



**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****Thirty-eighth session**

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Item 4 (c) of the provisional agenda

Implementation of the GHS:**cooperation with other bodies or international organizations****Review and update of references to OECD guidance
documents and test guidelines in the GHS****Transmitted by the Organisation for Economic Cooperation and
Development (OECD)*****Background**

1. At the thirty-sixth session of the Sub-Committee, the OECD secretariat was informally requested by the chair of the sub-committee to consider updating OECD related references in the GHS.
2. Following the meeting the GHS secretariat suggested that the OECD secretariat should also consider updating any references to OECD documents in the Manual of Tests and Criteria.
3. This document describes the review process followed by the OECD secretariat to update references to OECD documents in the GHS. It also contains the related proposed amendments to the GHS for consideration by the Sub-Committee.
4. Proposals to update the references to OECD documents in the Manual of Tests and Criteria will be submitted to both to the GHS Sub-Committee and to the Sub-Committee of Experts on the Transport of Dangerous Goods (TDG) at a later date.

Review process

5. The following approach was followed in reviewing the GHS to update references related to OECD documents:

* In accordance with the programme of work of the Sub-Committee for 2019-2020 approved by the Committee at its ninth session (see ST/SG/AC.10/C.3/108, paragraph 141 and ST/SG/AC.10/46, paragraph 14).

- (a) Focus to only update “out of date” references to OECD documents:
Flag to the Sub-Committee texts that could be outdated, for consideration of future update
- (b) Update the references in the lists of OECD test guidelines in the GHS based on the current OECD Test Guidelines
- (c) Remove the year of publication in references to a Test Guideline, unless used as a specific citation in the body of the text.
 - (i) This is proposed as Test Guidelines are periodically updated so the reference year becomes outdated in the GHS text. The number of the Test Guideline remains
 - (ii) Where specific text in the GHS reproduces text from an OECD Guidance Document or Test Guideline and this Guidance Document or Test Guideline has been updated, the older reference is suggested to be maintained, as this is where the text derives from. A footnote mentioning the availability of an updated Test Guideline or Guidance Document is proposed. It was considered beyond the scope of this initiative to ensure that texts in the GHS based on an OECD Test Guideline or Guidance Document also makes reference to the updated versions of the related OECD documents.
- (d) Chapter 3.3. on serious eye damage/eye irritation was not included in the review conducted by the OECD secretariat, as work is on-going at Sub-Committee level on this chapter.

Proposed amendments to GHS

6. The proposed list of amendments to the GHS related to the review of references to OECD documents is contained in the annex to this document for consideration by the Sub-Committee. The proposed changes to the GHS text in “track-changes” mode are reproduced in informal document INF.3.

Additional comments

7. When reviewing the GHS text for update of OECD related references, the OECD secretariat noted the following sections of text that the Sub-Committee of the GHS may wish to consider updating in the future. These are simply observations from the work done to update the references and consideration of the full text in this aspect was not done.

- (a) Chapter 3.5: Germ cell mutagenicity
In considering adding new OECD test guidelines to examples of tests in sections 3.5.2.5 to 3.5.2.9 it was noted that there may be some overlap between the sections. Maybe the titles could be defined more precisely including the three criteria that seem to be used (as done in sections 3.5.2.5 and 3.5.2.6), i.e: in vitro/in vivo; germ cells/somatic cells; mutagenicity/genotoxicity (non-mutagenicity)
- (b) Chapter 3.6: Carcinogenicity
 - (i) Paragraph 3.6.2.7 refers to the proceedings of a WHO/IPCS workshop pointing to a number of scientific questions and states that “Accordingly, there is a need to articulate the principles necessary to resolve these scientific issues which have led to diverging classifications in the past”. A revision of this reference may be necessary based on progress made since 1995 on the proceedings referred to in the GHS.

- (ii) Paragraph 3.6.5.3.1. The excerpts reproduced under this paragraph come from the preamble to monographs of the International Agency for Research on Cancer (IARC) dated on 1991. The document was amended in 2006 and completely reshaped in 2019*. The Sub-Committee may consider whether this section need to be updated.
- (c) Appendix 9: Guidance on Hazards to the Aquatic Environment.

This Appendix is based on an OECD document from 2001 “Guidance Document on the Use of the Harmonised System for the Classification of Chemicals). Since that time ten to fifteen OECD Test Guidelines related to this appendix have been updated and five to 10 new Test Guidelines have been adopted. Also, newer related guidance documents (e.g. on difficult to test substances) have become available. The Sub-Committee may consider updating Appendix 9 based on the latest developments on this topic.

* <https://monographs.iarc.fr/iarc-monographs-preamble-preamble-to-the-iarc-monographs/>

Annex

Proposed amendments to the GHS

Chapter 3.2, table 3.2.6

In the heading of the third column, amend the list of methods to read: "...Methods 1, 2, 3, 4 and 5".

In the row for category 1, on the third cell of the table, insert ", 5" in the list of methods before "< 50 %"

In the row for category 1A, on the fifth cell of the table, insert ", 5" in the list of methods before "< 15 %"

Chapter 3.5

3.5.2.7 (a) At the end of the current list, add: "Transgenic Rodent Somatic and Germ Cell Gene Mutation Assays (OECD 488)".

3.5.2.8 Insert the following references after the introductory sentence, before the current examples ("Liver..."):

"In vivo Mammalian Alkaline Comet Assay (OECD 489)

Transgenic Rodent Somatic and Germ Cell Gene Mutation Assays (OECD 488)"

3.5.2.9 Amend the end of the second example to read as follows: "OECD 476 and 490)".

Annex 9

In the heading, replace "ENVIRONMENT¹" with ""ENVIRONMENT^{1,2}" add insert the following related footnote:

² *Since the publication of this document in 2001, new OECD Test Guidelines or Guidance Documents have been adopted which are an additional source of information. Footnotes are included in this Annex to this effect.*"

A9.3.2.2 Replace "(OECD 1998):" by "(OECD 1998)³:" and insert the following related footnote:

³ *Updated reference: OECD (2001). Harmonized integrated hazard classification system for human health and environmental effects of chemical substances and Mixtures. Series on Testing and Assessment No. 33, OECD, Paris.*"

A9.3.2.7.2 Replace "(in preparation)" with "(in preparation)⁴" and insert the following related footnote:

⁴ *Published. OECD Test Guideline No. 221: Lemna sp. Growth Inhibition Test.*"

A9.3.5.1 Replace "(OECD 2000)" with "(OECD, 2000)⁵" and insert the following related footnote:

⁵ Updated document: OECD 2019. Second edition - Guidance Document on Aqueous-Phase Aquatic Toxicity Testing of Difficult Test Chemicals, Series on Testing and Assessment No. 23 (second edition). OECD, Paris. ”.

A9.3.5.2 In the last sentence of the introductory paragraph, replace “Difficult Substances and Mixtures” with “Difficult Substances and Mixtures⁶” and insert the following related footnote:

⁶ Updated guidance available in OECD 2019 above. ”.

A9.4.2.4.8 Consequential amendment: Current footnote “2” becomes footnote “7”.

A9.4.2.4.9 Replace “(...OECD Test Guideline 303)” with “(...OECD Test Guideline 303)⁸” and insert the following related footnote:

⁸ OECD test guidelines 311 “Anaerobic Biodegradability of Organic Compounds in Digested Sludge: by Measurement of Gas Production” and 314 “Simulation Tests to Assess the Biodegradability of Chemicals Discharged in Wastewater” are also available. ”.

A9.4.4 (b) Consequential amendment: Current footnote “3” becomes footnote “9”.

A9.5.1.1 Replace “(OECD 1998)” with “(OECD, 1998)¹⁰” and insert the following related footnote:

¹⁰ Updated reference: OECD (2001). Harmonized integrated hazard classification system for human health and environmental effects of chemical substances and Mixtures. Series on Testing and Assessment No. 33, OECD, Paris. ”.

A9.5.2.2 Replace “(OECD 305, 1996)”. with “(OECD 305, 1996)¹¹” and insert the following related footnote:

¹¹ OECD Test Guideline 305 was updated in 2012. ”.

A9.5.2.3.2 Replace “(OECD 305, 1996)”. with “(OECD 305, 1996)¹¹” and insert the following related footnote:

¹¹ OECD Test Guideline 305 was updated in 2012. ”.

A9.5.2.3.5 Replace “(OECD 306, 1996)”. with “(OECD 306, 1992).

A9.5.2.3.8.2 In the last sentence of the paragraph, replace “OECD 305 (1996)” with “OECD 305, 1996)¹¹” and insert the following related footnote:

¹¹ OECD Test Guideline 305 was updated in 2012. ”.

A9.5.2.4.1 Replace “(...OECD 117, 1989)”. with “(OECD 117, 1989)¹²” and insert the following related footnote:

¹² OECD Test Guideline 117 was updated in 2004. ”.

A9.5.3.2.1 Replace “(OECD 2000)”. with “(OECD 2000)¹³” and insert the following related footnote:

¹³ Updated document: OECD 2019. Second Edition - Guidance Document on Aqueous-Phase Aquatic Toxicity Testing of Difficult Test Chemicals, Series on Testing and Assessment No. 23 (second edition). OECD, Paris. ”.

- A9.7.1.1 Replace “(OECD 1998)”. with “(OECD 1998)¹⁴” and insert the following related footnote:

¹⁴ Updated reference: *OECD (2001). Harmonized integrated hazard classification system for human health and environmental effects of chemical substances and Mixtures. Series on Testing and Assessment No. 33, OECD, Paris.*”.

Annex 9, Appendix III

- 1.2.1 Replace “(OECD 305, 1996)” with “(OECD 305, 1996)¹” and insert the following related footnote:

¹ *OECD Test Guideline 305 was updated in 2012.*”.

- 2.2.1 Replace “OECD 117 (1983)”; with ““OECD 117 (1983)²” and insert the following related footnote:

² *OECD Test Guideline 117 was updated in 2004.*”.

Annex 9, Appendix V

1. (c) Replace “<http://www.oecd.org/env/testguidelines>)” with “<http://www.oecd.org/env/ehs/testing/oecdguidelinesforhetestingofchemicals.htm>”

2. Amend the references to the OECD guidelines listed below as follows:

- Test Guideline 201: Replace “(1984)” with “(1984)²” and insert the following related footnote:

² Updated in 2011.”.

- Test Guideline 202: Replace “(1984)” with “(1984)³” and insert the following related footnote:

³ Updated in 2004.”.

- Test Guideline 203: Replace “(1992)” with “(1992)⁴” and insert the following related footnote:

⁴ Updated in 2019.”.

- Test Guideline 210: Replace “(1992)” with “(1992)⁵” and insert the following related footnote:

⁵ Updated in 2013.”.

- Test Guideline 211: Replace “(1998)” with “(1998)⁶” and insert the following related footnote:

⁶ Updated in 2012.”.

- Test Guideline 221: Add a reference to footnote “7” at the end and insert the following related footnote:

⁷ *Additional OECD tests include:
OECD Test Guideline 219 (2004) Sediment-Water Chironomid Toxicity Using Spiked Water
OECD Test Guideline 233 (2010) Sediment-Water Chironomid Life-Cycle Toxicity Test Using Spiked Water or Spiked Sediment
OECD Test Guideline 238 (2014) Sediment-Free Myriophyllum Spicatum Toxicity Test*

OECD Test Guideline 240 (2015), Medaka Extended One-generation Test
OECD Test Guideline 242 (2016) Potamopyrgus antipodarum Reproduction Test
OECD Test Guideline 243 (2016) Lymnaea stagnalis Reproduction Test”.

3. Current footnote “3” becomes footnote “8”. Amend the references to the OECD guidelines listed below as follows:

- Test Guideline 209: Replace “(1984)” with “(1984)⁹” and insert the following related footnote:

“⁹ Updated in 2010.”.

- Test Guideline 307: Replace “307” with “307 (2002)”.
- Test Guideline 308: Replace “308” with “308 (2002)”.
- Test Guideline 309: Replace “309” with “309 (2004)”, add a reference to a footnote “10” at the end, after “chemicals” and insert the following related footnote:

“¹⁰ *Additional OECD Test Guidelines include:*
OECD Test Guideline 310 (2014) Ready Biodegradability - CO₂ in sealed vessels (Headspace Test)
OECD Test Guideline 311 (2006) Anaerobic Biodegradability of Organic Compounds in Digested Sludge: by Measurement of Gas Production
OECD Test Guideline 316 (2008) Phototransformation of Chemicals in Water – Direct Photolysis”.

4. Current footnote “3” becomes footnote “11”. Amend the references to the OECD guidelines listed below as follows:

- Test Guideline 117: Replace “, 1989” with “(1989)¹²” and insert the following related footnote:

“¹² *Updated in 2004.*”.

- Test Guideline 305: Replace “, 1996” with “(1996)¹³” and insert the following related footnote:

“¹³ *Updated in 2012.*”.

- Test Guideline 123: Add a reference to a footnote “14” at the end, after “chemicals” and insert the following related footnote:

“¹⁴ *Additional OECD Test Guideline: OECD Test Guideline 315 (2008) Bioaccumulation in Sediment-dwelling Benthic Oligochaetes*”.

Annex 9, Appendix VI

1. Amend the references to the OECD guidelines listed below as follows:

- OECD 1998: Replace “(Document ENV/JM/MONO(2001)6)” with (Document [ENV/JM/MONO\(2001\)6](#))¹ and insert the following related footnote:

“¹ *Updated reference: OECD 2001. Harmonized Integrated Hazard Classification System for Human Health and Environmental Effects of Chemical Substances and Mixtures. Series on Testing and Assessment No. 33, OECD, Paris.*”.

- OECD 2000: Add a reference to a footnote “2” at the end and insert the following related footnote:

^{“2} Updated guidance: OECD 2019. Second Edition - Guidance Document on Aqueous-Phase Aquatic Toxicity Testing of Difficult Test Chemicals, Series on Testing and Assessment No. 23 (second edition). OECD, Paris”.

2. Amend the references to the OECD guideline below as follows:
 - OECD (1998): Replace “(Document ENV/JM/MONO(2001)6)” with (Document ENV/JM/MONO(2001)6)¹” and insert the following related footnote:

^{“1} Updated reference: OECD 2001. Harmonized Integrated Hazard Classification System for Human Health and Environmental Effects of Chemical Substances and Mixtures. Series on Testing and Assessment No. 33, OECD, Paris.”.
3. Amend the references to the OECD guidelines below as follows:
 - OECD, 1998: Replace “November 1998” with “November 1998¹” and insert the following related footnote:

^{“1} Updated reference: OECD 2001. Harmonized Integrated Hazard Classification System for Human Health and Environmental Effects of Chemical Substances and Mixtures. Series on Testing and Assessment No. 33, OECD, Paris.”.
 - OECD, 2000: Replace “Paris” with “Paris²” and insert the following related footnote:

^{“2} Updated guidance: OECD 2019. Second Edition - Guidance Document on Aqueous-Phase Aquatic Toxicity Testing of Difficult Test Chemicals, Series on Testing and Assessment No. 23 (second edition). OECD, Paris”.
5. Amend the references to the OECD guidelines below as follows:
 - OECD (1998): Replace “(Document ENV/JM/MONO(2001)6)” with (Document ENV/JM/MONO(2001)6)¹” and insert the following related footnote:

^{“1} Updated reference: OECD 2001. Harmonized Integrated Hazard Classification System for Human Health and Environmental Effects of Chemical Substances and Mixtures. Series on Testing and Assessment No. 33, OECD, Paris.”.
 - OECD (2000): Replace “Mixtures” with “Mixtures²” and insert the following related footnote:

^{“2} Updated guidance: OECD 2019. Second Edition - Guidance Document on Aqueous-Phase Aquatic Toxicity Testing of Difficult Test Chemicals, Series on Testing and Assessment No. 23 (second edition). OECD, Paris”.

Annex 10, Appendix, Bibliography

3. Replace “Test” with “Test³” and insert the following related footnote:

^{“3} Updated in 2019”.
4. Current footnote “3” becomes “4”.
5. Replace “Test” with “Test⁵” and insert the following related footnote:

^{“5} Updated in 2013”.