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Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals

31 March 2014

Sub-Committee of Experts on the Transport of Dangerous Goods

Forty-fifth session

Geneva, 23 June – 2 July 2014

Item 11 (g) of the provisional agenda

Issues relating to the Globally Harmonized System of Classification and Labelling of Chemicals: corrosivity criteria

Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals

Twenty-seventh session

Geneva, 2 – 4 July 2014

Item 3 (c) of the provisional agenda

Classification criteria and hazard communication: Work of the TDG-GHS working group on corrosivity criteria

Addendum to the update on the work of the intersessional informal joint working group on corrosivity criteria

Transmitted by the expert of the Netherlands on behalf of the intersessional informal joint TDG-GHS working group on corrosivity criteria

Introduction

1. Reference is made to documents ST/SG/AC.10/C.3/2014/25 and ST/SG/AC.10/C.4/2014/3.

2. The intersessional joint GHS-TDG working group charged with the continuation of work on the development of a proposal on the basis of the outline present in paragraph 8 of INF.27 (GHS, 26th session) held a teleconference on 30 January 2014 and again on 27 February 2014 under the chairmanship of the Netherlands.

3. Outside the scope of the teleconferences were discussions on revisions of named entries on the (DGL) as any revisions to named entries on the Dangerous Goods List should follow already established procedures. At this stage in the process, there is no intention to change the named entries on the DGL. Also outside the scope of the discussion were issues associated with the implementation of GHS into supply and use legislation in the European Union (such as translation of classifications done under the European Directives 67/548/EEC and 1999/45/EC to classifications under Regulation 1272/2008) as this is a topic for discussions on global classification lists.

4. Annex 1 to this informal document contains the minutes of the first teleconference of the intersessional joint working group that was held on 30 January 2014.

5. Annex 2 to this information document contains the minutes of the second teleconference of the intersessional joint working group that was held on 27 February 2014.

Annex I

Minutes of the 1st teleconference on corrosivity 30 January 2014

v14.02.07final

Participants

Caroline Reid (Australia); Venessa Thelan (Australia); Renata Krätke (Germany); Joke Herremans (Netherlands); Martijn Beekman (Netherlands); Sjöfn Gunnarsdóttir (Netherlands); Maureen Ruskin (USA); Paul Brigandi (USA); Arne Bale (United Kingdom); Robin Foster (United Kingdom); Maurits-Jan Prinz (European Union); Sabine Böhmert (European Union); Eva Kessler (CEFIC); Fiona Woudenberg (AkzoNobel); Liz Anderson (RPMASA).

1. Start of the meeting, agreement on the Agenda

The agenda was adopted without changes.

2. Agree on the criteria for a workable solution

1. The aim of the teleconference was to examine the "other criteria" mentioned in the table from informal document INF.27. Under which circumstances are "other criteria" necessary and can we describe these "other criteria"?

Table 1

GHS hazard class	**Transport**		**Additional criteria and considerations**	**Transport conditions**
1A	8 A	Other criteria*	PG I based on "other criteria"	Special packing provisions, limited and excepted quantities and downstream transport provisions
			PG II	
1B	8 B		PG II	
1C	8 C		PG III	
1**	8		PG II	

2. Previous discussions and reactions received before the teleconference indicated that the implementation of GHS criteria into the Model Regulations must fulfill certain conditions. From these reactions, NL distilled criteria that a workable solution should fulfill. With some minor changes, there was general agreement on the criteria with the understanding that they do not comprise a complete list and other criteria may also be relevant.

3. The criteria as agreed upon:

(a) No change in the level of safety for transport;

(b) The transport conditions will not become more severe;

(c) No direct change in the classifications/PG of substances listed by name on the Dangerous Goods List;

(d) Hazard classification criteria for skin corrosive are consistent between GHS and transport sectors;

(e) The welfare of experimental animals is a concern. This ethical concern includes not only the alleviation of stress and suffering but also, in some countries, the use and consumption of test animals. Where possible and appropriate, tests and experiments that do not require the use of live animals are preferred to those using sentient live experimental animals.

4. It was clarified that under criteria (c), the focus of the current discussion lies on substances self-classified into not otherwise specified (n.o.s.) entries. The transport classification of named substances on the DGL will not change by the change of criteria. For revision of transport classification of named entries, existing procedures should be used. It was further clarified that the classification criteria referred to in criteria (d) are the hazard classification criteria. Moreover, the suggestion of a participant to use existing text from GHS section 1.3.2.4.6 in criteria (e) was followed.

3. Identify different pathways to GHS 1A

5. Different types of information can result in the classification GHS Skin Corr 1A. To assess whether the type of information used for classification influences the necessity to use "other criteria" to assign PG, Table 2 was used to illustrate which classification methods may result in a classification into GHS Skin Corr 1A. The group agreed that classification into 1A is possible using OECD 404, OECD 435, OECD 432, bridging principles, assimilation/QSAR/Read-across and additivity as shown in Table 2. It was noted that the methods that can classify into GHS Skin Corr 1A might not be able to do so in all cases. In this teleconference, the discussion focused on those cases where the substance/mixture is classified into GHS Skin Corr 1A based on the methods mentioned.

6. Germany also pointed out that OECD is developing a guidance document on integrated approaches to testing and assessment on skin corrosion and irritation. This document provides guidance on how to integrate information for decision-making (including decisions on the need for further testing) and when integrating all existing and generated information on the corrosive and irritant hazard potential of chemicals for final decisions for classification and labelling. (link http://www.oecd.org/env/ehs/testing/2013-12-18_IATA_GD_Skin_8th_draft2(CES)_CLEAN.pdf)

Table 2

Method	**Sub-classification into GHS 1A is possible?**
In vivo (OECD 404)	Yes
In vitro (OECD 435)	Yes
In vitro (OECD 431)	Yes, into 1A and 1B+1C when appropriate method is used
Bridging principles	Yes
"Assimilation", QSAR, Read-across	Yes
Additivity	Yes
In vitro (OECD 431)	No, if the inappropriate method is used
In vitro (OECD 430)	No
Non-additivity	No
pH	No
Human accident data	No

4. Identify pathways to GHS Skin Corr 1A were “other criteria” are needed to distinguish between PG I and PG II

7. The group discussed for which methods that do allow sub-classification into GHS Skin Corr 1A, are additional criteria needed for assignment of PG I.

8. The majority of participants expressed the view that when a substance/mixture is classified to GHS Skin Corr 1A based on results from OECD 404 in vivo tests, no additional criteria are needed to assign PG I. It was agreed that this is in line with the current criteria in the Model Regulations. Using additional criteria to assign PG I to substances classified as Skin Corr 1A based on OECD 404 results would be considered to change the level of safety. It should be kept in mind that in case information such as human experience or other considerations suggest that a lower packing group may be acceptable, it is possible to submit the information and a proposal to the TDG Sub-Committee that will assess whether a lower packing group and a new named entry are justified. Developing criteria for these exceptional cases will not be a part of the current work packet.

9. The majority of participants expressed the view (based on similar reasoning) that when a substance/mixture is classified as GHS Skin Corr 1A based on results from the in vitro tests in OECD 435 and 431, no additional criteria are needed to assign PG I.

10. Furthermore, when a substance/mixture is classified into GHS Skin Corr 1A based on the results from the bridging principles and assimilation/QSARs/read-across, no additional criteria are needed since these methods are based on extrapolations from test data.

11. In case GHS Skin Corr is 1A is the result of the application of the additivity method the majority of the participants shared the opinion that additional tools and/or criteria are necessary to discriminate between PG I and PGII as the additivity method was considered conservative. Several ideas for tools and criteria were proposed and briefly discussed. Suggestions included:

- The current "cut-off" criteria of 5% was a regulatory decision and a possible contribution to a solution would be deleting the note to table 3.2.3 (Chapter 3.2 of the GHS);
- Additional generic and/or specific concentration limits to assign PG, drawing on information from the DGL;
- Additional additivity criteria to assign PG, based on information from the DGL (similar to proposal as distributed by CEFIC).

12. For the situation where GHS Skin Corr is 1A is the result of the application of the additivity method, the group discussed the different approaches to distinguish between PG I and PG II. Two options are possible: assign PG I with a possibility to downgrade to PG II, or assign PG II with a possibility to upgrade to PG I. In both cases, information is needed for the proper assignment. It was pointed out that assignment to PG I with a possibility for downgrading would provide greater incentive to generate appropriate background information. On the other hand, as additivity was considered a worst-case classification, assignment to PG II with a possibility to upgrade might be sufficient.

13. The group also noted that the additivity method is primarily used for self-classification of mixtures. Any solution must therefore be usable to those doing the self-classification. The current practice of self-classification and assignment of PG in the transport sector might need to be considered in more detail to see whether the discrepancy between the number of substances classified as GHS Skin Corr 1A and Class 8 PG I is solely due to the additivity criteria. The UK pointed out that their paper on existing

corrosivity classification practices could provide valuable information for this purpose (see INF.40 (TDG, 41st session) & INF14 (GHS, 23rd session) : link http://www.unece.org/fileadmin/DAM/trans/doc/2012/dgac10c3/UN-SCETDG-41-INF40e.pdf)

Table 3

Method	**Sub-classification into GHS 1A is possible?**	**Additional criteria needed for PG assignment of 1A chemicals?**
In vivo (OECD 404)	Yes	No additional criteria needed
In vitro (OECD 435)	Yes	No additional criteria needed
In vitro (OECD 431)	Yes, into 1A and 1B+1C when appropriate method is used	No additional criteria needed
Bridging principles	Yes	No additional criteria needed
"Assimilation", QSAR, Read-across	Yes	No additional criteria needed
Additivity	Yes	Additional criteria/tools needed

5. Assignment of PG when subclassification is not possible based on the available information on the substance/mixture (i.e. last row of the table)

Due to lack of time, this issue was not discussed.

6. Conclusions, next steps

The group agreed to hold another teleconference to discuss the additional criteria needed for the additivity method and agenda item 5. Because of this additional teleconference, the original schedule of activities needed adjusting. The new schedule is provided below.

Participants are invited to share ideas on the ‘other criteria’ before the next teleconference.

2014-02-27 Second teleconference on corrosivity criteria 13:00 (GMT+1) (**action members**)

2014-03-07 Report 2nd teleconference and draft WP sent to members (**action NL**)

2014-03-19 Deadline for reactions on the draft working paper **(action members)**

2014-03-28 Submission of working paper to secretariat (**action NL**)

7. Closure of the meeting

Annex II

Minutes of the 2nd teleconference on corrosivity, 27 February 2014

V20.03.04final

Participants

Caroline Reid (Australia); Venessa Thelan (Australia); Marie-Noelle Blaude (Belgium); Renata Krätke (Germany); Joke Herremans (Netherlands); Martijn Beekman (Netherlands); Sjöfn Gunnarsdóttir (Netherlands); Maureen Ruskin (United States of America); Paul Brigandi (United States of America); Deana Holmes (United States of America); Jennifer Lawless (United States of America); Shane Kelley (United States of America); Arne Bale United Kingdom; Robin Foster United Kingdom; Maurits-Jan Prinz (European Union); Sabine Böhmert (European Union); Timo Aaltonen (European Union); Katinka van der Jagt (European Union); Juergen Pagel (CEFIC); Gernot Knoth (CEFIC); Todd Strobel (CEFIC); Rene Moonen (CEFIC); Fiona Woudenberg (CEFIC).

1. Start of the meeting, agreement on the Agenda

The agenda was adopted without changes.

2. Adoption of the minutes of the first teleconference

1. The minutes of the 1st teleconference were adopted with two minor editorial changes:

- Under point 3, OECD 432 should be OECD 431.
- Under point 4, the word ‘substances’ should be replaced by “mixtures” in the sentence “The current practice of self-classification and assignment of PG in the transport sector might need to be considered in more detail to see whether the discrepancy between the number of ~~substances~~ mixtures classified as GHS Skin Corr 1A and Class 8 PG I is solely due to the additivity criteria.”

3. Discussion on “other criteria” which are needed to distinguish between PG I and PG II in the situation where GHS 1A is based on additivity

2. CEFIC remarked that the approach currently being discussed used the GHS classification to lead to the transport classification. However, it could also be argued that determining the PG is a parallel classification process to the GHS classification, with the two processes being based on the same criteria. This was especially important for transport since the GHS classification Skin Corr 1A did not in all cases result in Class 8 PG I. CEFIC suggested to revise the relation between the hazard information and packing group (i.e. the rationalized approach). The desired result would be a system for self-classification that takes into account the same criteria and the same risk-based aspects as were used to

determine the packing group for the named substances, and use that to classify all substance.

3. Others pointed out that Chapter 2.8 in the Model Regulations appears to already use different rationale for classifying named substances than n.o.s. entries: Classification of n.o.s. entries is based on criteria and results from testing whereas experience and other factors play a bigger role in the classification of named substances. Designing a new comprehensive rationale that encompasses the logic used to classify named substances would be difficult since the named substances have been classified and assigned a packing group on a case-by-case basis that could be challenging to rationalize. It will not be easy to find a uniform approach for all these entries, and a lot of information and time would be needed to design such a rationale. In addition, the rationale also needs to be flexible to allow for expert judgment and deviation from the rationale by the TDG Sub-Committee of Experts where appropriate. Creation of new named entries would still be a possibility if the data and experience suggested inappropriate packing group assignment using the criteria.

4. It was also noted that a distinction must be made between the use of classification criteria and classification results. By implementing the criteria, it was not the intention of this working group to change the PG assignment of substances already mentioned by name on the DGL. The focus of the current exercise was to connect the GHS hazard criteria to Class 8 without changing the rationale. Furthermore it was reemphasized that issues associated with the implementation of GHS into supply and use legislation in the European Union (such as classification of individual substances) are outside the scope of the discussions.

5. The participants of the teleconference agreed that the issue at stake was the classification of mixtures in cases where GHS Corr 1A is reached by using the additivity approach. The Chair introduced the discussion on the 'other criteria' with a short recap of the point of departure, illustrated with table 1 and 2.

Table 1

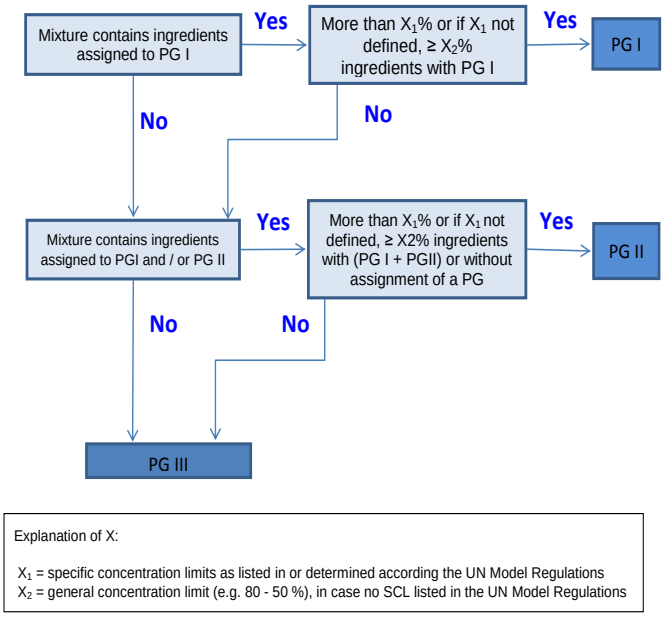
GHS hazard class	**Transport**		**Additional criteria and considerations**	**Transport conditions**
1A	8 A	Other criteria*	PGI based on "other criteria"	Special packing provisions, limited and excepted quantities and downstream transport provisions
			PG II	
1B	8 B		PG II	
1C	8 C		PG III	
1**	8		PG II	

Table 2

Method	**Sub-classification into GHS 1A is possible?**	**Additional criteria needed for PG assignment of 1A chemicals?**
In vivo (OECD 404)	Yes	No additional criteria needed
In vitro (OECD 435)	Yes	No additional criteria needed
In vitro (OECD 431)	Yes, into 1A and 1B+1C when appropriate method is used	No additional criteria needed
Bridging principles	Yes	No additional criteria needed
"Assimilation", QSAR, Read-across	Yes	No additional criteria needed
Additivity	Yes	Additional criteria needed

6. As concluded in the first teleconference additional criteria to assign a packaging group are needed in cases where the classification GHS Skin Corr 1A is reached by using the additivity method. Two approaches were considered. Firstly, criteria based on the PG of the ingredients of the mixture; secondly, criteria based on other properties of the mixture. For the criteria based on the PG of the ingredients Diagram 2 in CEFIC document "Corrosivity criteria Answer to RIVM 140120_final 17 02 2014" is the starting point of the discussion.

Diagram 2



7. The packing groups used in this scheme are the packing groups for the ingredients of the mixture. The ingredients can be named substances/mixtures and/or n.o.s. entries but in all cases, a packing group should be available (also for the n.o.s. entries). It was pointed out that diagram 2 is not used if the classification GHS Skin Corr 1A of the mixture is based on in vivo or in vitro testing, through use of the bridging principles or human accident data.

8. The variable X1 in the diagram denotes a specific threshold limit. Some entries on the DGL such as nitric acid, sulfuric acid and hydrazine have specific threshold limits. The specific threshold limits are described in the proper shipping name for the UN number. If such a limit exists, this limit is mandatory in the calculations. If there is no specific threshold listed on the DGL, then generic threshold limits will be used. This generic threshold is called X2 in the diagram. The numerical value of this generic threshold still needs to be determined. The number 50-80% in diagram 2 is derived by CEFIC based on information on available thresholds of substances already listed on the DGL.

9. The needs of industry for easy to use criteria and clarity on how to assign PG when there are no test data on the actual mixture are recognized. However, assurance is also needed that if diagram 2 is used, mixtures will not be assigned to a lower packing group than they would be based on test results. The likelihood of under-assignment of packing group will depend on the value of X2. Participants expressed the view that although this method would be used to reduce the number of mixtures assigned to PG I to maintain the current packing group ratios, assignment of PG should nevertheless be precautionary. A sufficient safety margin to prevent assigning a too-low packing group is needed while at the same time the current balance between PG I, II and III should be maintained. Australia noted that consignors that were consulted on the diagram expressed the view that if the

numerical value of X2 was appropriately chosen, assignment to a too low packing group using this diagram could be prevented.

10. It was noted that the current practice of transport classification and assignment of packing group is for many a black box where consignors use implicit expert judgment criteria, possibly by analogy to what is already listed in the DGL. Although we would like to know more about this black box and simulate that, the intention was not to invent a new system but try to use the existing systems with hazard information in line with GHS and a risk-based approach consistent with transport. Diagram 2 could provide a rule-based system for that black box and try to approximate what we have today.

11. There was a brief discussion on the nature of the concentration thresholds currently listed in the DGL, whether they were based on information on the properties of the mixtures or the specifications of the products being transported. Further information on the rationale behind the concentration thresholds would be welcome.

12. The group was not in favor of this alternative approach to use parameters such as vapour pressure or physical state as additional criteria for PG assignment since concentration thresholds would always be needed, and the physical characteristics are already used to choose the appropriate packaging and tanks.

13. The participants of the intersessional joint working group concluded that the principle shown in diagram 2 of taking the PG of the ingredients into consideration is the preferred method for the determination of the PG of a mixture that is classified using the additivity approach. This diagram could serve as a start for further work on this issue. More work is needed to determine the exact value of X2. The value of X2 is crucial for assigning precautionary packing groups with a sufficient safety margin while maintaining the current ratio in packing group assignments. The option of providing more information would always be possible as is submitting proposals to the TDG Sub-Committee. Ultimately, that determination of the exact value of X2 is within the domain of the TDG Sub-Committee. This is not a GHS issue.

14. Participants expressed the view that although diagram 2 is the preferred method, diagram 1 in the same CEFIC document could not be endorsed at this point.

4. Assignment of PG when subclassification is not possible based on the available information on the substance/mixture (i.e. last row of the table)

15. In some cases, for example when the available information is pH, human accident data, results from in vitro tests using OECD 430 or non-additivity, or when very little information is available, sub-classification of substances or mixtures is not possible (see table 3). In those cases, other methods are needed to assign packing groups.

Table 3

GHS hazard class	**Transport**		**Additional criteria and considerations**	**Transport conditions**
1A	8 A	Other criteria*	PGI based on “other criteria”	Special packing provisions, limited and excepted quantities and downstream transport provisions
			PG II	
1B	8 B		PG II	
1C	8 C		PG III	
1**	8		PG II	

16. The Netherlands outlined three possible approaches to solve this problem:

(a) The situation is not acceptable, data must be generated to allow subclassification and assignment of PG

(b) Default assignment into PG I

(c) Default assignment into PG II

17. The group noted that Approach 1 was not the way forward as a solution as this approach could be problematic for transport. For example, it could hinder transport of samples or one-off consignments with limited data. To test these substances and mixtures would often require transport to the testing facility but that such transport would not be allowed under this option. Provisions on how to transport samples already exist in Chapter 2.0 section 2.0.4 in the Model Regulations. These provisions may be useful for further discussions. The group agreed that requiring minimum data to allow subclassification was not the best approach. Allowing testing should always be possible but requiring testing would not be appropriate.

18. In cases where limited data is available, the current practice appears to assign packing group based on similar substances on the DGL through assimilation and read-across. A PG II may already be a default assignment unless PG I or PG III turn out to be more appropriate based on read-across/assimiliation. It was noted that a default assignment of PG II would provide limited incentive to generate good hazard information and from a precautionary point of view, PG I could be more appropriate as a default packing group. Assigning PG II and PG III based on more information would always be a possibility. It was noted that read-across using the GHS philosophy is precautionary.

19. It was pointed out that there is a precedent in the Model Regulations for assigning default PG II without first having applied the classification criteria. This applies to UN numbers UN 3175 (via SP216) UN 3243 (via SP217) and UN 3244 (via SP218).

20. The group concluded that in cases were subclassification is not possible, a default packaging group needs to be assigned. Furthermore the group concluded that more work and thought is needed to decide whether the most appropriate default packing group is PG I unless or PG II unless... Ultimately, that choice would be for the TDG Sub-Committee to make. This is not a GHS issue.

5. Conclusions, next steps

21. The group agreed that the work of this group would serve as recommendations to the joint working group in June/July 2014. The Netherlands offered to write a working paper on behalf of the intersessional joint working group. A draft of this working paper will be submitted to this group and the mailing list. A final working paper will be submitted to the joint working group and both subcommittees.

22. Due to limited time until the submission deadline, it will not be possible to submit a complete final solution in a working paper for the June/July session. However, it is feasible to submit a working paper reporting the progress of the work, the framework of the recommended solution, and with indications where further work is needed and where choices need to be made. A more complete recommendations could be provided as an INF paper for the June meeting. A third teleconference organized before the summer meeting would be beneficial to elaborate the details of the informal document.

23. How to structure the new chapter 2.8 is a point for further discussion. For example, the Model Regulations currently do not address the additivity method. Input on the best way forward here would be appreciated.

6. Closure of the meeting and the next steps

Participants were thanked for the constructive contributions and the participants expressed gratitude to the Netherlands for the organization of the work.

2014-03-07 Report 2nd teleconference and draft WP sent to members (**action NL**)

2014-03-19 Deadline for reactions on the draft working paper (**action members**)

2014-03-28 Submission of working paper to secretariat (**action NL**)

To be followed by:

Draft INF paper sent to members (**action NL**)

Deadline for reaction on the draft INF paper (**action members**)

Submission of INF paper to secretariat (**action NL**)

In parallel; organization of a 3rd teleconference **(action NL)**