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MI 547  
IND 276  
COMPET 746  
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ENV 707  
CONSOM 144  
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#### COVER NOTE

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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

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Subject:	ANNEX to the Commission Regulation (EU) .../... of XXX amending Regulation (EC) No 440/2008 as regards the test methods, to adapt them to technical progress
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Delegations will find attached document [...](2023) XXX - D 106549/03 ANNEX.

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Encl.: [...](2023) XXX - D 106549/03 ANNEX

**EN**  
**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	<i>In vitro:</i>	
	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 <i>In Vitro</i> 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: <i>In vitro</i> 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	<i>In vitro:</i>
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	OECD Test Guideline 442C: <i>In Chemico</i> Skin Sensitisation: Assays addressing the Adverse Outcome Pathway key event on covalent binding to proteins (2024)	(B.59.)
	OECD Test Guideline 442D: <i>In Vitro</i> Skin Sensitisation: Assays addressing the Adverse Outcome Pathway Key Event on Keratinocyte activation (2024)	(B.60.)
	OECD Test Guideline 442E: <i>In Vitro</i> Skin Sensitisation: <i>In Vitro</i> 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.)';
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- (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.)';
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- (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) <i>In Vitro</i> Assays to Detect Chemicals with ER Binding Affinity (2024)	(B.70.)';
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- (c) Table 3 is amended as follows:

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

	'OECD Test Guideline 321: <i>Hyalella azteca</i> Bioconcentration Test (HYBIT) (2024)'	
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- (vii) in the entry 'Endocrine disrupting properties', the following rows are inserted:

	'OECD Test Guideline 252: Rapid Estrogen Activity <i>In Vivo</i> (REACTIV) assay (2024)	'
	OECD Test Guideline 253: Short-term Juvenile Hormone Activity Screening Assay using <i>Daphnia magna</i> (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'.