

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

27 November 2012

Twenty-fourth session

Geneva, 12 – 14 December 2012

Item 2 (e) of the provisional agenda

Updating of the Globally Harmonized System of
Classification and Labelling of Chemicals (GHS):

Miscellaneous proposals

Deletion of several OECD Test Guidelines

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

Introduction

1. On 2 October 2012, the OECD Council adopted the deletion of the following Test Guidelines:

- TG 204 (Fish, Prolonged Toxicity Test: 14-Day Study);
- TG 477 (Genetic Toxicology: Sex-Linked Recessive Lethal Test in *Drosophila melanogaster*);
- TG 479 (Genetic Toxicology: *In vitro* Sister Chromatid Exchange Assay in Mammalian Cells);
- TG 480 (Genetic Toxicology: *Saccharomyces cerevisiae*, Gene Mutation Assay);
- TG 481 (Genetic Toxicology: *Saccharomyces cerevisiae*, Mitotic Recombination Assay);
- TG 482 (Genetic Toxicology: DNA Damage and Repair, Unscheduled DNA Synthesis in Mammalian Cells *In Vitro*);
- TG 484 (Genetic Toxicology: Mouse Spot Test)

2. The reasons for the deletion are because Test Guidelines are no longer used in practice by regulatory authorities and better Test Guidelines are available in the existing battery of genotoxicity tests for the same endpoints. Examples of other Test Guidelines that can be used for the same endpoints are already provided in the GHS.

3. The Test Guidelines will remain available from the OECD public website during an agreed transition period of 18 months. Such a transition period was agreed to allow regulatory systems in countries and regions that make reference to OECD Test Guidelines to implement the changes between the time of the Council decision and the effective deletion. Studies using any of these Test Guidelines initiated in the transition period will still be covered by the Mutual Acceptance of Data (MAD), but will cease to be covered by MAD if initiated after the end of the transition period.

4. Subsequently, the deleted Test Guidelines will effectively be removed from the collection of OECD Test Guidelines¹ on 2 April 2014. They will be available on the OECD Internet website on a page dedicated to deleted Test Guidelines, for reference.

5. Most other OECD Test Guidelines on genotoxicity are being updated. Please note that a Test Guideline on the in vivo Comet assay is under development and that a Test Guideline on Transgenic Rodent Somatic and Germ Cell Gene Mutation Assays (TG 488) was adopted on 28 July 2011.

Proposal

6. A reference to two of the Test Guidelines listed in paragraph 1 of this document exists in the GHS.

Test Guideline 204

- Annex 9, Appendix V, paragraph 2, under the heading “Test guidelines”
- Annex 10, Appendix, paragraph 4, under “Bibliography”

Test Guideline 484

- Chapter 3.5, paragraph 3.5.2.6

7. Bearing in mind that the deleted Test Guidelines may continue to be used until 2 April 2014, it is proposed to amend the references to test guidelines 204 and 484 in the next edition of the GHS as follows:

Chapter 3.5

In paragraph 3.5.2.6, for “Mouse spot test (OECD 484)”, insert a reference to the following new footnote:

“¹ This Test Guideline has been cancelled but may continue to be used until 2 April 2014.”.

Annex 9, Appendix V, paragraph 2

In the fourth line, after “OECD Test Guideline 204 (1984) Fish, Prolonged Toxicity Test: 14-Day Study”, insert a reference to the following new footnote:

“² This Test Guideline has been cancelled but may continue to be used until 2 April 2014.”.

Annex 10, Appendix, Bibliography

In the fourth line, after “OECD Guideline for Testing of Chemicals, Paris (1992). Guideline 204: Fish, Prolonged Toxicity Test: 14-Day Study”, insert a reference to the following new footnote:

“³ This Test Guideline has been cancelled but may continue to be used until 2 April 2014.”.

¹ http://www.oecd-ilibrary.org/content/package/chem_guide_pkg-en