

**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

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Item 10 of the provisional agenda

**Issues relating to the Globally Harmonized System of Classification
and Labelling of Chemicals (GHS)**

**Implementation of the GHS criteria in Class 8 of the UN
Model Regulations on the Transport of Dangerous Goods for
consideration by the experts on the transport of dangerous
goods.**

Addendum to ST/SG/AC.10/C.3/2010/10 (Netherlands)

Transmitted by the expert from the Netherlands

1. Reference is made to document ST/SG/AC.10/C.3/2010/10.
2. The Annex to this informal document contains the comments received by experts of the UNSCETDG on the draft proposal as circulated by e-mail on 3 February 2010, as well as the responses to the comments by the expert from the Netherlands.

Annex

Comments received and our responses

	Comments received from	Comments	Reaction
1.	Germany <i>Gudula Schwan</i>	2.8.1: include 'solutions and mixtures' in the general definition. Delete 'and mixtures' in sections 2.8.3.1 and 2.8.2.3.	Agree
2.	Germany	2.8.2.2: replace 'eventually' with 'if necessary'	Agree
3.	Germany	2.8.3 Replace title with 'Classification based on alternative information'. GHS does not contain 'additional criteria'. It describes methods how to determine if a substance is likely to meet the classification criteria. GE proposes the change of heading to avoid the impression that the criteria of 2.8.3 have to be applied additional to the criteria mentioned in 2.8.2.	We agree with the comments given. The heading of paragraph 2.8.3 is changed to prevent the confusion.
4.	Germany	2.8.3.1; In line with the comments on the heading of 2.8.3 a change in the second sentence is proposed: "In addition, GHS describes methods how to determine if a substance or mixture is likely to meet the criteria for skin corrosion based on alternative information."	We changed the second sentence, taking into account these concerns.
5.	Germany	2.8.3.1, replace 'these methods shall be used.' with 'these methods may be used.'	We do not agree with the proposed change as we see the use of the alternative methods not as an optional choice. In absence of results of <i>in vivo</i> or <i>in vitro</i> testing, these alternative methods shall be used.
6.	Germany	2.8.3.1 Extreme pH Insert sentence to clarify that aim was to allow assignment to PG I as worst case, in order to avoid costly tests for rare transport operations.	We included a proposal in square brackets as this was not a conclusion from the WG meeting.
7.	Germany	2.8.3.1 Extreme pH 'The absence of an extreme pH is not a proof for the absence of skin corrosive properties' Delete 'skin' as this statement is valid for metal corrosive properties as well, even if skin corrosive properties only are mentioned here.	As the paragraph is on skin corrosivity, we prefer to keep 'skin' in the sentence.

8.	Germany	Insert additional heading '2.8.3.2. additional provisions for mixtures.'	We did not take over this suggestion. In section 2.8.3 only notes to the classification methods as presented in GHS are included. An additional section suggests that actual provisions are presented, which is not the case.
9.	France <i>Guy Marlair</i>	Is it possible to mention to the test described in section 37 of the Manual of test and criteria for evaluating the "corrosivity for metals".	We did not take over this suggestion as it is outside the scope of the alignment with GHS. We invite France to present a separate proposal on this issue.
10.	United Kingdom <i>Nigel Reader</i>	2.8.3.1 Table 'relationship between packing groups and GHS skin corrosion categories'. The above table to allocate a packing group based on the skin corrosion sub-category should not be used as it may lead to the allocation of the incorrect packing group for transport purposes.	We did not take over this suggestion. The table illustrates the correlation between transport packing groups I, II and III and GHS sub-categories 1A, 1B and 1C. The working group on corrosivity criteria concluded this correlation should be underlined in Chapter 2.8.
11.	United Kingdom	2.8.3.1 Extreme pH ($\text{pH} \leq 2$ or ≥ 11) is an indication of corrosivity. Proposal to replace 'is' with 'may be'.	Based on this suggestion we changed the sentence, and reordered first two sentences of this paragraph.
12.	United Kingdom	2.8.3.1 Extreme pH. Change sentence 'To assign a packing group, an <i>in vitro</i> or <i>in vivo</i> test can be performed' to 'To assign a packing group, an <i>in vitro</i> or <i>in vivo</i> test has to be performed'.	Thank you for this suggestion, we did take over this suggestion.
13.	United Kingdom	2.8.3.1. Extreme pH, editorial comments	Agree
14.	United Kingdom	2.8.3.1. Bridging principles, editorial comments	Agree
15.	United Kingdom	2.8.3.1. Mixture calculation, editorial comments	Agree
16.	Canada <i>Linda Hume-Sastre</i>	The definition of Class 8, proposal for a new and more general definition; 'class 8 substances (corrosive substances) are substances which, by chemical action, will cause damage when in contact with living tissue, metal, other goods or means of transport and include solutions and mixtures of these substances'	We did not take over this suggestion as it is outside the scope of the alignment with GHS. We invite Canada to present a separate proposal on this issue.
17.	Canada	2.8.2.3; "packing group III or less", What does this mean?	We did not take over this suggestion as it is outside the scope of the alignment with GHS. We invite Canada to present a separate proposal on this issue.

18.	Canada	The 2.8.3. text should be notes in italicized text and not regulatory text. The text is not clear and does not provide addition help in determining packing groups and, indeed, seems to be in some instances a differently worded repetition of current UN text.	We included the notes in section 2.8.3.2. on the applicability of the alternative methods as regulatory text. However the Subcommittee may decide to present 2.8.3.2 in italicized text. The text has been rewritten for improved clarity, we hope the final proposal is an improvement.
19.	Canada	2.8.3.1. The text that Germany suggested should read: "In addition, GHS describes methods to determine if a substance is likely to meet the criteria for skin corrosion based on alternative information. "	Agree
20.	Canada	Insert a general statement in the beginning of the chapter, with packing group descriptions, applying to all Class 8 substances reading: "If a substance is known to be included in Class 8 though documentary evidence but testing is not done, the substance shall be included in Packing Group I."	We did not take over this suggestion as it is outside the scope of the alignment with GHS. We invite Canada to present a separate proposal on this issue.
21.	Riskom International Pty Ltd Australia <i>Ken Price</i>	I don't believe a substance can be a mixture, nor can a mixture be a substance. the definitions in GHS and the Orange book are both poor and inconsistent with basic science. At page 11, GHS defines a mixture as "a mixture..." for example. it is a nonsense of a circular definition and I seem to recall the Orange Book is just as poor but I can't find the exact text. This could be a good opportunity to put in a scientific and logically proper definition for mixtures at least. My chemical dictionary offers something like: Mixture. a heterogeneous blend of elements or compounds, which may be uniformly dispersed. I am sure there are others as good.	We judge the discussion on the definition of a substance relevant, though outside the scope of the present discussion on the alignment of Chapter 2.8 with GHS.

		<p>And I doubt that it is necessary to define substance, though once again any passable chemical dictionary can do the job.</p> <p>I suggest that sentence 3 of 2.8.1 be altered further than suggested by Gudula to read:</p> <p>"A substance that is corrosive to metals is a substance or a mixture which, by chemical action, will materially damage, or even destroy, metals".</p>	
22.	United States <i>Shane Kelly</i>	<p>Regarding the addition of the word "mixture" (2.8.1 and 2.8.2) - we are not convinced this amendment is necessary. The word substance is used throughout the model regulations in a general sense and includes mixtures. For example, reading the introductory text to Chapter 3.1, the term substance is used in reference to all listed materials in the Dangerous Goods List (see for example 3.1.1.1 and 3.1.1.2) and includes both "pure" substances and mixtures and solutions. Part 3 Appendix A also references "Substances or articles not mentioned specifically by name in the Dangerous Goods List". In general, the Model Regulations cover "substances" (which include solutions, mixtures, etc.) and "articles".</p>	<p>Based on the comments of Germany we made some changes to 2.8.1 and 2.8.2 on this point.</p>
23.	United States	<p>Regarding 2.8.2.2, we do not support adding a reference to 2.8.3 (GHS criteria), as the referenced criteria will not lead in all cases to a Packing Group determination.</p>	<p>The limitations to assign packing groups by the alternative methods are mentioned in 2.8.3. It is our understanding that when <i>in vitro</i> and/or <i>in vivo</i> data are not available, the alternative methods to assign a packing group shall be used where possible.</p>
24.	United States	<p>Regarding the proposed table in 2.8.3 which correlates PG and GHS Sub-categories, we are concerned that the GHS criteria allow classification within a sub-category without testing under the OECD 404 or 435 standards. We understand for example that some competent authorities are allowing classification within sub-categories based on</p>	<p>Global harmonization of classification does not happen overnight. During this process differences in interpretation of the criteria will occur. However differences in the interpretation of GHS criteria can not be an argument to slow down the process of harmonization.</p>

		concentration ranges. We believe introducing the table, particularly without any explanation, may cause potential confusion. For example, those preparing safety data sheets may mistakenly correlate the GHS sub-category to a transport PG without verifying whether the appropriate classification determination required by the transport regulations has been considered.	Similar to other changes in the Model Regulation, the implementation of the proposed changes in Chapter 2.8 will trigger training needs for those involved in the transport of dangerous goods.
25.	United States	Regarding 2.8.3.1, we are concerned with the addition of the sentence "These additional GHS classification criteria shall be used to assign the packing group in cases where the information mentioned in 2.8.2.4 is not available for the substance or mixture". As noted in our comment 2, the GHS criteria will not always lead to a PG determination. We also suggest that the sentence stating "To assign a packing group, an <i>in vitro</i> or <i>in vivo</i> test can be performed" should read "must be performed" as only the 404 and 435 standards lead to a PG determination. In addition, we believe that the sentence "Where results from <i>in vitro</i> or <i>in vivo</i> tests are available, a classification based on these results prevails over a classification based on pH" is misleading in that a pH determination will never by itself lead to a PG determination - we would therefore prefer the sentence be deleted.	<p>The sentence "To assign a packing group, an <i>in vitro</i> or <i>in vivo</i> test can be performed" has been changed to 'has to be performed' based on the suggestions received in the written round.</p> <p>We share the opinion that the alternative methods do not always lead to a PG determination. This has been highlighted in section 2.8.3.2. However, in those cases where a PG can be assigned based on the alternative methods expensive testing should not be made obligatory. Excluding the alternative methods would require every single mixture and substance to be tested in an expensive <i>in vivo</i> or <i>in vitro</i> test before transport.</p>
26.	United States	Regarding the final two paragraphs (bridging principles and mixture calculation principles) we believe these paragraphs would be misleading for transport classification purposes as there is no way to use bridging principles or mixture calculation principles to determine a PG and therefore they are not directly relevant to transport criteria. We believe the existing references to OECD Standards 430 and 431 in 2.8.2.4 are sufficient in that they authorize a "corrosive or not corrosive" determination. This essentially allows an initial determination as to whether the substance would be	We share the opinion that the alternative methods do not always lead to a PG determination. This has been highlighted in section 2.8.3.2. However, in those cases where a PG can be assigned based on the alternative methods expensive testing should not be made obligatory. Excluding the alternative methods would require every single mixture and substance to be tested in an expensive <i>in vivo</i> or <i>in vitro</i> test before transport.

		regulated for transport, however a substance for which a "corrosive" determination is made under the 430 or 431 standards would still further testing in accordance with the 404 or 435 (in vivo or in vitro) test methods to determine the transport PG.	
27.	Switzerland <i>David Gilabert</i>	In 2.8.3.1 you repeat four times that a classification based on results of tests prevail. It is enough to say this one time at the beginning.	Thank you for this comment. We realize there is a lot of repetition in this section. We leave this point to the Sub committee to decide. At this point in time we prefer clarity on this subject, though it might be overdone.
28.	Switzerland	In 2.8.3.1 from one side you say that in case of no information the additional criteria could be used. Additionally under "extreme pH" you give some explanatory text why the things are as they are. This information may be interesting but has no regulatory character. It is said that in order to assign a PG a test can be performed. This is already said in 2.8.2.4 so do we need to repeat this again? Was instead not the intention to say that it is also possible to assign a PG (say I) without tests in case of extreme pH? If so it should be said because for the moment being I only read that in case of extreme pH I can make tests. Which is interesting but I already know that from 2.8.2. I'll try to formulate some prescriptive test by my next e-mail.	Thank you for this comment. The suggestion to allow the assignment of PG I in case of extreme pH is now added in square brackets the proposal based on a suggestion from Germany. We did not shorten the text of this section. We are looking forward to your suggestions.
29.	Switzerland	Furthermore in Switzerland we are not convinced that the in vivo tests should be followed.	Remark is noted.
30.	DGAC <i>Frits Wybenga</i>	In a number of instances, the proposal uses the term "substances and mixtures." Note that 2.0.1.1 of the Model Regulations indicates that the term substances includes mixtures so that the change is unnecessary and confusing.	As suggested by Germany, solutions and mixtures has been included in the general definition of corrosive substances.
31.	DGAC	Regarding 2.8.3.1, we understood the subcommittee agreed that it would be inappropriate to make correlations to	The table in 2.8.3.1 illustrates the correlation between transport packing groups I, II and III and GHS sub-

		<p>Packing Groups and GHS Subcategories and that the table should not be included. We support this position for the following reasons:</p> <p>(a) the sub-categories unlike the packing groups don't allow for classification or assignment based on experience.</p> <p>(b) the GHS criteria for assignment of category 1A, 1B, 1C is based on extreme pH.</p> <p>(c) it is our experience that some MSDS or SDS writers also assign the transport classification. We would not want them to use this chart to assign packing group for transport.</p> <p>Alternatively, we could agree to retaining the table if it were accompanied with a note reading as follows: <u>Note: The use of the above table to allocate a packing group based on the skin corrosion sub-category should not be used as it may lead to the allocation of the incorrect packing group for transport purposes.</u></p>	<p>categories 1A, 1B and 1C. The working group on corrosivity criteria concluded this correlation should be underlined in Chapter 2.8.</p> <p>The understanding of the working group was that classification methods were not separate blocks in the building block approach, and that all methods leading to classification in a given block were part of the same block. (See Annex V paragraph 10 to ST/SG/AC.10/C.3/72.</p> <p>As with other changes in the Model Regulation the proposed changes in Chapter 2.8 will trigger training needs for those involved in the Transport of Dangerous Goods.</p>
32.	DGAC	<p>3. Regarding 2.8.3.1, concentration limits and pH/concentration are the additional GHS methodologies that we are aware of (GHS Tables 3.2.3 and 3.2.4). We disagree with the use of these methods. We recommend against including this new paragraph and recommend we await GHS consideration as recommended in 4 below.</p>	<p>We did not take over this suggestion. The methods mentioned are an integral part of the GHS building block on corrosivity.</p> <p>Proposals for improvement of the UN GHS can be submitted to the SubCommittee of Experts on GHS.</p>
33.	DGAC	<p>4. We disagree with referring to pH, bridging principles and mixture calculations. The text that refers to these methods should be deleted. There are flaws in the use of pH as we have noted. We also question whether the bridging principles/mixture calculations are directly relevant to corrosive classification. For example, we do not think that additivity can be assumed in the same manner as in the case of toxicity criteria. We provided examples in our detailed comment paper (e.g., mixing an acid and a base would not</p>	<p>We did not take over this suggestion.</p> <p>The proposal of the Netherlands is prepared according to the conclusions of the working group on the corrosivity criteria. The limitations of the use of pH, bridging principles and mixtures calculations are included in section 2.8.3.2.of Chapter 2.8.</p> <p>The classification based on <i>in vivo</i> and <i>in vitro</i> results has precedence over classification based on pH, bridging principles and mixture calculations.</p>

		result in the classification predicted by additivity). These criteria were applied to corrosives in a time when the work on GHS was intense. We recommend that the GHS Subcommittee/OECD be asked to reconsider this as part of their review of corrosives. DGAC provided considerable comment on pH, bridging principles and mixture calculations. We recommend these comments and those of others be considered as part of the GHS discussion.	Proposals for improvement of the UN GHS can be submitted to the SubCommittee of Experts on GHS.
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