2025/2573

19.12.2025

RIALACHÁN (AE) 2025/2573 ÓN gCOIMISIÚN

an 18 Nollaig 2025

lena leasaítear Rialachán (CE) Uimh. 440/2008 a mhéid a bhaineann leis na modhanna tástála, chun iad a chur in oiriúint don dul chun cinn teicniúil

(Téacs atá ábhartha maidir le LEE)

TÁ AN COIMISIÚN EORPACH,

Ag féachaint don Chonradh ar Fheidhmiú an Aontais Eorpaigh,

Ag féachaint do Rialachán (CE) Uimh. 1907/2006 ó Pharlaimint na hEorpa agus ón gComhairle an 18 Nollaig 2006 maidir le Clárú, Meastóireacht, Údarú agus Srianadh Ceimiceán (REACH), lena mbunaítear Gníomhaireacht Eorpach Ceimiceán, lena leasaítear Treoir 1999/45/CE agus lena n-aisghairtear Rialachán (CEE) Uimh. 793/93 ón gComhairle agus Rialachán (CE) Uimh. 1488/94 ón gCoimisiún, chomh maith le Treoir 76/769/CEE ón gComhairle agus Treoracha 91/155/CEE, 93/67/CEE, 93/105/CE agus 2000/21/CE ón gCoimisiún ([1]), agus go háirithe Airteagal 13(2) de,

De bharr an mhéid seo a leanas:

(1) San Iarscríbhinn a ghabhann le Rialachán (CE) Uimh. 440/2008 ón gCoimisiún ([2]), tá modhanna tástála a aithnítear mar mhodhanna iomchuí chun faisnéis a ghiniúint maidir le hairíonna fisiciceimiceacha, tocsaineolaíocha agus éiceathocsaineolaíocha substaintí chun críocha Rialachán (CE) Uimh. 1907/2006.

(2) Forbraíonn an Eagraíocht um Chomhar agus Forbairt Eacnamaíochta (ECFE) treoirlínte tástála comhchuibhithe a chomhaontaítear go hidirnáisiúnta le haghaidh ceimiceáin a thástáil chun críoch rialála. Eisíonn ECFE treoirlínte tástála nua leasaithe go tráthrialta, ag cur dul chun cinn eolaíoch sa réimse sin san áireamh.

(3) D'fhonn Rialachán (CE) Uimh. 440/2008 a choinneáil cothrom le dáta leis an dul chun cinn teicniúil agus chun líon na n-ainmhithe a úsáidtear chun críoch turgnaimh a laghdú, rud atá i gcomhréir freisin le Treoir 2010/63/AE ó Pharlaimint na hEorpa agus ón gComhairle ([3]), ba cheart an Iarscríbhinn a ghabhann le Rialachán (CE) Uimh. 440/2008 a athbhreithniú agus le trí mhodh tástála atá tugtha cothrom le dáta chun éifeachtaí ar shláinte an duine a chinneadh, mar atá éifeachtaí a bhaineann le tástálacha *in vitro* maidir le damáiste/greannú tromchúiseach súile agus íogrú craicinn ([4]), agus le trí mhodh tástála nua le haghaidh éiceatocsaineacht a mheasúnú a chur isteach ([5]).

([1]) IO L 396, 30.12.2006, lch. 1, ELI: https://data.europa.eu/eli/reg/2006/1907/oj.

([2]) Rialachán (CE) Uimh. 440/2008 ón gCoimisiún an 30 Bealtaine 2008 lena leagtar síos modhanna tástála de bhun Rialachán (CE) Uimh. 1907/2006 ó Pharlaimint na hEorpa agus ón gComhairle maidir le Clárú, Meastóireacht, Údarú agus Srianadh Ceimiceán (REACH) (IO L 142, 31.5.2008, lch. 1, ELI: https://data.europa.eu/eli/reg/2008/440/oj).

([3]) Treoir 2010/63/AE ó Pharlaimint na hEorpa agus ón gComhairle an 22 Meán Fómhair 2010 maidir le cosaint ainmhithe a úsáidtear chun críoch eolaíoch (IO L 276, 20.10.2010, lch. 33, ELI: https://eur-lex.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) Ina theannta sin, rinne ECFE na modhanna tástála seo a leanas, a áiríodh i Rialachán (CE) Uimh. 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]) – a cheartú in 2024. Dá bhrí sin, is iomchuí na modhanna sin san Iarscríbhinn a ghabhann le Rialachán (CE) Uimh. 440/2008 a thabhairt cothrom le dáta agus na leaganacha as dáta de na tuairiscí iomlána ar an dá mhodh tástála a leagtar amach i gCuid B (OECD Test Guideline 403 agus OECD Test Guideline 493) den Iarscríbhinn a ghabhann le Rialachán (CE) Uimh. 440/2008. Sa bhreis air sin, ba cheart modhanna tástála eile, atá ábhartha maidir leis an gcríochphointe deannachta (i gcás nanafhoirmeacha substainte) a chur isteach: 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 Is iomchuí an tuairisc iomlán le haghaidh an mhodha tástála a leagtar síos i gCuid A (Airíonna pireafóracha solad agus leachtanna) den Iarscríbhinn a ghabhann le Rialachán (CE) Uimh. 440/2008 a scriosadh mar go bhfuil leaganacha cothrom le dáta de na modhanna tástála ábhartha le haghaidh na gcríochphointí sin i gCuid 0 cheana féin.

(5) Dá bhrí sin, ba cheart Rialachán (CE) Uimh. 440/2008 a leasú dá réir sin.

(6) Chuathas i gcomhairle leis na páirtithe leasmhara ábhartha maidir leis an leasú atá beartaithe.

(7) Na bearta dá bhforáiltear sa Rialachán seo, tá siad i gcomhréir leis an tuairim ón gCoiste arna bhunú faoi Airteagal 133(1) de Rialachán (CE) Uimh. 1907/2006,

TAR ÉIS AN RIALACHÁN SEO A GHLACADH:

Airteagal 1

Leasaítear an Iarscríbhinn a ghabhann le Rialachán (CE) Uimh. 440/2008 i gcomhréir leis an Iarscríbhinn a ghabhann leis an Rialachán seo.

([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.

Airteagal 2

Tiocfaidh an Rialachán seo i bhfeidhm an fichiú lá tar éis lá a fhoilsithe in *Iris Oifigiúil an Aontais Eorpaigh*.

Beidh an Rialachán seo ina cheangal go huile agus go hiomlán agus beidh sé infheidhme go díreach i ngach Ballstát.

Arna dhéanamh sa Bhruiséil, an 18 Nollaig 2025.

Thar ceann an Choimisiúin
An tUachtarán
Ursula VON DER LEYEN

IARSCRÍBHINN

Leasaítear an Iarscríbhinn a ghabhann le Rialachán (CE) Uimh. 440/2008 mar a leanas:

(1) Leasaítear Cuid 0 mar a leanas:

(a) I dTábla 1, cuirtear an méid seo a leanas in ionad na hiontrála 'Deannacht (i gcás nanafhoirmeacha substainte'):

'Deannacht (i gcás nanafhoirmeacha substainte)	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) Leasaítear Tábla 2 mar a leanas:

(i) san iontráil 'Damáiste/greannú tromchúiseach súile' cuirtear an méid seo a leanas in ionad na roinne '*In vitro*':

Damáiste/greannú tromchúiseach súile	'*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) san iontráil 'Íogrú craicinn', cuirtear an méid seo a leanas in ionad na roinne '*In vitro*':

Íogrú craicinn	'*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) san iontráil 'Iogrú craicinn', sa roinn '*In vivo*' cuirtear an méid seo a leanas in ionad an ró a chomhfhreagraíonn do OECD Test Guideline 442B:

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

(iv) san iontráil 'Géarthocsaineacht', sa roinn 'Ionanálú' cuirtear an méid seo a leanas in ionad an ró a chomhfhreagraíonn do OECD Test Guideline 403:

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

(v) san iontráil 'Airíonna suaite inchrínigh', sa roinn '*In vitro*' cuirtear an méid seo a leanas in ionad an ró a chomhfhreagraíonn do OECD Test Guideline 493:

	'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) Leasaítear Tábla 3 mar a leanas:

(i) san iontráil 'Cinniúint agus iompraíocht sa chomhshaol', cuirtear an ró seo a leanas isteach:

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

(ii) san iontráil 'Airíonna suaite inchrínigh', cuirtear na rónna seo a leanas isteach:

	'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) i gcuid A, cuirtear an méid seo a leanas in ionad an téacs atá faoi bhun theideal Chaibidil A.13.: 'Scriosadh an tuairisc iomlán ar an modh tástála seo. Na modhanna tástála idirnáisiúnta coibhéiseacha, nó na modhanna tástála eile is infheidhme le haghaidh na gcríochphointí atá i gceist, tá siad i gCuid 0, Tábla 1'.

(3) i gcuid B, cuirtear an méid seo a leanas in ionad an téacs atá faoi bhun theideal Chaibidil B.2.: 'Scriosadh an tuairisc iomlán ar an modh tástála seo. Tá an modh tástála idirnáisiúnta coibhéiseach i gCuid 0, Tábla 2.'.

(4) i gcuid B, cuirtear an méid seo a leanas in ionad an téacs atá faoi bhun theideal Chaibidil B.70.: 'Scriosadh an tuairisc iomlán ar an modh tástála seo. Tá an modh tástála idirnáisiúnta coibhéiseach i gCuid 0, Tábla 2.'.