

REGOLAMENT TAL-KUMMISSJONI (UE) 2023/464

tat-3 ta' Marzu 2023

li jemenda, għall-finijiet tal-adattament tiegħu għall-progress tekniku, l-Anness tar-Regolament (KE) Nru 440/2008 li jstabilixxi 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

(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 jstabilixxi Aġenzija Ewropea għas-Sustanzi Kimiċi, li jemenda d-Direttiva 1999/45/KE u li jhassar 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 ⁽¹⁾ tal-Kummissjoni, u b'mod partikolari l-Artikolu 13(2) u (3) tiegħu,

Billi:

- (1) L-Artikolu 13(3) tar-Regolament (KE) Nru 1907/2006 jipprevedi li, fejn ikunu meħtieġa testijiet fuq sustanzi sabiex tiġi generata informazzjoni dwar il-proprjetajiet intrinġiċi tas-sustanzi, dawn iridu jsiru skont il-metodi tat-test disposti f'Regolament tal-Kummissjoni jew skont metodi ta' ttestjar oħra internazzjonali rikonoxxuti bħala adegwati mill-Kummissjoni jew mill-Aġenzija Ewropea għas-Sustanzi Kimiċi.
- (2) 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-fini tar-Regolament (KE) Nru 1907/2006.
- (3) Il-biċċa l-kbira tal-metodi ta' ttestjar li jinsabu fl-Anness tar-Regolament (KE) Nru 440/2008 huma ekwivalenti għall-metodi maqbula u aċċettati internazzjonalment (bħal-linji gwida ta' ttestjar tal-Organizzazzjoni għall-Kooperazzjoni u l-Iżvilupp Ekonomiki). Dawn il-metodi spiss jiġu rieżaminati u mmodifikati biex jirriflettaw l-istat tax-xjenza.
- (4) Ir-ripetizzjoni tad-deskrizzjoni shiħa ta' dawk il-metodi maqbula u aċċettati internazzjonalment fl-Anness tar-Regolament (KE) Nru 440/2008 għall-fini tal-inkorporazzjoni tagħhom fil-leġiżlazzjoni tal-Unjoni wasslet għal dewmien fl-adattament tar-Regolament għall-progress xjentifiku. Bħala konsegwenza, il-metodi ta' ttestjar stabbiliti fl-Anness tar-Regolament (KE) Nru 440/2008 spiss ma jkunux allinjati mal-aktar verżjoni aġġornata tal-metodi internazzjonali korrispondenti. F'dan ir-rigward, jiżiedu metodi ta' ttestjar internazzjonali ġodda fir-Regolament (KE) Nru 440/2008 biss wara perjodu twil ta' żmien.
- (5) Din is-sitwazzjoni holqot incertezza kemm għar-registranti skont ir-Regolament (KE) Nru 1907/2006, kif ukoll għad-detenturi tad-dover skont leġiżlazzjoni oħra tal-Unjoni, dwar liema metodi jenhtieg li jintużaw għall-ġenerazzjoni tad-*data* għall-finijiet ta' dak ir-Regolament u ta' leġiżlazzjoni oħra. L-Artikolu 13(2) tar-Regolament (KE) Nru 1907/2006 jipprevedi li l-metodi jridu jkun rieżaminati u mtejjba regolarment bil-għan li jitnaqqas l-ittestjar fuq l-annimali vertebrati u jitnaqqas in-numru ta' annimali involuti, u li l-Kummissjoni għandha, jekk ikun il-każ, tagħmel proposta mill-aktar fis biex temenda r-Regolament (KE) Nru 440/2008, sabiex jiġi sostitwit, imnaqqas jew irfinut l-ittestjar fuq l-annimali. Barra minn hekk, l-Artikolu 13 tad-Direttiva 2010/63/UE tal-Parlament Ewropew u tal-Kunsill ⁽³⁾ dwar il-protezzjoni tal-annimali li jintużaw għal skopijiet xjentifiċi, jagħmilha obbligu ġuridiku għall-Unjoni li fiha jintuża metodu alternattiv li ma jinvolvi l-użu ta' annimali ħaj, minflok metodu li jinvolvi l-użu ta' annimali, ladarba tali metodu jkun rikonoxxut skont il-leġiżlazzjoni tal-Unjoni. Kwalunkwe dewmien fil-proċess tal-introduzzjoni ta' metodi alternattivi ġodda fir-Regolament (KE) Nru 440/2008 għalhekk jista' jxekkel l-adozzjoni f'waqtha ta' tali metodi ladarba dawn jiġu adottati fil-livell internazzjonali.

⁽¹⁾ ĠU L 396, 30.12.2006, p. 1.

⁽²⁾ Ir-Regolament tal-Kummissjoni (KE) Nru 440/2008 tat-30 ta' Mejju 2008 li jstabilixxi 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).

⁽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).

- (6) Fid-Deciżjoni fil-każ 23/2018/SRS, l-Ombudsman Ewropew issuġġerixxa li l-Kummissjoni tintensifika l-isforzi tagħha biex tissimplifika u thaffef il-proċess għall-introduzzjoni ta' metodi ta' ttestjar alternattivi skont ir-Regolament (KE) Nru 440/2008. Barra minn hekk, il-Parlament Ewropew, fir-risoluzzjoni tiegħu 2021/2784(RSP) tas-16 ta' Settembru 2021 dwar pjanijiet u azzjonijiet biex tithaffef it-tranzizzjoni lejn l-innovazzjoni mingħajr l-użu ta' annimali fir-riċerka, l-ittestjar regolatorju u l-edukazzjoni, fakkar li l-Artikolu 13 tar-Regolament (KE) Nru 1907/2006 jirrikjedi li r-rekwiżiti tal-metodu ta' ttestjar jiġu aġġornati hekk kif isiru disponibbli metodi li ma jinvolvux l-użu ta' annimali.
- (7) Għalhekk, sabiex jiġi żgurat li r-Regolament (KE) Nru 440/2008 jipprovdi metodi ta' ttestjar korretti, aġġornati u rilevanti li huma xierqa biex tiġi ġenerata l-informazzjoni skont ir-Regolament (KE) Nru 1907/2006, jenhtieg li tiġi inkluża tabella fl-Anness ta' dak ir-Regolament, li tagħti lista komprensiva ta' tali metodi b'referenza għall-metodu ta' ttestjar internazzjonali rispettiv. Jenhtieg li l-inklużjoni ta' referenza għal metodu ta' ttestjar fit-tabella titqies bhala rikonoxximent ta' tali metodu mill-Kummissjoni għall-finijiet tal-Artikolu 13(3) tar-Regolament (KE) Nru 1907/2006.
- (8) Jenhtieg li d-deskrizzjonijiet kompluti tal-metodi ta' ttestjar fil-Partijiet A, B u C tal-Anness tar-Regolament (KE) Nru 440/2008 li ma għadhomx jikkorrispondu għall-aktar verżjoni reċenti ta' metodu ta' ttestjar internazzjonali jithassru minn dak l-Anness biex jiġu evitati t-testijiet li jitwettqu abbazi tal-protokollu li ma jipprovdux informazzjoni xjentifika tal-ogħla livell ta' żvilupp tekniku.
- (9) Ċerti metodi ta' ttestjar stabbiliti fl-Anness tar-Regolament (KE) Nru 440/2008, kif ukoll il-metodi ta' ttestjar internazzjonali korrispondenti tagħhom, ma għadhomx jitqiesu xierqa biex tiġi ġġenerata l-informazzjoni skont ir-Regolament (KE) Nru 1907/2006. Il-metodi ta' ttestjar B.22. Test letali dominanti tar-roditori; B.25. It-trażlokazzjoni tal-ġrieden li tintiret; B.34. Test ta' tossiċità riproduttiva fuq ġenerazzjoni waħda; B.35. Studju ta' tossiċità riproduttiva fuq żewġ ġenerazzjonijiet; B.39. Test *in vivo* ta' sintezi mhux programmata ta' DNA (UDS) fuq ċelloli tal-fwied tal-mammiferi; u C.15. Testijiet tat-tossiċità għal perjodu qasir fuq il-Ħut fl-Istadji tal-Embrijun u tal-Borża u tal-Qixx; għalhekk jenhtieg li jithassru minn dak l-Anness u jenhtieg li ma jkun hemm l-ebda entrata li tirreferi għalihom fit-tabella stabbilita f'dak l-Anness.
- (10) Għalhekk, jenhtieg li r-Regolament (KE) Nru 440/2008 jiġi emendat skont dan.
- (11) Il-miżuri previsti f'dan ir-Regolament huma skont l-opinjoni tal-Kumitat stabbilit f'konformità mal-Artikolu 133 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.

Artikolu 2

Dan ir-Regolament għandu jidhol fis-seħh 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-3 ta' Marzu 2023.

Għall-Kummissjoni
Il-President
Ursula VON DER LEYEN

ANNEX

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

(1) qabel il-Parti A, tiddaħhal il-Parti 0 li ġejja

"PARTI 0: IL-METODI TA' TTESTJAR RIKONOXXUTI BĦALA XIERQA GHALL-ĠENERAZZJONI TA' INFORMAZZJONI DWAR IL-PROPRJETAJIET INTRINSIČI TAS-SUSTANZI GHALL-FINIJIET TAR-REGOLAMENT (KE) NRU 1907/2006

TABELLA 1

METODI TA' TTESTJAR GHALL-PROPRJETAJIET FIŽIKOKIMIČI TAS-SUSTANZA

Punt tat-tmiem	Metodu ta' ttestjar	Kapitolu korrispondenti, li fi h id-deskrizzjoni shiha tal-metodu ta' ttestjar, fil-Parti A ta' dan l-Anness (in-numri fil-parenteži jindikaw li d-deskrizzjoni kompluta tal-metodu ta' ttestjar thassret 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.
Punt tat-togħlija	OECD Test Guideline 103: Boiling point (1995)	A.2.
Densità	OECD Test Guideline 109: Density of Liquids and Solids (2012)	(A.3.)
Pressjoni tal-fwar	OECD Test Guideline 104: Vapour Pressure (2006)	(A.4)
Tensjoni tas-superfiċje	OECD Test Guideline 115: Surface Tension of Aqueous Solutions (1995)	A.5.
Solubilità fl-ilma	OECD Test Guideline 105: Water Solubility (1995)	A.6.
Koeffiċjent ta' partizzjoni n-ottanol/ilma	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.
Kostanti ta' dissoċjazzjoni	OECD Test Guideline 112: Dissociation Constants in Water. (1981)	A.25.
Viskożità	OECD Test Guideline 114: Viscosity of Liquids (2012)	
Punt ta' fjamabilità	Test methods according to table 2.6.3 of Annex I, Part 2 of Regulation (EC) No 1272/2008	
Limiti inferjuri u superjuri tal-isplużjoni	EN 1839:2017 – Determination of the explosion limits and the limiting oxygen concentration (LOC) for flammable gases and vapours	
Fjamabilità	Test methods according to section 2.2.4.1. of Annex I, Part 2 of Regulation (EC) No 1272/2008	
	Test L.2: sustained combustibility test, Part III, section 32 of the UN RTDG Manual of Tests and Criteria	

	Test N.1: test method for readily combustible solids, Part III, sub-section 33.2.4 of the UN RTDG Manual of Tests and Criteria	
	Test N.5: test method for substances which in contact with water emit flammable gases, Part III, sub-section 33.5.4 of the UN RTDG Manual of Tests and Criteria	
Temperatura tal-awtofjammabilità (solidi)	Test N.4: test method for self-heating substances, Part III, sub-section 33.4.6 of the UN RTDG Manual of Tests and Criteria	
	EN 15188:2020 – Determination of the spontaneous ignition behaviour of dust accumulations	
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	Test Series H, part II, section 28, of the UN RTDG Manual of Tests and Criteria	
Proprjetajiet esplożivi	Test methods according to Test series 1-3, Part I, sections 11-13 of the UN RTDG Manual of Tests and Criteria	
	EU Test method A.14 Explosive Properties	A.14
Proprjetajiet ossidanti	Test method according to section 2.4.4. of Annex I, Part 2 of Regulation (EC) No 1272/2008	
	Test O.2: test for oxidizing liquids, Part III, sub-section 34.4.2 of the UN RTDG Manual of Tests and Criteria	
	Test O.1: Test for oxidizing solids, Part III, sub-section 34.4.1 of the UN RTDG Manual of Tests and Criteria	
	Test O.3 Gravimetric test for oxidizing solids, Part III, sub-section 34.4.3 of the UN RTDG Manual of Tests and Criteria	
Piroforiċità	Test N.3: test method for pyrophoric liquids, Part III, sub-section 33.3.1.5 of the UN RTDG Manual of Tests and Criteria	
	Test N.2: test method for pyrophoric solids, Part III, sub-section 33.3.1.4 of the UN RTDG Manual of Tests and Criteria	
Granulometrija/karatteristiċi tal-partikoli	EU test method A.22. Length Weighted Geometric Mean Diameter of Fibres	A.22.
	ISO 13318 - Determination of Particle Size Distribution by Centrifugal Liquid Sedimentation Methods	
	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 (2022)	

pH	OECD Test Guideline 122: Determination of pH, Acidity and Alkalinity (2013)	
Proprietajiet 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.)

TABELLA 2: METODI TA' TTESTJAR GHALL-PROPRJETAJIET TOSSIKOLOĠIĊI

Punt tat-tmiem	Metodu ta' ttestjar	Kapitolu korrispondenti, li fih id-deskrizzjoni shiha tal-metodu ta' ttestjar, fil-Parti B ta' dan l-Anness (in-numri fil-parenteżi jindikaw li kapitolu, li fih id-deskrizzjoni kompluta tal-metodu ta' ttestjar, thassar mill-Parti B; ċellola vojta: l-ebda metodu ta' ttestjar korrispondenti fil-Parti B ta' dan l-Anness)
Korrużjoni/irritazzjoni tal-ġilda	<i>In vitro:</i>	
	OECD Test Guideline 430: <i>In vitro</i> Skin Corrosion: Transcutaneous Electrical Resistance Test Method (TER) (2015)	B.40.
	OECD Test Guideline 431: <i>In vitro</i> Skin Corrosion: Reconstructed Human Epidermis (RhE) Test Method (2019)	(B.40bis.)
	OECD Test Guideline 435: <i>In vitro</i> Membrane Barrier Test Method for Skin Corrosion (2015)	B.65.
	OECD Test Guideline 439: <i>In vitro</i> Skin Irritation: Reconstructed Human Epidermis Test Method (2021)	(B.46.)
	<i>In vivo:</i>	
	OECD Test Guideline 404: Acute Dermal Irritation/Corrosion (2015)	B.4.
Hsara serja lill-ghajnejn/irritazzjoni tal-ghajnejn	<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 (2020)	(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 (2018)	(B.48.)

	OECD Test Guideline 460: Fluorescein Leakage Test Method for Identifying Ocular Corrosives and Severe Irritants (2017)	(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 (2020)	(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 (2019)	(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: <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 (2019)	
	OECD Test Guideline 467: Defined Approaches for Serious Eye Damage and Eye Irritation (2022)	
	<i>In vivo</i> :	
	OECD Test Guideline 405: Acute Eye Irritation/Corrosion (2021)	(B.5.)
Sensitizzazzjoni tal-gilda	<i>In vitro</i> :	
	OECD Test Guideline 442C: <i>In Chemico</i> Skin Sensitisation: Direct Peptide Reactivity Assay (DPRA) (2022)	(B.59.)
	OECD Test Guideline 442D: <i>In Vitro</i> Skin Sensitisation Assays Addressing the AOP Key Event on Keratinocyte Activation (2022)	(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 (2022)	(B.71.)
	OECD Test Guideline 497: Defined Approaches on Skin Sensitisation (2021)	
	<i>In vivo</i> :	
	OECD Test Guideline 429: Skin Sensitisation - Local Lymph Node Assay (2010)	B.42.
	OECD Test Guideline 442 A: Skin Sensitisation - Local Lymph Node Assay: DA (2010)	B.50.
	OECD Test Guideline 442B: Skin Sensitisation - Local Lymph Node Assay: BrdU-ELISA or -FCM (2018)	(B.51.)

	OECD Test Guideline 406: Skin Sensitisation Guinea Pig Maximisation Test and Buehler Test (2022)	(B.6.)
Mutageniċità	<i>In vitro:</i>	
	OECD Test Guideline 471: Bacterial Reverse Mutation Test (2020)	(B.13./14.)
	OECD Test Guideline 476: <i>In Vitro</i> Mammalian Cell Gene Mutation Test Using the Hprt and xprt Genes (2016)	(B.17.)
	OECD Test Guideline 490: <i>In Vitro</i> Mammalian Cell Gene Mutation Tests Using the Thymidine Kinase Gene (2016)	B.67.
	OECD Test Guideline 473: <i>In vitro</i> Mammalian Chromosome Aberration Test (2016)	B.10.
	OECD Test Guideline 487: <i>In vitro</i> Mammalian Cell Micronucleus Test (2016)	B.49.
	<i>In vivo:</i>	
	OECD Test Guideline 475: Mammalian Bone Marrow Chromosome Aberration Test (2016)	B.11.
	OECD Test Guideline 474: Mammalian Erythrocyte Micronucleus Test (2016)	B.12.
	OECD Test Guideline 483: Mammalian Spermatogonial Chromosome Aberration Test (2016)	B.23.
	OECD Test Guideline 488: Transgenic Rodent Somatic and Germ Cell Gene Mutation Assays (2022)	(B.58.)
	OECD Test Guideline 489: <i>In Vivo</i> Mammalian Alkaline Comet Assay (2016)	B.62.
	OECD Test Guideline 470: Mammalian Erythrocyte Pig-a Gene mutation Assay (2022)	
Tossiċità akuta	Oral:	
	OECD Test Guideline 420: Acute Oral Toxicity: Fixed Dose Procedure (2002)	B.1 bis.
	OECD Test Guideline 423: Acute Oral Toxicity: Acute Toxic Class Method (2002)	B.1 tris.
	OECD Test Guideline 425: Acute Oral Toxicity: Up-and-Down Procedure (2022)	
	Dermal:	
	OECD Test Guideline 402: Acute Dermal Toxicity - Fixed Dose Procedure (2017)	(B.3.)
	Inhalation:	
	OECD Test Guideline 403: Acute Inhalation Toxicity (2009)	B.2.
	OECD Test Guideline 436: Acute Inhalation Toxicity - Acute Toxic Class Method (2009)	B.52.
	OECD Test Guideline 433: Acute Inhalation Toxicity: Fixed Concentration Procedure (2018)	

Tossicità b'doża ripetuta	OECD Test Guideline 407: Repeated Dose 28-Day Oral Toxicity Study in Rodents (2008)	B.7.
	OECD Test Guideline 412: Subacute Inhalation Toxicity: 28-Day Study (2018)	(B.8.)
	OECD Test Guideline 410: Repeated Dose Dermal Toxicity: 21/28-Day Study (1981)	B.9.
	OECD Test Guideline 422: Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (2016)	B.64.
	OECD Test Guideline 408: Repeated Dose 90-Day Oral Toxicity Study in Rodents (2018)	(B.26.)
	OECD Test Guideline 409: Repeated Dose 90-Day Oral Toxicity Study in Non-Rodents (1998)	B.27.
	OECD Test Guideline 413: Subchronic Inhalation Toxicity: 90-Day Study (2018)	(B.29.)
	OECD Test Guideline 411: Subchronic Dermal Toxicity: 90-Day Study (1981)	B.28.
	OECD Test Guideline 452: Chronic Toxicity Studies (2018)	(B.30.)
	OECD Test Guideline 453: Combined Chronic Toxicity/ Carcinogenicity Studies (2018)	(B.33.)
Tossicità riproduttiva/ tal-iżvilupp	OECD Test Guideline 443: Extended One-Generation Reproduction Toxicity Study (2018)	(B.56.)
	OECD Test Guideline 421: Reproduction/Developmental Toxicity Screening Test (2016)	B.63.
	OECD Test Guideline 422: Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (2016)	B.64.
	OECD Test Guideline 414: Prenatal Developmental Toxicity Study (2018)	(B.31.)
Tossikokinetika	OECD Test Guideline 417: Toxicokinetics (2010)	B.36.
	OECD Test Guideline 428: Skin Absorption: <i>In Vitro</i> Method (2004)	B.45.
	OECD Test Guideline 427: Skin Absorption: <i>In Vivo</i> Method (2004)	B.44.
Karcinogenicità	OECD Test Guideline 451: Carcinogenicity Studies (2018)	(B.32.)
	OECD Test Guideline 453: Combined Chronic Toxicity/ Carcinogenicity Studies (2018)	(B.33.)
	EU test method B.21. <i>In Vitro</i> Mammalian Cell Transformation Test	B.21.

Newrotossicità (tal-izvilupp)	OECD Test Guideline 424: Neurotoxicity Study in Rodents (1997)	B.43.
	OECD Test Guideline 426: Developmental Neurotoxicity Study (2007)	B.53.
	OECD Test Guideline 418: Delayed Neurotoxicity of Organophosphorus Substances Following Acute Exposure (1995)	B.37.
	OECD Test Guideline 419: Delayed Neurotoxicity of Organophosphorus Substances: 28-day Repeated Dose Study (1995)	B.38.
Proprietajiet li jfixklu s-sistema endokrinali	<i>In vitro</i>	
	OECD Test Guideline 455: Performance-Based Test Guideline for Stably Transfected Transactivation <i>In Vitro</i> Assays to Detect Estrogen Receptor Agonists and Antagonists (2021)	(B.66.)
	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)	
	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 (2015)	B.70.
	<i>In vivo</i>	
	OECD Test Guideline 440: Uterotrophic Bioassay in Rodents A short-term screening test for oestrogenic properties (2007)	B.54.
	OECD Test Guideline 441: Hershberger Bioassay in Rats, A Short-term Screening Assay for (Anti)Androgenic Properties (2009)	B.55.
Fototossicità	OECD Test Guideline 432: <i>In Vitro</i> 3T3 NRU Phototoxicity Test (2019)	(B.41.)
	OECD Test Guideline 495: Ros (Reactive Oxygen Species) Assay for Photoreactivity (2019)	
	OECD Test Guideline 498: <i>In Vitro</i> Phototoxicity Test Method Using the Reconstructed Human Epidermis (RhE) (2021)	

TABELLA 3: METODI TA' TTESTJAR GHALL-PROPRJETAJIET EKOTOSSIKOLOĠIĊI

Punt tat-tmiem	Metodu ta' ttestjar	Kapitolu korrispondenti fil-Parti C, li fih id-deskrizzjoni shiha tal-metodu ta' ttestjar, ta' dan l-Anness (in-numri fil-parenteżi jindikaw li kapitolu, li fih id-deskrizzjoni kompluta tal-metodu ta' ttestjar, thassar mill-Parti C; ċellola vojta: l-ebda metodu ta' ttestjar korrispondenti fil-Parti C ta' dan l-Anness)
Tossicità akkwatika	OECD Test Guideline 201: Freshwater Alga and Cyanobacteria, Growth Inhibition Test (2011)	C.3.
	OECD Test Guideline 209: Activated Sludge, Respiration Inhibition Test (Carbon and Ammonium Oxidation) (2010)	C.11.
	OECD Test Guideline 224: Determination of the Inhibition of the Activity of Anaerobic Bacteria (2007)	C.34.
	OECD Test Guideline 244: Protozoan Activated Sludge Inhibition Test (2017)	
	OECD Test Guideline 221: Lemna sp. Growth Inhibition Test (2006)	C.26.
	OECD Test Guideline 202: Daphnia sp. Acute Immobilisation Test (2004)	C.2.
	OECD Test Guideline 211: Daphnia magna Reproduction Test (2012)	C.20.
	OECD Test Guideline 203: Fish, Acute Toxicity Test (2019)	(C.1.)
	OECD Test Guideline 210: Fish, Early-life Stage Toxicity Test (2013)	C.47.
	OECD Test Guideline 215: Fish, Juvenile Growth Test (2000)	C.14.
	OECD Test Guideline 236: Fish Embryo Acute Toxicity (FET) Test (2013)	C.49.
	OECD Test Guideline 249: Fish Cell Line Acute Toxicity - the RTgill-W1 Cell Line Assay (2021)	
	OECD Test Guideline 242: Potamopyrgus antipodarum Reproduction Test (2016)	
	OECD Test Guideline 243: Lymnaea stagnalis Reproduction Test (2016)	
Id-Degradazzjoni	OECD Test Guideline 111: Hydrolysis as a Function of pH (2004)	C.7.
	OECD Test Guideline 301: Ready Biodegradability (1992)	C.4.
	OECD Test Guideline 302 A: Inherent Biodegradability: Modified SCAS Test (1981)	C.12.

	OECD Test Guideline 302 B: Inherent Biodegradability: Zahn-Wellens/EMPA Test (1992)	(C.9).
	OECD Test Guideline 302C: Inherent Biodegradability: Modified MITI Test (II) (2009)	
	OECD Test Guideline 303: Simulation Test - Aerobic Sewage Treatment – A: Activated Sludge Units; B: Biofilms (2001)	C.10.
	OECD Test Guideline 304 A: Inherent Biodegradability in Soil (1981)	
	OECD Test Guideline 306: Biodegradability in Seawater (1992)	C.42.
	OECD Test Guideline 307: Aerobic and Anaerobic Transformation in Soil (2002)	C.23.
	OECD Test Guideline 308: Aerobic and Anaerobic Transformation in Aquatic Sediment Systems (2002)	C.24.
	OECD Test Guideline 309: Aerobic Mineralisation in Surface Water – Simulation Biodegradation Test (2004)	C.25.
	OECD Test Guideline 310: Ready Biodegradability - CO ₂ in sealed vessels (Headspace Test) (2014)	C.29.
	OECD Test Guideline 311: Anaerobic Biodegradability of Organic Compounds in Digested Sludge: by Measurement of Gas Production (2006)	C.43.
	OECD Test Guideline 314: Simulation Tests to Assess the Biodegradability of Chemicals Discharged in Wastewater (2008)	
	OECD Test Guideline 316: Phototransformation of Chemicals in Water – Direct Photolysis (2008)	
	EU test method C.5. Degradation – Biochemical Oxygen Demand	C.5.
	EU test method C.6. Degradation – Chemical Oxygen Demand	C.6.
Id-destin u l-imġiba fl-ambjent	OECD Test Guideline 305: Bioaccumulation in Fish: Aqueous and Dietary Exposure (2012)	C.13.
	OECD Test Guideline 315: Bioaccumulation in Sediment-Dwelling Benthic Oligochaetes (2008)	C.46.
	OECD Test Guideline 317: Bioaccumulation in Terrestrial Oligochaetes (2010)	C.30.
	OECD Test Guideline 318: Dispersion Stability of Nanomaterials in Simulated Environmental Media (2017)	
	OECD Test Guideline 121: Estimation of the Adsorption Coefficient (K _{oc}) on Soil and on Sewage Sludge using High Performance Liquid Chromatography (HPLC) (2001)	C.19.
	OECD Test Guideline 106: Adsorption - Desorption Using a Batch Equilibrium Method (2000)	C.18.
	OECD Test Guideline 312: Leaching in Soil Columns (2004)	C.44.

	OECD Test Guideline 313: Estimation of Emissions from Preservative - Treated Wood to the Environment (2007)	C.45.
	OECD Test Guideline 319 A: Determination of In Vitro Intrinsic Clearance Using Cryopreserved Rainbow Trout Hepatocytes (RT-HEP) (2018)	
	OECD Test Guideline 319 B: Determination of In Vitro Intrinsic Clearance Using Rainbow Trout Liver S9 Sub-Cellular Fraction (RT-S9) (2018)	
	OECD Test Guideline 320: Anaerobic Transformation of Chemicals in Liquid Manure (2022)	
Effetti fuq organiżmi tal-art	OECD Test Guideline 216: Soil Microorganisms: Nitrogen Transformation Test (2000)	C.21.
	OECD Test Guideline 217: Soil Microorganisms: Carbon Transformation Test (2000)	C.22.
	OECD Test Guideline 207: Earthworm, Acute Toxicity Tests (1984)	C.8.
	OECD Test Guideline 222: Earthworm Reproduction Test (<i>Eisenia fetida</i> / <i>Eisenia andrei</i>) (2016)	(C.33.)
	OECD Test Guideline 220: Enchytraeid Reproduction Test (2016)	(C.32.)
	OECD Test Guideline 226: Predatory Mite (<i>Hypoaspis</i> (<i>Geolaelaps</i>) <i>aculeifer</i>) Reproduction Test in Soil (2016)	(C.36.)
	OECD Test Guideline 232: Collembolan Reproduction Test in Soil (2016)	(C.39.)
	OECD Test Guideline 208: Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test (2006)	C.31.
	OECD Test Guideline 227: Terrestrial Plant Test: Vegetative Vigour Test (2006)	
Effetti fuq l-organiżmi sedimentarji	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.
	OECD Test Guideline 233: Sediment-Water Chironomid Life-Cycle Toxicity Test Using Spiked Water or Spiked Sediment (2010)	C.40.
	OECD Test Guideline 235: <i>Chironomus</i> sp., Acute Immobilisation Test (2011)	
	OECD Test Guideline 225: Sediment-Water <i>Lumbriculus</i> Toxicity Test Using Spiked Sediment (2007)	C.35.
	OECD Test Guideline 238: Sediment-Free <i>Myriophyllum Spicatum</i> Toxicity Test (2014)	C.50.
	OECD Test Guideline 239: Water-Sediment <i>Myriophyllum Spicatum</i> Toxicity Test (2014)	C.51.

Effetti fuq l-ghasafar	OECD Test Guideline 205: Avian Dietary Toxicity Test (1984)	
	OECD Test Guideline 206: Avian Reproduction Test (1984)	
	OECD Test Guideline 223: Avian Acute Oral Toxicity Test (2016)	
Effetti fuq l-insetti	OECD Test Guideline 213: Honeybees, Acute Oral Toxicity Test (1998)	C.16.
	OECD Test Guideline 214: Honeybees, Acute Contact Toxicity Test (1998)	C.17.
	OECD Test Guideline 237: Honey Bee (<i>Apis Mellifera</i>) Larval Toxicity Test, Single Exposure (2013)	
	OECD Test Guideline 245: Honey Bee (<i>Apis Mellifera</i> L.), Chronic Oral Toxicity Test (10-Day Feeding) (2017)	
	OECD Test Guideline 246: Bumblebee, Acute Contact Toxicity Test (2017)	
	OECD Test Guideline 247: Bumblebee, Acute Oral Toxicity Test (2017)	
	OECD Test Guideline 228: Determination of Developmental Toxicity to Dipteran Dung Flies (<i>Scathophaga stercoraria</i> L. (<i>Scathophagidae</i>), <i>Musca autumnalis</i> De Geer (<i>Muscidae</i>)) (2016)	
Proprietajiet li jfixklu s-sistema endokrinali	OECD Test Guideline 230: 21-Day Fish Assay (2009)	C.37.
	OECD Test Guideline 229: Fish Short Term Reproduction Assay (2012)	C.48.
	OECD Test Guideline 231: Amphibian Metamorphosis Assay (2009)	C.38.
	OECD Test Guideline 234: Fish Sexual Development Test (2011)	C.41.
	OECD Test Guideline 240: Medaka Extended One Generation Reproduction Test (MEOGRT) (2015)	C.52.
	OECD Test Guideline 241: The Larval Amphibian Growth and Development Assay (LAGDA) (2015)	C.53.”
	OECD Test Guideline 248: <i>Xenopus</i> Eleutheroembryonic Thyroid Assay (XETA) (2019)	
	OECD Test Guideline 250: EASZY assay - Detection of Endocrine Active Substances, Acting Through Estrogen Receptors, Using Transgenic tg(<i>cyp19a1b:GFP</i>) Zebrafish embrYos (2021)’	
	OECD Test Guideline 251: Rapid Androgen Disruption Activity Reporter (RADAR) Assay (2022)	

(2) fil-parti A, it-test taht it-titolu ta' kull wiehed mill-Kapitoli A.3., A.4., A.8. sa A.12., A.15. sa A.17., A.20 u A.21. huwa sostitwit b'dan li ġej: "Id-deskrizzjoni kompluta ta' dan il-metodu ta' ttestjar thassret. Il-metodu ta' ttestjar internazzjonali ekwivalenti, jew metodi ta' ttestjar applikabbli ohra ghall-punt tat-tmiem inkwistjoni jidhru fit-Tabella 1 tal-Parti 0."

(3) fil-parti B, it-test taht it-titolu ta' kull wiehed mill-Kapitoli B.3., B.5., B.6., B.8., B. 13/14., B.17., B.26., B.29. sa B.33., B.40bis., B.41., B.46. sa B.48., B.51., B.56., B.58. sa B.61., B.66., B.68., B.69. u B.71. huwa sostitwit b'dan li ġej: "Id-deskrizzjoni kompluta ta' dan il-metodu ta' ttestjar thassret. Il-metodu ta' ttestjar internazzjonali ekwivalenti jidher fit-Tabella 2 tal-Parti 0."

- (4) fil-parti B, it-test taht it-titolu ta' kull wiehed mill-Kapitoli B.22., B.25., B.34., B.35., B.39. huwa sostitwit b'dan li ġej: "Dan il-metodu ta' ttestjar thassar, peress li ma ghadux rikonoxxut bhala xieraq ghall-generazzjoni ta' informazzjoni dwar il-proprietajiet tossikologiċi tas-sustanzi kimiċi ghall-finijiet tar-Regolament (KE) Nru 1907/2006. Il-metodi ta' ttestjar applikabbli ghall-punt tat-tmiem inkwistjoni jidhru fit-Tabella 2 tal-Parti 0."
 - (5) fil-parti C, it-test taht it-titolu ta' kull wiehed mill-Kapitoli C.1., C.9., C.32., C.33., C.36. u C.39. huwa sostitwit b'dan li ġej: "Id-deskrizzjoni kompluta ta' dan il-metodu ta' ttestjar thassret. Il-metodu ta' ttestjar internazzjonali ekwivalenti jidher fit-Tabella 3 tal-Parti 0."
 - (6) fil-parti C, it-test taht it-titolu tal-Kapitoli C.15 huwa sostitwit b'dan li ġej: "Dan il-metodu ta' ttestjar thassar, peress li ma ghadux rikonoxxut bhala xieraq ghall-generazzjoni ta' informazzjoni dwar il-proprietajiet ekotossikologiċi tas-sustanzi kimiċi ghall-finijiet tar-Regolament (KE) Nru 1907/2006. Il-metodi ta' ttestjar applikabbli ghall-punt tat-tmiem inkwistjoni jidhru fit-Tabella 3 tal-Parti 0."
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