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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

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

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Item 2 (c) of the provisional agenda

UPDATING OF THE SECOND REVISED EDITION OF THE GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELLING OF CHEMICALS (GHS)

Environmental hazards

Explanatory notes to the proposals in documents ST/SG/AC.10/C.4/2007/8 and -2007/10

Transmitted by the Organization for Economic Co-operation and Development (OECD)

This document contains the explanatory notes to the proposal for the revision of Chapter 4.1, Sections A9.1 to A9.3 of Annex 9 and Appendix VI. It is submitted for information to support the draft proposal for revision of GHS Chapter 4.1 (document ST/SG/AC.10/C.4/2007/8), Annex 9 (Sections A9.1 to A9.3) and Appendix VI (document ST/SG/AC.10/C.4/2007/10).

Background

1. In December 2002, the UN Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals (UN SCEGHS) requested the OECD to start a further “*development of the classification scheme to accommodate chronic toxicity to aquatic organisms for assigning a chronic hazard category*” during the biennium 2003-2004. In December 2004, the Sub-Committee renewed the mandate and requested the submission of a scientific issue paper to be completed in 2005.

2. The *scientific issue paper* that summarizes the scientific background and the basis required for the identification of chronic hazards relevant for aquatic organisms was submitted to the UN SCEGHS at its eleventh session (12-14 July 2006) and circulated as document ST/SG/AC.10/C.4/2006/17. In December 2006, the Sub-Committee requested the submission of a proposal in 2007.

3. Before, the OECD task Force had at its 15th Meeting (15-16 March 2006 in Rome) agreed on the principles for (i) a new proposed classification scheme and (ii) how the work should be completed. The agreed classification scheme is attached to this document as Annex 1.

4. Despite efforts to simplify the proposal as much as possible, accommodating chronic toxicity to aquatic organisms cannot be achieved in a very simple way. In order to facilitate understanding of the classification system by the users, several paragraphs have been moved or slightly revised (strictly respecting the mandate), and it would be too confusing to propose the changes one by one. Therefore, the revision of the whole Chapter 4.1, sections A9.1 to A9.3 of Annex 9 and Appendix VI is proposed.

5. This proposal includes corrections of Chapter 4.1 (first revised edition) already agreed by the UN SCEGHS at its 12th session, and editorial corrections made by the Secretariat of the UN SCEGHS during the preparation of the text of the 2nd revised edition of the GHS (See Annex 2).

Annex 1:

A. GENERAL EXPLANATORY NOTES TO THE PROPOSED TEXT OF CHAPTER 4.1 AND ANNEX 9 (SECTIONS A9.1 to A9.3)

General The term and sub-class ‘Chronic hazard’ has been changed to ‘Long-term hazard’ throughout the chapter.

Rationale: The term ‘*chronic hazard*’ is etiologically suspect and at best shorthand for the hazard of a chemical associated with its chronic toxicity. The term ‘*Long term hazard*’ on the other hand has been defined as the hazard of a chemical associated with its chronic toxicity and its intrinsic potential to cause enhanced long-term exposure levels in the aquatic environment. Therefore the latter term is better thought to describe the sub-class of concern.

Note: Everyone is now familiar with the present category names and in order not to change too much unless it really improves the understanding, the names of the categories Chronic 1 to Chronic 4 are retained. Also, the introduction of the use of chronic toxicity data for assigning a chronic hazard category does give a reason to retain the names of the categories.

General The text has been revised as to include ‘*NOEC or ECx*’ or ‘*NOEC or equivalent ECx*’ consistently throughout the chapter.

Rationale: That ECx in relation to the criteria can be used as an alternative to NOEC for measuring chronic toxicity has previously been agreed and is currently part of the GHS criteria. Also in the scientific issue paper (recently submitted to the UN Sub-Committee of Experts on GHS) it is stated in paragraph 14 that "The development and concepts presented in this document can also be applied to expressions of chronic toxicity based on ECx. Additional guidance from the OECD is available (OECD 2006)."

B. Specific explanatory notes to the proposed text of Chapter 4.1 (See also Annex 2)

4.1 HAZARDOUS TO THE AQUATIC ENVIRONMENT

4.1.1 Definitions and general considerations

4.1.1.1 Insertion of definitions for *Acute (short term) hazard, ECx, Long-term hazard and NOEC*. Updating the definitions for *Chronic aquatic toxicity* and *Acute aquatic toxicity*, to ensure consistency.

4.1.1.2-6 Change of order the basic elements are presented, to reflect the accommodation of chronic toxicity to aquatic organisms for assigning a chronic hazard category.

4.1.2 Classification criteria for substances

4.1.2.1-2 The text is revised, to a) reflect the accommodation of chronic toxicity to aquatic organisms for assigning a chronic hazard category, and b) to clarify that the core part of the system consists of three acute classification categories and three chronic classification categories and that the system in addition also introduces a “safety net” classification (referred to as Category Chronic 4).

4.1.2.2 This paragraph is former paragraph 4.1.2.12, but the word “organic” is deleted in the third sentence and the last sentence is revised to reflect the new classification criteria for long term hazards.

4.1.2.3 New paragraph, inserted as new part of the system to accommodate chronic toxicity to aquatic organisms for assigning a chronic hazard category.

Note: as a consequence of the insertion of paragraphs 4.1.2.2 and 4.1.2.3 former paragraphs 4.1.2.2 to 4.1.2.5 have become paragraphs 4.1.2.4 to 4.1.2.7.

Table 4.1.1 (Categories for substances hazardous to the aquatic environment)

Former Figure 4.1.1 is changed into new Table 4.1.1 to a) reflect the fact that it is a table and not a figure and b) accommodate chronic toxicity to aquatic organisms for assigning a chronic hazard category;

New Note 1 inserted to explain the use of test data on other organisms than ‘fish, crustacea and algae’;

New Note 2 inserted to emphasize the necessity when classifying substances as Acute 1 and/or Chronic 1 to also indicate an appropriate M-factor to apply the summation method;

Note 3 is former Note 1b to former Table 4.1.1; former Note 2b is deleted as it is no longer relevant;

Note 4 is former Note 3 to former Table 4.1.1 (the text has been amended to clarify that “When no useful data on degradability are available - either experimentally determined or estimated data - the substance should be regarded as not rapidly degradable”);

Note 5 is former Note 4 to former Table 4.1.1;

Note: as a consequence of changing Figure 4.1.1 into Table 4.1.1, former Tables 4.1.1 to 4.1.5 has become Tables 4.1.2 to 4.1.6.

Figure 4.1.1 (Categories for substances long-term hazardous to the aquatic environment)

New figure to describe the accommodation of chronic toxicity to aquatic organisms for assigning a chronic hazard category.

Note: Former Table 4.1.1 (now 4.1.2) is moved to new paragraph 4.1.2.14. Former Notes 1a and 2a to former Table 4.1.1 are moved under new Table 4.1.2.

4.1.2.5 Text was added in the third sentence to clarify the lowest toxicity value that should be considered for classifying. The last sentence has been deleted as a consequence of the development of the classification scheme to accommodate chronic toxicity to aquatic organisms for assigning a chronic hazard category.

- 4.1.2.7** (i) The wording “> water solubility” is inserted for consistency.
- (ii) The text is also updated as a consequence of the development of the classification scheme to accommodate chronic toxicity to aquatic organisms for assigning a chronic hazard category.

Note: Former 4.1.2.6 is deleted as a consequence of the development of the classification scheme to accommodate chronic toxicity to aquatic organisms for assigning a chronic hazard category.

Note: As a consequence of the insertion of paragraphs 4.1.2.2 and 4.1.2.3 and deletion of former paragraph 4.1.2.6, former paragraphs 4.1.2.7 to 4.1.2.11 have become paragraphs 4.1.2.8 to 4.1.2.12. All sub-paragraphs have been renumbered accordingly.

Note: Former paragraph 4.1.2.12 is new paragraph 4.1.2.2.

- 4.1.2.10** A sentence was added to indicate the relationships between chronic toxicity and bioaccumulation potential.

- 4.1.2.14** This new paragraph is called “*The Classification criteria for substances diagrammatically summarized*” and consists of a revised version of former Table 4.1.1 (now 4.1.2).

Table 4.1.2 (Classification scheme for substances hazardous to the aquatic environment)

As explained above, this table is a revised version of former Table 4.1.1. As it diagrammatically summarizes the classification criteria for substances it is thought to fit better at the end of subchapter 4.1.2 (Classification criteria for substances). The table itself has been updated to properly reflect the proposal for the development of the classification scheme to accommodate chronic toxicity to aquatic organisms for assigning a chronic hazard category as presented in subchapter 4.1.2.

- (i) Note 1 is former Note 1a to former Table 4.1.1;
- (ii) Note 2 is inserted to emphasize the ‘escape clause’.
- (iii) Note 3 is former Note 2a to former Table 4.1.1, slightly revised;
- (iv) Notes 4 and 5 are inserted as explanation for Category: Chronic 4.

4.1.3 Classification criteria for mixtures

- 4.1.3.1** “Relevant ingredients of a mixture” are described more precisely.

Figure 4.1.2 Tiered approach to classification of mixtures for acute and chronic aquatic environmental hazards

The figure has been updated as chronic toxicity data can be applied in the additivity formula for mixtures where there is either aquatic toxicity or classification data for all relevant components.

4.1.3.3 Classification of mixtures when toxicity data are available for the complete mixture

The text for this complete section has been revised to include the classification for the Chronic Categories when there is adequate chronic toxicity data available for the mixture. Former Paragraph 4.1.3.3.2 has been replaced with 4 new paragraphs (4.1.3.3.2 to 4.1.3.3.5).

4.1.3.5 Classification of mixtures when data are available for all components or only for some components of the mixture

4.1.3.5.2 The end of the paragraph has been modified as now there are two different additivity formulas, one based on acute aquatic toxicity, and a new one based on chronic aquatic toxicity. The equation based on chronic aquatic toxicity considers both the rapidly and the non-rapidly degradable components.

4.1.3.5.3 The word “species” has been replaced by “taxonomic group” and at the end of the paragraph now the chronic categories 1,2,3 are included.

4.1.3.5.5.1.2 The text has been modified as chronic toxicity is now included.

Table 4.1.3 is former Table 4.1.2.

4.1.3.5.5.4.1 An editorial change is proposed for clarification.

Table 4.1.4 is former Table 4.1.3.

4.1.3.5.5.5 The text has been revised to include Chronic Category 1 together with the concentration of both the rapidly and the non-rapidly degradable fractions.

Table 4.1.5 Multiplying factors for highly toxic components of mixtures

It is Formerly Table 4.1.4, but has been revised. The multiplying factors are separated in short-term toxicity and long-term toxicity.

4.1.4 Hazard communication

There are no proposed changes to this part of Chapter 4.1.

Table 4.1.6 is former Table 4.1.5.

4.1.5 Decision logic for substances and mixtures hazardous to the aquatic environment

The decision logics are organized as follows:

4.1.5.1 Acute (short term) aquatic hazard classification

4.1.5.1.1 Decision logic 4.1.1 for substances and mixtures hazardous to the aquatic environment (*all parts related to chronic classification have been deleted*)
Mixtures decision logic 4.1.2 (additivity formula)

4.1.5.2 Long-term aquatic hazard classification (*new*)

4.1.5.2.1 Decision logic 4.1.3 (a) for substances

Decision logic 4.1.3 (b) for substances (when adequate chronic toxicity data are not available for all three trophic levels)

Decision logic 4.1.3 (c) for substances (when adequate chronic toxicity data are available for all three trophic levels)

4.1.5.2.2 Decision logic 4.1.4 for mixtures.

C. Specific explanatory notes to the proposed text of Annex 9.1-9.3 and Appendix VI

Proposed editorial changes to Annex 9.1-9.3 as a consequence of the proposed changes to Chapter 4.1

I As a consequence of the proposed changes to Chapter 4.1 to reflect the accommodation of chronic toxicity to aquatic organisms for assigning a chronic hazard category, there are proposed:

- editorial changes in paragraphs A9.1.3, A9.1.5, A9.1.8, A9.1.10a, A9.1.11, A9.2.3.2, A9.2.3.4, A9.2.3.5, A9.2.3.7, A9.2.4.2, A9.2.4.4, A9.3.3.2.4, A9.3.5.4, A9.3.5.7.2d, A9.3.5.8a, and A9.3.5.8c;
- insertion of a sentence in A9.3.2.2 to introduce a reference on statistical analysis;
- insertion of new explanatory paragraphs A9.2.3.3, A9.2.4.3;
- replacement of paragraph A9.3.3.2.2 with 2 new paragraphs: A9.3.3.2.2 and A9.3.3.2.3;
- delete the last part of a sentence in A9.3.2.7.1;
- deletion of former paragraph A9.3.3.2.4;

Note: as a consequence of the insertion of paragraphs A9.2.3.3, A9.2.4.3, and A9.3.3.2.3, former paragraph A9.2.3.3 to A9.2.3.6 has become A9.2.3.4 to A9.2.3.7; former A9.2.4.3 to A9.2.4.4 has become A9.2.4.4 to A9.2.4.5 and former A9.3.3.2.2 to A9.3.3.2.3 has become A9.3.3.2.3 to A9.3.3.2.4.

II As a consequence of the proposed changes to Chapter 4.1 to change the term and sub-class 'Chronic hazard' into 'Long-term hazard' there are proposed editorial changes in paragraphs A9.2.1, A9.2.3.1, A9.2.3.2, A9.2.4.4, and A9.2.6.3.

III Additional editorial changes are proposed to paragraphs A9.2.2 and A9.3.3.2.1, as a consequence of the proposed changes to Chapter 4.1.

Proposed additional editorial changes to Annex 9.1-9.3:

IV Additional editorial changes are proposed to paragraphs A9.1.4, A9.1.10b, A9.2.4.1, A9.2.4.5, A9.3.1, A9.3.2.2, A9.3.3.4, A9.3.4.1, A9.3.4.2, A9.3.5.2a, and A9.3.5.7.2d.

Proposed addition to Appendix VI (references)

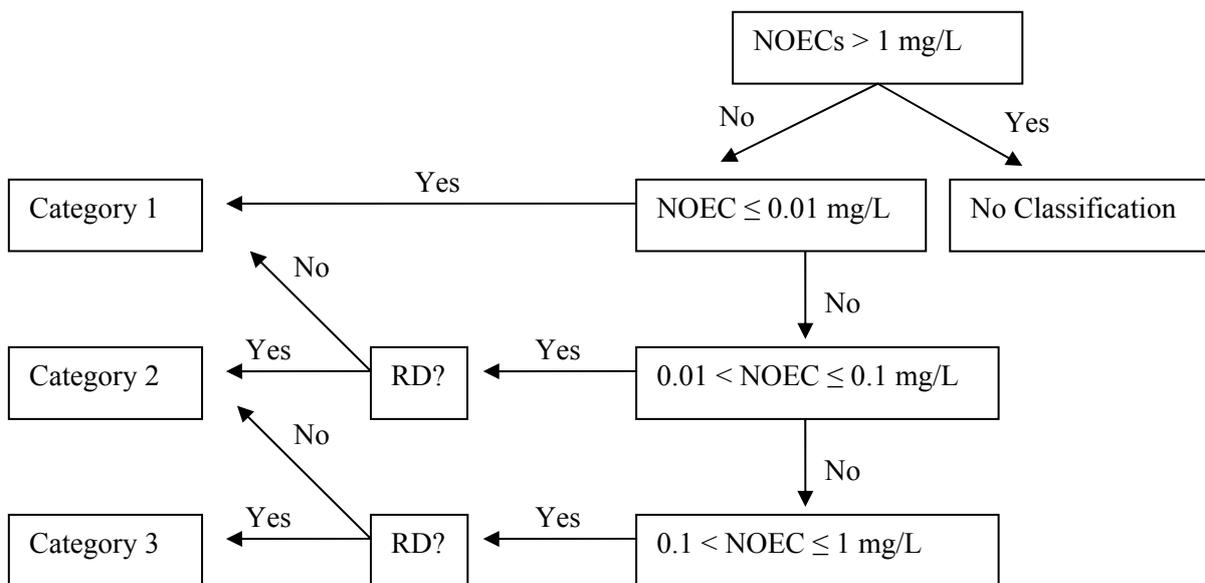
V A reference on statistical analysis was added.

Annex 1:

Annex 3 of the report from the OECD Task Force meeting in Rome 15-16 March 2006

Proposed scheme, developed in the margin of the Task Force meeting and agreed by the Task Force on 16th March 2006

Flowchart for classification when chronic data are available



RD: rapidly degradable

Proposed classification scheme (Changes to GHS Table 4.1.1¹)

Classification criteria elements			Classification categories				
Toxicity		Degradability	Bioaccumulation	Acute hazard	Chronic hazard		
Acute (L(E)C ₅₀)	Chronic (NOEC)				Non-rapidly Degradable	Rapidly degradable	In absence of long- term toxicity data
Box 1 value ≤ 1.00 mg/L	Box 8 value ≤ 0.01 mg/L	Box 5 Lack of rapid degradability	Box 6 BCF ≥ 500 or, If absent log K _{ow} ≥ 4	Category: Acute 1 Box 1	Category: Chronic 1 Boxes 8 or 9	Category: Chronic 1 Box 8	Category: Chronic 1 Boxes 1+5+6 Boxes 1+5 Boxes 1+6
Box 2 1 < value ≤ 10.0 mg/L	Box 9 0.01 < value ≤ 0.1 mg/L			Category: Acute 2 Box 2	Category: Chronic 2 Box 10	Category: Chronic 2 Box 9	Category: Chronic 2 Boxes 2+5+6 Boxes 2+5 Boxes 2+6
Box 3 10 < value ≤ 100 mg/L	Box 10 0.1 < value ≤ 1 mg/L			Category: Acute 3 Box 3		Category: Chronic 3 Box 10	Category: Chronic 3 Boxes 3+5+6 Boxes 3+5 Boxes 3+6
Box 4 No acute toxicity (Note 5)	Box 7 value > 1.00 mg/L						Category: Chronic 4 Boxes 4+5+6 Unless Box 7

¹ Changes are highlighted in shaded boxes

Annex 2

This document was submitted by the UNECE Secretariat. It includes corrections already adopted by the Sub-Committee and editorial corrections made during the preparation of the text of the 2nd revised edition of the GHS

1. The UNECE Secretariat has noticed that the text in document ENV/JM/HCL/M(2006)4 does not take into account the corrections to the text of Chapter 4.1 of the GHS which were adopted during the twelfth session of the GHS Sub-Committee of Experts in December 2006 (see paragraph 22 of the report of the Sub-Committee of Experts on its twelfth session ST/SG/AC.10/C.4/24).

2. The UNECE Secretariat would like to recall that, as from January 2007, all new proposals of amendments to the GHS text should be based on the text of the second revised edition of the GHS (i.e.: the text of the first revised edition as corrected by ST/SG/AC.10/30/Rev.1/Corr.1, -Rev.1/Corr.2 and -Rev.1/Corr.3 and as amended by ST/SG/AC.10/34/Add.3 and -34/Add.3/Corr.1).

3. On the other hand, a limited number of editorial corrections to the text of the GHS have been made during the preparation of the second revised edition of the GHS, to ensure consistency in the use of the terminology through the text. The corrections applicable to the text of chapter 4.1 are listed in section 2 of this document.

Note: Unless otherwise specified the paragraph numbers hereafter refer to those in OECD proposal

1. Corrections to the first revised edition of the GHS adopted by the Sub-Committee at its 12th session

4.1.3.5.5.3.1, 4.1.3.5.5.3.2
and 4.1.3.5.5.3.3 Replace “greater than 25%” with “greater than or equal to 25%”

Table 4.1.3 Replace “> 25%” with “≥ 25%”

4.1.3.5.5.4.1, 4.1.3.5.5.4.2, 4.1.3.5.5.4.3
and 4.1.3.5.5.4.4 Replace “greater than 25%” with “greater than or equal to 25%”

Table 4.1.4 Replace “> 25%” with “≥ 25%”

2. Editorial corrections made during the preparation of the text of the 2nd revised edition of the GHS

Replace “components” with “ingredients”

Justification: Harmonization of the different terms used in the text of the GHS to designate the individual substances making up a mixture.

4.1.2.6 In the second sentence, replace “Category I” with “Category 1”

- 4.1.3.5.3 In the first sentence, replace “substance” with “ingredient”
- 4.1.3.5.5.1.1 Replace (once) “substance” with “ingredient” and “substances” with “ingredients” (twice).
- 4.1.3.5.5.5 At the end of the first sentence, replace “the summation of classification approach” with “the summation method”

3. Additional correction to be submitted to the Sub-Committee for consideration

- 4.1.1.6.1 In the last sentence, replace “> 0.5” with “ ≥ 0.5 ”

Note by the UNECE Secretariat: Correction to be submitted to the UN Sub-Committee of experts on the GHS for consideration. Not yet taken into account in the text of the second revised edition of the GHS.

Justification: See paragraph 4.1.2.11.3 and Annex 9 of the GHS, paras. A9.4.3.3.1 and A9.4.4 (e) of the GHS.
