2024/2492

24.9.2024

REGOLAMENT TAL-KUMMISSJONI (UE) 2024/2492

tat-23 ta' Settembru 2024

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 tal-Kummissjoni 91/155/KEE, 93/67/KEE, 93/105/KE u 2000/21/KE ([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 kimiċi għall-finijiet tar-Regolament (KE) Nru 1907/2006.

(2) L-Organizzazzjoni għall-Kooperazzjoni u l-Iżvilupp Ekonomiċi (OECD) 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 jiżdiedu seba' metodi ta' ttestjar mal-Anness tar-Regolament (KE) Nru 440/2008: metodu ta' ttestjar wieħed ġdid għall-karatteristiċi fiżikokimiċi bażiċi ([4]), metodu ta' ttestjar wieħed ġdid u tnejn aġġornati għad-determinazzjoni tal-effetti fuq is-saħħa tal-bniedem, marbuta mat-testijiet *in vitro* għall-immunotossiċità u s-sensitizzazzjoni tal-ġilda ([5]), u tliet metodi ta' ttestjar aġġornati għall-valutazzjoni tal-ekotossiċità ([6]).

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

([5]) OECD Test Guideline 444 A: *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 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.

(4) Barra minn hekk, l-OECD fl-2023 ħarġet verżjonijiet ikkoreġuti ġodda tal-metodi ta' ttestjar li ġejjin, li kienu inklużi fir-Regolament (KE) Nru 440/2008: OECD Test Guideline 125 ([7]); OECD Test Guideline 316 ([8]); OECD Test Guideline405 ([9]); OECD Test Guideline 437 ([10]); OECD Test Guideline 438 ([11]); OECD Test Guideline 456 ([12]); OECD Test Guideline 458 ([13]); OECD Test Guideline 460 ([14]); OECD Test Guideline 487 ([15]); OECD Test Guideline 491 ([16]); OECD Test Guideline 492 ([17]); OECD Test Guideline 496 ([18]); OECD Test Guideline 497 ([19]); OECD Test Guideline 498 ([20]). Jixraq għalhekk li l-verżjonijiet skaduti tad-deskrizzjonijiet sħaħ għal dawk il-metodi ta' ttestjar jitħassru mill-Partijiet B u C tal-Anness tar-Regolament (KE) Nru 440/2008.

(5) Sabiex ikun hemm allinjament aħjar mal-leġiżlazzjoni relatata, partikolarment ir-Regolament (KE) Nru 1272/2008 tal-Parlament Ewropew u tal-Kunsill ([21]), jenħtieġ li jiġi ristrutturat l-elenkar tal-metodi ta' ttestjar għall-karatteristiċi fiżikokimiċi mal-Parti 0, it-Tabella 1, tal-Anness tar-Regolament (KE) Nru 440/2008 u jenħtieġ li jiżdiedu metodi ta' ttestjar rilevanti: 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 NOAA 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;* il-metodi ta' ttestjar li ġejjin: kif previsti fl-Anness I, il-Parti 2, tar-Regolament (KE) Nru 1272/2008 tal-Parlament Ewropew u tal-Kunsill: il-metodu ta' ttestjar għall-gassijiet piroforiċi ([22]); il-metodu ta' ttestjar għall-instabilità kimika ([23]); il-metodi ta' ttestjar għad-determinazzjoni tal-punt tat-togħlija inizjali tal-likwidi fjammabbli ([24]); il-metodi ta' ttestjar għad-determinazzjoni tal-punt ta' fjammabilità tal-likwidi fjammabbli ([25]); il-metodu ta' ttestjar għas-sustanzi awtoreattivi ([26]); il-metodu ta' ttestjar għall-perossidi organiċi ([27]); il-metodu ta' ttestjar għas-sustanzi korrużivi għall-metall ([28]), u l-metodu ta' ttestjar għall-isplussivi desensitizzati ([29]).

([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]) Ir-Regolament (KE) Nru 1272/2008 tal-Parlament Ewropew u tal-Kunsill tas-16 ta' Diċembru 2008 dwar il-klassifikazzjoni, l-ittikkettar u l-imballaġġ tas-sustanzi u t-taħlitiet, li jemenda u jħassar id-Direttivi 67/548/KEE u 1999/45/KE, u li jemenda r-Regolament (KE) Nru 1907/2006, (ĠU L 353, 31.12.2008, p. 1, ELI: http://data.europa.eu/eli/reg/2008/1272/oj).
([22]) It-Taqsima 2.2.4.2 tal-Anness I, il-Parti 2, tar-Regolament (KE) Nru 1272/2008.
([23]) It-Taqsima 2.2.4.4 tal-Anness I, il-Parti 2, tar-Regolament (KE) Nru 1272/2008.
([24]) It-Tabella 2.6.4 tal-Anness I, il-Parti 2, tar-Regolament (KE) Nru 1272/2008.
([25]) It-Taqsima 2.6.4.4 tal-Anness I, il-Parti 2, tar-Regolament (KE) Nru 1272/2008.
([26]) It-Taqsima 2.8.4.1 tal-Anness I, il-Parti 2, tar-Regolament (KE) Nru 1272/2008.
([27]) It-Taqsima 2.15.4.1 tal-Anness I, il-Parti 2, tar-Regolament (KE) Nru 1272/2008.
([28]) It-Taqsima 2.16.2.1 tal-Anness I, il-Parti 2, tar-Regolament (KE) Nru 1272/2008.
([29]) It-Taqsima 2.17.2.1, il-punti (b) u (c), u t-Taqsima 2.17.2.2 tal-Anness I, il-Parti 2, tar-Regolament (KE) Nru 1272/2008.

(6) Għalhekk, jenħtieġ li r-Regolament (KE) Nru 440/2008 jiġi emendat skont dan.

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

(8) Il-miżuri provvduti minn dan ir-Regolament huma skont l-opinjoni tal-Kumitat stabbilita taħt l-Artikolu 133(1) tar-Regolament (KE) Nru 1907/2006,

ADOTTAT DAN IR-REGOLAMENT:

Artikolu 1

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

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-23 ta' Settembru 2024.

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) It-Tabella 1 hija sostitwita b'din li ġejja:

"TABELLA 1: METODI TA' TTESTJAR GĦALL-PROPRJETAJIET FIŻOKIMIĊI TAS-SUSTANZA

Proprjetajiet fiżikokimiċi bażiċi		
Punt tat-tmiem	Metodu ta' ttestjar	Kapitolu korrispondenti, li fih id-deskrizzjoni sħiħa tal-metodu ta' ttestjar, fil-Parti A ta' dan l-Anness (in-numri fil-parenteżi jindikaw li d-deskrizzjoni kompluta tal-metodu ta' ttestjar tħassret mill-Parti A; ċellola vojta: l-ebda metodu ta' ttestjar korrispondenti fil-Parti A ta' dan l-Anness)
Punt tat-tidwib/tal-iffriżar	OECD Test Guideline 102: Melting Point/Melting Range (1995)	A.1.
	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)	
Punt tat-togħlija	OECD Test Guideline 103: Boiling point (1995)	A.2.
	Test methods according to Table 2.6.4 of Annex I, Part 2 of Regulation (KE) Nru 1272/2008	
Fjammabilità	EN 15188:2020 – Determination of the spontaneous ignition behaviour of dust accumulations	
Limiti inferjuri u superjuri tal-isplużjoni	Test methods according to section 2.2.4.1. of Annex I, Part 2 of Regulation (KE) Nru 1272/2008 (ISO 10156 and EN 1839)	
Punt ta' fjammabilità	Test methods according to table 2.6.3 of Annex I, Part 2 of Regulation (KE) Nru 1272/2008	
Temperatura tal-awtofjammabilità (likwidi, gassijiet)	ISO/IEC 80079-20-1:2017 – Explosive atmospheres - Part 20-1: Material characteristics for gas and vapour classification - Test methods and data	
Temperatura tad-dekompożizzjoni	Calorimetric test methods according to section 20.3.3.3 of Part II of the UN Manual of Tests and Criteria	
	Test Series H, part II, section 28, of the UN Manual of Tests and Criteria for the self-accelerating decomposition temperature (SADT) (with reference to a specific package)	

pH	OECD Test Guideline 122: Determination of pH, Acidity and Alkalinity (2013)	
Viskożità kinematika	OECD Test Guideline 114: Viscosity of Liquids (2012)	
Solubilità fl-ilma	OECD Test Guideline 105: Water Solubility (1995)	A.6.
Partition coefficient n-octanol/water	OECD Test Guideline 107: Partition Coefficient (n-octanol/water): Shake-Flask Method (1995)	(A.8.)
	OECD Test Guideline 123: Partition Coefficient (1-Octanol/Water): Slow-Stirring Method (2022)	A.23.
	OECD Test Guideline 117: Partition Coefficient (n-octanol/water): HPLC Method (2022)	A.24.
Pressjoni tal-fwar	OECD Test Guideline 104: Vapour Pressure (2006)	(A.4)
Densità/Densità relattiva	OECD Test Guideline 109: Density of Liquids and Solids (2012)	(A.3.)
	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	
Il-karatteristiċi tal-partikoli	EU test method A.22. Length Weighted Geometric Mean Diameter of Fibres	A.22.
	ISO 21501 - Determination of Particle Size Distribution - Single Particle Light Interaction Methods	
	OECD Test Guideline 124: Determination of the Volume Specific Surface Area of Manufactured Nanomaterials (2022)	
	OECD Test Guideline 125: Particle Size and Particle Size Distribution of Nanomaterials (2023)	
	ISO/TR 14187:2020 - Surface chemical analysis -Characterization of nanostructured materials	
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	
	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	

Tensjoni tal-wiċċ	OECD Test Guideline 115: Surface Tension of Aqueous Solutions (1995)	A.5.
Kostanti ta' dissoċjazzjoni	OECD Test Guideline 112: Dissociation Constants in Water. (1981)	A.25.
Idrofobiċità	OECD Test Guideline 126: Determination of the Hydrophobicity Index of Manufactured Nanomaterials Through an Affinity Measurement (2023)	
Karatteristiċi ta' periklu fiżikokimiku		
Splussivi	Test methods for explosives according to section 2.1.2.1. and 2.1.2.3. of Annex I, Part 2 of Regulation (KE) Nru 1272/2008	
	EU Test method A.14 Explosive Properties	A.14
Gassijiet fjammabbli	Test method for the fundamental burning velocity according to section 2.2.4.1. of Annex I, Part 2 of Regulation (KE) Nru 1272/2008	
	Test method for pyrophoric gases according to section 2.2.4.2. of Annex I, Part 2 of Regulation (KE) Nru 1272/2008	
	Test method for the chemical instability according to section 2.2.4.4. of Annex I, Part 2 of Regulation (KE) Nru 1272/2008	
Gassijiet ossidanti	Test method for oxidising gases according to section 2.4.4. of Annex I, Part 2 of Regulation (KE) Nru 1272/2008	
Likwidi fjammabbli	Test method for the sustained combustibility according to section 2.6.4.5. of Annex I, Part 2 of Regulation (KE) Nru 1272/2008	
	Test methods for determining the flash point of flammable liquids according to section 2.6.4.4. of Annex I, Part 2 of Regulation (KE) Nru 1272/2008	
Solidi fjammabbli	Test method for flammable solids according to section 2.7.2.3. of Annex I, Part 2 of Regulation (KE) Nru 1272/2008	
Sustanzi awtoreattivi	Test method for self-reactive substances according to section 2.8.4.1. of Annex I, Part 2 of Regulation (KE) Nru 1272/2008	
Likwidi piroforiċi	Test method for pyrophoric liquids according to section 2.9.2.1. of Annex I, Part 2 of Regulation (KE) Nru 1272/2008	
Solidi piroforiċi	Test method for pyrophoric solids according to section 2.10.2.1. of Annex I, Part 2 of Regulation (KE) Nru 1272/2008,	
Sustanzi li jisħnu waħedhom	Test method for self-heating substances according to section 2.11.2.2 of Annex I, Part 2 of Regulation (KE) Nru 1272/2008	
Sustanzi li, meta jmissu mal-ilma, jarmu gassijiet li jaqbdu	Test method for substances which in contact with water emit flammable gases according to section 2.12.2.1. of Annex I, Part 2 of Regulation (KE) Nru 1272/2008	

Likwidi ossidanti	Test method for oxidising liquids according to section 2.13.2.1. of Annex I, Part 2 of Regulation (KE) Nru 1272/2008	
Solidi ossidanti	Test method for oxidising solids according to section 2.14.2.1. of Annex I, Part 2 of Regulation (KE) Nru 1272/2008	
Perossidi organiċi	Test methods according to section 2.15.4.1 of Annex I, Part 2 of Regulation (KE) Nru 1272/2008	
Sustanzi korrużivi għall-metalli	Test method for substances corrosive to metals according to section 2.16.2.1. of Annex I, Part 2 of Regulation (KE) Nru 1272/2008	
Splussivi desensitizzati	Test methods according to section 2.17.2.1 (b) and (c) and according to section 2.17.2.2 of Annex I, Part 2 of Regulation (KE) Nru 1272/2008	
Proprjetajiet tal-polimeri	OECD Test Guideline 118: Determination of the Number-Average Molecular Weight and the Molecular Weight Distribution of Polymers using Gel Permeation Chromatography (1996)	A.18.
	OECD Test Guideline 119: Determination of the Low Molecular Weight Content of a Polymer Using Gel Permeation Chromatography (1996)	A.19.
	OECD Test Guideline 120: Solution/Extraction Behaviour of Polymers in Water (2000)	(A.20.)"

(b) It-Tabella 2 hija emendata kif ġej:

(i) l-entrata "Ħsara serja lill-għajnejn/irritazzjoni tal-għajnejn" 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 (2023)	(B.69.)
	OECD Test Guideline 492B: Reconstructed Human Cornea-like Epithelium (RHCE) Test Method for Eye Hazard Identification (2022)	
	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 (2023)	
	OECD Test Guideline 467: Defined Approaches for Serious Eye Damage and Eye Irritation (2022)	
	In vivo:	
	OECD Test Guideline 405: Acute Eye Irritation/Corrosion (2023)	(B.5.)”

(ii) fl-entrata “Sensitizzazzjoni tal-ġilda”, it-taqsima “In vitro” hija sostitwita b’dan li ġej:

“*In vitro:*	
OECD Test Guideline 442C: *In Chemico* Skin Sensitisation Assays addressing the Adverse Outcome Pathway key event on covalent binding to proteins (2023)	(B.59.)
OECD Test Guideline 442D: *In Vitro* Skin Sensitisation Assays Addressing the AOP Key Event on Keratinocyte Activation (2022)	(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 (2023)	(B.71.)”
OECD Test Guideline 497: Defined Approaches on Skin Sensitisation (2023)	

(iii) fl-entrata “Mutaġeniċità”, ir-ringiela:

	“OECD Test Guideline 487. *In vitro* Mammalian Cell Micronucleus Test (2016)	B.49.”

hija sostitwita b'dan li ġej:

	"OECD Test Guideline 487. *In vitro* Mammalian Cell Micronucleus Test (2023)	(B.49.)";

(iv) fl-entrata "Proprjetajiet li jfixklu s-sistema endokrinali", ir-ringieli:

	"OECD Test Guideline 456: H295R Steroidogenesis Assay (2022)	B.57."
	OECD Test Guideline 458: Stably Transfected Human Androgen Receptor Transcriptional Activation Assay for Detection of Androgenic Agonist and Antagonist Activity of Chemicals (2020)	

huma sostitwiti b'dan li ġej:

	"OECD Test Guideline 456: H295R Steroidogenesis Assay (2023)	(B.57.)"
	OECD Test Guideline 458: Stably Transfected Human Androgen Receptor Transcriptional Activation Assay for Detection of Androgenic Agonist and Antagonist Activity of Chemicals (2023)	

(v) fl-entrata "Fototossiċità", ir-ringiela:

	"OECD Test Guideline 498: *In Vitro* Phototoxicity Test Method Using the Reconstructed Human Epidermis (RhE) (2021)"	

hija sostitwita b'dan li ġej:

	"OECD Test Guideline 498: *In Vitro* Phototoxicity Reconstructed Human Epidermis Phototoxicity test method (2023)"	

(vi) l-entrata li ġejja tiddaħħal wara t-taqsima "Fototossiċità":

"Immunotossiċità	OECD Test Guideline 444 A: *In vitro* immunotoxicity IL-2 Luc assay (2023)"	

(c) It-Tabella 3 hija emendata kif ġej:

(i) fl-entrata "Degradazzjoni", ir-ringiela:

	"OECD Test Guideline 316: Phototransformation of Chemicals in Water – Direct Photolysis (2008)"	

hija sostitwita b'dan li ġej:

	"OECD Test Guideline 316: Phototransformation of Chemicals in Water – Direct Photolysis (2023)"	

(ii) fl-entrata "Effetti fuq l-organiżmi sedimentarji", ir-ringieli:

	"OECD Test Guideline 218: Sediment-Water Chironomid Toxicity Using Spiked Sediment (2004)	C.27.
	OECD Test Guideline 219: Sediment-Water Chironomid Toxicity Using Spiked Water (2004)	C.28."

huma sostitwiti b'dan li ġej:

	"OECD Test Guideline 218: Sediment-Water Chironomid Toxicity Test Using Spiked Sediment (2023)	(C.27.)
	OECD Test Guideline 219: Sediment-Water Chironomid Toxicity Test Using Spiked Water (2023)	(C.28.)"

(iii) fl-entrata "Proprjetajiet li jfixklu s-sistema endokrinali", ir-ringiela:

	"OECD Test Guideline 240: Medaka Extended One-Generation Reproduction Test (MEOGRT) (2015)	C.52."

hija sostitwita b'dan li ġej:

	"OECD Test Guideline 240: Medaka Extended One Generation Reproduction Test (MEOGRT) (2023)	(C.52.)"

(2) fil-parti B, it-test taħt it-titolu ta' kull wieħed mill-Kapitoli B.49. u B.57. 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.";

(3) fil-parti C, it-test taħt it-titolu ta' kull wieħed mill-Kapitoli C.27., C.28. u C.52. 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 3."