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⁽¹⁾ Text with EEA relevance.

EN

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⁽¹⁾ Text with EEA relevance.

II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2022/824

of 15 March 2022

amending Delegated Regulation (EU) 2015/98 on the implementation of the Union's international obligations, as referred to in Article 15(2) of Regulation (EU) No 1380/2013 of the European Parliament and of the Council, under the International Convention for the Conservation of Atlantic Tunas and the Convention on Future Multilateral Cooperation in the Northwest Atlantic Fisheries

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1380/2013 of the European Parliament and of the Council of 11 December 2013 on the Common Fisheries Policy, amending Council Regulations (EC) No 1954/2003 and (EC) No 1224/2009 and repealing Council Regulations (EC) No 2371/2002 and (EC) No 639/2004 and Council Decision 2004/585/EC⁽¹⁾, and in particular Article 15(2) thereof,

Whereas:

- (1) Paragraph 3 of Recommendation 21-09 of the International Commission for the Conservation of Atlantic Tunas ('ICCAT')⁽²⁾ prohibits the retaining on board, transshipping and landing, whole or in part, of North Atlantic shortfin mako caught in association with ICCAT fisheries in 2022 and 2023.
- (2) To ensure consistency between Recommendation 21-09 and European Union law, the landing obligation in Article 15(1) of Regulation (EU) No 1380/2013 should not apply to Union vessels that catch North Atlantic shortfin mako as by-catch.
- (3) Commission Delegated Regulation (EU) 2015/98⁽³⁾ should therefore be amended to include new provisions reflecting the fishing conditions established in ICCAT Recommendation 21-09.
- (4) Since ICCAT Recommendation 21-09 encourages Contracting Parties to implement it prior to its entry into force on 17 June 2022, and in view of the importance of these provisions for the preservation of North Atlantic shortfin mako, this delegated act should apply from the third day after its publication.
- (5) For the same reasons, this delegated act should enter into force as a matter of urgency,

⁽¹⁾ OJ L 354, 28.12.2013, p. 22.

⁽²⁾ https://www.iccat.int/Documents/Recs/COMPENDIUM_ACTIVE_ENG.pdf

⁽³⁾ Commission Delegated Regulation (EU) 2015/98 of 18 November 2014 on the implementation of the Union's international obligations, as referred to in Article 15(2) of Regulation (EU) No 1380/2013 of the European Parliament and of the Council, under the International Convention for the Conservation of Atlantic Tunas and the Convention on Future Multilateral Cooperation in the Northwest Atlantic Fisheries (OJ L 16, 23.1.2015, p. 23).

HAS ADOPTED THIS REGULATION:

Article 1

In Delegated Regulation (EU) 2015/98, the following Article 5b is inserted:

‘Article 5b

By way of derogation from Article 15(1) of Regulation (EU) No 1380/2013, it shall be prohibited to retain on board, tranship or land any part or whole North Atlantic shortfin mako (*Isurus oxyrinchus*) caught in association with fisheries in the ICCAT Convention Area in 2022 and 2023.’.

Article 2

This Regulation shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

It shall apply until 31 December 2023.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 15 March 2022.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION DELEGATED REGULATION (EU) 2022/825**of 17 March 2022****amending Annex II to Delegated Regulation (EU) No 1062/2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ⁽¹⁾, and in particular the first subparagraph of Article 89(1) thereof,

Whereas:

- (1) Annex II to Commission Delegated Regulation (EU) No 1062/2014 ⁽²⁾ includes a list of active substance/product-type combinations included in the programme of review of existing active substances contained in biocidal products on 6 November 2018.
- (2) The identities of certain active substances listed in Annex II to Delegated Regulation (EU) No 1062/2014 have been redefined pursuant to Article 13 of that Regulation in order to identify in a more precise manner those active substances and establish the corresponding new substance identity.
- (3) Following the publication by the European Chemicals Agency ('the Agency') of an open invitation to take over the role of participant for certain active substance/product-type combinations covered by the existing substance identity but not by the new substance identity, substance/product-type combinations notified pursuant to Article 14(1), point (b), and found by the Agency to be compliant with Article 17(2) of Delegated Regulation (EU) No 1062/2014 should be included in Annex II to that Regulation pursuant to Article 18 of that Regulation.
- (4) Following the declarations received pursuant to Article 16(4) of Delegated Regulation (EU) No 1062/2014, the Agency published an invitation so that any person with an interest could notify active substances in product-type 19 that benefitted from the derogation for food and feed provided for by Article 6 of Commission Regulation (EC) No 1451/2007 ⁽³⁾. Two notifications for peanut butter and brandy for use in product-type 19 were submitted pursuant to Article 16(5) and found by the Agency to be compliant with Article 17(2) of Delegated Regulation (EU) No 1062/2014. Those active substances should therefore be included in Annex II to that Regulation pursuant to Article 18 of that Regulation.
- (5) In the Annex to this Regulation, it is appropriate to state the Member States whose competent authorities should be the evaluating competent authorities for the active substance/product-type combinations to be added to Annex II to Delegated Regulation (EU) No 1062/2014.
- (6) Active substances for which a decision of approval or non-approval has been adopted after 6 November 2018 for one or more product-types, or which were included in Annex I to Regulation (EU) No 528/2012 pursuant to Article 28(1) of that Regulation, are no longer in the review programme. Therefore, those active substances should no longer be included in Annex II to Delegated Regulation (EU) No 1062/2014 for the concerned product-types.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 (OJ L 294, 10.10.2014, p. 1).

⁽³⁾ Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (OJ L 325, 11.12.2007, p. 3).

- (7) In order to reflect the actual situation and for transparency, it is appropriate to provide a list of active substance/product-type combinations included in the programme of review of existing active substances contained in biocidal products on the day of adoption of this Regulation.
- (8) Delegated Regulation (EU) No 1062/2014 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Delegated Regulation (EU) No 1062/2014 is replaced by the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 17 March 2022.

For the Commission
The President
Ursula VON DER LEYEN

SUBSTANCE/PRODUCT-TYPE COMBINATIONS INCLUDED IN THE REVIEW PROGRAMME ON 17 MARCH 2022

Active substance/product-type combinations supported on 17 March 2022, excluding any other nanomaterial than that explicitly mentioned in entry 1017 and excluding any generation in situ of the active substance except when explicitly mentioned with the reference to the supported precursor(s)

Entry number	Substance name	Rapporteur Member State	EC number	CAS number	1	2	3	4	5	6	7	8	9	10	11	12	13	17	18	19	21	22
1	Formaldehyde	DE	200-001-8	50-00-0																		x
9	Bronopol	ES	200-143-0	52-51-7		x				x					x	x						x
36	Ethanol	EL	200-578-6	64-17-5	x	x		x														
37	Formic acid	BE	200-579-1	64-18-6		x	x	x	x	x												
1025	Performic acid generated from formic acid and hydrogen peroxide	BE				x		x							x	x						
43	Salicylic acid	NL	200-712-3	69-72-7		x	x	x														
52	Ethylene oxide	NO	200-849-9	75-21-8		x																
69	Glycolic acid	NL	201-180-5	79-14-1		x	x	x														
1026	Peracetic acid generated from tetraacetythylenediamine (TAED) and hydrogen peroxide	AT				x																
1027	Peracetic acid generated from 1,3-diacetyloxypropan-2-yl acetate and hydrogen peroxide	AT				x																
71	L-(+)-lactic acid	DE	201-196-2	79-33-4						x												

Entry number	Substance name	Rapporteur Member State	EC number	CAS number	1	2	3	4	5	6	7	8	9	10	11	12	13	17	18	19	21	22
79	(2R,6aS,12a-S)-1,2,6,6a,12,12a-Hexahydro-2-isopropenyl-8,9-dimethoxychromeno[3,4-b]furo[2,3-h]chromen-6-one (Rotenone)	PL	201-501-9	83-79-4														x				
85	Symclosene	DE	201-782-8	87-90-1		x	x	x	x						x							
92	Biphenyl-2-ol	ES	201-993-5	90-43-7							x		x	x								
113	3-Phenyl-propen-2-al (Cinnamaldehyde)	PL	203-213-9	104-55-2		x																
117	Geraniol	FR	203-377-1	106-24-1															x	x		
122	Glyoxal	FR	203-474-9	107-22-2		x	x	x														
133	Hexa-2,4-dienoic acid (Sorbic acid)	DE	203-768-7	110-44-1						x												
171	2-Phenoxyethanol	IT	204-589-7	122-99-6	x	x		x		x							x					
180	Sodium dimethylarsinate (Sodium Cacodylate)	PT	204-708-2	124-65-2															x			
185	Tosylchloramide sodium (Chloramin T)	ES	204-854-7	127-65-1		x	x	x	x													
187	Potassium dimethyldithiocarbamate	SE	204-875-1	128-03-0									x		x	x						
188	Sodium dimethyldithiocarbamate	SE	204-876-7	128-04-1									x		x	x						
227	2-Thiazol-4-yl-1H-benzimidazole (Thiabendazole)	ES	205-725-8	148-79-8							x		x	x								

Entry number	Substance name	Rapporteur Member State	EC number	CAS number	1	2	3	4	5	6	7	8	9	10	11	12	13	17	18	19	21	22
235	Diuron	DK	206-354-4	330-54-1							x			x								
239	Cyanamide	DE	206-992-3	420-04-2			x												x			
283	Terbutryn	SK	212-950-5	886-50-0							x		x	x								
292	(1,3,4,5,6,7-Hexahydro-1,3-dioxo-2H-isoindol-2-yl)methyl (1R-trans)-2,2-dimethyl-3-(2-methylprop-1-enyl) cyclopropanecarboxylate (d-Tetramethrin)	DE	214-619-0	1166-46-7															x			
321	Monolinuron	HU	217-129-5	1746-81-2		x																
330	N-(3-Aminopropyl)-N-dodecylpropane-1,3-diamine (Diamine)	PT	219-145-8	2372-82-9		x	x	x		x		x			x	x	x					
336	2,2'-Dithiobis [N-methylbenzamide] (DTBMA)	PL	219-768-5	2527-58-4						x												
339	1,2-Benzisothiazol-3 (2H)-one (BIT)	ES	220-120-9	2634-33-5		x				x			x		x	x	x					
341	2-Methyl-2H-isothiazol-3-one (MIT)	SI	220-239-6	2682-20-4						x												
346	Sodium dichloroisocyanurate dihydrate	DE	220-767-7	51580-86-0		x	x	x	x						x							
345	Troclosene sodium	DE	220-767-7	2893-78-9		x	x	x	x						x							
348	Mecetronium ethylsulfate (MES)	PL	221-106-5	3006-10-8	x																	

Entry number	Substance name	Rapporteur Member State	EC number	CAS number	1	2	3	4	5	6	7	8	9	10	11	12	13	17	18	19	21	22
359	Formaldehyde released from (Ethylenedioxy) dimethanol (Reaction products of ethylene glycol with paraformaldehyde (EGForm))	PL	222-720-6	3586-55-8						x					x	x	x					
365	Pyridine-2-thiol 1-oxide, sodium salt (Sodium pyrrithione)	SE	223-296-5	3811-73-2		x				x	x		x	x			x					
368	Methenamine 3-chloroallylochloride (CTAC)	PL	223-805-0	4080-31-3						x						x	x					
377	2,2',2''-(Hexahydro-1,3,5-triazine-1,3,5-triyl)triethanol (HHT)	PL	225-208-0	4719-04-4						x					x	x	x					
382	Tetrahydro-1,3,4,6-tetakis(hydroxymethyl)imidazo[4,5-d]imidazole-2,5(1H,3H)-dione (TMAD)	ES	226-408-0	5395-50-6						x					x	x	x					
392	Methylene dithiocyanate	FR	228-652-3	6317-18-6												x						
393	1,3-Bis(hydroxymethyl)-5,5-dimethylimidazolidine-2,4-dione (DMDMH)	PL	229-222-8	6440-58-0						x							x					
397	Didecyl dimethylammonium chloride (DDAC)	IT	230-525-2	7173-51-5	x	x				x				x	x	x						
401	Silver	SE	231-131-3	7440-22-4		x		x	x						x							

Entry number	Substance name	Rapporteur Member State	EC number	CAS number	1	2	3	4	5	6	7	8	9	10	11	12	13	17	18	19	21	22
405	Sulfur dioxide generated from sulfur by combustion	DE						x														
424	Active bromine generated from sodium bromide and sodium hypochlorite	NL				x									x	x						
1030	Active bromine generated from sodium bromide and calcium hypochlorite	NL				x									x	x						
1031	Active bromine generated from sodium bromide and chlorine	NL				x									x	x						
1032	Active bromine generated from sodium bromide by electrolysis	NL				x									x	x						
1033	Active bromine generated from hypobromous acid and urea and bromourea	NL													x	x						
1034	Active bromine generated from sodium hypobromite and N-bromosulfamate and sulfamic acid	NL													x							
434	Tetramethrin	DE	231-711-6	7696-12-0															x			
439	Hydrogen peroxide	FI	231-765-0	7722-84-1											x	x						

Entry number	Substance name	Rapporteur Member State	EC number	CAS number	1	2	3	4	5	6	7	8	9	10	11	12	13	17	18	19	21	22
1036	Hydrogen peroxide released from sodium percarbonate	FI				x	x															
444	7a-Ethyl-dihydro-1H,3H,5H-oxazolo [3,4-c]oxazole (EDHO)	PL	231-810-4	7747-35-5						x							x					
450	Silver nitrate	SE	231-853-9	7761-88-8	x																	
453	Disodium peroxodisulfate	PT	231-892-1	7775-27-1				x														
432	Active chlorine released from sodium hypochlorite	IT													x	x						
455	Active chlorine released from calcium hypochlorite	IT													x							
457	Active chlorine released from chlorine	IT													x							
458	Monochloramine generated from ammonium sulfate and a chlorine source	FR													x	x						
1016	Silver chloride	SE	232-033-3	7783-90-6	x	x				x	x		x									
1076	Silver-polyethylenimine-chloride	SE			x	x							x									
491	Chlorine dioxide	DE	233-162-8	10049-04-4		x	x	x	x						x	x						

Entry number	Substance name	Rapporteur Member State	EC number	CAS number	1	2	3	4	5	6	7	8	9	10	11	12	13	17	18	19	21	22
1037	Chlorine dioxide generated from sodium chlorite by electrolysis	PT				x	x	x	x						x	x						
1038	Chlorine dioxide generated from sodium chlorite by acidification	PT				x	x	x	x						x	x						
1039	Chlorine dioxide generated from sodium chlorite by oxidation	PT				x	x	x	x						x	x						
1040	Chlorine dioxide generated from sodium chlorate and hydrogen peroxide in the presence of a strong acid	PT				x			x						x	x						
494	2,2-Dibromo-2-cyanoacetamide (DBNPA)	DK	233-539-7	10222-01-2		x		x		x					x	x						
1022	Dialuminium chloride pentahydroxide	NL	234-933-1	12042-91-0		x																
1075	Reaction products of aluminium trihydroxide and hydrochloric acid and aluminium and water	NL				x																
515	Bromide activated chloramine (BAC) generated from precursors ammonium bromide and sodium hypochlorite	SE													x	x						

Entry number	Substance name	Rapporteur Member State	EC number	CAS number	1	2	3	4	5	6	7	8	9	10	11	12	13	17	18	19	21	22
522	Pyrethione zinc	SE	236-671-3	13463-41-7		x				x	x		x	x							x	
524	Dodecylguanidine monohydrochloride	ES	237-030-0	13590-97-1						x					x							
529	Active bromine generated from bromine chloride	NL													x							
531	(Benzyloxy)methanol	AT	238-588-8	14548-60-8						x							x					
550	D-Gluconic acid, compound with N,N"-bis (4-chlorophenyl)-3,12-diimin-2,4,11,13-tetraazatetradecanediamidine (2:1) (CHDG)	PT	242-354-0	18472-51-0	x	x	x															
554	p-[(Diodomethyl) sulphonyl]toluene	CH	243-468-3	20018-09-1						x	x		x	x								
559	(Benzothiazol-2-ylthio) methyl thiocyanate (TCMTB)	NO	244-445-0	21564-17-0									x			x						
562	2-Methyl-4-oxo-3-(prop-2-ynyl)cyclopent-2-en-1-yl 2,2-dimethyl-3-(2-methylprop-1-enyl) cyclopropanecarboxylate (Prallethrin)	EL	245-387-9	23031-36-9															x			
566	Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1) (HPT)	AT				x				x					x		x					

Entry number	Substance name	Rapporteur Member State	EC number	CAS number	1	2	3	4	5	6	7	8	9	10	11	12	13	17	18	19	21	22
571	2-Octyl-2H-isothiazol-3-one (OIT)	FR	247-761-7	26530-20-1						x	x		x	x	x		x					
577	Dimethyloctadecyl [3-(trimethoxysilyl) propyl]ammonium chloride	ES	248-595-8	27668-52-6		x					x		x									
588	Bromochloro-5,5-dimethylimidazolidine-2,4-dione (BCDMH)	NL	251-171-5	32718-18-6		x									x	x						
590	3-(4-Isopropylphenyl)-1,1-dimethylurea (Isoproturon)	DE	251-835-4	34123-59-6							x			x								
599	S-[(6-Chloro-2-oxooxazolo[4,5-b]pyridin-3(2H)-yl)methyl] O,O-dimethyl thiophosphate (Azamethiphos)	IT	252-626-0	35575-96-3															x			
608	Dimethyltetradecyl [3-(trimethoxysilyl) propyl]ammonium chloride	PL	255-451-8	41591-87-1									x									
1045	<i>Eucalyptus citriodora</i> oil, hydrated, cyclized	CZ		1245629-80-4																x		
1046	<i>Cymbopogon winterianus</i> oil, fractionated, hydrated, cyclized	CZ	Not available	Not available																x		

Entry number	Substance name	Rapporteur Member State	EC number	CAS number	1	2	3	4	5	6	7	8	9	10	11	12	13	17	18	19	21	22
619	3-Iodo-2-propynylbutylcarbamate (IPBC)	DK	259-627-5	55406-53-6							x		x	x								
620	Tetrakis(hydroxymethyl) phosphonium sulphate(2:1) (THPS)	MT	259-709-0	55566-30-8						x					x	x						
648	4,5-Dichloro-2-octylisothiazol-3(2H)-one (4,5-Dichloro-2-octyl-2H- isothiazol-3-one (DCOIT))	NO	264-843-8	64359-81-5							x		x	x	x							
656	Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2) (MBO)	AT				x				x					x	x	x					
667	Alkyl (C ₁₂₋₁₈) dimethylbenzyl ammonium chloride (ADBAC (C ₁₂₋₁₈))	IT	269-919-4	68391-01-5	x	x	x	x						x	x	x						x
671	Alkyl (C ₁₂₋₁₆) dimethylbenzyl ammonium chloride (ADBAC/BKC (C ₁₂ .C ₁₆))	IT	270-325-2	68424-85-1	x	x								x	x	x						x
673	Didecyldimethylammonium chloride (DDAC (C ₈₋₁₀))	IT	270-331-5	68424-95-3	x	x	x	x		x				x	x	x						

Entry number	Substance name	Rapporteur Member State	EC number	CAS number	1	2	3	4	5	6	7	8	9	10	11	12	13	17	18	19	21	22
690	Quaternary ammonium compounds, benzyl-C ₁₂₋₁₈ -alkyldimethyl, salts with 1,2-benzisothiazol-3 (2H)-one 1,1-dioxide (1:1) (ADBAS)	MT	273-545-7	68989-01-5		x		x														
691	Sodium N-(hydroxymethyl) glycinate	AT	274-357-8	70161-44-3						x												
693	Pentapotassium bis (peroxymonosulfate)bis (sulfate) (KPMS)	SI	274-778-7	70693-62-8		x	x	x	x													
939	Active chlorine generated from sodium chloride by electrolysis	SK													x							
1049	Active chlorine generated from sodium chloride and pentapotassium bis (peroxymonosulfate)bis (sulfate)	SI				x	x	x	x													
1050	Active chlorine generated from seawater (sodium chloride) by electrolysis	FR													x							
1051	Active chlorine generated from magnesium chloride hexahydrate and potassium chloride by electrolysis	FR				x																

Entry number	Substance name	Rapporteur Member State	EC number	CAS number	1	2	3	4	5	6	7	8	9	10	11	12	13	17	18	19	21	22
1054	Active chlorine generated from sodium N-chlorosulfamate	SI						x							x	x						
701	Dihydrogen bis [monoperoxyphthalato (2-)-O1,OO1]magnesate (2-) (MMPP)	PL	279-013-0	84665-66-7		x																
1024	Margosa extract from cold-pressed oil of the kernels of Azadirachta Indica extracted with super-critical carbon dioxide	DE																	x			
724	Alkyl (C ₁₂ -C ₁₄) dimethylbenzylammonium chloride (ADBAC (C ₁₂ -C ₁₄))	IT	287-089-1	85409-22-9	x	x	x	x						x	x	x						x
725	Alkyl (C ₁₂ -C ₁₄) dimethyl (ethylbenzyl)ammonium chloride (ADEBAC (C ₁₂ -C ₁₄))	IT	287-090-7	85409-23-0	x	x	x	x						x	x	x						x
1057	<i>Chrysanthemum cinerariaefolium</i> extract from open and mature flowers of <i>Tanacetum cinerariifolium</i> obtained with hydrocarbon solvent	ES																	x	x		

Entry number	Substance name	Rapporteur Member State	EC number	CAS number	1	2	3	4	5	6	7	8	9	10	11	12	13	17	18	19	21	22
1058	<i>Chrysanthemum cinerariaefolium</i> extract from open and mature flowers of <i>Tanacetum cinerariifolium</i> obtained with supercritical carbon dioxide	ES																	x	x		
744	Lavender, <i>Lavandula hybrida</i> , ext./Lavandin oil	PT	294-470-6	91722-69-9																x		
779	Reaction products of: glutamic acid and N-(C ₁₂ -C ₁₄ -alkyl) propylenediamine (Glucoprotamin)	DE	403-950-8	164907-72-6		x		x														
785	6-(Phthalimido) peroxyhexanoic acid (PAP)	IT	410-850-8	128275-31-0	x	x																
791	2-Butyl-benzo[d] isothiazol-3-one (BBIT)	CZ	420-590-7	4299-07-4						x	x		x	x			x					
792	Chlorine dioxide generated from tetrachlorodecaoxide complex (TCDO) by acidification	DE				x		x														
811	Silver sodium hydrogen zirconium phosphate	SE	422-570-3	265647-11-8				x					x									

Entry number	Substance name	Rapporteur Member State	EC number	CAS number	1	2	3	4	5	6	7	8	9	10	11	12	13	17	18	19	21	22
797	cis-1-(3-Chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride (cis CTAC)	PL	426-020-3	51229-78-8						x							x					
1014	Silver zeolite	SE	Not available	Not available				x					x									
152	Reaction products of 5,5-dimethylhydantoin, 5-ethyl-5-methylhydantoin with bromine and chlorine (DCDMH)	NL	Not available	Not available											x							
459	Reaction mass of titanium dioxide and silver chloride	SE	Not available	Not available	x	x				x	x		x	x	x							
777	Reaction products of 5,5-dimethylhydantoin, 5-ethyl-5-methylhydantoin with chlorine (DCEMH)	NL	Not available	Not available											x							
810	Silver phosphate glass	SE	Not available	308069-39-8		x					x		x									
1077	Silver borophosphate glass	SE				x					x		x									
1078	Silver phosphoborate glass	SE				x					x		x									
824	Silver zinc zeolite	SE	Not available	130328-20-0		x		x			x		x									

Entry number	Substance name	Rapporteur Member State	EC number	CAS number	1	2	3	4	5	6	7	8	9	10	11	12	13	17	18	19	21	22
1013	Silver copper zeolite	SE	Not available	130328-19-7				x					x									
1017	Silver adsorbed on silicon dioxide (as a nanomaterial in the form of a stable aggregate with primary particles in the nanoscale)	SE	Not available	Not available									x									
854	(RS)-3-Allyl-2-methyl-4-oxocyclopent-2-enyl-(1R,3R;1R,3S)-2,2-dimethyl-3-(2-methylprop-1-enyl)-cyclopropanecarboxylate (mixture of 4 isomers 1R trans, 1R: 1R trans, 1S: 1R cis, 1R: 1R cis, 1S 4:4:1:1) (d-Allethrin)	DE	Plant protection product	231937-89-6															x			
843	4-Bromo-2-(4-chlorophenyl)-1-ethoxymethyl-5-trifluoromethylpyrrole-3-carbonitrile (Chlorfenapyr)	PT	Plant protection product	122453-73-0															x			
859	Polymer of N-Methylmethanamine (Einecs 204-697-4 with (chloromethyl)oxirane (Einecs 203-439-8)/ Polymeric quaternary ammonium chloride (PQ Polymer)	HU	Polymer	25988-97-0		x									x							

Entry number	Substance name	Rapporteur Member State	EC number	CAS number	1	2	3	4	5	6	7	8	9	10	11	12	13	17	18	19	21	22
869	Poly (oxy-1,2-ethanediyl),. alpha.-[2-(didecylmethylammonio)ethyl]-.omega.-hydroxy-, propanoate (salt) (Bardap 26)	IT	Polymer	94667-33-1		x		x						x								
872	N-Didecyl-N-dipolyethoxyammonium borate/ Didecylpolyoxethylammonium borate (Polymeric betaine)	EL	Polymer	214710-34-6								x										
1070	Orange, sweet, ext. <i>Extractives and their physically modified derivatives such as tinctures, concretes, absolutes, essential oils, oleoresins, terpenes, terpene-free fractions, distillates, residues, etc., obtained from Citrus sinensis, Rutaceae.</i>	CH	232-433-8	8028-48-6																x		
1071	Garlic, ext. <i>Extractives and their physically modified derivatives such as tinctures, concretes, absolutes, essential oils, oleoresins, terpenes, terpene-free fractions, distillates, residues, etc., obtained from Allium sativum, Liliaceae.</i>	AT	232-371-1	8008-99-9																x		

Entry number	Substance name	Rapporteur Member State	EC number	CAS number	1	2	3	4	5	6	7	8	9	10	11	12	13	17	18	19	21	22
1072	Brandy	tbd	Not available	Not available																x		
1073	Peanut butter	BE	Not available	Not available																x		
1074	Copper, powder	FR	231-159-6	7440-50-8																	x'	

COMMISSION DELEGATED REGULATION (EU) 2022/826**of 23 March 2022****correcting and amending Regulation (EU) 2019/1241 of the European Parliament and of the Council
as regards exemptions from the plaice box**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2019/1241 of the European Parliament and of the Council of 20 June 2019 on the conservation of fisheries resources and the protection of marine ecosystems through technical measures, amending Council Regulations (EC) No 1967/2006, (EC) No 1224/2009 and Regulations (EU) No 1380/2013, (EU) 2016/1139, (EU) 2018/973, (EU) 2019/472 and (EU) 2019/1022 of the European Parliament and of the Council, and repealing Council Regulations (EC) No 894/97, (EC) No 850/98, (EC) No 2549/2000, (EC) No 254/2002, (EC) No 812/2004 and (EC) No 2187/2005 ⁽¹⁾, and in particular Article 15(2) thereof,

Whereas:

- (1) Regulation (EU) 2019/1241 on the conservation of fisheries resources and the protection of marine ecosystems through technical measures contains an error in Annex V, Part C which must be corrected.
- (2) While recital 5 of Delegated Regulation (EU) 2021/1160 ⁽²⁾ refers to 'Danish anchor seines', the corresponding provision in the annex refers to 'Danish seines' only. Given that Article 6(18) of Regulation (EU) 2019/1241 does not distinguish between Danish seines and Scottish seines/flyshooters', the provision in Annex V as it stands can therefore be read as incorrectly applying to both Danish anchor seines and Scottish seines.
- (3) Delegated Regulation (EU) 2021/1160 is based on a joint recommendation submitted on 19 October 2020 by Belgium, Denmark, Germany, France, the Netherlands and Sweden (Scheveningen Group), who have a direct fisheries management interest in the North Sea. Section 3.1.2 of the joint recommendation specifically distinguished between Danish seine that does the hauling of the fishing gear while the vessel is at anchor (anchor seining) and Scottish seine, confirming that Member States intended the requested exemption to apply to Danish anchor seine only.
- (4) The STECF assessment, concluding that the introduction of the specific exemption for Danish seine is not expected to have any significant effect on the level of protection inside the area, referred only to Danish 'anchor seine' (gear code SDN ⁽³⁾) and not to 'Scottish' or flyshooter/flydragger seines (gear code SSC ⁽³⁾).
- (5) Annex V to Regulation (EU) 2019/1241 should therefore be corrected to clarify that the proposed exemption applies only to those Danish seines that do the hauling of the fishing gear while the vessel is at anchor (Danish anchor seine (gear code SDN)).
- (6) As the measures provided for in this Regulation have a direct impact on the planning of the fishing season of Union vessels and on related economic activities, this Regulation should enter into force immediately after its publication,

⁽¹⁾ OJ L 198, 25.7.2019, p. 105.

⁽²⁾ Commission Delegated Regulation (EU) 2021/1160 of 12 May 2021 amending Regulation (EU) 2019/1241 of the European Parliament and of the Council as regards the sprat box and the plaice box in the North Sea (OJ L 250, 15.7.2021, p. 4).

⁽³⁾ Annex XI to Commission Implementing Regulation (EU) No 404/2011 of 8 April 2011 laying down detailed rules for the implementation of Council Regulation (EC) No 1224/2009 establishing a Community control system for ensuring compliance with the rules of the Common Fisheries Policy (OJ L 112, 30.4.2011, p. 64).

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EU) 2019/1241 is corrected in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 23 March 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Part C of Annex V to Regulation (EU) 2019/1241 is amended as follows:

(1) point 2.2(d) is replaced as follows:

- ‘(d) vessels whose engine power exceeds 221 kW using Danish seines which haul the fishing gear while the vessel is at anchor (Danish anchor seine – SDN), provided that such vessels comply with the mesh size provided for in point 1.1 of Part B of this Annex.’
-

COMMISSION IMPLEMENTING REGULATION (EU) 2022/827**of 20 May 2022****correcting the Danish language version of Implementing Regulation (EU) 2019/1842 laying down rules for the application of Directive 2003/87/EC of the European Parliament and of the Council as regards further arrangements for the adjustments to free allocation of emission allowances due to activity level changes**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2003/87/EC of the European Parliament and of the Council of 13 October 2003 establishing a system for greenhouse gas emission allowance trading within the Union and amending Council Directive 96/61/EC ⁽¹⁾, and in particular Article 10a(21) thereof,

Whereas:

- (1) The Danish language version of Commission Implementing Regulation (EU) 2019/1842 ⁽²⁾ contains errors in Article 6(1) and (2) that alter the meaning of the provisions.
- (2) The Danish language version of Implementing Regulation (EU) 2019/1842 should therefore be corrected accordingly. The other language versions are not affected.
- (3) The measures provided for in this Regulation are in accordance with the opinion of the Climate Change Committee,

HAS ADOPTED THIS REGULATION:

*Article 1**(Does not concern the English language.)**Article 2*This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 20 May 2022.

For the Commission
The President
Ursula VON DER LEYEN

⁽¹⁾ OJ L 275, 25.10.2003, p. 32.

⁽²⁾ Commission Implementing Regulation (EU) 2019/1842 of 31 October 2019 laying down rules for the application of Directive 2003/87/EC of the European Parliament and of the Council as regards further arrangements for the adjustments to free allocation of emission allowances due to activity level changes (OJ L 282, 4.11.2019, p. 20).

COMMISSION IMPLEMENTING REGULATION (EU) 2022/828**of 25 May 2022****correcting the Polish language version of Regulation (EU) 2017/2195 establishing a guideline on electricity balancing****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2019/943 of the European Parliament and of the Council of 5 June 2019 on the internal market for electricity ⁽¹⁾, and in particular Article 59(1)(c) and Article 61(2) thereof,

Whereas:

- (1) The Polish language version of Commission Regulation (EU) 2017/2195 ⁽²⁾ contains an error in Article 12(3), point (g) that alters the object of and the deadline for discharging the obligation of transmission system operators to publish information.
- (2) The Polish language version of Regulation (EU) 2017/2195 should therefore be corrected accordingly. The other language versions are not affected.
- (3) The measures provided for in this Regulation are in accordance with the opinion of the Electricity cross-border Committee,

HAS ADOPTED THIS REGULATION:

*Article 1**(Does not concern the English language.)**Article 2*This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 25 May 2022.

For the Commission
The President
Ursula VON DER LEYEN

⁽¹⁾ OJ L 158, 14.6.2019, p. 54.

⁽²⁾ Commission Regulation (EU) 2017/2195 of 23 November 2017 establishing a guideline on electricity balancing (OJ L 312, 28.11.2017, p. 6).

COMMISSION IMPLEMENTING REGULATION (EU) 2022/829**of 25 May 2022****amending Regulation (EC) No 31/96 as regards the institutions eligible for exemption from excise duty**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Directive 2008/118/EC of 16 December 2008 concerning the general arrangements for excise duty and repealing Directive 92/12/EEC ⁽¹⁾, and in particular Article 13(2) thereof,

Whereas:

- (1) Directive 2008/118/EC was amended by Council Directive (EU) 2019/2235 ⁽²⁾, which introduced exemptions from payment of VAT and excise duty for defence efforts undertaken within the Union framework.
- (2) The Annex to Commission Regulation (EC) No 31/96 ⁽³⁾ sets out the exemption certificate to be used to confirm that a certain transaction qualifies for exemption from payment of excise duty under Article 12 of Directive 2008/118/EC. In order to enable Member States to apply the exemption from payment of excise duty for defence efforts as set out in Article 12(1), point (ba), of Directive 2008/118/EC, that certificate should be amended.
- (3) Regulation (EC) No 31/96 should therefore be amended accordingly.
- (4) As Article 12(1), point (ba), of Directive 2008/118/EC applies from 1 July 2022, the application of this Regulation should be deferred to that date.
- (5) The measures provided for in this Regulation are in accordance with the opinion of the Committee on Excise Duty,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EC) No 31/96 is replaced by the text in the Annex to this Regulation.

*Article 2*This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 July 2022.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 25 May 2022.

For the Commission
The President
Ursula VON DER LEYEN

⁽¹⁾ OJ L 9, 14.1.2009, p. 12.

⁽²⁾ Council Directive (EU) 2019/2235 of 16 December 2019 amending Directive 2006/112/EC on the common system of value added tax and Directive 2008/118/EC concerning the general arrangements for excise duty as regards defence efforts within the Union framework (OJ L 336, 30.12.2019, p. 10).

⁽³⁾ Commission Regulation (EC) No 31/96 of 10 January 1996 on the excise duty exemption certificate (OJ L 8, 11.1.1996, p. 11).

ANNEX

EUROPEAN UNION

EXCISE DUTY EXEMPTION CERTIFICATE
(Council Directive 2008/118/EC - Art. 12 (1))

Serial No (optional):

1. ELIGIBLE INSTITUTION/INDIVIDUAL

Designation/name.....

Street and No.....

Postal code, place

(Host) Member State

2. COMPETENT AUTHORITY FOR ISSUING THE STAMP

(Name, address, email address and telephone No)

3. DECLARATION BY THE ELIGIBLE INSTITUTION OR PERSON

The eligible institution or individual (*) hereby declares

(a) that the goods set out in box 5 are intended (*)

- ☐ for the official use of
- ☐ a foreign diplomatic mission
 - ☐ a foreign consular representation
 - ☐ an international organization
 - ☐ an armed force of a State being a party to the North Atlantic Treaty (NATO force)
 - ☐ the armed forces of any Member State taking part in a Union activity under the common security and defence policy (CSDP)

- ☐ for the personal use of
- ☐ a member of a foreign diplomatic mission
 - ☐ a member of a foreign consular representation
 - ☐ a staff member of an international organization

(designation of the institution) (see box 4)

(b) that the goods described at box 5 comply with the conditions and limitations applicable to the exemption in the host Member State mentioned in box 1, and

(c) that the information above is furnished *in good faith*. The eligible institution or individual hereby undertakes to pay to the Member State from which the goods were dispatched, the excise duty which would be due if these goods did not comply with the conditions of exemption, or if the goods were not used in the manner intended.

Place, date

Name and status of signatory

Signature

4. STAMP OF THE INSTITUTION (in case of exemption for personal use)

Place, date

Name and status of signatory

Signature

Explanatory notes

1. For the authorised warehousekeeper, this certificate serves as a supporting document for the tax exemption of the consignments of goods to eligible institutions/individuals referred to in Article 12(1) of Directive 2008/118/EC. Accordingly, one certificate shall be drawn up for each warehousekeeper. Moreover, the warehousekeeper is required to keep this certificate as part of his records in accordance with the legal provisions applicable in his Member State.
2. (a) The general specification of the paper to be used is as laid down in the *Official journal of the European Communities* No C 164 of 1. 7. 1989.

The paper is to be white for all copies and should be 210 millimetres by 297 millimetres with a maximum tolerance of 5 millimetres less or 8 millimetres more with regard to their length.

The exemption certificate shall be drawn up in duplicate:

- (i) one copy to be kept by the consignor,
 - (ii) one copy to accompany the administrative accompanying document
- (b) Any unused space in box 5.B is to be crossed out so that nothing can be added.
 - (c) The document must be completed legibly and in a manner that makes entries indelible. No erasures or overwriting are permitted. It shall be completed in a language recognized by the host Member State.
 - (d) If the description of the goods (box 5.B of the certificate) refers to a purchase order form drawn up in a language other than a language recognized by the host Member State, a translation must be attached by the eligible institution/individual.
 - (e) On the other hand, if the certificate is drawn up in a language other than a language recognized by the Member State of the warehousekeeper, a translation of the information concerning the goods in box 5.B must be attached by the eligible institution/individual.
 - (f) A recognized language means one of the languages officially in use in the Member State or any other official language of the Union, which the Member State declares, can be used for this purpose.
3. By its declaration in box 3 of the certificate, the eligible institution/individual provides the information necessary for the evaluation of the request for exemption in the host Member State.
 4. By its declaration in box 4 of the certificate, the institution confirms the details in boxes 1 and 3 (a) of the document and certifies that the eligible individual is a staff member of the institution.
 5. (a) The reference to the purchase order form (box 5.B of the certificate) must contain at least the date and order number. The order form should contain all the elements that figure at box 5 of the certificate. If the certificate has to be stamped by the competent authority of the host Member State, the order form shall also be stamped.
 - (b) The indication of the excise No as defined in Article 19(2), point (a), of Council Regulation (EU) No 389/2012 ⁽¹⁾ of the authorised warehousekeeper is optional.
 - (c) The currencies should be indicated by means of a three-letter code in conformity with the international ISO 4217 standard established by the International Standards Organization.

⁽¹⁾ Council Regulation (EU) No 389/2012 of 2 May 2012 on administrative cooperation in the field of excise duties and repealing Regulation (EC) No 2073/2004 (OJ L 121, 8.5.2012, p. 1).

6. The abovementioned declaration by the eligible institution/individual shall be authenticated at box 6 by the stamp of the competent authority of the host Member State. That authority can make its approval dependent on the agreement of another authority in its Member State. It is up to the competent tax authority to obtain such agreement.
 7. To simplify the procedure, the competent authority can dispense with the obligation on the eligible institution to ask for the stamp in the case of exemption for official use. The eligible institution should mention this dispensation at box 7 of the certificate.
-

DECISIONS

COUNCIL DECISION (EU) 2022/830

of 20 May 2022

on the position to be adopted on behalf of the European Union in the seventy-fifth session of the World Health Assembly as regards certain amendments to the International Health Regulations (2005)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 168(5), in conjunction with Article 218(9) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) In the field of public health, Union action, which is to complement national policies, is to be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health. Such action is also to cover monitoring, early warning of and combating serious cross-border threats to health. To that effect, the Union and the Member States are to foster cooperation with third countries and the competent international organisations in the sphere of public health.
- (2) The International Health Regulations ('IHR') (2005) were adopted by the World Health Assembly of the World Health Organization ('WHO') on 23 May 2005 and entered into force on 15 June 2007.
- (3) On 3 March 2022, the Council adopted Decision (EU) 2022/451 authorising the opening of negotiations on behalf of the European Union for an international agreement on pandemic prevention, preparedness and response, as well as complementary amendments to the International Health Regulations (2005) ⁽¹⁾.
- (4) The World Health Assembly, during its seventy-fifth session starting on 22 May 2022, is to adopt a decision on the amendment of Article 59 of the IHR (2005), in order to shorten the period necessary to further amend the provisions of the IHR (2005), notably by reducing from twenty-four to twelve months the period for the entry into force of the amendments thereof, together with related amendments to Article 55(3), Articles 61 and 62 and Article 63(1), which are necessary to bring those articles in line with the envisaged amendments to Article 59 of the IHR (2005).
- (5) Pursuant to Article 60(b) of the WHO Constitution, the World Health Assembly may adopt decisions by a majority of the members of the WHO present and voting.
- (6) The Union supports the objective of shortening the period necessary to further amend the provisions of the IHR (2005), and considers that the amendments to Article 59 of the IHR (2005), as well as to Article 55(3), Articles 61 and 62 and Article 63(1) thereof, will allow addressing changing needs more rapidly in the areas covered by the IHR (2005).
- (7) It is appropriate to establish, for matters falling within Union competence, the position to be adopted on the Union's behalf in the World Health Assembly with respect to the decision, which the World Health Assembly is called upon to adopt, with a view to amending Article 59 of the IHR (2005), as well as Article 55(3), Articles 61 and 62 and Article 63(1) of the IHR (2005).
- (8) The Union's position is to be expressed by the Member States of the Union that are members of the WHO, acting jointly,

⁽¹⁾ OJ L 92, 21.3.2022, p. 1.

HAS ADOPTED THIS DECISION:

Article 1

The position to be adopted on the European Union's behalf during the seventy-fifth session of the World Health Assembly as regards amendments to Article 59 of the IHR (2005), and related amendments to Article 55(3), Articles 61 and 62 and Article 63(1) thereof, shall be in accordance with the Annex to this Decision.

Adjustments to the amendments set out in the Annex to this Decision, which do not jeopardise the attainment of the objective of those amendments and do not result in shortening further the generally applicable periods indicated in the Annex, may be agreed by the Commission in consultation with the Member States and without further decision of the Council.

Article 2

The position referred to in Article 1 shall be expressed by the Member States of the Union that are members of the World Health Organization, acting jointly on behalf of the Union.

Article 3

This Decision shall enter into force on the date of its adoption.

Done at Brussels, 20 May 2022.

For the Council

The President

J. BORRELL FONTELLES

ANNEX

A. Amendments to Article 59 of the International Health Regulations (2005)

The Union supports the following amendments to Article 59 of the International Health Regulations (2005) (the deleted text is in square brackets and the new text is underlined):

*Article 59***Entry into force; period for rejection or reservations**

1. The period provided in execution of Article 22 of the Constitution of WHO for rejection of, or reservation to, these Regulations [or an amendment thereto,] shall be 18 months from the date of the notification by the Director-General of the adoption of these Regulations [or of an amendment to these Regulations]by the Health Assembly. Any rejection or reservation received by the Director-General after the expiry of that period shall have no effect.

1bis. The period provided in execution of Article 22 of the Constitution of WHO for rejection of, or reservation to, an amendment to these Regulations shall be 9 months from the date of the notification by the Director-General of the adoption of an amendment to these Regulations by the Health Assembly. Any rejection or reservation received by the Director-General after the expiry of that period shall have no effect.

2. These Regulations shall enter into force 24 months after the date of notification referred to in paragraph 1 of this Article, and amendments to these Regulations shall enter into force 12 months after the date of notification referred to in paragraph 1bis of this Article, except for:

(...)

(b) a State that has made a reservation, for which these Regulations or an amendment thereto shall enter into force as provided in Article 62;

(...)

3. If a State is not able to adjust its domestic legislative and administrative arrangements fully with these Regulations or an amendment thereto within the periods set out in paragraph 2 of this Article, as applicable, that State shall submit within the applicable period specified in paragraph 1 or 1bis of this Article a declaration to the Director-General regarding the outstanding adjustments and achieve them no later than 12 months after the entry into force of these Regulations for that State Party and no later than 6 months after the entry into force of an amendment to these Regulations for that State Party.

B. Amendments to Article 55(3), Articles 61 and 62 and Article 63(1) of the International Health Regulations (2005)

The Union also supports the following technical amendments to Article 55(3), Articles 61 and 62 and Article 63(1) of the International Health Regulations (2005) (the deleted text is in square brackets and the new text is underlined):

*Article 55***Amendments**

(...)

3. Amendments to the Regulations adopted by the Health Assembly pursuant to this Article shall come into force for all States Parties on the same terms, and subject to the same rights and obligations, as provided for in Article 22 of the Constitution of WHO and Article 59 to 64 of these Regulations, subject to the periods provided for in those Articles with respect to amendments to these Regulations.

*Article 61***Rejection**

If a State notifies the Director-General of its rejection of these Regulations or of an amendment thereto within the applicable period provided in paragraph 1 or 1bis of Article 59, these Regulations or the amendment concerned shall not enter into force with respect to that State. Any international sanitary agreement or regulations listed in Article 58 to which such State is already a party shall remain in force as far as such State is concerned.

*Article 62***Reservation**

1. States may make reservations to these Regulations or an amendment thereto in accordance with this Article. Such reservations shall not be incompatible with the object and purpose of these Regulations.

2. Reservations to these Regulations or an amendment thereto shall be notified to the Director-General in accordance with paragraphs 1 and 1bis of Article 59 and Article 60, paragraph 1 of Article 63 or paragraph 1 of Article 64, as the case may be. A State not a Member of WHO shall notify the Director-General of any reservation with its notification of acceptance of these Regulations. States formulating reservations should provide the Director-General with reasons for the reservations.

3. A rejection in part of these Regulations or an amendment thereto shall be considered as a reservation.

4. The Director-General shall, in accordance with paragraph 2 of Article 65, issue notification of each reservation received pursuant to paragraph 2 of this Article. The Director-General shall:

(...)

(c) if the reservation was made to an amendment to these Regulations, request States Parties to notify him or her within three months of any objection to the reservation. States Parties objecting to a reservation to an amendment to these Regulations should provide the Director-General with reasons for the objection.

States objecting to a reservation should provide the Director-General with reasons for the objection.

5. After this period, the Director-General shall notify all States Parties of the objections he or she has received with regard to reservations. In the case of a reservation made to these Regulations, [U]nless by the end of six months from the date of the notification referred to in paragraph 4 of this Article a reservation has been objected to by one-third of the States referred to in paragraph 4 of this Article, it shall be deemed to be accepted and these Regulations shall enter into force for the reserving State, subject to the reservation. In the case of a reservation made to an amendment to these Regulations, unless by the end of three months from the date of the notification referred to in paragraph 4 of this Article a reservation has been objected to by one-third of the States referred to in paragraph 4 of this Article, it shall be deemed to be accepted and the amendment shall enter into force for the reserving State, subject to the reservation.

6. If at least one-third of the States referred to in paragraph 4 of this Article object to the reservation to these Regulations by the end of six months from the date of the notification referred to in paragraph 4 of this Article[,] or, in the case of a reservation to an amendment to these Regulations, by the end of three months from the date of the notification referred to in paragraph 4 of this Article, the Director-General shall notify the reserving State with a view to its considering withdrawing the reservation within three months from the date of the notification by the Director-General.

(...)

9. The Director-General shall submit the reservation, and the views of the Review Committee if applicable, to the Health Assembly for its consideration. If the Health Assembly, by a majority vote, objects to the reservation on the ground that it is incompatible with the object and purpose of these Regulations, the reservation shall not be accepted and these Regulations or an amendment thereto shall enter into force for the reserving State only after it withdraws its reservation pursuant to Article 63. If the Health Assembly accepts the reservation, these Regulations or an amendment thereto shall enter into force for the reserving State, subject to its reservation.

Article 63

Withdrawal of rejection and reservation

1. A rejection made under Article 61 may at any time be withdrawn by a State by notifying the Director-General. In such cases, these Regulations or an amendment thereto, as applicable, shall enter into force with regard to that State upon receipt by the Director-General of the notification, except where the State makes a reservation when withdrawing its rejection, in which case these Regulations or an amendment thereto, as applicable, shall enter into force as provided in Article 62. In no case shall these Regulations enter into force in respect to that State earlier than 24 months after the date of notification referred to in paragraph 1 of Article 59 and in no case shall an amendment to these Regulations enter into force in respect to that State earlier than 12 months after the date of notification referred to in paragraph 1bis of Article 59.

(...)

COUNCIL DECISION (EU) 2022/831**of 23 May 2022****on the position to be adopted, on behalf of the European Union, within the EEA Joint Committee, concerning the amendment of Annex I (Veterinary and phytosanitary matters) to the EEA Agreement****(Text with EEA relevance)**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 in conjunction with Article 218(9) thereof,

Having regard to Council Regulation (EC) No 2894/94 of 28 November 1994 concerning arrangements for implementing the Agreement on the European Economic Area ⁽¹⁾, and in particular Article 1(3) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) The Agreement on the European Economic Area ⁽²⁾ ('the EEA Agreement') entered into force on 1 January 1994.
- (2) Pursuant to Article 98 of the EEA Agreement, the EEA Joint Committee established by the EEA Agreement (the 'EEA Joint Committee') may decide to amend, inter alia, Annex I to the EEA Agreement, which contains provisions on veterinary and phytosanitary matters.
- (3) Commission Implementing Decision (EU) 2019/300 ⁽³⁾ is to be incorporated into the EEA Agreement.
- (4) Annex I (Veterinary and phytosanitary matters) to the EEA Agreement should therefore be amended accordingly.
- (5) The position of the Union in the EEA Joint Committee should therefore be based on the attached draft Decision of the EEA Joint Committee,

HAS ADOPTED THIS DECISION:

Article 1

The position to be adopted on the Union's behalf within the EEA Joint Committee concerning the amendment of Annex I (Veterinary and phytosanitary matters) to the EEA Agreement shall be based on the draft Decision of the EEA Joint Committee attached to this Decision.

Article 2

This Decision shall enter into force on the date of its adoption.

⁽¹⁾ OJ L 305, 30.11.1994, p. 6.

⁽²⁾ OJ L 1, 3.1.1994, p. 3.

⁽³⁾ Commission Implementing Decision (EU) 2019/300 of 19 February 2019 establishing a general plan for crisis management in the field of the safety of food and feed (OJ L 50, 21.2.2019, p. 55).

Done at Brussels, 23 May 2022.

For the Council
The President
M. BEK

DRAFT
DECISION OF THE EEA JOINT COMMITTEE No ...
of ...
amending Annex I (Veterinary and phytosanitary matters) to the EEA Agreement

THE EEA JOINT COMMITTEE,

Having regard to the Agreement on the European Economic Area ('the EEA Agreement'), and in particular Article 98 thereof,

Whereas:

- (1) Commission Implementing Decision (EU) 2019/300 of 19 February 2019 establishing a general plan for crisis management in the field of the safety of food and feed ⁽¹⁾ is to be incorporated into the EEA Agreement.
- (2) Implementing Decision (EU) 2019/300 repeals Commission Decision 2004/478/EC, which is incorporated into the EEA Agreement and which is consequently to be repealed under the EEA Agreement.
- (3) This Decision concerns legislation regarding veterinary matters and feedingstuffs. Legislation regarding veterinary matters and feedingstuffs shall not apply to Liechtenstein as long as the application of the Agreement between the European Community and the Swiss Confederation on trade in agricultural products is extended to Liechtenstein, as specified in the sectoral adaptations to Annex I to the EEA Agreement. This Decision is therefore not to apply to Liechtenstein.
- (4) Annex I to the EEA Agreement should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

Annex I to the EEA Agreement shall be amended as follows:

1. The following is inserted after point 59 (Commission Implementing Decision 2013/503/EU) in Part 7.2 of Chapter I:

‘60. **32019 D 0300:** Commission Implementing Decision (EU) 2019/300 of 19 February 2019 establishing a general plan for crisis management in the field of the safety of food and feed (OJ L 50, 21.2.2019, p. 55).

The provisions of the Decision shall, for the purposes of this Agreement, be read with the following adaptation:

Where the Commission identifies a situation referred to in Article 56(1) of Regulation (EC) No 178/2002 in which an EFTA State is directly concerned and sets up a crisis unit in accordance with Article 56(2) of Regulation (EC) No 178/2002, the crisis coordinator(s) designated by the EFTA State directly concerned and the crisis coordinator designated by the EFTA Surveillance Authority shall take part in the work of the crisis unit.’
2. The following is inserted after point 47a (Commission Regulation (EU) No 16/2011) of Chapter II:

‘47b. **32019 D 0300:** Commission Implementing Decision (EU) 2019/300 of 19 February 2019 establishing a general plan for crisis management in the field of the safety of food and feed (OJ L 50, 21.2.2019, p. 55).

The provisions of the Decision shall, for the purposes of this Agreement, be read with the following adaptation:

⁽¹⁾ OJ L 50, 21.2.2019, p. 55.

Where the Commission identifies a situation referred to in Article 56(1) of Regulation (EC) No 178/2002 in which an EFTA State is directly concerned and sets up a crisis unit in accordance with Article 56(2) of Regulation (EC) No 178/2002, the crisis coordinator(s) designated by the EFTA State directly concerned and the crisis coordinator designated by the EFTA Surveillance Authority shall take part in the work of the crisis unit.'

3. The text of points 31 (Commission Decision 2004/478/EC) in Part 7.2 of Chapter I and 43 (Commission Decision 2004/478/EC) of Chapter II is deleted.

Article 2

The text of Implementing Decision (EU) 2019/300 in the Icelandic and Norwegian languages, to be published in the EEA Supplement to the *Official Journal of the European Union*, shall be authentic.

Article 3

This Decision shall enter into force on [...], provided that all the notifications under Article 103(1) of the EEA Agreement have been made *.

Article 4

This Decision shall be published in the EEA Section of, and in the EEA Supplement to, the *Official Journal of the European Union*.

Done at Brussels, [...].

For the EEA Joint Committee
The President

The Secretaries
To the EEA Joint Committee

(*) [No constitutional requirements indicated.] [Constitutional requirements indicated.]

COUNCIL DECISION (EU) 2022/832**of 24 May 2022****appointing the members and alternates of the Management Board of the European Institute for Gender Equality**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1922/2006 of the European Parliament and of the Council of 20 December 2006 on establishing a European Institute for Gender Equality ⁽¹⁾, and in particular Article 10 thereof,

Whereas:

- (1) Regulation (EC) No 1922/2006 provides that the Council is to appoint 18 members, as well as alternates, to the Management Board of the European Institute for Gender Equality for a period of three years. For each term of office, the members and alternates appointed by the Council are to represent eighteen Member States in the order of the rotating Presidencies, one member and one alternate being nominated by each Member State concerned.
- (2) Regulation (EC) No 1922/2006 further provides that the members and the alternates of the Management Board are to be appointed in such a way as to secure the highest standards of competence and a broad range of relevant and transdisciplinary expertise in the area of gender equality, and that a balanced representation between men and women on the Management Board should be aimed at.
- (3) The Governments of Hungary, Poland, Denmark, Cyprus, Ireland, Lithuania, Greece, Italy, Latvia, Luxembourg, Netherlands, Slovakia, Malta, Estonia, Bulgaria, Austria, Romania and Finland have submitted nominations to the Council for the members and alternates to be appointed to the Management Board for the period from 1 June 2022 to 31 May 2025,

HAS ADOPTED THIS DECISION:

Article 1

The following persons are hereby appointed to the Management Board of the European Institute for Gender Equality as members and alternates for the period from 1 June 2022 to 31 May 2025 to represent the Member States concerned:

GOVERNMENT REPRESENTATIVES

Country	Member	Alternate
Hungary	Ms Brigitta GYEBNÁR	Ms Rita NAGYLAKI
Poland	Mr Paweł KOSMULSKI	Ms Karolina MICHALCZYK
Denmark	Ms Kira UITTERDIJK APPEL	Mr Jeppe HOLM NIELSEN
Cyprus	Mr Stavros CHRISTOFI	Mr Alexandros ALEXANDROU
Ireland	Ms Jane Ann DUFFY	Ms Deirdre NÍ NÉILL
Lithuania	Ms Jolanta SAKALAUSKIENĖ	Ms Greta TUMĖNIENĖ
Greece	Ms Eleni NTALAKA	Ms Sophia NIKOLAOU
Italy	Ms Laura MENICUCCI	Mr Stefano PIZZICANNELLA

⁽¹⁾ OJ L 403, 30.12.2006, p. 9.

Latvia	Ms Ieva JUHŅĒVIČA	Ms Agnese GAILE
Luxembourg	Ms Maryse FISCH	Ms Valérie DEBOUCHÉ
Netherlands	Ms Esther VAN DIJK	Mr Michael NINABER VAN EIJBEN
Slovakia	Ms Zuzana BRIXOVÁ	Mr Ján TOMAŠTÍK
Malta	Ms Annalise DESIRA	Ms Sasha Na Jeong FARRUGIA
Estonia	Ms Lee MARIPUU	Ms EVA Liina KLIIMAN
Bulgaria	Ms Irina IVANOVA	Ms Mila NIKOLOVA
Austria	Ms Jacqueline NIAVARANI	Ms Katja GERSTMANN
Romania	Mr Dan MOLDOVAN	Ms Maria ULICAN
Finland	Ms Tanja AUVINEN	Ms Eeva RAEVAARA

Article 2

This Decision shall enter into force on the date of its adoption.

Done at Brussels, 24 May 2022.

For the Council
The President
M. FESNEAU

COUNCIL DECISION (EU) 2022/833**of 24 May 2022****amending Decision 1999/70/EC concerning the external auditors of the national central banks, as regards the external auditors of Národná banka Slovenska**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to Protocol No 4 on the Statute of the European System of Central Banks and of the European Central Bank, annexed to the Treaty on European Union and the Treaty on the Functioning of the European Union, and in particular Article 27.1 thereof,

Having regard to the Recommendation of the European Central Bank of 5 April 2022 to the Council of the European Union on the external auditors of Národná banka Slovenska (ECB/2022/16) ⁽¹⁾,

Whereas:

- (1) The accounts of the European Central Bank (ECB) and of the national central banks of the Member States whose currency is the euro are to be audited by independent external auditors recommended by the Governing Council of the ECB and approved by the Council of the European Union.
- (2) In 2017, Národná banka Slovenska selected Deloitte Audit s.r.o. as its external auditors for the financial years 2017 to 2020, with an option to extend the mandate to the financial years 2021 to 2023.
- (3) The mandate of Deloitte Audit s.r.o. ended after the audit for the financial year 2020 in accordance with Council Decision (EU) 2017/1849 ⁽²⁾, and Národná banka Slovenska extended the mandate of Deloitte Audit s.r.o. to the financial year 2021.
- (4) The mandate of the current external auditors of Národná banka Slovenska, Deloitte Audit s.r.o., ended after the audit for the financial year 2021 in accordance with Council Decision (EU) 2021/1169 ⁽³⁾. It is therefore necessary to appoint external auditors from the financial year 2022.
- (5) Národná banka Slovenska intends to extend the mandate of Deloitte Audit s.r.o. to the financial years 2022 and 2023. This extension is possible in accordance with the contractual arrangements between Národná banka Slovenska and Deloitte Audit s.r.o.
- (6) The Governing Council of the ECB recommended that Deloitte Audit s.r.o. be appointed as the external auditors of Národná banka Slovenska for the financial years 2022 and 2023.
- (7) Following the recommendation of the Governing Council of the ECB, Council Decision 1999/70/EC ⁽⁴⁾ should be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

In Article 1 of Decision 1999/70/EC, paragraph 16 is replaced by the following:

‘16. Deloitte Audit s.r.o. are hereby approved as the external auditors of Národná banka Slovenska for the financial years 2022 and 2023.’.

⁽¹⁾ OJ C 160, 13.4.2022, p. 9.

⁽²⁾ Council Decision (EU) 2017/1849 of 10 October 2017 amending Decision 1999/70/EC concerning the external auditors of the national central banks, as regards the external auditors of Národná banka Slovenska (OJ L 264, 13.10.2017, p. 5).

⁽³⁾ Council Decision (EU) 2021/1169 of 13 July 2021 amending Decision 1999/70/EC concerning the external auditors of the national central banks, as regards the external auditors of Národná banka Slovenska (OJ L 255, 16.7.2021, p. 1).

⁽⁴⁾ Council Decision 1999/70/EC of 25 January 1999 concerning the external auditors of the national central banks (OJ L 22, 29.1.1999, p. 69).

Article 2

This Decision shall take effect on the date of its notification.

Article 3

This Decision is addressed to the European Central Bank.

Done at Brussels, 24 May 2022.

For the Council
The President
B. LE MAIRE

COMMISSION IMPLEMENTING DECISION (EU) 2022/834**of 25 May 2022****pursuant to Article 31(1) of Directive 2010/35/EU of the European Parliament and of the Council, on a measure taken by France concerning the withdrawal from the market of certain gas cylinders manufactured by Xinchang Burong Machinery Co. Ltd before 31 October 2019***(notified under document C(2022) 3372)***(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2010/35/EU of the European Parliament and of the Council of 16 June 2010 on transportable pressure equipment and repealing Council Directives 76/767/EEC, 84/525/EEC, 84/526/EEC, 84/527/EEC and 1999/36/EC ⁽¹⁾, and in particular Article 31(1) thereof,

Whereas:

- (1) In August 2019, as part of the market surveillance of transportable pressure equipment performed in accordance with the provisions of Articles 16 to 26 of Regulation (EC) No 765/2008 of the European Parliament and of the Council ⁽²⁾ and with the provisions of Article 30 of Directive 2010/35/EU, the French Market Surveillance Authority investigated the case of a pressure cylinder manufactured by Xinchang Burong Machinery Co. Ltd (China). The cylinder was imported and distributed by VZ Trend Goods GmbH (Germany) and by Alsino GmbH (Germany) and sold online by www.amazon.fr (France), under the trademark 'PARTY FACTORY'.
- (2) The French Market Surveillance Authority examined the case in accordance with the applicable rules on manufacturing and placing on the market, as set out in Section I.1 of Annex I to Directive 2008/68/EC of the European Parliament and of the Council ⁽³⁾, in the EN ISO 11118:2015 standard and in Articles 4 and 6 of Directive 2010/35/EU. The examination revealed that the product had not undergone a conformity assessment and that it displayed an undue Pi marking. Moreover, the manufacturer held neither the certificates for initial inspections and tests, nor the certificates for supervision of the manufacture required pursuant to subsections 1.8.7.3 and 1.8.7.4 of Section I.1 of Annex I to Directive 2008/68/EC.
- (3) An anonymously purchased cylinder was put to the test by the French Market Surveillance Authority. Test report number 2019-6-RSPT-XBN-V2 revealed several non-conformities, as well as a physical defect that could have endangered the health and safety of users.
- (4) One non-conformity identified by the test report related to Article 6(3) of Directive 2010/35/EU, namely, the product's certificate of conformity had not indicated the name and address at which the importer could be contacted, this thereby preventing the distributors from complying with the obligation to place on the market only transportable pressure equipment accompanied by the certificate of conformity and the address where the importer could be contacted, provided for in Article 7(1) of that Directive.
- (5) Another non-conformity identified by the test report was that the cylinder's type approval certificate, issued by the notified body Technická inšpekcia (Slovakia) on 9 November 2018 with number 602/5/2018, did not include a complete list of the relevant parts of the technical documentation, as set out in paragraph 1.8.7.2.3 of Section I.1 of Annex I to Directive 2008/68/EC.

⁽¹⁾ OJ L 165, 30.6.2010, p. 1.⁽²⁾ Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).⁽³⁾ Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods (OJ L 260, 30.9.2008, p. 13).

- (6) Type approval certificate number 602/5/2018 did not indicate helium among the gases the cylinder's valve had been approved for. Therefore, the cylinder should not have been filled with helium.
- (7) The marking affixed on the cylinder by the manufacturer did not comply with Article 15 of Directive 2010/35/EU concerning the physical shape of the Greek letter Pi symbol. Nor did it comply with either the requirements in subsection 6.2.2.8 of Section I.1 to Annex I to Directive 2008/68/EC or with paragraph 12.2.2 of the EN ISO 11118:2015 standard regarding the height of the Pi symbol and of the wording 'DO NOT REFILL'. In addition, the marking did not comply with the requirements in paragraphs 6.2.2.7.2 to 6.2.2.7.4 of Section I.1 of Annex I to Directive 2008/68/EC, or with the EN ISO 11118:2015 standard regarding the information to be displayed. Namely, the working pressure indication was missing, and the reference standard and the number of the notified body were wrongly indicated. The dimensions of the label for 'non-flammable, non-toxic gases' were also smaller than those set out in paragraph 5.2.2.2.1.1.2 of Section I.1 of Annex I to Directive 2008/68/EC.
- (8) The marking on the packaging also presented non-conformities, namely a CE marking, which is not authorised by Directive 2010/35/EU, and a wrong number of the notified body.
- (9) The tested cylinder had a crack at the bottom of the neck, in the brazing weld. A crystal deposit indicated that a leak had occurred.
- (10) The French Market Surveillance Authority informed the importer and distributor regarding the non-conformities observed during the investigation. However, no appropriate answer was provided by those economic operators.
- (11) On 31 October 2019, a new certificate of approval was issued by the notified body Technická inšpekcia (Slovakia).
- (12) In accordance with Article 30(4) of Directive 2010/35/EU, the French Market Surveillance Authority provisionally withdrew from the market the cylinders manufactured before 31 October 2019 and notified the measure to the Commission and to the Member States. The decision was published on 3 January 2020.
- (13) On 23 January 2020, the Swedish Civil Contingencies Agency objected to one of the findings of the test report drawn up by the French Market Surveillance Authority. The objection triggered the application of Article 31(1) of Directive 2010/35/EU, according to which the Commission has to adopt a decision, after consulting the Member States and the relevant economic operators.
- (14) On 15 April 2021, the Commission invited the Member States, the manufacturer and the importers to provide their views on the case, in particular regarding the appropriateness of the measure adopted by the French Market Surveillance Authority and the risk posed by the product.
- (15) On 10 June 2021, the case was presented by the Commission to the Administrative Cooperation Group of the Market Surveillance Authorities, established in accordance with Article 28(b) of Directive 2010/35/EU. On 14 June 2021, the Commission presented the case to the Expert Group on Transport of Dangerous Goods, established in accordance with Article 8a(4) of Directive 2008/68/EC.
- (16) Six Member States and no economic operator submitted contributions in the consultation process. The opinions forwarded to the Commission confirmed that the product presents non-conformities regarding the packaging, documentation, marking and labelling, the initial inspection and test, and the supervision of the manufacture. In addition, the cylinder posed a clear risk for the safety of the users. No Member State considered that the measure adopted by the French Market Surveillance Authority not to be justified.
- (17) Examination of the evidence provided by the French Market Surveillance Authority confirms that the above-mentioned helium cylinders fail to comply with the requirements set out in Directive 2008/68/EC and in Directive 2010/35/EU. These helium cylinders therefore present a clear risk for the safety of the users and should be withdrawn from the market.

- (18) The measures provided for in this Decision are in accordance with the opinion of the Committee established under Article 9 of Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods,

HAS ADOPTED THIS DECISION:

Article 1

The measure taken by France, consisting of the withdrawal from the market of gas cylinder type BR1C, manufactured by Xinchang Burong Machinery Co. Ltd before 31 October 2019 and having the following characteristics:

- cylinder type: non-refillable,
- filled with gas: UN 1046 – HELIUM, COMPRESSED,
- working pressure: PW = 12 bar,
- hydraulic test pressure: PH = 28 bar,
- temperature range: TS = – 20 / + 60 °C,
- volume: V = 0,75 l

is justified.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 25 May 2022.

For the Commission
Adina VĂLEAN
Member of the Commission

COMMISSION IMPLEMENTING DECISION (EU) 2022/835**of 25 May 2022****on the unresolved objections regarding the conditions for granting an authorisation for the biocidal product Primer Stain TIP in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council***(notified under document C(2022) 3379)***(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ⁽¹⁾, and in particular Article 36(3) thereof,

Whereas:

- (1) On 29 April 2016, the company Lanxess Deutschland GmbH ('the applicant') submitted an application to France for the mutual recognition in parallel in accordance with Article 34 of Regulation (EU) No 528/2012 of the biocidal product Primer Stain TIP ('the biocidal product'). The biocidal product is a wood preservative of product-type 8 to be used for the preventive treatment against wood discolouring fungi, wood destroying basidiomycetes and wood boring beetles (larvae). The product is applied by brushing and rolling, automated dipping, manual dipping and deluge and contains as active substances tebuconazole, IPBC and permethrin. Germany is the reference Member State responsible for the evaluation of the application as referred to in Article 34(1) of Regulation (EU) No 528/2012.
- (2) On 28 August 2020, pursuant to Article 35(2) of Regulation (EU) No 528/2012, France referred objections to the coordination group, indicating that the conditions of the authorisation set by Germany do not ensure that the biocidal product meets the requirement laid down in Article 19(1), point (b)(iii), of that Regulation. France considers that in order to ensure the safe handling of the biocidal product, wearing of personal protective equipment consisting of protective chemical resistant gloves meeting the requirements of the European Standard EN 374 (glove material to be specified by the authorisation holder within the product information) is required for application by brushing and rolling and automated dipping, wearing of personal protective equipment consisting of protective chemical resistant gloves meeting the requirements of the European Standard EN 374 (glove material to be specified by the authorisation holder within the product information) and coverall of at least type 6 as specified in European Standard EN 13034 is required for application by manual dipping and deluge, and wearing of chemical resistant gloves meeting the requirements of the European Standard EN 374 is required for subsequent manual processing of the freshly treated timber. According to France, the application of technical and organisational measures in accordance with Council Directive 98/24/EC ⁽²⁾ as a possible replacement for wearing personal protective equipment does not ensure an adequate protection if those measures are not specified and evaluated in the assessment of the biocidal product.
- (3) Germany considers that Directive 98/24/EC establishes the order of preference of different risk mitigation measures for protection of workers and prioritises the application of technical and organisational measures over wearing personal protection equipment for the use of the biocidal product. According to Germany, pursuant to that Directive the employer is to decide which technical and organisational measures are to be applied, and as there is a broad range of such measures, it is not feasible to describe and evaluate the measures in the authorisation of the biocidal product.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11).

- (4) As no agreement was reached by the coordination group, on 28 October 2020 Germany referred the unresolved objection to the Commission pursuant to Article 36(1) of Regulation (EU) No 528/2012. It thereby provided the Commission with a detailed statement of the matter on which Member States were unable to reach agreement and the reasons for their disagreement. That statement was forwarded to the Member States concerned and the applicant.
- (5) Article 2(3), points (b) and (c), of Regulation (EU) No 528/2012 provides that that Regulation is to be without prejudice to Council Directive 89/391/EEC ⁽⁹⁾ and Directive 98/24/EC.
- (6) Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012 indicates as one of the criterion for granting an authorisation that the biocidal product has no unacceptable effects itself, or as a result of its residues, on the health of humans.
- (7) Point 9 of Annex VI to Regulation (EU) No 528/2012 states that the application of the common principles laid down in that Annex for the evaluation of dossiers for biocidal products referred to in Article 19(1), point (b), of that Regulation, when taken together with the other conditions set out in its Article 19, is to lead to the competent authorities or the Commission deciding whether or not a biocidal product is to be authorised. Such authorisation may include restrictions on the use of the biocidal product or other conditions.
- (8) Point 18(d) of Annex VI to Regulation (EU) No 528/2012 states that the risk assessment conducted for the product is to determine the measures necessary to protect humans, animals and the environment, both during the proposed normal use of the biocidal product and in a realistic worst-case situation.
- (9) Point 56(2) of Annex VI to Regulation (EU) No 528/2012 indicates that in establishing compliance with the criteria set out in Article 19(1), point (b), of that Regulation, one of the conclusions to which the evaluating body is to make, is that subject to specific conditions/restrictions the biocidal product can comply with the criteria.
- (10) Point 62 of Annex VI to Regulation (EU) No 528/2012 states that the evaluating body is, where appropriate, to conclude that the criterion under Article 19(1), point (b)(iii), of that Regulation can only be complied with by application of prevention and protection measures including the design of work processes, engineering controls, use of adequate equipment and materials, application of collective protection measures and, where exposure cannot be prevented by other means, application of individual protection measures including the wearing of personal protective equipment such as respirators, breathing-masks, overalls, gloves and goggles, in order to reduce exposure for professional operators.
- (11) However, point 62 of Annex VI to Regulation (EU) No 528/2012 does not provide that the assessment leading to the conclusion that the criterion under Article 19(1), point (b)(iii), of that Regulation can only be complied with by application of prevention and protection measures is to be done in accordance with Directive 98/24/EC. It also does not explicitly provide that that Directive would not apply. Therefore, it should not be inferred from those provisions that Directive 98/24/EC does not apply. In addition, the relevant obligations under Directive 98/24/EC are imposed on employers, not on the authorities of Member States.
- (12) Article 4 of Directive 98/24/EC provides that for the assessment of any risk to the safety and health of workers arising from the presence of chemical agents, employers are to obtain additional information needed from the supplier or from other readily available sources and that where appropriate, that information is to comprise the specific assessment concerning the risk to users established on the basis of Union legislation on chemical agents.
- (13) Article 6 of Directive 98/24/EC lays down prioritisation of the measures to be taken by the employer for the protection of workers from the risks related to chemical agents at work. Priority is to be given to replacement of the hazardous substance and when this is not possible, the risk from a hazardous chemical agent to the safety and health of workers at work needs to be reduced to a minimum by application of protection and prevention measures. If it is not possible to prevent exposure to the hazardous substance by other means, protection of the workers is to be ensured by applying individual protection measures including personal protective equipment.

⁽⁹⁾ Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (OJ L 183, 29.6.1989, p. 1).

- (14) Taking into account the methods of application of the biocidal product and the available information from the evaluating body, no such technical or organisational measures have been identified in the application for authorisation of the biocidal product, nor during the evaluation of that application.
- (15) The Commission therefore considers that the biocidal product meets the criterion laid down in Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012, provided that the following condition regarding its use is included in the authorisation and on the label of the biocidal product: 'The wearing of protective chemical resistant gloves meeting the requirements of the European Standard EN 374 (glove material to be specified by the authorisation holder within the product information) is required for application by brushing and rolling and automated dipping, wearing of protective chemical resistant gloves meeting the requirements of the European Standard EN 374 (glove material to be specified by the authorisation holder within the product information) and coverall of at least type 6 as specified in European Standard EN 13034 is required for application by manual dipping and deluge, and wearing of chemical resistant gloves meeting the requirements of European Standard EN 374 (glove material to be specified by the authorisation holder within the product information) is required for subsequent manual processing of the freshly treated timber. This is without prejudice to the application by employers of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work'.
- (16) However, if the applicant for authorisation identifies effective technical or organisational measures and the authorising authority agrees that such measures lead to an equivalent or higher level of exposure reduction, or the authorising authority itself identifies measures leading to an equivalent or higher level of exposure reduction, those measures should replace the wearing of personal protective equipment and should be specified in the authorisation and on the label of the biocidal product.
- (17) On 15 February 2022, the Commission provided the applicant with the opportunity to provide written comments in accordance with Article 36(2) of Regulation (EU) No 528/2012. The applicant did not provide comments.
- (18) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DECISION:

Article 1

The biocidal product identified by the case number BC-NF023903-46 in the Register for Biocidal Products meets the condition laid down in Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012 provided that the following condition regarding its use is included in the authorisation and on the label of the biocidal product: 'The wearing of protective chemical resistant gloves meeting the requirements of the European Standard EN 374 (glove material to be specified by the authorisation holder within the product information) is required for application by brushing and rolling and automated dipping, wearing of chemical resistant gloves meeting the requirements of the European Standard EN 374 (glove material to be specified by the authorisation holder within the product information) and coverall of at least type 6 as specified in European Standard EN 13034 is required for application by manual dipping and deluge, and wearing of chemical resistant gloves meeting the requirements of European Standard EN 374 (glove material to be specified by the authorisation holder within the product information) is required for subsequent manual processing of the freshly treated timber. This is without prejudice to the application by employers of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work.'

However, where the applicant for authorisation identifies technical or organisational measures and the authorising authority agrees that such measures achieve a level of exposure reduction equivalent to or higher than the reduction achieved by wearing the protective equipment referred to in the first paragraph, or the authorising authority itself identifies such measures leading to an equivalent or higher level of exposure reduction than the reduction achieved by wearing the protective equipment referred to in the first paragraph, those measures shall be used instead of that personal protective equipment and shall be specified in the authorisation and on the label of the biocidal product. In that case the obligation to include the condition regarding the use of the biocidal product laid down in the first paragraph shall not apply.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 25 May 2022.

For the Commission
Stella KYRIAKIDES
Member of the Commission

CORRIGENDA**Corrigendum to Rules of Procedure of the European Economic and Social Committee – May 2022**

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