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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

Seventh session, 14-16 July 2004
Item 2 (b) (vi) of the provisional agenda

**UPDATING OF THE GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND
LABELLING OF CHEMICALS (GHS)**

Health hazards

Proposal for revision of Chapter 3.7 in order to clarify the terminology

Transmitted by the Organization for Economic Cooperation and Development (OECD)

1. In December 2002, the UN Sub-Committee of Experts on the GHS requested that the OECD, in the biennium 2003-2004, clarifies the following terms used in Chapter 3.7, paragraphs 3.7.2.1 and 3.7.2.2.1, of the GHS: reproductive toxicity, developmental toxicity, reproductive ability and capacity, class and category.
2. The main proposed change is to replace “reproductive ability or capacity” with “sexual function and fertility” throughout the Chapter, except in Paragraph 3.7.2.5.3. With this change, it is clear that “reproductive toxicity” and “reproductive toxicant” includes and refers to (i) effects on the sexual function and the fertility and (ii) effects on development. The text in the two bullets in 3.7.1.1, currently inconsistent, becomes coherent with this change. In Figure 3.7.1 (a), the titles of the categories and the text included for Category 1B are also revised for consistency.
3. Paragraph 3.7.2.2.1 is revised according to this clarification. In the context of paragraph 3.7.2.5.3, which refers to repeated dose toxicity studies, it is considered appropriate to use the term “reproductive function” which includes developmental toxicity.

4. For classification, effects referred to in (i) and (ii) above are considered, but not as separate issues (see change in Paragraph 3.7.2.1). This proposal does not change however the previous agreement that an indication of specific effect (e.g. relating either to sexual function and fertility, or to development) has to be provided, if known, in the Hazard Statement.

5. The OECD proposal relies on a compilation and comparison of descriptions of the terms: “Reproductive toxicity”, “Developmental toxicity”, “Reproductive ability” and “Reproductive Capacity” contained in the GHS, in the IPCS document: Environmental Health Criteria (EHC) 225 *Principles for Evaluating Health Risks to Reproduction Associated with Exposure to Chemicals*, as well as those provided by a number of OECD member countries. The proposed changes are in line with the IPCS working definitions used in document EHC 225, which is a more recent reference than the OECD/IPCS Workshop in Carshalton (see change in the first paragraph of Section 3.7.1.1).

6. The second sentence of the first paragraph of Section 3.7.1.2 provides some examples of adverse effects included in the working definition of the IPCS document, but not all of them. For example, adverse effects on gestation are not included. Considering that some reproductive effects cannot be clearly assigned to either impairment of sexual function and fertility or to development toxicity, the proposed compromise is to add a sentence to reflect this uncertainty (see the new sentence in 3.7.1.1) and to only add in the list of examples of adverse effects the words “pregnancy outcomes”, which are also mentioned in the working definition of the IPCS document.

7. The words “alterations to the related endocrine system” are also mentioned in the working definition of the IPCS document. However, considering that the classification for reproductive toxicity captures adverse effects produced by endocrine disrupters but does not provide specific classification criteria for endocrine disrupters, it was not proposed to add these words in the list of example of Section 3.7.1.2.

8. Clarification of the words “class” and “category” was requested in relation to “Effects on or via lactation”. In Figure 3.7.1 (b), it is already clearly indicated that these effects are assigned to a category and not to a class: “Effects on or via lactation are allocated to a separate single category”. So no change is considered necessary.

9. Clarification of the terms “Developmental Toxicity” is not necessary because the text in Paragraph 3.7.1.3 is already consistent with the IPCS working definition of ‘Developmental Toxicity’.

10. The modifications proposed for revision of Chapter 3.7 are presented in the annex to this document.

Annex

Proposal for revision of Chapter 3.7 in order to clarify the Terminology

3.7.1.1 In the third line, replace “at the IPCS/OECD Workshop for the Harmonization of risk assessment for Reproductive and Developmental Toxicity, Carshalton, UK, 17-21 October, 1994” with “as working definitions in IPCS/EHC Document N° 225, Principles for Evaluating Health Risks to reproduction Associated with Exposure to Chemicals” and delete the footnote.

In the first bullet, replace “reproductive ability or capacity” with “sexual function and fertility”.

Insert the following new sentences in the end:

“Some reproductive toxic effects cannot be clearly assigned to either impairment of sexual function and fertility or to developmental toxicity. Nonetheless, chemicals with these effects would be classified as reproductive toxicants with a general hazard statement.”

3.7.1.2 In the title and in the first line, replace “reproductive ability or capacity” with “sexual function and fertility”.

In the fourth line, insert “pregnancy outcomes,” between “parturition,” and “premature reproductive senescence,”.

3.7.2.1 Replace “reproductive ability and capacity” with “sexual function and fertility” and delete “as separate issues”.

Figure 3.7.1 (a)

CATEGORY 1 In the title, delete “or development”.

In the second line, replace “reproductive ability or capacity” with sexual function and fertility”.

CATEGORY 1A In the title, replace “to have produced an adverse effect on reproductive ability or capacity or on development in humans” with “human reproductive toxicant”.

CATEGORY 1B In the title, replace “to produce an adverse effect on reproductive ability or capacity or on development in humans” with “human reproductive toxicant”.

In the second sentence under the title, replace “specific reproductive toxicity” with “an adverse effect on sexual function and fertility or on development”.

CATEGORY 2 In the title, delete “or development”.

In the third line, replace “reproductive ability or capacity” with “sexual function and fertility”.

3.7.2.2.1 In the second sentence, delete “or developmental” after “reproductive” and “or development” after reproduction.

3.7.2.5.3 In the second line, replace “reproductive ability and capacity” with “reproductive function”.

3.7.5.1 In the second box on the left, replace the text in the two bullets with the following text:

- “a known human reproductive toxicant, or”
- “a presumed human reproductive toxicant?”.

In the third box on the left, replace “suspected to produce an adverse effect on reproductive ability or capacity, or on development, in humans” with “a suspected human reproductive toxicant”.
