Official Journal
of the European Union

EN
L series

2025/2573

19.12.2025

COMMISSION REGULATION (EU) 2025/2573

of 18 December 2025

amending Regulation (EC) No 440/2008 as regards the test methods, to adapt them to technical progress

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC ([1]), and in particular Article 13(2) thereof,

Whereas:

(1) Commission Regulation (EC) No 440/2008 ([2]) contains, in its Annex, test methods recognised as being appropriate for generating information on the physicochemical, toxicological and ecotoxicological properties of substances for the purposes of Regulation (EC) No 1907/2006.

(2) The Organisation for Economic Co-operation and Development (OECD) develops harmonised and internationally agreed test guidelines for the testing of chemicals for regulatory purposes. The OECD regularly issues new and revised test guidelines, taking account of scientific progress in this area.

(3) In order to keep Regulation (EC) No 440/2008 up to date with technical progress and to reduce the number of animals used for experimental purposes, also in accordance with Directive 2010/63/EU of the European Parliament and of the Council ([3]), the Annex of Regulation (EC) No 440/2008 should be reviewed with three updated test methods for the determination of effects on human health, relating to *in vitro* tests for serious eye damage/eye irritation and skin sensitisation ([4]), and by adding three new test methods for the assessment of ecotoxicity ([5]).

([1]) OJ L 396, 30.12.2006, p. 1, ELI: https://data.europa.eu/eli/reg/2006/1907/oj.

([2]) 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) (OJ L 142, 31.5.2008, p. 1, ELI: https://data.europa.eu/eli/reg/2008/440/oj).

([3]) Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33, ELI: http://data.europa.eu/eli/dir/2010/63/oj).

([4]) OECD Test Guideline 442D: *In Vitro* Skin Sensitisation: Assays addressing the Adverse Outcome Pathway Key Event on Keratinocyte activation (2024) https://doi.org/10.1787/9789264229822-en; OECD Test Guideline 467: Defined Approaches for Serious Eye Damage and Eye Irritation (2024) https://doi.org/10.1787/28fe2841-en; OECD Test Guideline 496: *In vitro* Macromolecular Test Method for Identifying Chemicals Inducing Serious Eye Damage and Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage (2024) https://doi.org/10.1787/970e5cd9-en.

([5]) OECD Test Guideline 252: Rapid Estrogen Activity *In Vivo* (REACTIV) assay (2024) https://doi.org/10.1787/54066090-en; OECD Test Guideline 253: Short-term Juvenile Hormone Activity Screening Assay using *Daphnia magna* (JHASA) (2024) https://doi.org/10.1787/03cb5c08-en; OECD Test Guideline 321: *Hyallela azteca* Bioconcentration Test (HYBIT) (2024) https://doi.org/10.1787/8ac30c4e-en.

(4) In addition, the following test methods, which were included in Regulation (EC) No 440/2008 – OECD Test Guideline 403 ([6]), OECD Test Guideline 442B ([7]), OECD Test Guideline 442C ([8]), OECD Test Guideline 442E ([9]), OECD Test Guideline 492 ([10]), OECD Test Guideline 492B ([11]), OECD Test Guideline 493 ([12]) – have been corrected by the OECD in 2024. It is therefore appropriate to update these methods in the Annex to Regulation (EC) No 440/2008 and to delete the outdated versions of the full descriptions for the two test methods that are laid down in Part B (OECD Test Guideline 403 and OECD Test Guideline 493) of the Annex to Regulation (EC) No 440/2008. Furthermore, other test methods, relevant for the endpoint of dustiness (for nanoforms of a substance) should be added: EN 17199-2:2019 Workplace exposure – Measurement of dustiness of bulk materials that contain or release respirable NOAA and other respirable particles – Part 2: Rotating drum method; EN 17199-3:2019 Workplace exposure – Measurement of dustiness of bulk materials that contain or release respirable NOAA and other respirable particles – Part 3: Continuous drop method; EN 17199-4:2019 Workplace exposure – Measurement of dustiness of bulk materials that contain or release respirable NOAA and other respirable particles – Part 4: Small rotating drum method; EN 17199-5:2019 Workplace exposure – Measurement of dustiness of bulk materials that contain or release respirable NOAA and other respirable particles – Part 5: Vortex shaker method. It is also appropriate to delete the full description for the test method that is laid down in Part A (Pyrophoric properties of solids and liquids) of the Annex to Regulation (EC) No 440/2008 because Part 0 already includes up to date versions of test methods relevant for those endpoints.

(5) Regulation (EC) No 440/2008 should therefore be amended accordingly.

(6) The relevant stakeholders have been consulted on the proposed amendment.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Committee established under Article 133(1) of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EC) No 440/2008 is amended in accordance with the Annex to this Regulation.

([6]) OECD Test Guideline 403: Acute Inhalation Toxicity (2024) https://doi.org/10.1787/9789264070608-en.
([7]) OECD Test Guideline 442B: Skin Sensitization: Local Lymph Node Assay: BrdU-ELISA or –FCM (2024) https://doi.org/10.1787/9789264090996-en.
([8]) OECD Test Guideline 442C: *In Chemico* Skin Sensitisation: Assays addressing the Adverse Outcome Pathway key event on covalent binding to proteins (2024) https://doi.org/10.1787/9789264229709-en.
([9]) OECD Test Guideline 442E: *In Vitro* Skin Sensitisation: *In Vitro* Skin Sensitisation assays addressing the Key Event on activation of dendritic cells on the Adverse Outcome Pathway for Skin Sensitisation (2024) https://doi.org/10.1787/9789264264359-en.
([10]) OECD Test Guideline 492: Reconstructed human Cornea-like Epithelium (RhCE) test method for identifying chemicals not requiring classification and labelling for eye irritation or serious eye damage (2024) https://doi.org/10.1787/9789264242548-en.
([11]) OECD Test Guideline 492B: Reconstructed Human Cornea-like Epithelium (RHCE) Test Method for Eye Hazard Identification (2024) https://doi.org/10.1787/0d603916-en.
([12]) OECD Test Guideline 493: Performance-Based Test Guideline for Human Recombinant Estrogen Receptor (hrER) *In Vitro* Assays to Detect Chemicals with ER Binding Affinity (2024) https://doi.org/10.1787/9789264242623-en.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 18 December 2025.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

The Annex to Regulation (EC) No 440/2008 is amended as follows:

(1) Part 0 is amended as follows:

(a) In Table 1 the entry 'Dustiness (for nanoforms of a substance)' is replaced by the following:

'Dustiness (for nanoforms of a substance)	EN 17199-1:2019 – Workplace exposure – Measurement of dustiness of bulk materials that contain or release respirable NOAA and other respirable particles – Part 1: Requirements and choice of test methods	
	EN 17199-2:2019 Workplace exposure – Measurement of dustiness of bulk materials that contain or release respirable NOAA and other respirable particles – Part 2: Rotating drum method	
	EN 17199-3:2019 Workplace exposure – Measurement of dustiness of bulk materials that contain or release respirable NOAA and other respirable particles – Part 3: Continuous drop method	
	EN 17199-4:2019 Workplace exposure – Measurement of dustiness of bulk materials that contain or release respirable NOAA and other respirable particles – Part 4: Small rotating drum method	
	EN 17199-5:2019 Workplace exposure – Measurement of dustiness of bulk materials that contain or release respirable NOAA and other respirable particles – Part 5: Vortex shaker method	
	EN 15051-1:2013 Workplace exposure – Measurement of the dustiness of bulk materials – Part 1: Requirements and choice of test methods	
	EN 15051-2:2016 Workplace exposure – Measurement of the dustiness of bulk materials – Part 2: Rotating drum method	
	EN 15051-3:2013 Workplace exposure – Measurement of the dustiness of bulk materials – Part 3: Continuous drop method'	

(b) Table 2 is amended as follows:

(i) in the entry 'Serious eye damage/eye irritation' the '*In vitro*' section is replaced by the following:

Serious eye damage/ eye irritation	'*In vitro:*	
	OECD Test Guideline 437: Bovine Corneal Opacity and Permeability Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage (2023)	(B.47.)

	OECD Test Guideline 438: Isolated Chicken Eye Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage (2023)	(B.48.)
	OECD Test Guideline 460: Fluorescein Leakage Test Method for Identifying Ocular Corrosives and Severe Irritants (2023)	(B.61.)
	OECD Test Guideline 491: Short Time Exposure *In Vitro* Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage (2023)	(B.68.)
	OECD Test Guideline 492: Reconstructed human Cornea-like Epithelium (RhCE) test method for identifying chemicals not requiring classification and labelling for eye irritation or serious eye damage (2024)	(B.69.)'
	OECD Test Guideline 492B: Reconstructed Human Cornea-like Epithelium (RHCE) Test Method for Eye Hazard Identification (2024)	
	OECD Test Guideline 494: Vitrigel-Eye Irritancy Test Method for Identifying Chemicals Not Requiring Classification and Labelling for Eye Irritation or Serious Eye Damage (2021)	
	OECD Test Guideline 496: *In vitro* Macromolecular Test Method for Identifying Chemicals Inducing Serious Eye Damage and Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage (2024)	
	OECD Test Guideline 467: Defined Approaches for Serious Eye Damage and Eye Irritation (2024)	

(ii) in the entry 'Skin sensitisation', the '*In vitro*' section is replaced by the following:

Skin sensitisation	'*In vitro:*	
	OECD Test Guideline 442C: *In Chemico* Skin Sensitisation: Assays addressing the Adverse Outcome Pathway key event on covalent binding to proteins (2024)	(B.59.)
	OECD Test Guideline 442D: *In Vitro* Skin Sensitisation: Assays addressing the Adverse Outcome Pathway Key Event on Keratinocyte activation (2024)	(B.60.)
	OECD Test Guideline 442E: *In Vitro* Skin Sensitisation: *In Vitro* Skin Sensitisation assays addressing the Key Event on activation of dendritic cells on the Adverse Outcome Pathway for Skin Sensitisation (2024)	(B.71.)'
	OECD Test Guideline 497: Defined Approaches on Skin Sensitisation (2023)	

(iii) in the entry 'Skin sensitisation', in the '*In vivo*' section the row corresponding to the OECD Test Guideline 442B is replaced by the following:

	'OECD Test Guideline 442B: Skin Sensitisation – Local Lymph Node Assay: BrdU-ELISA or – FCM (2024)	(B.51.)'

(iv) in the entry 'Acute toxicity', in the 'Inhalation' section the row corresponding to the OECD Test Guideline 403 is replaced by the following:

	'OECD Test Guideline 403: Acute Inhalation Toxicity (2024)	(B.2.)'

(v) in the entry 'Endocrine disrupting properties', in the '*In vitro*' section the row corresponding to the OECD Test Guideline 493 is replaced by the following:

	'OECD Test Guideline 493: Performance-Based Test Guideline for Human Recombinant Estrogen Receptor (hrER) *In Vitro* Assays to Detect Chemicals with ER Binding Affinity (2024)	(B.70.)'

(c) Table 3 is amended as follows:

(i) in the entry 'Fate and behaviour in the environment', the following row is inserted:

	'OECD Test Guideline 321: *Hyalella azteca* Bioconcentration Test (HYBIT) (2024)'	

(ii) in the entry 'Endocrine disrupting properties', the following rows are inserted:

	'OECD Test Guideline 252: Rapid Estrogen Activity *In Vivo* (REACTIV) assay (2024)	
	OECD Test Guideline 253: Short-term Juvenile Hormone Activity Screening Assay using *Daphnia magna* (JHASA) (2024)'	

(2) in part A, the text below the heading of the Chapter A.13. is replaced by the following: 'The full description of this test method has been deleted. The equivalent international test methods, or other applicable test methods for the endpoints in question, appear in Part 0, Table 1'.

(3) in part B, the text below the heading of the Chapter B.2. is replaced by the following: 'The full description of this test method has been deleted. The equivalent international test method appears in Part 0, Table 2'.

(4) in part B, the text below the heading of the Chapter B.70. is replaced by the following: 'The full description of this test method has been deleted. The equivalent international test method appears in Part 0, Table 2'.