

## II

(Non-legislative acts)

## REGULATIONS

### COMMISSION DELEGATED REGULATION (EU) 2019/227

of 28 November 2018

amending Delegated Regulation (EU) No 1062/2014 as regards certain active substances/product-type combinations for which the competent authority of the United Kingdom has been designated as the evaluating competent authority

(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 (<sup>1</sup>) and in particular the first subparagraph of Article 89(1) thereof,

Whereas:

- (1) Commission Delegated Regulation (EU) No 1062/2014 (<sup>2</sup>) sets out in its Annex II a list of active substance/product-type combinations included in the programme of review of existing active substances contained in biocidal products ('review programme').
- (2) The competent authority of the United Kingdom of Great Britain and Northern Ireland ('the United Kingdom') is the evaluating competent authority for several active substance/product-type combinations listed in Annex II to Delegated Regulation (EU) No 1062/2014.
- (3) The United Kingdom submitted on 29 March 2017 the notification of its intention to withdraw from the Union pursuant to Article 50 of the Treaty on European Union. As a result, the United Kingdom will withdraw from the Union on 30 March 2019 and the Union legislation will no longer apply to and in the United Kingdom. A withdrawal agreement is currently being negotiated between the European Union and the United Kingdom, which includes a 'transition period'. According to draft provisions of the Withdrawal Agreement as agreed between the EU and the United Kingdom at negotiator's level, during the transition period, a competent authority of the United Kingdom can not act as evaluating competent authority for any active substance/product-type combination included in the review programme. Moreover, there is no certainty whether the Withdrawal Agreement, once finalised, will be signed and ratified by both parties, and this before the 30 March 2019.
- (4) Therefore, as regards the active substances/product-type combinations included in the review programme for which the competent authority of the United Kingdom has been designated as the evaluating competent authority, it is necessary to designate a new evaluating competent authority from among the competent authorities of the remaining 27 Member States of the European Union, EEA countries, or Switzerland, with effect from 30 March 2019.
- (5) Notwithstanding the stage of evaluation of the application, the Member States whose competent authorities are designated to replace that of the United Kingdom should be allowed to request fees for the services provided, in accordance with Article 80 of Regulation (EU) No 528/2012.

(<sup>1</sup>) OJ L 167, 27.6.2012, p. 1.

(<sup>2</sup>) 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 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).

- (6) Taking into account that the review programme has to be finalised by the target date indicated in Article 89(1) of Regulation (EU) No 528/2012, appropriate time limits should be established for finalising the evaluations of the reallocated applications for active substance/product-type combinations.

- (7) Delegated Regulation (EU) No 1062/2014 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

*Article 1*

Delegated Regulation (EU) No 1062/2014 is amended as follows:

- (1) the following Article is inserted:

*'Article 6a*

**Applications for which the competent authority of the United Kingdom was the evaluating competent authority before 30 March 2019**

1. This Article is applicable to applications for which the competent authority of the United Kingdom was the evaluating competent authority before 30 March 2019 for the entries 79, 85, 113, 171, 187, 188, 321, 345, 346, 458, 531, 554, 571, 599, 609, 1045, 1046 and 1047 of Annex II.

2. The evaluating competent authority of a Member State having replaced the competent authority of the United Kingdom in relation to an application that has been submitted before 30 March 2019, shall inform the participant of the fees payable under Article 80(2) of Regulation (EU) No 528/2012 at the latest by 30 April 2019, and shall reject the application if the participant fails to pay the fees within a period of time fixed by the evaluating competent authority. It shall inform the participant and the Agency accordingly.

3. By derogation from the time limits laid down in Article 6(3), the assessment report and the conclusions shall be sent by the evaluating competent authority within either of the following time limits, whichever is the later:

(a) 31 December 2020;

(b) the time limit for submitting the assessment report pursuant to Article 6(3)(b) set out in Annex III.';

- (2) the table set out in Annex II is replaced by the table set out 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 30 March 2019.

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

Done at Brussels, 28 November 2018.

*For the Commission*

*The President*

Jean-Claude JUNCKER

## ANNEX

The table set out in Annex II to Delegated Regulation (EU) No 1062/2014 is replaced by the following table:

'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
1029	Peracetic acid generated by perhydrolysis of N-acetylcaprolactam by hydrogen peroxide in alkaline conditions	AT				x																
71	L-(+)-lactic acid	DE	201-196-2	79-33-4						x												
79	(2R,6aS,12aS)-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	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												
154	Clorophene	NO	204-385-8	120-32-1		x																
171	2-Phenoxyethanol	IT	204-589-7	122-99-6	x	x		x		x						x						
1072	Carbon dioxide	FR	204-696-9	124-38-9													x					
179	Carbon dioxide generated from propane, butane or a mixture of both by combustion	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
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	x						
195	Sodium 2-biphenylate	ES	205-055-6	132-27-4			x		x	x		x	x				x					
206	Thiram	BE	205-286-2	137-26-8								x										
210	Metam-sodium	BE	205-293-0	137-42-8								x		x								
227	2-Thiazol-4-yl-1H-benzoimidazole (Thiabendazole)	ES	205-725-8	148-79-8						x		x	x									
235	Diuron	DK	206-354-4	330-54-1						x			x									
239	Cyanamide	DE	206-992-3	420-04-2		x												x				
253	Tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione (Dazomet)	BE	208-576-7	533-74-4					x						x							
283	Terbutryl	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					

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
321	Monolinuron	HU	217-129-5	1746-81-2		x																
330	N-(3-Aminopropyl)-N-do-decylpropane-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-Benzothiazol-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	x						
345	Troclosene sodium	DE	220-767-7	2893-78-9		x	x	x	x						x	x						
348	Mecetronium ethylsulfate (MES)	PL	221-106-5	3006-10-8	x																	
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	x					
365	Pyridine-2-thiol 1-oxide, sodium salt (Sodium pyrithione)	SE	223-296-5	3811-73-2		x				x	x		x	x		x		x				
368	Methenamine 3-chloroallylochloride (CTAC)	PL	223-805-0	4080-31-3						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
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-tetrakis(hydroxymethyl)imidazo[4,5-d]imidazole-2,5(1H,3H)-dione (TMAD)	ES	226-408-0	5395-50-6		x				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	Didecyldimethylammonium chloride (DDAC)	IT	230-525-2	7173-51-5	x	x	x	x		x				x	x	x						
401	Silver	SE	231-131-3	7440-22-4		x		x	x						x							
1023	Silver, as a nanomaterial	SE	231-131-3	7440-22-4		x		x						x								
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						

'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
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								
1035	Active bromine generated from ozone and bromide of natural water and sodium bromide	NL				x																
434	Tetramethrin	DE	231-711-6	7696-12-0														x				
439	Hydrogen peroxide	FI	231-765-0	7722-84-1										x	x							
1036	Hydrogen peroxide released from sodium percarbonate	FI				x	x		x													
444	7a-Ethyldihydro-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							

'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
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									
473	Pyrethrins and Pyrethroids	ES	232-319-8	8003-34-7														x	x			
491	Chlorine dioxide	DE	233-162-8	10049-04-4		x	x	x	x						x	x						
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						



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
529	Active bromine generated from bromine chloride	NL											x									
531	(Benzyoxy)methanol	AT	238-588-8	14548-60-8						x						x						
550	D-Gluconic acid, compound with N,N'-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediamidine (2:1) (CHDG)	PT	242-354-0	18472-51-0	x	x	x															
554	p-[(Diiodomethyl)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			
563	Potassium (E,E)-hexa-2,4-dienoate (Potassium Sorbate)	DE	246-376-1	24634-61-5					x													
566	Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1) (HPT)	AT				x				x					x		x					
571	2-Octyl-2H-isothiazol-3-one (OIT)	FR	247-761-7	26530-20-1					x	x		x	x		x	x	x	x				
577	Dimethyloctadecyl[3-(trimethoxysilyl)propyl]ammonium chloride	ES	248-595-8	27668-52-6		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
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									
597	1-[2-(Allyloxy)-2-(2,4-dichlorophenyl)ethyl]-1H-imidazole (Imazalil)	DE	252-615-0	35554-44-0			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	Eucalyptus citriodora oil, hydrated, cyclized	CZ		1245629-80-4														x				
1046	Cymbopogon winterianus oil, fractionated, hydrated, cyclized	CZ	Not available	Not available														x				
1047	Eucalyptus citriodora oil and citronellal, hydrated, cyclized	CZ	Not available	Not available														x				
609	2-Hydroxy- $\alpha,\alpha,4$ -trimethylcyclohexanemethanol	CZ	255-953-7	42822-86-6														x				
619	3-Iodo-2-propynylbutylcarbamate (IPBC)	DK	259-627-5	55406-53-6							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
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	x	x	x						x	x						
1048	Active chlorine released from hypochlorous acid	SK				x	x	x	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																
1052	Active chlorine generated from magnesium chloride hexahydrate by electrolysis	FR				x																
1053	Active chlorine generated from potassium chloride by electrolysis	DK				x		x														
1054	Active chlorine generated from sodium N-chlorosulfamate	SI						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
1055	Active chlorine generated from sodium chloride and pentapotassium bis(peroxymonosulfate)bis(sulfate) and sulfamic acid	SI				x	x															
1056	Active chlorine generated from hydrochloric acid by electrolysis	SI				x		x	x													
701	Dihydrogen bis[monoperoxypythalato(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 <i>Azadirachta Indica</i> 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	
731	<i>Chrysanthemum cinerariaefolium</i> , ext.	ES	289-699-3	89997-63-7														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
1017	Silver adsorbed on silicon dioxide (as a nanomaterial in the form of a stable aggregate with primary particles in the nano-scale)	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				
855	(RS)-3-Allyl-2-methyl-4-oxocyclopent-2-enyl (1R,3R)-2,2-dimethyl-3-(2-methylprop-1-enyl)-cyclopropanecarboxylate (mixture of 2 isomers 1R trans: 1R/S only 1:3) (Esbiothrin)	DE	Plant protection product	260359-57-7														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
868	Polyhexamethylene biguanide hydrochloride with a mean number-average molecular weight (Mn) of 1415 and a mean polydispersity (PDI) of 4,7 (PHMB(1415;4,7))	FR	Polymer	32289-58-0 and 1802181-67-4			x					x		x								
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										
1059	<i>Capsicum oleoresin</i> Extractives and their physically modified derivatives. It is a product which may contain resin acids and their esters, terpenes, and oxidation or polymerization products of these terpenes. ( <i>Capsicum frutescens</i> , Solanaceae)	BE	Not available	8023-77-6														x				
1060	<i>Capsicum annuum</i> , ext. Extractives and their physically modified derivatives such as tinctures, concretes, absolutes, essential oils, oleoresins, terpenes, terpene-free fractions, distillates, residues, etc., obtained from <i>Capsicum annuum</i> , Solanaceae.	BE	283-403-6	84625-29-6														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
1061	Reaction mass of (6E)-N-(4-hydroxy-3-methoxy-2-methylphenyl)-8-methylnon-6-enamide and N-(4-hydroxy-3-methoxy-2-methylphenyl)-8-methylnonanamide	BE	Not available	Not available														x				
1062	D-Fructose	AT	200-333-3	57-48-7														x				
1063	Honey	AT		8028-66-8														x				
1064	Malt, ext. Extractives and their physically modified derivatives such as tinctures, concretes, absolutes, essential oils, oleoresins, terpenes, terpene-free fractions, distillates, residues, etc., obtained from <i>Hordeum, Gramineae</i> .	AT	232-310-9	8002-48-0														x				
1065	Vinegar (food grade containing a maximum of 10 % acetic acid)	AT	Not available	8028-52-2														x				
1066	Cheese	AT	Not available	Not available														x				
1067	Powdered egg	NL	Not available	Not available														x				
1068	<i>Saccharomyces cerevisiae</i>	NL	Not available	68876-77-7														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
1069	Concentrated apple juice	NL	Not available	Not available														x				
1070	Orange, sweet, ext. Extractives and their physically modified derivatives such as tinctures, concretes, absolutes, essential oils, oleoresins, terpenes, terpene-free fractions, distillates, residues, etc., obtained from <i>Citrus sinensis</i> , Rutaceae.	CH	232-433-8	8028-48-6															x			
1071	Garlic, ext. Extractives and their physically modified derivatives such as tinctures, concretes, absolutes, essential oils, oleoresins, terpenes, terpene-free fractions, distillates, residues, etc., obtained from <i>Allium sativum</i> , Liliaceae.	AT	232-371-1	8008-99-9														x'				