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

18 June 2013

Sub-Committee of Experts on the Transport of Dangerous Goods

Forty-third session Geneva, 24 – 28 June 2013 Item 11 (a) 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-fifth session Geneva, 1 – 3 July 2013 Item 2 (c) of the provisional agenda Classification criteria and hazard communication: corrosivity criteria

Consistency of classification criteria in the UN Model Regulations and in the GHS: Options for a way forward and agenda for the meeting of the joint working group on corrosivity criteria

Transmitted by the expert from the United Kingdom

Purpose

1. At the joint meeting in December 2012 the United Kingdom undertook to prepare an options paper to help identify appropriate ways forward.

2. An agenda for the meeting of the joint informal correspondence group on corrosivity criteria, to take place on 1 July 2013^1 may be found in the Annex to this document.

Taking stock

3. In line with its terms of reference² the Joint informal correspondence group has identified several reasons why the classification of a substance or mixture may differ between transport and supply:

(a) A list of prescribed classifications for substances or mixtures can overrule a classification derived from direct application of the classification criteria.

An example is the Dangerous Goods List (DGL) in Section 3.2 of the Model Regulations on the Transport of Dangerous Goods. An entry on the list trumps any other considerations. Such an entry may reflect historical accident experience in transport as well as test data (risk as well as hazard), though the rationale may be lost in the mists of time.



¹ The provisional timetable for the meetings of the informal working groups is circulated as INF.12.

 $^{^2\,}$ Refer to ST/SG/AC.10/C.4/48, Annex IV , item 1 (h).

(b) The requirements for transport packaging.

In particular, transport reserves Packing Group I (PGI) for corrosive substances or mixtures that experience indicates require the highest available standards of containment in transport. In the context of transport this is understandable and cost effective. However, there is no comparable constraint on the scope of skin corrosivity category 1A. More generally it appears the distribution of substances and mixtures classified as skin corrosive categories 1A, 1B and 1C is very different from those assigned packing groups I, II and III (refer to informal document INF.26 (TDG 43rd session) –INF.9 (GHS, 25th session) and –Add.1 (CEFIC)).

(c) The availability of an array of alternative methods to animal testing to classify substances or mixtures for skin corrosivity – human data, in vitro tests, bridging principles, additivity and non-additivity rules, pH, and total weight of evidence applying expert judgement.

The use of alternative methods is fully documented in the "Purple Book" for supply, but not in the "Orange Book" for transport. These alternative methods:

- (i) Are intended to avoid animal testing, an important issue in some jurisdictions;
- (ii) Are designed to provide a classification that is not less severe than that which would be derived from animal testing, though in so doing can provide a classification that is conservative;
- (iii) Do not always distinguish the GHS skin corrosive sub-categories 1A, 1B and 1C or between sub-divisions of Class 8;
- (iv) Are nevertheless used by practitioners in the transport sector.
- (d) Differences in the availability of data for classification and in data interpretation.
- 4. The joint informal correspondence group has also noted that:
 - (a) The hazard categories skin corrosion 1A, 1B, 1C do not have to be adopted in all jurisdictions;
 - (b) One of the PGs I, II or III is always assigned for transport of a corrosive substance or mixture, together with other packaging conditions as appropriate;
 - (c) Any sub-categorisation of the hazard class skin corrosion or Class 8 does not lead to differences in hazard communication in both transport and supply.

5. Inconsistencies in classification for skin corrosion of specific substances and mixtures arising from 3 (a) and (d) are arguably inevitable, at least in the short to medium term. While transport has it own global list serving its purposes, there is presently no global equivalent for supply, though early thinking is underway in the GHS Sub-Committee on the possibility of developing such a list in future. Meanwhile some jurisdictions have their own lists. Inevitably lists of classifications for specific substances or mixtures tend to become out of date over time, as resources to keep them updated are limited.

6. Differences in data availability and in data interpretation are also inevitable. Issues of data availability may reduce as inventories of data on chemicals continue to develop and become available on-line. Over time this may also help to reduce differences in data interpretation and expert judgement. For example, in the European Union notifiers of

entries on the classification and labelling inventory are encouraged to agree on hazard classification, and the European Chemicals Agency has provided a platform to facilitate this.

7. Reasons 3 (a) and (d) are not, therefore, considered further in this paper. However, reasons 3 (b) and (c) reflect the criteria and approach to skin corrosion classification in transport and supply. They should be addressed by the Informal Joint Correspondence Group working within its terms of reference, and drawing on the willingness and flexibility the Group has already shown.

Options for a way forward

General considerations

- 8. In generating and evaluating options the following (inter-related) questions arise:
 - (a) Does "classification" in transport mean the same as in the GHS, i.e. intrinsic hazard, or does it mean something broader incorporating risk considerations?
 - (b) Given the problems that arise in seeking to correlate sub-categories within Skin corrosion category 1 in the GHS and within Class 8 in transport, should the sub-categories 1A, 1B and 1C in the GHS be retained³?
 - (c) How does classification, or hazard classification, relate to assignment of PG^4 ?
 - (i) Is PG part of transport classification or additional to classification?
 - (ii) If additional to classification, or if the GHS sub-categories 1A, 1B and 1C are removed, does transport need to sub-divide Class 8 to indicate gradation of hazard or danger?
 - (d) What are the criteria for assigning PG?

If not the same as the GHS criteria, what additional criteria are needed?

(e) To what extent should transport formally adopt the GHS alternative methods in classifying as Class 8 and/or in assigning PG?

If the alternative methods are adopted in transport do the outcomes relate to PG in the same way as animal test data relates to PG in the "Orange Book"?

9. Useful work has already been done by CEFIC in exploring some of these issues and in providing initial drafts of, for example, an expanded version of Chapter 2.8 of the Model Regulations on the Transport of Dangerous Goods incorporating text from the GHS Chapter 3.2 (INF.27 (TDG, 41st session) – INF.11 (GHS 23rd session), and on criteria for assigning packing groups for corrosive mixtures (INF.26 (TDG, 43rd session) – INF.9 (GHS, 25th session).

10. A number of options are presented in paragraphs 12 to 30 below. For transport they should be considered in the context that the first step in classifying a substance or mixture

³ As already noted, adoption of these GHS sub-categories is optional, the alternative methods do not always distinguish sub-categories, and hazard communication is the same for each sub-category.

⁴ INF53 (TDG, 41st session) – INF18 (GHS, 23rd session) notes that to establish multi-modal transport conditions substances and mixtures need to be distinguished as presenting low, medium or high danger, but this distinction does not have to be based solely on hazard classification.

for transport and assigning a PG is to check the DGL. The criteria for classification and for assignment of PG are applied only where there is no named entry in the DGL for the substance or mixture concerned, or when an existing entry is being revised.

11. In considering the options below, the advantages and disadvantages are assessed in terms of how well each option secures the desired outcomes of:

- (a) Consistency between skin corrosion classification in transport and supply?
- (b) Maintaining an appropriate distribution of PG assignments for skin corrosion (estimated in INF.26 (TDG, 43rd session) INF.9 (GHS, 25th session) as currently 1 : 8 : 12 for PGs I, II and III respectively)?
- (c) Securing an outcome for skin corrosion that does not create awkward precedents?

Options based on packing group as part of transport classification

Option 1:

Adopt GHS classification criteria, including alternative methods, in transport; force alignment of PGs I, II and III with hazard categories 1A, 1B and 1C

12. This option is shown diagrammatically in Table 1. Transport adopts the GHS criteria including the criteria for sub-categories 1A, 1B and 1C and alternative methods. PG assignment is part of hazard classification indicating gradation of hazard, and so Class 8 is divided into three sub-categories designated by PG. There is a direct correlation between PGs I, II and III and hazard sub-categories 1A, 1B and 1C.

		Hazard classification		
Classification criteria		GHS	Transport	Other transport conditions
Exposure ≤ 3 minutes Observation ≤ 1 hour		Skin Corrosive 1A	Class 8 PG I	Special packing
Exposure > 3 minutes \leq 1 hour Observation \leq 14 days	Alternative methods	Skin Corrosive 1B	Class 8 PG II	provisions, limited and excepted quantities and
Exposure > 1 hour \leq 4 hour Observation \leq 14 days		Skin Corrosive 1C	Class 8 PG III	downstream transport provisions

Table 1

13. Advantages include:

Consistent hazard-based classification for transport and supply

- 14. Disadvantages include:
 - Some significant changes in transport classification compared to the present position;
 - Forced alignment leads to a distribution of PGs that is out of line with the present position and introduces inappropriate transport requirements. For example, correlation between Class 8 PGI and skin corrosive 1A leads to too many substances and mixtures being assigned PGI.

Option 2:

Remove skin corrosion sub-categories 1A, 1B and 1C from the GHS and adopt in transport the GHS criteria as amended; include alternative methods; establish criteria for assignment of PGs I, II and III.

15. This option is shown diagrammatically in Table 2. The skin corrosion subcategories 1A, 1B and 1C are removed, leaving skin corrosion category 1. Transport adopts these revised, undifferentiated GHS criteria, together with the alternative methods. PG assignment is part of classification, and so Class 8 is divided into three sub-categories designated by PG.

Note: Option with no subdivision in transport and PG part of classification is academic because it would not allow different PGs – not acceptable for transport

		Table 2		
		Classifi		
Classification criteria		GHS	Transport	Other transport conditions
Exposure ≤ 3 minutes			Class 8 PG I	Special packing provisions, limited and excepted quantities and
Observation ≤ 1 hour	Alternative methods		Class 8 PG II [*]	
Exposure > 3 minutes \leq 1 hour		s Skin corrosive Category 1		
Observation ≤ 14 days			Class 8 PG III	downstream transport
Exposure > 1 hour \leq 4 hour				provisions
Observation ≤ 14 days				-

* As a starting point it has been suggested PGII is assigned by default, unless there are reasons to justify PGI or PGIII. Criteria will be hazard and risk based.

16. Further work will be needed on:

Additional criteria for assignment of PG (though this has been started by CEFIC and the Netherlands)

17. Advantages include:

The desired distribution of PGs for transport is achieved, e.g. criteria are established so assignment of PG I applies only to substances/mixtures that pose a very high risk in transport (~5%).

- 18. Disadvantages include:
 - Inconsistent classification for transport and supply, in that transport subdivides Class 8 but GHS does not;
 - Transport classification includes risk-based elements (a disadvantage for consistency where arguably classification should mean the same in both GHS and transport);
 - Potentially awkward for jurisdictions who have already adopted GHS sub-categories 1A, 1B and 1C.

Options based on decoupling packing group and hazard classification

Option 3:

Adopt GHS classification criteria in transport, including alternative methods; provide three sub-categories for both GHS and transport; assign PG separately from transport classification.

19. This option is shown diagrammatically in Table 3. Transport adopts the GHS criteria including alternative methods. Three hazard sub-categories are provided in both GHS and transport. PG is assigned separately from classification, and is based on whatever additional risk-based criteria the transport sector considers appropriate.

Table 3

		Hazard class	ification		
Classification criteria		GHS	Transport*	Transport conditions	
Exposure $\leq 3 \min$		Skin Corrosive	Class 8 1A	PG I	Special packing
Observation ≤ 1 hour		1A	Class 8 1A	PGII ^{**} and except quantities a downstrea PGIII transpor	provisions, limited
Exposure > 3 min \leq 1 hour	Alternative methods	Skin Corrosive	CI 0.1D		and excepted
Observation ≤ 14 days	methods	1B	Class 8 1B		downstream
Exposure > 1 hour \leq 4 hour Observation \leq 14 days		Skin Corrosive 1C	Class 8 1C		transport provisions

* If preferred the sub-categories could be termed divisions to align with terminology in other transport classes

** As a starting point it has been suggest PG II is assigned by default, unless there are reasons to justify PG I or PG III. Criteria for assignment of PG will be hazard and risk based.

- 20. Further work will be needed on:
 - (a) The additional criteria for assignment of PG (though this has been started by CEFIC and the Netherlands);
 - (b) The application of alternative methods in transport classification;
 - (c) Minor amendments to the Model Regulations to clarify that for transport classes where risk considerations are important in assigning PG to secure the desired transport conditions, transport hazard classification and PG will not always align.
- 21. Advantages include:
 - Consistent hazard-based classification for transport and supply;
 - The desired distribution of PGs for transport is achieved, e.g. the criteria ensure PGI applies only to substances/mixtures that pose a very high risk in transport.
- 22. Disadvantages include:
 - Clarification may be needed that generally in transport PG is used as a risk-based tool to determine multi-modal transport conditions. In consequence, for transport classes where risk considerations are important in assigning PG, transport hazard classification and PG will not always align;
 - May require changes to the DGL to insert Class 8 sub-category.

Option 4:

Adopt GHS classification criteria in transport, including alternative methods; provide three hazard sub-categories for GHS but do not sub-categorise within Class 8; assign PG separately from transport classification.

23. This option is shown diagrammatically in Figure 4. The GHS hazard sub-categories are maintained but are not adopted in transport, so Class 8 is not sub-divided. Otherwise transport adopts the GHS criteria including alternative methods. PG is therefore not part of transport hazard classification, and is based on whatever additional risk-based criteria the transport sector considers appropriate.

		Hazard cla	ssification		
Classification criteria		GHS	Transport	Transpo	ort conditions
Exposure $\leq 3 \min$		Skin		PG I	Special packing
Observation ≤ 1 hour		Corrosive 1A		PGII*	provisions, limited
Exposure > 3 min \leq 1 hour	Alternative methods	Skin	Class 8	POIL.	and excepted
Observation ≤ 14 days method	methous	Corrosive 1B		PGIII	quantities and downstream
Exposure > 1 hour ≤ 4 hour	1	Skin			transport
Observation ≤ 14 days		Corrosive 1C			provisions

* As a starting point it has been suggest PG II is assigned by default, unless there are reasons to justify PG I or PGIII. Criteria for assignment of PG will be hazard and risk based.

- 24. Further work will be needed on:
 - (a) The additional criteria for assignment of PG (though this has been started by CEFIC and Netherlands)
 - (b) The application of alternative methods in transport classification
 - (c) Minor amendments to the Model Regulations to clarify that for transport classes where risk considerations are important in assigning PG to secure the desired transport conditions, transport hazard classification and PG will not always align.
- 25. Advantages include:
 - Semi-consistent hazard-based classification for transport and supply (though the GHS has sub-categories and transport does not)
 - The desired distribution of PGs for transport is achieved, e.g. the criteria ensure PG I applies only to substances/mixtures that pose a very high risk in transport.
 - Adoption of the GHS criteria in transport is simplified as Class 8 is not subdivided for classification, avoiding complexities where alternative methods do not distinguish sub-categories.
- 26. Disadvantages include:

May require greater distinction in future between transport hazard classification and PG assignment to determine multi-modal transport conditions.

Table	4
-------	---

Option 5:

Adopt in transport GHS classification criteria, including alternative methods; no hazard sub-categories in both GHS and transport; assign PG separately from transport classification

27. This option is shown diagrammatically in Figure 5. Transport adopts the GHS criteria including alternative methods. There is no sub-division of hazard in Skin corrosion category 1 or Class 8. PG is assigned separately from transport classification, and is based on whatever additional risk-based criteria the transport sector considers appropriate.

Table 5

		Hazard cl	assification		
Classification criteria		GHS	Transport	Trans	port conditions
Exposure $\leq 3 \min$				PG I	Special packing
Observation ≤ 1 hour	methods			PGII [*]	provisions, limited
Exposure > 3 min \leq 1 hour		Skin	~		and excepted
Observation ≤ 14 days		Corrosive 1	Class 8	PGIII	quantities and
Exposure > 1 hour \leq 4 hour					downstream
Observation ≤ 14 days					transport provisions
<u>-</u>					provisions

* As a starting point it has been suggest PG II is assigned by default, unless there are reasons to justify PG I or PGIII. Criteria for assignment of PG will be hazard and risk based.

- 28. Further work will be needed on:
 - (a) The application of alternative methods in transport classification (already started by CEFIC);
 - (b) The criteria for assignment of PG (already started by CEFIC and the Netherlands);
 - (c) Revision of Chapter 3.2 in the GHS to remove sub-categories 1A, 1B and 1C.
 - (d) Minor amendments to the Model Regulations to clarify that for transport classes where risk considerations are important in assigning PG to secure the desired transport conditions, transport hazard classification and PG will not always align.
- 29. Advantages include:
 - Consistent hazard-based classification for transport and supply
 - The desired distribution of PGs for transport is achieved, e.g. the criteria ensure PGI applies only to substances/mixtures that pose a very high risk in transport.
 - Adoption of the GHS criteria is simplified in both GHS and transport, avoiding complexities where alternative methods do not distinguish sub-categories.
- 30. Disadvantages include:
 - May require greater distinction in future between transport hazard classification and PG assignment to determine multi-modal transport conditions;
 - Potentially awkward for jurisdictions who have already adopted GHS sub-categories 1A, 1B and 1C.

31. In considering the Options 3, 4 and 5 it is appropriate to consider whether decoupling PG from transport classification in Class 8 would cause difficulties in other transport classes. The following observations may be helpful:

- (a) Some PGs in the DGL are evidently assigned following consideration of accident experience and other factors rather than strictly in accordance with hazard classification criteria.
- (b) The transport sector adopts within Class 9 the GHS environment hazard classes and categories Aquatic hazard (Acute) category 1 and Aquatic hazard (Chronic) categories 1 and 2. In doing so transport adopts the relevant GHS hazard classification criteria without change. PG is assigned directly in the DGL, apparently without reference to the classification criteria. Where transport classifies for hazards to the aquatic environment, it has been agreed that risks for transport are relatively low so PGIII is always assigned. This means there is no direct relationship between hazard classification and PG.
- (c) The health hazards within the transport system are acute toxicity (Class 6.1) and corrosivity (Class 8). The extent of discrepancies between GHS and transport classifications for acute toxicity has not yet been explored. However, brief examination indicates that the same issues of alternative methods, including additive and non-additive effects, arise as these are included in the GHS but not in transport. In addition, the criteria adopted in transport Division 6.1 for assigning the three Packing Groups do not fully align with those for GHS categories 1, 2 and 3, at least for inhalation (though they do for dermal and oral routes).
- (d) For physical hazards the GHS adopted the same hazard classification classes and categories/division as transport. PGs are not assigned in transport Classes 1 (Explosives), 2 (Gases) and for Division 4.1 (self-reactive substances) and Division 5.2 (Organic Peroxides). In other physical hazard classes and Divisions PG is used to indicate subdivision of hazard as well as multi-modal transport conditions, which are aligned.

32. The implication is that the overall correlation between transport classification and PG is a mixed picture. For physical hazards, where PG are used, there is a direct correlation between PG and Class sub-category/division; however, this is not necessarily the case for health hazard classes used in transport, where other criteria seem to be applied to establish PG in addition to hazard.

Further options

33. In addition to Options 1 to 5 above it is possible to envisage hybrid options in which the results of animal tests in accordance with specified OECD standards are directly translated to sub-categories of Class 8 and/or into packing groups, but the outcomes of at least some of the alternative methods do not translate unless additional criteria are applied.

34. An indication of what such an approach (option 6) might look like is in Table 6, which is a variation of Option 1. It would add additional complexity and would result in discrepancies between GHS and transport classifications/assignments of packing group, unless the GHS criteria were also adjusted in a similar way. Such additional options are not pursued further in this paper, pending a steer from the Joint Informal Correspondence Group.

Option 6: Adopt GHS classification criteria in transport, including alternative methods; force alignment of PG I, PG II and PG III with hazard categories 1A, 1B, 1C for animal test data only; for alternative methods apply other criteria to assign PG.

Table 6

		Classific		
Classification criteria		GHS	Transport	Other transport conditions
Exposure $\leq 3 \text{ min}$ Observation $\leq 1 \text{ hour}$	Test data	Skin Corrosive 1A	Class 8 PG I	Special packing
Exposure > 3 min \le 1 hour Observation \le 14 days	Test data	Skin Corrosive 1B	Class 8 PG II	provisions, limited and excepted quantities and
Exposure > 1 hour \leq 4 hour Observation \leq 14 days	Test data	Skin Corrosive 1C	Class 8 PG III	downstream transport provisions
Exposure $\leq 3 \text{ min}$ Observation $\leq 1 \text{ hour}$	Alternative methods	Skin corrosive 1	Class 8 PG I	Special packing provisions, limited and
Exposure > 3 min \le 1 hour Observation \le 14 days	Alternative methods	(1A, 1B or 1C where alternative methods allow sub-	Class 8 PG II [*]	excepted quantities and downstream transport
Exposure > 1 hour \leq 4 hour Observation \leq 14 days	Alternative methods	classification)	Class 8 PG III	provisions

* As a starting point it has been suggest PGII is assigned by default, unless there are reasons to justify PGI or PGIII. Criteria for assignment of PG will be hazard and risk based.

Additional issues

- 35. Further issues that are prompted by the considerations in this paper include:
 - (a) In both the GHS and transport, human experience appears to be given priority over animal data. For example, 2.8.2.4 in the "Orange book" states:

"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 or 435."

However, is human experience considered in the same way in transport and the GHS?.

One view is that while positive human experience (i.e. evidence of skin corrosion in humans) is always regarded as indicative of classification, negative human experience (e.g. in accident/incident databases) would be regarded in transport as indicative of no classification even if there was positive animal data, whereas in the GHS positive animal data would be indicative of classification without regard to human experience.

(b) If the sub-categories 1A, 1B and 1C in the GHS skin corrosion category 1 are retained, should the criteria for these sub-categories be reviewed in future?

Although such a review is arguably outside the terms of reference of the Joint Informal Correspondence Group, the Group could, if it so wished, make a recommendation to this effect in its report to both sub-committees (GHS and TDG).

Action

- 36. The Joint Informal Correspondence Group is invited to comment on:
 - (a) The résumé in paragraphs 3 11;
 - (b) The options identified and discussed in paragraphs 12 32;
 - (c) The possible further options other issues touched on in paragraphs 33-35.

Annex

Agenda for meeting of the Joint TDG/GHS informal correspondence group on corrosivity criteria⁵

to be held at the Palais des Nations (Room XII), Geneva, on Monday 1 July 2013 following the opening of the plenary session at $10:00^6$

- 1. Welcome and introduction
- 2. Discussion of informal documents:

INF.43 (TDG) – INF. 11 (GHS) (UK)	Consistency of classification criteria in the UN Model Regulations and in the GHS: Options for a way forward
INF.26 (TDG) - INF. 9 (GHS) and	Harmonisation of the skin corrosion
–/Add.1 (CEFIC)	classification criteria in the UN Model Regulations with those in GHS

Any other documents submitted prior to the meeting.

- 3. Next steps
- 4. Any other business

⁵ For the terms of reference of the joint working group refer to ST/SG/AC.10/C.4/48, Annex IV , item 1 (h).

⁶ Refer to the provisional agenda for the 25th session of the Sub-Committee, ST/SG/AC.10/C.4/49/Add.1 and INF. 12.