Il-Ġurnal Uffiċjali
tal-Unjoni Ewropea

MT
Is-serje L

2025/2573

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REGOLAMENT TAL-KUMMISSJONI (UE) 2025/2573

tat-18 ta' Diċembru 2025

li jemenda r-Regolament (KE) Nru 440/2008 fir-rigward tal-metodi ta' ttestjar, biex jadattahom għall-progress tekniku

(Test b'rilevanza għaż-ŻEE)

IL-KUMMISSJONI EWROPEA,

Wara li kkunsidrat it-Trattat dwar il-Funzjonament tal-Unjoni Ewropea,

Wara li kkunsidrat ir-Regolament (KE) Nru 1907/2006 tal-Parlament Ewropew u tal-Kunsill tat-18 ta' Diċembru 2006 dwar ir-reġistrazzjoni, il-valutazzjoni, l-awtorizzazzjoni u r-restrizzjoni ta' sustanzi kimiċi (REACH), li jistabbilixxi Aġenzija Ewropea għas-Sustanzi Kimiċi, li jemenda d-Direttiva 1999/45/KE u li jħassar ir-Regolament (KEE) Nru 793/93 tal-Kunsill u r-Regolament (KE) Nru 1488/94 tal-Kummissjoni kif ukoll id-Direttiva 76/769/KEE tal-Kunsill u d-Direttivi 91/155/KEE, 93/67/KEE, 93/105/KE u 2000/21/KE tal-Kummissjoni [1], u b'mod partikolari l-Artikolu 13(2) tiegħu,

Billi:

(1) Ir-Regolament tal-Kummissjoni (KE) Nru 440/2008 [2] fih, fl-Anness tiegħu, il-metodi ta' ttestjar rikonoxxuti bħala xierqa għall-ġenerazzjoni ta' informazzjoni dwar il-proprjetajiet fiżikokimiċi, tossikoloġiċi u ekotossikoloġiċi tas-sustanzi għall-finijiet tar-Regolament (KE) Nru 1907/2006.

(2) L-Organizzazzjoni għall-Kooperazzjoni u l-Iżvilupp Ekonomiċi (OECD, Organisation for Economic Co-operation and Development) tiżviluppa linji gwida armonizzati u miftiehma f'livell internazzjonali għall-ittestjar ta' sustanzi kimiċi għal skopijiet regolatorji. L-OECD b'mod regolari toħroġ linji gwida ġodda u riveduti dwar l-ittestjar, filwaqt li tqis il-progress xjentifiku f'dan il-qasam.

(3) Sabiex ir-Regolament (KE) Nru 440/2008 jinżamm aġġornat mal-progress tekniku u biex jitnaqqas l-għadd ta' annimali li jintużaw għal skopijiet sperimentali, ukoll f'konformità mad-Direttiva 2010/63/UE tal-Parlament Ewropew u tal-Kunsill [3], jenħtieġ li l-Anness tar-Regolament (KE) Nru 440/2008 jiġi rieżaminat bi tliet metodi ta' ttestjar aġġornati għad-determinazzjoni tal-effetti fuq is-saħħa tal-bniedem, marbuta mat-testijiet *in vitro* għal ħsara serja lill-għajnejn/l-irritazzjoni tal-għajnejn u s-sensitizzazzjoni tal-ġilda [4], u billi jiżdiedu tliet metodi ġodda ta' ttestjar għall-valutazzjoni tal-ekotossiċità [5].

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

[2] Ir-Regolament tal-Kummissjoni (KE) Nru 440/2008 tat-30 ta' Mejju 2008 li jistabbilixxi metodi ta' ttestjar skont ir-Regolament (KE) Nru 1907/2006 tal-Parlament Ewropew u tal-Kunsill dwar ir-reġistrazzjoni, il-valutazzjoni, l-awtorizzazzjoni u r-restrizzjoni ta' sustanzi kimiċi (REACH) (ĠU L 142, 31.5.2008, p. 1, ELI: https://data.europa.eu/eli/reg/2008/440/oj).

[3] Id-Direttiva 2010/63/UE tal-Parlament Ewropew u tal-Kunsill tat-22 ta' Settembru 2010 dwar il-protezzjoni tal-annimali li jintużaw għal skopijiet xjentifiċi (ĠU 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) Barra minn hekk, il-metodi ta' ttestjar li ġejjin, inklużi fir-Regolament (KE) Nru 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]) – ġew ikkoreġuti mill-OECD fl-2024. Għalhekk huwa xieraq li dawn il-metodi jiġu aġġornati fl-Anness tar-Regolament (KE) Nru 440/2008 u li jitħassru l-verżjonijiet skaduti tad-deskrizzjonijiet sħaħ għaż-żewġ metodi ta' ttestjar li huma stabbiliti fil-Parti B (OECD Test Guideline 403 u OECD Test Guideline 493) tal-Anness tar-Regolament (KE) Nru 440/2008. Barra minn hekk, jenħtieġ li jiżdiedu metodi oħra ta' ttestjar, rilevanti għall-punt tat-tmiem tat-trab (għan-nanoforom ta' sustanza): 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: 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. Huwa xieraq ukoll li titħassar id-deskrizzjoni sħiħa għall-metodu ta' ttestjar li huwa stabbilit fil-Parti A (Proprjetajiet piroforiċi ta' solidi u likwidi) tal-Anness tar-Regolament (KE) Nru 440/2008 minħabba li l-Parti 0 diġà tinkludi verżjonijiet aġġornati tal-metodi ta' ttestjar rilevanti għal dawk il-punti ta' tmiem.

(5) Għalhekk, jenħtieġ li r-Regolament (KE) Nru 440/2008 jiġi emendat kif xieraq.

(6) Il-partijiet ikkonċernati rilevanti ġew ikkonsultati dwar l-emenda proposta.

(7) Il-miżuri previsti f'dan ir-Regolament huma f'konformità mal-opinjoni tal-Kumitat stabbilit skont l-Artikolu 133(1) tar-Regolament (KE) Nru 1907/2006,

ADOTTAT DAN IR-REGOLAMENT:

Artikolu 1

L-Anness tar-Regolament (KE) Nru 440/2008 huwa emendat f'konformità mal-Anness ta' dan ir-Regolament.

([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.

Artikolu 2

Dan ir-Regolament għandu jidħol fis-seħħ fl-għoxrin jum wara dak tal-pubblikazzjoni tiegħu f'*Il-Ġurnal Uffiċjali tal-Unjoni Ewropea*.

Dan ir-Regolament għandu jorbot fl-intier tiegħu u japplika direttament fl-Istati Membri kollha.

Magħmul fi Brussell, it-18 ta' Diċembru 2025.

Għall-Kummissjoni
Il-President
Ursula VON DER LEYEN

ANNESS

L-Anness tar-Regolament (KE) Nru 440/2008 huwa emendat kif ġej:

(1) il-Parti 0 hija emendata kif ġej:

(a) Fit-Tabella 1 l-entrata "Ħolqien ta' trab (għan-nanoforom ta' sustanza)" hija sostitwita b'dan li ġej:

"Ħolqien ta' trab (għan-nanoforom ta' sustanza)	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) It-tabella 2 hija emendata kif ġej:

(i) fl-entrata "Ħsara serja lill-għajnejn/irritazzjoni tal-għajnejn", it-taqsima "*In vitro*" hija sostitwita b'dan li ġej:

Ħsara serja lill-għajnejn/irritazzjoni tal-għajnejn	"*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) fl-entrata "Sensitizzazzjoni tal-ġilda", it-taqsima "*In vitro*" hija sostitwita b'dan li ġej:

Sensitizzazzjoni tal-ġilda	"*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) fl-entrata "Sensitizzazzjoni tal-ġilda", fit-taqsima "*In vivo*" ir-ringiela li tikkorrispondi għall-OECD Test Guideline 442B hija sostitwita b'dan li ġej:

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

(iv) fl-entrata "Tossiċità akuta", fit-taqsima "Inhalation" ir-ringiela li tikkorrispondi għall-OECD Test Guideline 403 hija sostitwita b'dan li ġej:

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

(v) fl-entrata "Proprjetajiet li jfixklu s-sistema endokrinali", fit-taqsima "*In vitro*" ir-ringiela li tikkorrispondi għall-OECD Test Guideline 493 hija sostitwita b'dan li ġej:

	"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) It-tabella 3 hija emendata kif ġej:

(i) fl-entrata "Id-destin u l-imġiba fl-ambjent", tiddaħħal ir-ringiela li ġejja:

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

(ii) fl-entrata "Proprjetajiet li jfixklu s-sistema endokrinali", jiddaħħlu r-ringieli:

	"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) fil-parti A, it-test taħt it-titolu tal-Kapitolu A.13. huwa sostitwit b'dan li ġej: "Id-deskrizzjoni sħiħa ta' dan il-metodu ta' ttestjar tħassret. Il-metodi ta' ttestjar internazzjonali ekwivalenti, jew metodi ta' ttestjar oħra applikabbli għall-punti tat-tmiem ikkonċernati, jinsabu fil-Parti 0, it-Tabella 1".

(3) fil-parti B, it-test taħt it-titolu tal-Kapitolu B.2. huwa sostitwit b'dan li ġej: "Id-deskrizzjoni kompluta ta' dan il-metodu ta' ttestjar tħassret. Il-metodu ta' ttestjar internazzjonali ekwivalenti jidher fil-Parti 0, it-Tabella 2".

(4) fil-parti B, it-test taħt it-titolu tal-Kapitolu B.70. huwa sostitwit b'dan li ġej: "Id-deskrizzjoni kompluta ta' dan il-metodu ta' ttestjar tħassret. Il-metodu ta' ttestjar internazzjonali ekwivalenti jidher fil-Parti 0, it-Tabella 2".