "mixture(s)". The group also discussed whether the term "chemical" should be revised to "substance(s)" or "mixture(s)", as

² Ref. 1: UN/SCEGHS/12/INF.12 (CEFIC); Ref. 2: UN/SCEGHS/13/INF.6 "Pilot program to test mixtures classification criteria" (USA); Ref.3: UN/SCEGHS/14/INF.24 (European Commission); Ref. 4: UN/SCEGHS/14/INF.15 ("OECD workshop on the application of the GHS classification criteria to HPVC"); Ref. 5: UN/SCEGHS/14/INF.17 (Germany); Ref.6: UN/SCEGHS/11/INF.12 ("Correspondence group on the building block approach"); Ref.7: UN/SCEGHS/11/INF.20 (France); Ref.8: UN/SCEGHS/14/INF.16 (UNITAR); Ref.9: UN/SCEGHS/13/INF.10 (South Africa).

appropriate, throughout the GHS, but there was not consensus on this issue, as not all members of the group considered that such changes were necessary.

The Sub-Committee is invited to agree to the addition of a definition for “chemical(s)”, and to consider the changes in text in the separate proposal from the Secretariat.

Issue 1.3: The informal group considers that the term “endpoint” is generally used in the GHS synonymous with “hazard class” but there are examples where the term is taken to mean a specific adverse effect and not necessarily a GHS hazard class.

The informal group proposes that this is not a priority issue for the Sub-Committee, but notes that the informal group may bring specific proposals forward to the Sub-Committee for their consideration to address inconsistent use of the terms.

Issue 1.4: The informal group proposes that definitions for the terms “no data available”, “not applicable” and “not classified” would be useful, as difficulties may be encountered in their interpretation which might have an impact on classification. For example, chemicals may be “not classified” either because there are no data upon which to base a classification, or there are sufficient data to demonstrate that chemical does not meet the criteria for classification (e.g., an LD₅₀ with an LD₅₀ higher than 5000 mg/kg).

The Sub-Committee is invited to agree that text changes in the GHS be brought back for their consideration by the informal group in a separate paper at a later date.

Issue 1.5: Paragraph 3.1.3.6.2.3 provides the formulae for the ATE when > 10 % of ingredients are of unknown toxicity. As there is a difference regarding which formula to be used, clarification of the terms “known” or “unknown” would be useful.

The informal group proposes that the Sub-Committee agree that text changes in the GHS to be brought back for their consideration in a separate paper at a later date.

Alternatively, paragraph 3.1.3.6.2.2 (relating to classification of mixtures) states:

“In the event than an ingredient without any useable information at all is used in a mixture at a concentration of $\geq 1\%$, it is concluded that the mixture cannot be attributed a definitive acute toxicity estimate. In this situation the mixture should be classified on the basis of known ingredients only....”.

On that basis, an ingredient of unknown toxicity is one “without any useable information for classification”. The Sub-Committee should consider whether this is a suitable definition of the term “unknown” to address this issue.

Issue 1.6: The informal group proposes that, for consistency, the Sub-Committee agrees that the more commonly used term “structure-activity relationship” should replace the occasional use of the term “structure-property relationship” in the GHS. The informal group notes that the term “structure-property relationship” is only used in Chapter 1.2 (Definitions and abbreviations), Chapter 3.2 (Skin Corrosion/Irritation) and Chapter 3.3

(Serious eye damage/Eye irritation), and that the issue can be addressed with the proposed revision of chapters 3.2 and 3.3 (see below), if agreed by the Sub-Committee.

Issue 1.7: The informal group proposes that the issue of definitions of “packaging” and “packages”, and the consistency between the transport and GHS definitions, be addressed by the informal correspondence group on labelling of very small packagings.

4.2 *Issues relating to the classification of mixtures*

Issue 2.1: The informal group proposes that the issue of clarity regarding the tiered approach for the application of bridging principles is being addressed by the correspondence group on classification of mixtures.

Issue 2.2: The informal group proposes that the issue of clarity for the conditions necessary for use of the bridging principles has been addressed by the correspondence group on classification of mixtures.

Issue 2.3: The informal group proposes that the use of descriptors for the bridging principles for “Interpolation within one toxicity category” and “Substantial similar mixtures” have been addressed by clarifying text developed by the correspondence group on classification of mixtures.

4.3 *Issues relating to specific hazard classes*

(a) Acute toxicity

Issue 3.1: The informal group proposes that the issue relating to routes of exposure for classification of mixtures be addressed by the correspondence group on classification of mixtures.

Issue 3.2: The informal group proposes that the issue relating to classification of mixtures using the dilution or cATpe approach be addressed by the correspondence group on classification of mixtures.

Issue 3.3: The informal group noted that, for mixtures, paragraph 3.1.3.6.2.1 (a) allows extrapolation between oral, dermal and inhalation acute toxicity estimates. In contrast, this possibility is not included in the criteria for substances.

The group generally considered that if the Sub-Committee wished to clarify, in the GHS, that similar extrapolation was also possible for substances, a proposal could be brought back to the Sub-Committee at a later date, but that it was not a priority at this time.

Relating to the same paragraph in the GHS, the informal group also considered that guidance would be useful to explain how extrapolation between oral, dermal and inhalation acute toxicity estimates could be undertaken when data are lacking for an ingredient in a mixture. As this process may require considerable expert judgement,

the development of such guidance could be complex and time consuming, and the informal group does not propose that such guidance be developed as a priority at this time. However, guidance material may be developed at the regional or national level, at which time the Sub-Committee should consider whether that material is useful as GHS guidance material.

Issue 3.4: The informal group proposes that the issue of converted acute toxicity point estimates has been addressed at the fifteenth session of the Sub-Committee.

(b) Skin corrosion/irritation and serious eye damage/eye irritation

Issues 3.5 to 3.12: The informal group considers that the review of Chapters 3.2 and 3.3 is a priority for the GHS, and that a review of these Chapters includes consideration of the issues raised in UN/SCEGHS/15/INF.25 and UN/SCEGHS/15/INF.5, as well as other issues identified during the review process.

The issues identified in those informal papers are mainly editorial in nature. However, some of the issues may prove to be more technical or substantive in nature, including Issue 3.7 (flow diagram 3.2.1 indicates that a negative response in a validated *in vitro* test requires *in vivo* testing - consider the need for *in vivo* testing should depend on whether the *in vitro* test can reliably identify non-corrosives/irritants or not) and 3.10 (Step 1c in flow diagram 3.3.1 for serious eye damage/eye irritation allows for classification in Cat 2 if substance is a skin irritant.).

Informal group members have identified that it is important that any revision of the chapters provides a balance between weight of evidence approaches and tiered testing strategies, and is consistent with the previously agreed principles of harmonisation. The informal group discussed options for the Sub-Committee for a review of the Chapters, including:

- (i) Referring the work to the OECD as the focal point, and asking that the work be undertaken to review the chapters;
- (ii) Refer the review of the chapters to the informal working group on implementation for the next biennium;
- (iii) Refer the review to an informal group specific for the purpose of the revision of the chapters,

The informal group considered that work to revise the chapters should be done in a timely manner, given the priority for the review of these chapters and to assist in implementation of the GHS. The informal group considers that, in the case of an editorial revision of the chapters undertaken under options (i) or (ii) above, with proposed changes to the GHS being referred to the Sub-Committee for decision in either option, the revision could be completed within the 2009-2010 biennium. A number of Sub-Committee members have expressed interest in working as an informal group to revise the chapters, and there has been an offer to lead the project.

Undertaking the revision by using an informal group was considered to be the more effective and efficient method for conducting the revision.

The informal group also considered that, should the revision highlight technical or complex issues that would result in more substantive changes to the GHS, the Sub-Committee should refer the issue to the OECD, as the relevant focal point, consistent with the process previously agreed by the Sub-Committee.

The informal group proposes that the Sub-Committee agree that the review of Chapters 3.2 and 3.3 be undertaken in the 2009-2010 biennium, and agree if the work should be overseen by the informal group on implementation (Option (ii)) or a separate informal group established for that specific purpose (Option (iii)). The informal group also proposes that if the review requires agreement on complex technical substantive changes to the GHS, it should be referred to the OECD in their role as the relevant focal point.

(iii) Respiratory or Skin sensitisation

Issue 3.13: The informal group considered whether it was necessary to clarify for respiratory or skin sensitisation that the classification should distinguish the route of exposure that may lead to sensitisation of the airways or the skin, respectively the informal group proposes that this is not a high priority but clarification would be useful. The European Commission originally raised this issue and has suggested that it could be resolved and clarified by the addition of a paragraph 3.4.1.5 that reads:

"3.4.1.5 The hazard class Respiratory or Skin Sensitisation is differentiated into:

- Respiratory sensitisation
- Skin sensitisation"

The informal group proposes that the Sub-Committee agrees that the issue can be resolved by the use of this, or modified, text.

(iv) Carcinogenicity, Mutagenicity and Reproductive toxicity

Issue 3.14: The informal group considered that the issue of inconsistency between cut-off tables and flow diagrams for Categories 1A and 2B was a low priority and does not propose that the Sub-Committee take any action at this time on this issue.

However, should the Sub-Committee agree that the correspondence group on the classification of mixtures should continue to address issues related to mixtures in the 2009-2010 biennium, the informal working group on implementation proposes that this issue could be considered by the correspondence group on the classification of mixtures as part of that work.

Issue 3.15: The informal group considered whether a change to the order of reporting the classification of mixtures for carcinogenicity, mutagenicity and reproductive toxicity (CMR) hazard classes within the GHS was necessary.

The informal group proposes that this is not a priority issue for the Sub-Committee at this time. If the issue proves to be an impediment to implementation of the GHS, based on experiences of Sub-Committee members, the Sub-Committee could reconsider changing the order of reporting the classification of mixtures for CMR hazard classes at that time.

Issue 3.16: The informal group proposes that no further work is needed at this time on how to label a substance or mixture which is both a Category 1 and Category 2 reproductive toxin (for an adverse effect on development and fertility respectively).

Issue 3.17: The informal group considers that the issue of clarity for classification for “effects on or via lactation” for a substance or mixture that is also classified for developmental and/or impaired fertility is not a priority at this time, and proposes that the Sub-Committee could consider changes to the text if a formal proposal is brought to the Sub-Committee at a later date.

Issue 3.18: The informal group considered that guidance to determine toxic levels of substances in breast milk would be helpful.

The informal group proposes that if scientifically supported material becomes available to allow the development of such guidance material, the Sub-Committee should decide at that time if a process for further work for the GHS is necessary.

(v) Specific target organ toxicity single exposure

Issue 3.19: The informal group considered that the issue of clarity for respiratory irritation and narcotic effects was discussed at the fifteenth session of the Sub-Committee and will consequently be addressed by the Sub-Committee.

The informal group proposes that further additional work on this issue is not required.

Issue 3.20: The informal group considered that this issue will be addressed by the correspondence group on classification of mixtures, and proposes that further additional work on this issue is not required at this time.

Issue 3.21: The informal group considered that this issue was not a priority and proposes that no further work is required at this time.

(vi) Aquatic environment

Issues 3.22 to 3.26: The informal group does not consider that the issues raised relating to the aquatic environment are a priority and proposes that no further work from the Sub-Committee is required at this time.

4.4 *Other issues*

(a) Packaging

The informal group considered that the issue of inner package labelling is not a priority and does not propose that the Sub-Committee work on this issue at this time;

(b) Monitoring different implementation timetables among countries

The informal group considered that monitoring of implementation activities would be best achieved through the information provided on the GHS website, maintained by the Secretariat, and proposes that the Sub-Committee encourages the provision of implementation information via this process;

(c) Monitoring legislative changes for GHS implementation

The informal group considered that the UN website, maintained by the Secretariat, was the appropriate vehicle for communicating and exchanging information on the legislative approaches being taken to implement the GHS, and proposes that the Sub-Committee agrees that the relevant information on the website be updated in a timely manner by members;

(d) Interpretation of the building block approach

The informal group considered that the issue of building block approaches had been addressed by the Sub-Committee, and proposes that further activity on this issue is not a priority for the Sub-Committee at this time. If implementation experiences demonstrate that the building block approach should be reconsidered, the Sub-Committee can make that decision at that time. Examples of the application of the building block approach should be provided under the monitoring of implementation activities via the GHS website, as discussed above;

(e) Training

The informal group considered that the issue of training material was being addressed by UNITAR, who are developing training courses (called Basic Course: Introduction to the GHS, and Advanced Course: Classifying Chemicals according to the GHS and Preparing GHS Labels and SDS). The informal group proposes that the Sub-Committee agree that the issue of training be dealt with by UNITAR, and that the GHS Capacity Building Library, maintained by UNITAR, be updated regularly to assist in training initiatives;

(f) Arrangements to minimise trade disruption

The informal group proposes that the Sub-Committee agree that the GHS website is the appropriate place to share information on implementation timetables, to

assist in the decision-making processes in other countries for the GHS and to maximise benefits to trade;

(g) International list for classifications

At its fifteenth session, the Sub-Committee welcomed the feedback provided by UNITAR on the proliferation of lists of classification of chemicals according to the GHS (UN/SCEGHS/15/INF.32) and considered that this might be an issue that will have to be addressed in the near future. The Sub-Committee asked the informal working group on implementation to consider this issue when defining the priorities for matters to be addressed by the group.

The informal group discussed this issue at its meeting in July 2008, and sought additional comments out of session from members. The two issues raised by UNITAR were:

- Why classifications were resulting in different findings, and whether there was a need for more guidance to ensure consistency in classifications; and
- Whether there was a need for an internationally- developed and maintained list.

With respect to the first issue raised by UNITAR, there has been no firm proposal for how to address issues of differing classifications, or whether such differences are a significant problem for the GHS. If implementation experience identifies that there are specific areas of the GHS that would benefit from revision and/or the development of guidance material, then the Sub-Committee could decide how best to address those issues at that time. The development and utilisation of the training material being developed may address such issues in the future. However, if differences in classification arise due to the use of expert scientific judgement in interpreting complex data, then it may not always be possible to resolve differences in classification.

With respect to the second issue raised by UNITAR, there was considerable support from members of the informal group for discussing the concept of an international or global list of chemicals, classified in accordance with the GHS. However, it was noted by all commentators that there would be a number of high level policy decisions to be made about such a list, including who would develop and maintain such a list, before the Sub-Committee could consider whether to proceed with a proposal for a list. Not all informal group members indicated support for a global classification list. Some countries have a mandated classification list, and would welcome some international consistency for classification. Some countries do not have a system that uses a classification list, and other countries have lists but the classification in the list is not mandated, and so a global list could cause issues at the national level. There is no single clear position from NGOs on the need for an international list, in addition to the differences of views from government representatives. A detailed discussion on

this issue has not yet been held within the informal group or by the Sub-Committee.

Some of the questions listed below have been raised by members of the informal working group, but further discussion on this topic by the informal group will be necessary if a more detailed paper should be prepared for consideration by the Sub-Committee. It is proposed that the Sub-Committee agree that the implementation working group further develop a proposal for the consideration of the Sub-Committee for the December 2009 meeting.

- (i) Who would develop and maintain the list, and from where would the initial classifications for the list be sourced? What would be the resource implications for this development and maintenance?;
- (ii) What would be the scope of the list, at least initially? Would it be a “core” list of high production volume (HPV) chemicals, for example? Who would decide on the “core” list? Such an approach may have benefits, particularly to developing economies;
- (iii) Would the aim be to develop a comprehensive list, or as complete a list as possible, in a stepwise manner over a number of years?;
- (iv) Would the focus be on the hazard classes covered, for example, by transport (physical hazards and acute toxicity) so there would be consistency between transport and supply and use sectors?;
- (v) What would be the process for checking the veracity of the classifications? And if there were classification disputes, how would such disputes be settled? Would it be necessary to establish a “competent authorities panel” to make classification decisions?;
- (vi) Given that the GHS is non-binding, what would be the status of the list? If some countries mandated the list, but others didn't, where would the global benefits be? Would it have the same status as the classification list in the UN Model Regulations on the transport of dangerous goods?;
- (vii) Would each country be required to undertake a cost/benefit analysis before deciding to use a global list? If individual countries could not justify benefits, the use of the list might be variable and fragmented.
