

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**

8 November 2019

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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 documents and test guidelines in annexes 9 and 10 of the GHS and comments to ST/SG/AC.10/C.4/2019/14

Note by the secretariat

1. Annexes 9 and 10 contain numerous references to standards and guidelines prepared by different organisations or standardisation bodies. An exhaustive list of references appears in the appendices to these annexes.
2. The standards and guidelines referred to in annexes 9 and 10 are those available at the time the GHS was adopted. Since then, some may have been replaced by revised or new versions or even cancelled.
3. The proposal by the OECD secretariat (see ST/SG/AC.10/C.4/2019/14, Annex) is to add a footnote against the references to OECD documents, where applicable, informing readers of the availability of a more recent revised version.
4. Bearing in mind that the GHS contains references to many other standards and test guidelines that may also be outdated, the secretariat would like to invite the Sub-Committee to consider a systematic approach for the updating of all references to standards and guidelines in annexes 9 and 10 to facilitate future updates, while avoiding repetition, insertion of a significant number of footnotes and cumbersome renumbering of existing ones.
5. The Sub-Committee is invited to consider the two options below as an alternative to the proposals for amendment to annexes 9 and 10 in ST/SG/AC.10/C.4/2019/14. The proposed amendments to Chapter 3.5 in that document remain unchanged.

Option 1: Addressing updates in a general statement

6. The list of references to test guidelines in appendix V contains a footnote indicating that “The list below will need to be regularly updated as new guidelines are adopted or draft guidelines are elaborated”. However, no regular reviews to identify revisions or new editions of the listed guidelines have been conducted since the list was introduced in the GHS for the first time, particularly as regards references to OPPTS, EC, ASTM, ISO or EPA guidelines.
7. Paragraph 1 in appendix V to annex 9 of the GHS indicates that most of these documents can be found in online compilations available from the organisations issuing them., e.g.: the European Commission (EC); the International Standardization Organization

(ISO); the Office of Prevention, Pesticides and Toxic Substances (OPPTS) of the US Environment Protection Agency; or the American Society for Testing and Materials (ASTM).

8. Given the number of references to standards, test guidelines and other guidance documents listed in appendices V and VI to Annex 9, undertaking regular reviews looking for updates, revisions, or repealed versions and preparing the relevant proposals for amendment to the list in the GHS can be rather cumbersome and time consuming.

9. In addition, bearing in mind that:

- (a) the text of annexes 9 and 10 remains unchanged (i.e.: with the references to the standards that were available at the time they were drafted); and that
- (b) information on new or revised versions of standards and test and other guidance documents is readily accessible by a simple internet search on the websites of the relevant organisations issuing them,

the secretariat would like to invite the Sub-Committee to consider the following proposal.

Proposal

Annex 9

Insert the following Note under the heading of Annex 9 and delete current footnote 1:

“NOTE: The text of Annex 9 is largely based on the “Guidance document on the use of the harmonised system for the classification of chemicals which are hazardous for the aquatic environment” published by OECD in 2001, as Series on Testing and Assessment No.27 (ENV/JM/MONO(2001)8). The Guidance document has remained unchanged since its publication in 2001, but since then, new OECD Test Guidelines or Guidance Documents have been adopted which are an additional source of information (see paragraph 1 of appendix V to this annex).”

Annex 9, Appendix V

Amend the text currently in paragraph 1 of appendix V to Annex 9 to read as follows (*new text: blue, underlined*):

“The guidelines mentioned in Annex 9 are those available at the time the GHS text was adopted in 2002. Since then, some may have been revised or updated. Information on the status of the guidelines referred to in the GHS may be obtained directly mentioned. Most of the guidelines mentioned are found in compilations from the organisation issuing them: ~~-.The main references to these are:~~

- (a) EC guidelines: Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH);
- (b) ISO guidelines: Available from the national standardisation organisations or ISO (~~Homepage:~~<http://www.iso.org/iso/home.html>);
- (c) OECD guidelines for the testing of chemicals. OECD, Paris, 1993 with regular updates (~~http://www.oecd.org/env/testguidelines~~); <http://www.oecd.org/env/ehs/testing/oecdguidelinesforthetestingofchemicals.htm>);

- (d) OPPTS guidelines: US-EPA homepage
~~(<http://www.epa.gov/opptsfrs/home/guidelin.htm>); (<https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances>)~~
- (e) ASTM: ~~ASTM's homepage (<http://www.astm.org>). Further search via "standards":~~ (<https://www.astm.org/Standard/standards-and-publications.html>)".

Delete the current footnotes 1, 2 and 3 in appendix V to annex 9.

Consequential amendment:

In the appendix to Annex 10, replace “**Bibliography**” with “**Bibliography***” and insert a footnote to read as follows: “* For information on available updates refer to the OECD website: <http://www.oecd.org/env/ehs/testing/oecdguidelinesforthetestingofchemicals.htm>”

Justification: The general statement in paragraph 1 makes readers aware of the fact that the references to guidelines in Annex 9 have been kept unchanged and that they should refer to the authors of such guidelines for further information on available updates. Readers will always have access to the most recent information on the updates directly from the authors without having to wait for a new revised version of the GHS. The general statement would also avoid a cumbersome review of all references in the GHS every two years to look for updates.

Option 2: addressing updates individually

10. If the simplified approach proposed in option 1 is not acceptable, the Sub-Committee may wish to consider updating all references on an individual basis (i.e.: references to EC, ISO, OPPTS, ASTM and OECD documents).

11. The proposal by the OECD secretariat in ST/SG/AC.10/C.4/2019/14 is to add a footnote against the references to OECD documents, where applicable, informing readers of the availability of a more recent revised version. This results in a significant number of new footnotes in annexes 9 and 10, some of them repeated several times, and consequential renumbering of existing ones.

12. Since it is likely that guidelines will continue to be revised in the future and new guidelines be developed, updating of all those references by inserting, replacing or amending footnotes may end up being a cumbersome and time-consuming task.

13. Bearing in mind that the full list of guidelines, references and test methods mentioned in annexes 9 and 10 is reproduced in appendices V and VI to annex 9 and in the appendix to annex 10, the secretariat suggests to give all information on updates in the appendices instead of inserting it as a footnote in the annexes against all references to a given guideline or test method. Readers will be informed about the availability of a list of references with details about updated versions, when applicable, in the introductory note under the heading of Annex 9.

14. The approach followed in option 2 ensures that information about updates is located at one place, avoids cumbersome referencing and repetition of footnotes throughout the text of annexes 9 and 10 and facilitates future updates.

15. The list of amendments for the updating of references to OECD documents following option 2 is reproduced below and takes account of the proposals made by the OECD secretariat in document ST/SG/AC.10/C.4/2019/14.

16. The **Sub-Committee is invited to note** that should option 2 be followed, a review of current references to EC, ISO, OPPTS and ASTM standards, guidelines and test methods in annex 9 would also have to be undertaken.

Proposal

Annex 9

Insert the following Note under the heading of Annex 9 and delete current footnote 1:

“NOTE: The text of Annex 9 is largely based on the “Guidance document on the use of the harmonised system for the classification of chemicals which are hazardous for the aquatic environment” published by OECD in 2001, as Series on Testing and Assessment No.27 (ENV/JM/MONO(2001)8). The Guidance document has remained unchanged since its publication in 2001, but since then, new OECD Test Guidelines or Guidance Documents have been adopted which are an additional source of information. For a list of updated references, refer to appendices V and VI to Annex 9.”

A9.3.2.7.2 Replace “OECD Test Guideline on Lemna (in preparation)” with “OECD Test Guideline on Lemna (in preparation)*” and add a footnote to read as follows: “* *Published. OECD Test Guideline No. 221: Lemna sp. Growth Inhibition Test.*”

Note by the secretariat: Adding a footnote in annex 9 in this case is relevant since the text does not contain a specific reference to the OECD test guideline that was in preparation at the time the annex was adopted.

A9.4.2.4.9 Replace “(e.g. the OECD Test Guideline 303)” with “(e.g. the OECD Test Guideline 303)*” and add a footnote to read as follows: “* *OECD Test Guidelines 311 and 314 are also available.*”

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

Note by the secretariat: The reference to 1996 was a mistake

Appendix V to Annex 9

Amend the following entries as indicated:

- Item 1

Amend sub-paragraphs (b) to (e) as follows:

- “(b) ISO guidelines: Available from the national standardisation organisations or ISO (~~Homepage:~~<http://www.iso.org/iso/home.html>);
- (c) OECD guidelines for the testing of chemicals. OECD, Paris, 1993 with regular updates (~~http://www.oecd.org/env/testguidelines~~); (<http://www.oecd.org/env/ehs/testing/oecdguidelinesforthetestingofchemicals.htm>);
- (d) OPPTS guidelines: US-EPA homepage (~~http://www.epa.gov/opptsfrs/home/guidelin.htm~~); (<https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances>)
- (e) ASTM: ~~ASTM's homepage (http://www.astm.org). Further search via “standards”.~~ (<https://www.astm.org/Standard/standards-and-publications.html>).

- Item 2

Amend the following entries as indicated (new text: **bold underlined**)

“OECD Test Guideline 201 (1984) (**Updated in 2011**). Alga, Growth Inhibition Test”

Note by the secretariat: The reference to OECD Test Guideline 201 appears in A9.3.2.2 and A9.3.2.7.1.

“OECD Test Guideline 202 (1984) (**Updated in 2004**) Daphnia sp. Acute Immobilisation Test and Reproduction Test”

Note by the secretariat: The reference to OECD Test Guideline 202 appears in A9.3.2.2 and A9.3.2.7.1.

“OECD Test Guideline 203 (1992) (**Updated in 2019**) Fish, Acute Toxicity Test”

Note by the secretariat: The reference to OECD Test Guideline 203 appears in 3.2.5.3.1, 3.2.5.3.2.1, table 3.2.7, 4.1.1.3, A9.3.2.2, A9.3.2.5.1, A10.5.1.3 (footnote 2) and Annex 10 (appendix).

“OECD Test Guideline 210 (1992) (**Updated in 2013**) Fish, Early-Life Stage Toxicity Test”

Note by the secretariat: The reference to OECD Test Guideline 201 appears in 4.1.1.4, A9.3.2.2, A9.3.2.5.2 and Annex 10, Appendix (Bibliography).

“OECD Test Guideline 211 (1998) (**Updated in 2012**) Daphnia magna Reproduction Test. Additional OECD test guidelines 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”

Note by the secretariat: The reference to OECD Test Guideline 211 appears in 4.1.1.4 and A9.3.2.2.

There is no reference in the GHS text to the additional test guidelines listed. Are they to be used in conjunction with or as an alternative to 211?.

The Sub-Committee is invited to consider a systematic approach to avoid additional listing of entries that will need to be regularly updated.

- Item 3

Amend the following entries as indicated (new text: **bold underlined**)

“OECD Test Guideline 209 (1984) (**Updated in 2010**). Activated sludge, respiration inhibition test. OECD guidelines for testing of chemicals”

“OECD Test Guideline 303A (1981). Simulation test-aerobic sewage treatment: couple units tests. OECD guidelines for testing of chemicals. **Additional test guidelines include:**

OECD Test Guideline 311 (2006), Anaerobic Biodegradability of Organic Compounds in Digested Sludge: by Measurement of Gas Production

OECD Test Guideline 314 (2008) Simulation Tests to Assess the Biodegradability of Chemicals Discharged in Wastewater.”

“OECD Test Guideline 307 (2002). Aerobic and anaerobic transformation in soil. OECD guidelines for testing of chemicals”

OECD Test Guideline 308 (2002). Aerobic and anaerobic transformation in aquatic sediment systems. OECD guidelines for testing of chemicals

OECD Test Guideline 309 (2004). Aerobic mineralisation in surface water – Simulation biodegradation test. OECD guidelines for testing of chemicals.

Additional 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

Note by the secretariat: There is no reference in the GHS text to the additional test guidelines listed. Are they to be used in conjunction with or as an alternative to 309?.

The Sub-Committee is invited to consider a systematic approach to avoid exhaustive listing of entries.

- Item 4

Amend the following entries as indicated (*new text: **bold underlined***):

“OECD Test Guideline 117, 1989 (**Updated in 2004**). OECD Guideline for testing of chemicals. Partition Coefficient (n-octanol/water), High Performance Liquid Chromatography (HPLC) Method.”.

Note by the secretariat: The reference to OECD Test Guideline 117 appears in 4.1.1.5, A9.5.2.4.1 and A9.5.2.4.2.

“OECD Test Guideline 305, 1996 (**Updated in 2012**). Bioconcentration: Flow-through Fish Test. OECD Guidelines for testing of Chemicals.”

Note by the secretariat: The reference to OECD Test Guideline 305 appears in A9.5.2.2, A9.5.2.3.2, A9.5.2.3.8.1, A9.5.2.3.8.2 and A9.5.2.3.9.4.

“OECD Test Guideline 123. Partition Coefficient (1-Octanol/Water). Slow-stirring method. OECD Guidelines for testing of chemicals. **Additional test guidelines include: OECD Test Guideline 315 (2008) Bioaccumulation in Sediment-dwelling Benthic Oligochaetes**”.

Annex 9, Appendix VI

Amend all references to the following entries as indicated (*new text **bold underlined***):

“OECD 1998. Harmonized Integrated Hazard Classification System for Human Health and Environmental Effects of Chemical Substances. OECD, Paris. (Document ENV/JM/MONO(2001)6). (**Updated in 2001) Series on Testing and Assessment No. 33, OECD, Paris.**”

Note by the secretariat: The reference to OECD 1998 appears in A9.3.2.2, A9.5.1.1, A9.7.1.1.

“OECD 2000. Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, Series on Testing and Assessment No. 23, OECD, Paris. Updated in 2019: 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.”

Note by the secretariat: The reference to OECD 2000 appears in A9.3.5.1, A9.5.3.2.1, A9.7.2.1.2.3.

Annex 10, Appendix

Amend the references to OECD Test Guidelines 201, 203 and 210 as indicated above.

Amend the footnote to OECD Test Guideline 204 to read: “This test guideline has been cancelled.”.

Justification: The introduction of the note under the heading of Annex 9 would inform readers of the availability of a list of references with details about updated versions when applicable. All references will be located at one place. This approach would avoid cumbersome referencing and repetition of footnotes throughout the text of Annexes 9 and 10 and would facilitate future updates.