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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
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To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
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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 [\[...\]](#)(2024) XXX draft.

Encl.: [\[...\]](#)(2024) XXX draft



EUROPEAN
COMMISSION

Brussels, XXX
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[...] (2024) 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, seven test methods should be added to the Annex of Regulation (EC) No 440/2008: one new test method for basic physicochemical properties⁴, one new and two updated test methods for the determination of effects on human health, relating to *in vitro* tests for immunotoxicity and skin sensitisation⁵, and three updated test methods for the assessment of ecotoxicity⁶.

¹ OJ L 396, 30.12.2006, p. 1, ELI: <http://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: <http://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 126: Determination of the Hydrophobicity Index of Nanomaterials Through an Affinity Measurement (2023), <https://doi.org/10.1787/ae9c0fd1-en>.

⁵ OECD Test Guideline 444A: In Vitro Immunotoxicity: IL-2 Luc Assay (2023) <https://doi.org/10.1787/27b10ba3-en>; OECD Test Guideline 442C: In Chemico Skin Sensitisation: Assays addressing the Adverse Outcome Pathway key event on covalent binding to proteins (2023) <https://doi.org/10.1787/9789264229709-en>; OECD Test Guideline 442E: In Vitro Skin Sensitisation: In

- (4) In addition, OECD has issued in 2023 new, corrected versions of the following test methods, which were included in Regulation (EC) No 440/2008: OECD Test Guideline 125⁷; OECD Test Guideline 316⁸; OECD Test Guideline 405⁹; OECD Test Guideline 437¹⁰; OECD Test Guideline 438¹¹; OECD Test Guideline 456¹²; OECD Test Guideline 458¹³; OECD Test Guideline 460¹⁴; OECD Test Guideline 487¹⁵; OECD Test Guideline 491¹⁶; OECD Test Guideline 492¹⁷; OECD Test Guideline 496¹⁸; OECD Test Guideline 497¹⁹; OECD Test Guideline 498²⁰. It is therefore appropriate to delete the outdated versions of the full descriptions for those test methods from Parts B and C of the Annex to Regulation (EC) No 440/2008.
- (5) In order to achieve better alignment with related legislation, in particular Regulation (EC) 1272/2008 of the European Parliament and of the Council²¹, the listing of the test

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- Vitro Skin Sensitisation assays addressing the Key Event on activation of dendritic cells on the Adverse Outcome Pathway for Skin Sensitisation (2023), <https://doi.org/10.1787/9789264264359-en>.
- 6 OECD Test Guideline No. 240: Medaka Extended One Generation Reproduction Test (MEOGRT) (2023) <https://doi.org/10.1787/9789264242258-en>; OECD Test Guideline 218: Sediment-Water Chironomid Toxicity Using Spiked Sediment (2023) <https://doi.org/10.1787/9789264070264-en>; OECD Test Guideline 219: Sediment-Water Chironomid Toxicity Using Spiked Water (2023) <https://doi.org/10.1787/9789264070288-en>.
- 7 OECD Test Guideline 125: Nanomaterial Particle Size and Size Distribution of Nanomaterials (2023) <https://doi.org/10.1787/af5f9bda-en>.
- 8 OECD Test Guideline 316: Phototransformation of Chemicals in Water – Direct Photolysis (2023) <https://doi.org/10.1787/9789264067585-en>.
- 9 OECD Test Guideline 405: Acute Eye Irritation/Corrosion (2023) <https://doi.org/10.1787/9789264185333-en>.
- 10 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), <https://doi.org/10.1787/9789264203846-en>.
- 11 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) <https://doi.org/10.1787/9789264203860-en>.
- 12 OECD Test Guideline 456: H295R Steroidogenesis Assay (2023) <https://doi.org/10.1787/9789264122642-en>.
- 13 OECD Test Guideline 458: Stably Transfected Human Androgen Receptor Transcriptional Activation Assay for Detection of Androgenic Agonist and Antagonist Activity of Chemicals (2023) <https://doi.org/10.1787/9789264264366-en>.
- 14 OECD Test Guideline 460: Fluorescein Leakage Test Method for Identifying Ocular Corrosives and Severe Irritants (2023) <https://doi.org/10.1787/9789264185401-en>.
- 15 OECD Test Guideline 487: In Vitro Mammalian Cell Micronucleus Test (2023) <https://doi.org/10.1787/9789264264861-en>.
- 16 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) <https://doi.org/10.1787/9789264242432-en>.
- 17 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 (2023) <https://doi.org/10.1787/9789264242548-en>.
- 18 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 (2023) <https://doi.org/10.1787/970e5cd9-en>.
- 19 OECD Test Guideline 497: Defined Approaches on Skin Sensitisation (2023) <https://doi.org/10.1787/b92879a4-en>.
- 20 OECD Test Guideline 498: In vitro Phototoxicity - Reconstructed Human Epidermis Phototoxicity test method (2023) <https://doi.org/10.1787/7b2f9ea0-en>.
- 21 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p.1, ELI: <http://data.europa.eu/eli/reg/2008/1272/oj>).

methods for physicochemical properties in Part 0, Table 1 of the Annex to Regulation (EC) No 440/2008 should be restructured and relevant test methods should be added: ASTM D4359-90: Standard Test Method for Determining whether a Material Is a Liquid or a Solid; Test for determining fluidity according to section 2.3.4 of Annex A of the Agreement concerning the International Carriage of Dangerous Goods by Road (ADR); Calorimetric test methods according to section 20.3.3.3 of Part II of the UN Manual of Tests and Criteria; DIN 66137-2 - Determination of solid state density - Part 2: Gas pycnometry; ISO 12154- Determination of density by volumetric displacement - Skeleton density by gas pycnometry; ISO/TR 14187:2020 - Surface chemical analysis -Characterization of nanostructured materials; EN 17199-1:2019 – Workplace exposure - Measurement of dustiness of bulk materials that contain or release respirable NOA and other respirable particles; EN 15051-1: Workplace exposure - Measurement of the dustiness of bulk materials - Part 1: Requirements and choice of test methods; EN 15051-2: Workplace exposure - Measurement of the dustiness of bulk materials - Part 2: Rotating drum method; EN 15051-3: Workplace exposure - Measurement of the dustiness of bulk materials - Part 3: Continuous drop method; the following tests methods, as provided for in Annex I, Part 2, of Regulation (EC) 1272/2008 of the European Parliament and of the Council: test method for pyrophoric gases²²; test method for chemical instability²³; test methods for determining the initial boiling point of flammable liquids²⁴; test methods for determining the flash point of flammable liquids²⁵; test method for self-reactive substances²⁶; test methods for organic peroxides²⁷; test method for substances corrosive to metals²⁸, and test methods for desensitised explosives²⁹.

- (6) Regulation (EC) No 440/2008 should therefore be amended accordingly.
- (7) The relevant stakeholders have been consulted on the proposed amendment.
- (8) 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.

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- ²² Section 2.2.4.2. of Annex I, Part 2, of Regulation (EC) No 1272/2008 of the European Parliament and of the Council.
 - ²³ Section 2.2.4.4. of Annex I, Part 2, of Regulation (EC) No 1272/2008 of the European Parliament and of the Council.
 - ²⁴ Table 2.6.4 of Annex I, Part 2 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council.
 - ²⁵ Section 2.6.4.4. of Annex I, Part 2 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council.
 - ²⁶ Section 2.8.4.1. of Annex I, Part 2, of Regulation (EC) No 1272/2008 of the European Parliament and of the Council.
 - ²⁷ Section 2.15.4.1. of Annex I, Part 2, of Regulation (EC) No 1272/2008 of the European Parliament and of the Council.
 - ²⁸ Section 2.16.2.1. of Annex I, Part 2, of Regulation (EC) No 1272/2008 of the European Parliament and of the Council.
 - ²⁹ Section 2.17.2.1., points (b) and (c), and Section 2.17.2.2 of Annex I, Part 2 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council.

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