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)

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[(1)] and in particular the first subparagraph of Article 89(1) thereof,

Whereas:

(1) Commission Delegated Regulation (EU) No 1062/2014[(2)] 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

Changes to legislation: *There are currently no known outstanding effects for the Commission Delegated Regulation (EU) 2019/227. (See end of Document for details)*

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.

(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

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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	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	x															x
9	Bronopol	ES	200-143-0	52-51-7	x				x			x		x	x						x
36	Ethanol	FI	200-578-6	64-17-5	x		x														
37	Formic acid	BE	200-579-1	64-18-6	x	x	x	x	x					x	x						
1025	Peracetic acid generated from formic acid and hydrogen peroxide	BE			x	x	x	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 tetraacetylethylenediamine (TAED) and hydrogen peroxide	AT			x																
1027	Peracetic acid generated from 1,3-diacetyloxypropan-2-yl acetate and	AT			x		x														

	hydrogen peroxide																					
1028	Peracetic acid generated from tetraacetylethylenediamine (TAED) and sodium perborate monohydrate	AT					x															
1029	Peracetic acid generated by perhydrolysis of N-acetylcaprolactam by hydrogen peroxide in alkaline conditions	AT				x																
71	L-(+)-lactic acid	DE	201-79-6-2-4							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	201-83-7-9-6															x				
85	Symclosene	DE	201-87-2-0-1	x	x	x	x							x	x							
92	Biphenyl-2-ol	ES	201-90-4-5-7						x		x	x										
113	3-Phenyl-propen-2-al (Cinnamaldehyde)	PL	203-213-5-5-2	x																		
117	Geraniol	FR	203-376-2-4-1															x	x			
122	Glyoxal	FR	203-474-2-2-2	x	x	x																