



Brussels, 16 July 2025
(OR. en)

11657/25

ENT 131
MI 547
IND 276
COMPET 746
SAN 457
ENV 707
CONSOM 144
CHIMIE 70

COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	14 July 2025
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	[...](2025) XXX draft
Subject:	COMMISSION REGULATION (EU) .../... of XXX amending Regulation (EC) No 440/2008 as regards the test methods, to adapt them to technical progress

Delegations will find attached document [...](2025) XXX draft.

Encl.: [...](2025) XXX draft



EUROPEAN
COMMISSION

Brussels, XXX
D106549/03
[...] (2025) XXX draft

COMMISSION REGULATION (EU) .../...

of XXX

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

(Text with EEA relevance)

Commission Regulation (EU) .../... of **XXX 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/EC¹, and in particular Article 13(2) thereof,

Whereas:

- (1) Commission Regulation (EC) No 440/2008² 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 Council³, 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

-

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: <https://eur-lex.europa.eu/eli/dir/2010/63/oj>).

eye damage/eye irritation and skin sensitisation⁴, and by adding three new test methods for the assessment of ecotoxicity⁵.

- (4) In addition, the following test methods, which were included in Regulation (EC) No 440/2008 – OECD Test Guideline 403⁶, OECD Test Guideline 442B⁷, OECD Test Guideline 442C⁸, OECD Test Guideline 442E⁹, OECD Test Guideline 492¹⁰, OECD Test Guideline 492B¹¹, OECD Test Guideline 493¹² – 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

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>.

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>.

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.

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,

For the Commission
The President
Ursula VON DER LEYEN