
**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 Transport of
Dangerous Goods**

Forty-first session

Geneva, 25 June – 4 July

Item 10(a) of the provisional agenda

**Issues relating to GHS and labelling of chemicals:
corrosivity criteria**

**Sub-Committee of Experts on the Globally Harmonized
System of Classification and Labelling of Chemicals
Twenty-third session**

Geneva, 4-6 July 2012

Item 4 (c) of the provisional agenda

**Cooperation with other bodies or international
organizations: corrosivity criteria**

**Update on the work of the joint informal correspondence
group on corrosivity classification**

**Transmitted by the expert from the United Kingdom on behalf of the
joint informal correspondence group**

Purpose of document

1. This document summarises the current status of work within the informal joint TDG-GHS working group on corrosivity criteria. It also suggests some issues for discussion at the meeting of the joint working group to take place in room XII on 4th July 2012 from 14:30-17:30. A suggested agenda for the meeting is also provided.

Background

2. The terms of reference of the joint working group were agreed at the 20th session of the GHS Subcommittee (December 2010) and are as follows:

- (a) Verify the definition of “skin destruction” as mentioned in the Model Regulations on the transport of dangerous goods complemented with reference to the Organisation for Economic Co-operation and development (OECD) test guidelines. If the definition is not aligned with paragraph 3.2.2.4.1 in Chapter 3.2 of the GHS, propose appropriate improvements.
- (b) Identify and analyse the discrepancies between assignment to subcategories 1A, 1B and 1C, based on in vitro and in vivo testing and alternative approaches (bridging principles, mixtures calculations, pH...)
- (c) Identify differences in assignment to categories in lists provided by different regulations and guidance documents for a few representative common substances. Analyse the underlying data and origin of these differences and use these results for the work under paragraphs a, b and d.
- (d) Check the way OECD guidelines are referenced and their relevance.

(e) Report findings and make recommendations that meet the need of all sectors with the aim of achieving consistent classification outcomes for skin corrosivity.

3. Since the work of the joint informal working group was initiated a number of documents have been submitted containing contributions to the group's work. These are summarised below:

21st Session (June 2011):

- **UN/SCEGHS/21/INF.6 – UN/SCETDG/39/INF.14** - (United Kingdom) Update on work of the informal joint correspondence group on corrosivity criteria.

22nd Session (December 2011):

- **UN/SCEGHS/22/INF.12 - UN/SCETDG/INF.9** (ICCA) Harmonization of classification criteria for transport with the classification criteria of the GHS for substances and mixtures corrosive to skin
- **UN/SCEGHS/22/INF.13 - UN/SCETDG/40/INF.10** (ICCA) Harmonization of classification criteria for transport with the classification criteria of the GHS for substances and mixtures corrosive to skin
- **UN/SCEGHS/22/INF.17 - UN/SCETDG/40/INF.30** - (ICPP) Harmonization of classification criteria for transport with the classification criteria of the GHS for substances and mixtures corrosive to skin
- **UN/SCEGHS/22/INF.18 - UN/SCETDG/40/INF.33** (United Kingdom) Work of the joint correspondence group on corrosivity criteria
- **UN/SCEGHS/22/INF.18/Add.1 - UN/SCETDG/40/INF.33/Add.1** - (United Kingdom) Work of the joint correspondence group on corrosivity criteria: agenda for the meeting and additional information

23rd Session (July 2012):

- **UN/SCEGHS/23/INF.11 - UN/SCETDG/41/INF.27** (CEFIC) - Harmonisation of the skin corrosion classification criteria in the UN Model Regulations with those in GHS.
- **UN/SCETDG/41/INF.28** (CEFIC) – Adoption of expert judgement and weight of evidence procedures into the UN Model Regulations.
- **UN/SCETDG/41/INF.40 - UN/SCEGHS/23/INF.13** (United Kingdom) – Contribution to the work of the joint informal correspondence group on corrosivity classification – approaches to classifying corrosive mixtures under Class 8.
- **UN/SCETDG/41/INF.53 – UN/SCEGHS/23/INF.18** – (United Kingdom) Corrosivity classification – Assignment of categories packing groups.

4. A face-to-face meeting of the joint informal correspondence group was held between the UNSCETDG and UNSCEGHS sessions in December 2010. The outcomes of discussions at that meeting are summarised in document **UN/SCEGHS/22/INF.28/Rev.1**.

Summary of progress to date under each workstream

5. This section summarises the main issues and contributions to date under each of the workstreams, and proposes some issues for discussion at the face-to-face meeting.

Workstream a) Verify the definition of “skin destruction” as mentioned in the Model Regulations on the transport of dangerous goods complemented with reference to the Organisation for Economic Co-operation and development (OECD) test guidelines. If the definition is not aligned with paragraph 3.2.2.4.1 in Chapter 3.2 of the GHS, propose appropriate improvements.

6. The informal correspondence group has previously noted that GHS chapter 3.2 and the UN Model Regulations use slightly different terminology to characterize the definition of and criteria for skin corrosion. In summary, the UN Model Regulations refer in the definition of a Class 8 substance, to ‘Substances that which, by chemical action, will cause severe damage when in contact with living tissue...’ and the criteria for assigning substances to packing groups I, II and III refer to ‘substances that cause full thickness destruction of intact skin tissue’ within certain observation periods. However, the GHS defines skin corrosion slightly differently with reference to ‘irreversible damage to the skin; namely, visible necrosis through the epidermis and into the dermis’ following the application of a test substance for up to 4 hours, together with a further list of typical features of corrosive reactions. The situation was described in more detail in UN/SCEGHS/21/INF.6 – UN/SCETDG/39/INF.14.

7. Experts at the joint meeting of the informal working group in December 2011 agreed that despite the different wording used, both definitions lead to the same interpretation, since they were both linked to the results obtained using the same OECD Test Guidelines. However, most experts considered that the text in the UN Model Regulations should be aligned with that of the GHS.

8. It would therefore be appropriate to develop a proposal to amend the UN Model Regulations to align with the GHS definition of skin corrosion. However, as further changes to the text in Chapter 2.8 of the Model Regulations are still under discussion, the expert from the UK proposes that further discussion of this point is postponed until the extent of further changes is clearer.

Suggestion issues for discussion: None at present.

Workstream b) Identify and analyse the discrepancies between assignment to subcategories 1A, 1B and 1C, based on in vitro and in vivo testing and alternative approaches (bridging principles, mixtures calculations, pH...)

9. The informal working group has previously noted that while the UN Model Regulations classify for skin corrosion based on human experience and testing, the GHS contains additional rules and principles for classifying for skin corrosion that are not currently referenced in the Model Regulations. This potentially gives rise to discrepancies between classifications based on the transport criteria and those derived using GHS criteria.

10. Document UN/SCETDG/40/INF.10 – UN/SCEGHS/22/INF.13 (submitted for the last GHS/TDG sessions by ICCA) set out an analysis of the classification methods that exist in GHS that are not currently adopted in the UN Model Regulations. ICCA’s paper noted that TDG and GHS classifications are harmonised when based directly on test data according to OECD Test Guidelines 404 and 435, for both substances and mixtures, if relevant data are available. However other GHS methods are not directly adopted in the UN Model Regulations. These include the principle of classification

based on human experience and expert judgment, rules for classification of a mixture based on the ingredient substances (additivity approach), classification based on ingredients using a non-additivity approach (including use of pH), and the GHS's tiered approach to the sequence and application of GHS criteria. ICCA's paper makes a proposal to adopt the GHS expert judgment and additivity rules into the UN Model Regulations, together with a modified non-additivity rule into Chapter 2.8 of the GHS.

11. Although the UN Model Regulations do not refer explicitly to alternative methods to testing for classification purposes, it was noted at the face-to-face discussion in December 2011 that they nevertheless allow use of such methods (e.g. use of bridging principles) and that from a legal point of view this was being allowed by competent authorities provided that the classification derived from these alternative methods did not lower the level of safety. It was suggested during that discussion that an amendment to Chapter 2.8 of the Model Regulations might be needed if the option of using such methods was not clear.

12. Document UN/SCETDG/41/INF.27 – UN/SCEGHS/23/INF.11 (submitted to this session by CEFIC) makes a proposal to incorporate the GHS criteria and alternative methods into the UN Model Regulations. CEFIC's proposal is based largely on sections of Chapter 3.2 of the GHS, however it also suggests additional text (not derived from GHS) in Chapter 2.8 of the UN Model Regulations to cover the case where the additivity approach does not apply. CEFIC's paper UN/SCETDG/41/INF.28 also makes a proposal to adopt the GHS expert judgment and weight of evidence procedures into the UN Model Regulations, however CEFIC proposes that this is included in the introductory text in Chapter 2.0 of the Model Regulations as it applies across hazard classes.

13. ICCA's and CEFIC's papers bring out that while GHS sets out detailed rules and principles for classifying mixtures as corrosive, the UN Model Regulations do not currently give such detailed rules. The expert from the UK has therefore gathered some information from expert practitioners on how in practice mixtures are classified as corrosive under the Model Regulations (in the UK). This information is set out in document UN/SCETDG/41/INF.40 – UN/SCEGHS/23/INF.13. One of the notable conclusions from the information submitted by the expert from the UK is that (based on the information obtained) mixtures are typically classified for transport based on expert judgment with reference to information in the Dangerous Goods List and information from the previous EU regulatory regime, rather than the current GHS mixtures rules.

Suggested points for discussion:

- Comments on CEFIC's proposals for amendment to the UN Model Regulations including the proposals:
 - In INF.27/INF.11 to adopt text based on the GHS into Chapter 2.8 of the UN Model Regulations.
 - In INF.27/INF.11 for new text for Chapter 2.8 of the UN Model Regulations referring to the non-additivity approach.
 - In UN/SCETDG/41/INF.28 to introduce text on expert judgment and weight of evidence into the UN Model Regulations.
- Does the information submitted by the expert from the UK on current practices for classification of mixtures for transport correspond to what happens elsewhere?
- How should this workstream now be taken forward?

Workstream c): Identify differences in assignment to categories in lists provided by different regulations and guidance documents for a few representative common substances. Analyse the underlying data and origin of these differences and use these results for the work under paragraphs a, b and d.

14. A considerable amount of work has been done by the joint informal group so far on this workstream, leading to a picture of the extent of differences and discrepancies between classifications in different official lists and guidance documents.

15. Documents UN/SCEGHS/21/INF.6-UN/SCETDG/39/INF.14 (UK on behalf of the joint informal group) and UN/SCETDG/40/INF.9 – UN/SCEGHS/22/INF.12 (ICCA) give an overview of the relationship between classifications in the Dangerous Goods List and Annex VI of Regulation (EC) No 1272/2008 – the ‘CLP Regulation’ – which gives the EU list of mandatory ‘harmonised’ classifications based on the GHS. Annex IV of UN/SCEGHS/21/INF.6-UN/SCETDG/39/INF.14 (contributed by the Netherlands) also compares classifications in these lists of certain substances with the CLP Inventory of industry self-classifications and the GESAMP Composite list EHS 47/9.

16. ICCA note that of the 217 substances classified in both CLP Annex VI and the DGL for corrosivity, 94 have the same PG/ corrosivity sub-categorisation, though 26 have a stricter PG in the DGL and 70 have a less strict PG. However it as also been noted that these comparisons have certain limitations. For example because many CLP classifications were derived from a translation table they may not correspond to the result of applying the GHS criteria directly to the same substances.

17. Several experts presented case studies and other information for the December 2011 session (summarised in UN/SCEGHS/22/INF.18 – UN/SCETDG/40/INF.33 and Add.1 to this document), which gave further insight into the reasons for differing classifications. In the case studies and subsequent discussion a number of reasons were identified for how such discrepancies were likely to have arisen, including different datasets used to classify, different interpretations of the data, different application of the classification criteria, as well as cases where classifications were based on human experience only or where classifications had been ‘grandfathered’ and not revisited based on recent data.

18. However it has also come to light that historical information on the evidence behind classifications in lists was very difficult to locate and none of the case studies carried out so far has given a clear picture of the reasons in that case why discrepant classifications have arisen.

Suggested points for discussion:

- Are there further lists that should be analysed, or additional sources of information where more information or data could be obtained to explain the sources of divergent classifications? Should further work be carried out to locate such information? Is there value in further case studies?
- What action, if any, should be taken in response to the divergent classifications that currently exist in different official lists?
- How should this workstream now be taken forward?

Workstream d) Check the way OECD guidelines are referenced and their relevance

19. It was noted in UN/SCEGHS/21/INF.6 – UN/SCETDG/39/INF.14 that relevant OECD test guidelines are referenced in a slightly different way in Chapter 2.8 of the Model Regulations and GHS Chapter 3.2.

20. By way of summary, in the UN Model Regulations, OECD test guidelines are referenced in paragraph 2.8.2.4:

“In assigning the packing group to a substance in accordance with 2.8.2.2, account shall be taken of human experience in instances of accidental exposure. In the absence of human experience the grouping shall be based on data obtained from experiments in accordance with OECD Test Guideline 404 [1] or 435 [2]. A substance which is determined not to be corrosive in accordance with OECD Test Guideline 430 [3] or 431 [4] may be considered not to be corrosive to skin for the purposes of these Regulations without further testing.”

21. The GHS refers to OECD test methods for corrosion only as a note to the tiered testing and evaluation strategy of skin corrosion and irritation potential in Figure 3.2.1 of Chapter 3.2. Step 5 in this tiered testing strategy is, ‘Valid and accepted *in vitro* skin corrosion test (d)’ and note (d) states that ‘*Examples of internationally accepted validated in vitro test methods for skin corrosion are OECD Test Guidelines 430 and 431*’.

22. There are therefore some differences in the way that OECD Test Guidelines are referred to in GHS and the Model Regulations, including:

(a) The UN Model Regulations makes prescriptive references to OECD Test Guidelines whereas GHS refers to them only as examples of internationally validated test methods.

(b) The UN Model Regulations make a specific reference to non-classification in case a substance is determined not to be corrosive in accordance with OECD Test Guideline 430 and 431, whereas GHS Chapter 3.2 does not contain such a specific reference.

23. Two further points are worth noting:

(a) The latest text under consideration within the editorial review of Chapters 3.2 and 3.3 of the GHS makes an updated reference to OECD test methods, stating that “examples of internationally accepted, validated test methods for skin corrosion include OECD Test Guideline 430 (Transcutaneous Electrical Resistance Test (TER)), 431 (Human Skin Model Test), and 435 (Membrane Barrier Test Method).” However, the review of Chapters 3.2 and 3.3 of GHS is still ongoing and this revised text has not yet been adopted by the GHS Subcommittee and may change further.

(b) A new draft version of OECD Test Guideline 431 (Human Skin Model Test) is currently under development at OECD. A draft version is available on the OECD website at:

http://www.oecd.org/document/55/0,3746,en_2649_37465_2349687_1_1_1_37465,00.html. The test guideline may allow further subcategorisation of corrosive substances and mixtures into 3 categories: Category 1A corrosives, Category 1B/1C corrosives and non-corrosives.

Suggested points for discussion:

- Are the differences in the way that OECD test methods are referenced in GHS and the UN Model Regulations significant? If so, should any action be taken to address this?

- Are there any other issues with the way in which OECD Test Guidelines are referenced in GHS and the UN Model Regulations?
- How should this workstream now be taken forward?

Workstream e: Report findings and make recommendations that meet the need of all sectors with the aim of achieving consistent classification outcomes for skin corrosivity

24. Apart from the specific points for discussion listed above, the outcome of the discussion at the December 2011 face-to-face meeting indicated that many experts considered that:

- (a) Hazard classification for transport purposes should be dissociated from transport conditions (i.e. assignment of packing groups); and,
- (b) The aspiration was one classification for a substance or mixture for both transport and supply/use and based on hazard, with Packing Groups for transport assigned on the basis of hazard and risk.

25. One option would be to explain this approach in Chapter 2.0 of the UN Model Regulations, where the general principles of classification are introduced. This would also make clear that the same approach would apply to other Chapters within the UN Model Regulations.

26. An example of how to take forward assignment to Packing Groups based on hazard and risk is tabled for discussion by the expert from the United Kingdom in informal paper UN/SCETDG/41/INF.53 – UN/SCEGHS/23/INF.18.

Suggested points for discussion:

- Comments on the proposals in the UK INF paper.
- Is it appropriate to include further text in Chapter 2.0 of the UN Model Regulations explaining the above two-stage approach (single hazard classification for transport and supply based on hazard; Packing Group assigned based on hazard and risk?) If so, what should be the content of this text and who should prepare a draft for discussion?
- What other actions should be undertaken to move forward?

Proposed agenda for the meeting of the joint informal working group on corrosivity criteria, 4th July 2012 14:30 - 17:30 (Room XII)

1. Welcome and introductory remarks
2. Opportunity for general discussion and comments on progress to date
3. Discussion on progress within each workstream of the Working Group's Terms of Reference, including the suggested discussion points in Section C of this document:
 - (a) Verify the definition of "skin destruction" as mentioned in the Model Regulations on the transport of dangerous goods complemented with reference to the Organisation for Economic Co-operation and development (OECD) test guidelines. If the definition is not aligned with paragraph 3.2.2.4.1 in Chapter 3.2 of the GHS, propose appropriate improvements.

- (b) Identify and analyse the discrepancies between assignment to subcategories 1A, 1B and 1C, based on in vitro and in vivo testing and alternative approaches (bridging principles, mixtures calculations, pH...)

 - (c) Identify differences in assignment to categories in lists provided by different regulations and guidance documents for a few representative common substances. Analyse the underlying data and origin of these differences and use these results for the work under paragraphs a, b and d.

 - (d) Check the way OECD guidelines are referenced and their relevance.

 - (e) Report findings and make recommendations that meet the need of all sectors with the aim of achieving consistent classification outcomes for skin corrosivity.
- 4. Summary of next steps
 - 5. Any other business
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