EUROPEAN
COMMISSION

Brussels, XXX
SANTE/10332/2020
(POOL/E4/2020/10332/10332-EN.doc)
[…](2020) XXX draft

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

postponing the expiry date of approval of acrolein for use in biocidal products of product-type 12

(Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

postponing the expiry date of approval of acrolein for use in biocidal products of product-type 12

(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 14(5) thereof,

After consulting the Standing Committee on Biocidal Products,

Whereas:

(1) The active substance acrolein was included in Annex I to Directive 98/8/EC of the European Parliament and of the Council[2] for use in biocidal products of product-type 12, and pursuant to Article 86 of Regulation (EU) No 528/2012 is therefore considered approved under that Regulation subject to the specifications and conditions set out in Annex I to that Directive.

(2) The approval of acrolein for use in biocidal products of product-type 12 will expire on 31 August 2020. On 28 February 2019, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval of acrolein.

(3) On 25 February 2020, the evaluating competent authority of Czechia informed the Commission that it had decided, pursuant to Article 14(1) of Regulation (EU) No 528/2012, that a full evaluation of the application was necessary. Pursuant to Article 8(1) of Regulation (EU) No 528/2012, the evaluating competent authority is to perform a full evaluation of the application within 365 days of its validation.

(4) The evaluating competent authority may, as appropriate, request the applicant to provide sufficient data to carry out the evaluation, in accordance with Article 8(2) of Regulation (EU) No 528/2012. In such case, the 365-day period is suspended for a period that may not exceed 180 days in total unless a longer suspension is justified by the nature of the data requested or by exceptional circumstances.

(5) Within 270 days of receipt of a recommendation from the evaluating competent authority, the European Chemicals Agency ('the Agency') is to prepare and submit to the Commission an opinion on renewal of the approval of the active substance in accordance with Article 14(3) of Regulation (EU) No 528/2012.

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1 OJ L 167, 27.6.2012, p. 1.

2 Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).

(6) Consequently, for reasons beyond the control of the applicant, the approval of acrolein for use in biocidal products of product-type 12 is likely to expire before a decision has been taken on its renewal. It is therefore appropriate to postpone the expiry date of approval of acrolein for use in biocidal products of product-type 12 for a period of time sufficient to enable the examination of the application. Considering the time-limits for the evaluation by the evaluating competent authority and for the preparation and submission of the opinion by the Agency, it is appropriate to postpone the expiry date of approval to 28 February 2023.

(7) Except for the expiry date of the approval, acrolein remains approved for use in biocidal products of product-type 12 subject to the specifications and conditions set out in Annex I to Directive 98/8/EC,

HAS ADOPTED THIS DECISION:

Article 1

The expiry date of approval of acrolein for use in biocidal products of product-type 12 is postponed to 28 February 2023.

Article 2

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

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN

EUROPEAN
COMMISSION

Brussels, XXX
SANTE/10350/2020 Rev. 1
(POOL/E4/2020/10350/10350R1-EN.docx)
[…](2020) XXX draft

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

postponing the expiry date of approval of creosote for use in biocidal products of product-type 8

(Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

postponing the expiry date of approval of creosote for use in biocidal products of product-type 8

(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 14(5) thereof,

After consulting the Standing Committee on Biocidal Products,

Whereas:

(1) The active substance creosote was included into Annex I to Directive 98/8/EC of the European Parliament and of the Council[2] for use in biocidal products for product-type 8, and pursuant to Article 86 of Regulation (EU) No 528/2012 is therefore considered approved under that Regulation subject to the specifications and conditions set out in Annex I to that Directive.

(2) On 27 October 2016, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval of creosote.

(3) The expiry date of approval of creosote has been postponed to 31 October 2020 by Commission Implementing Decision (EU) 2017/2334[3] in order to allow sufficient time for the examination of the application.

(4) On 16 September 2019, the former evaluating competent authority of the United Kingdom submitted a recommendation on the renewal to the European Chemicals Agency ('the Agency'). The competent authority of Poland has taken over the role of evaluating competent authority on the application on 30 January 2020. As the competent authority carried out a full evaluation of the application, in accordance with Article 14(3) of Regulation (EU) No 528/2012, the Agency is to prepare and submit to the Commission an opinion on renewal of the approval of the active substance within 270 days of receipt of the recommendation from the evaluating competent authority.

(5) In addition, as creosote is classified as carcinogen category 1B in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council[4] and

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1 OJ L 167, 27.6.2012, p. 1.

2 Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).

3 Commission Implementing Decision (EU) 2017/2334 of 14 December 2017 postponing the expiry date of approval of creosote for use in biocidal products of product-type 8 (OJ L 333, 15.12.2017, p. 64).

4 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives

meets the criteria for being a persistent, bioaccumulative and toxic substance and a very persistent and very bioaccumulative substance according to Annex XIII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council[5], it meets the exclusion criteria set out in points (a) and (e) of Article 5(1) of Regulation (EU) No 528/2012. Further examination is therefore necessary to decide whether at least one of the conditions of the first subparagraph of Article 5(2) of Regulation (EU) No 528/2012 is fulfilled, and whether the approval of creosote may therefore be renewed.

(6) Furthermore, creosote, its compounds and wood treated with them are subject to restrictions laid down in Annex XVII to Regulation (EC) No 1907/2006. Following Commission Implementing Decision (EU) 2019/961[6], France is to submit to the Agency a dossier in accordance with Annex XV to Regulation (EC) No 1907/2006, initiating a Union restrictions procedure in accordance with Articles 69 to 73 of that Regulation. Further examination needs to take place in order to ensure consistency between the assessment of the renewal of the approval of creosote as an active substance under Regulation (EU) No 528/2012 and the Union restriction procedure under Regulation (EC) No 1907/2006, and to provide for an effective control of creosote and wood treated with it.

(7) Consequently, for reasons beyond the control of the applicant, the approval of creosote for use in biocidal products of product-type 8 is likely to expire before a decision has been taken on its renewal. It is therefore appropriate to further postpone the expiry date of approval of creosote for a period of time sufficient to enable the examination of the application.

(8) Considering the period necessary for the preparation and submission of the opinion by the Agency, the period necessary to decide if at least one of the conditions of the first subparagraph of Article 5(2) of Regulation (EU) No 528/2012 is fulfilled and whether the approval of creosote may therefore be renewed, it is appropriate to postpone the expiry date of approval of creosote to 31 October 2021.

(9) Except for the expiry date of the approval, creosote remains approved subject to the specifications and conditions set out in Annex I to Directive 98/8/EC,

HAS ADOPTED THIS DECISION:

Article 1

The expiry date of approval of creosote for use in biocidal products of product-type 8 is postponed to 31 October 2021.

67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

5 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

6 Commission Implementing Decision (EU) 2019/961 of 7 June 2019 authorising a provisional measure taken by the French Republic in accordance with Article 129 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) to restrict the use and the placing on the market of certain wood treated with creosote and other creosote-related substances (OJ L 154, 12.6.2019, p. 44).

Article 2

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

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN

EUROPEAN
COMMISSION

Brussels, XXX
SANTE/2019/11734
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[…](2020) XXX draft

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

on the non-approval of certain active substances in biocidal products pursuant to Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

on the non-approval of certain active substances in biocidal products pursuant to 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 third subparagraph of Article 89(1) thereof,

Whereas:

(1) Commission Delegated Regulation (EU) No 1062/2014[2], as last amended by Commission Delegated Regulation (EU) 2019/227[3], establishes in its Annex II a list of active substance/product-type combinations included in the review programme of existing active substances in biocidal products on 30 March 2019.

(2) For a number of active substance/product-type combinations included in that list, all the participants have withdrawn their support in a timely manner.

(3) The Commission was informed, in accordance with Article 12(3) of Delegated Regulation (EU) No 1062/2014, of those active substance/product-type combinations for which all participants made a timely withdrawal and for which the role of participant had previously been taken over. In accordance with point (a) of the first paragraph of Article 20 of Delegated Regulation (EU) No 1062/2014, those active substance/product-type combinations should not be approved for use in biocidal products.

(4) An open invitation was published to take over the role of participant for those active substance/product-type combinations for which the role of participant had not previously been taken over. For some of those combinations no notification has been submitted or a notification has been submitted and rejected pursuant to paragraph 4 or paragraph 5 of Article 17 of Delegated Regulation (EU) No 1062/2014. In accordance with point (b) of the first paragraph of Article 20 of Delegated Regulation (EU) No 1062/2014, those active substance/product-type combinations should not be approved for use in biocidal products.

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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 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).

3 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 (OJ L 37, 8.2.2019, p. 1).

(5) 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 active substances listed in the Annex are not approved for the product-types indicated therein.

Article 2

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

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN

EUROPEAN
COMMISSION

Brussels, XXX
SANTE/11734/2019 Rev. 1 ANNEX
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to the

COMMISSION IMPLEMENTING DECISION (EU) .../...

on the non-approval of certain active substances in biocidal products pursuant to Regulation (EU) No 528/2012 of the European Parliament and of the Council

ANNEX

Active substance/product-type combinations not approved, including any nanomaterial forms:

Entry Number in Annex II to Regulation (EU) No 1062/2014	Substance name	Rapporteur Member State	EC number	CAS number	Product-type(s)
37	Formic acid	BE	200-579-1	64-18-6	11, 12
1025	Performic acid generated from formic acid and hydrogen peroxide	BE	n/a	n/a	3, 5, 6
1027	Peracetic acid generated from 1,3- diacetyloxypropan-2-yl acetate and hydrogen peroxide	AT	n/a	n/a	4
1028	Peracetic acid generated from tetraacetylethylenediamine (TAED) and sodium perborate monohydrate	AT	n/a	n/a	3
1029	Peracetic acid generated by perhydrolysis of N-acetylcaprolactam by hydrogen peroxide in alkaline conditions	AT	n/a	n/a	2
85	Symclosene	DE	201-782-8	87-90-1	12
195	Sodium 2-biphenylate	ES	205-055-6	132-27-4	4, 6, 7, 9, 10, 13
253	Tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione (Dazomet)	BE	208-576-7	533-74-4	6, 12
346	Sodium dichloroisocyanurate dihydrate	DE	220-767-7	51580-86-0	12
345	Troclosene sodium	DE	220-767-7	2893-78-9	12
359	Formaldehyde released from (Ethylenedioxy)dimethanol (Reaction products of ethylene glycol with paraformaldehyde (EGForm))	PL	222-720-6	3586-55-8	2

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	2
1035	Active bromine generated from ozone and bromide of natural water and sodium bromide	NL	n/a	n/a	2
1036	Hydrogen peroxide released from sodium percarbonate	FI	n/a	n/a	5
473	Pyrethrins and Pyrethroids	ES	232-319-8	8003-34-7	18, 19
1041	Chlorine dioxide generated from sodium chloride by electrolysis	DE	n/a	n/a	2, 3, 4, 5, 11, 12
1044	Chlorine dioxide generated from sodium chlorite and sodium persulfate	DE	n/a	n/a	12
597	1-[2-(Allyloxy)-2-(2,4-dichlorophenyl)ethyl]-1H-imidazole (Imazalil)	DE	252-615-0	35554-44-0	3
939	Active chlorine generated from sodium chloride by electrolysis	SK	n/a	n/a	12
1052	Active chlorine generated from magnesium chloride hexahydrate by electrolysis	FR	n/a	n/a	2
1053	Active chlorine generated from potassium chloride by electrolysis	DK	n/a	n/a	2, 4
1055	Active chlorine generated from sodium chloride and pentapotassium bis(peroxymonosulfate)bis(sulfate) (KPMS) and sulfamic acid	SI	n/a	n/a	2, 3
1056	Active chlorine generated from hydrochloric acid by electrolysis	SI	n/a	n/a	2, 4, 5
731	*Chrysanthemum cinerariaefolium*, ext.	ES	289-699-3	89997-63-7	18
811	Silver sodium hydrogen zirconium phosphate	SE	422-570-3	265647-11-8	1
1014	Silver zeolite	SE	n/a	n/a	5

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	1802181-67-4 /32289-58-0	3, 9, 11

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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

approving icaridin as an existing active substance for use in biocidal products of product-type 19

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

approving icaridin as an existing active substance for use in biocidal products of product-type 19

(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 third subparagraph of Article 89(1) thereof,

Whereas:

(1) Commission Delegated Regulation (EU) No 1062/2014[2] establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That list includes icaridin.

(2) Icaridin has been evaluated for use in biocidal products of product-type 19, repellents and attractants as described in Annex V to Directive 98/8/EC of the European Parliament and of the Council[3], which corresponds to product-type 19 as described in Annex V to Regulation (EU) No 528/2012.

(3) Denmark was designated as a rapporteur Member State and its evaluating competent authority submitted the assessment report together with its recommendations to the Commission on 14 January 2011.

(4) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the opinion of the European Chemicals Agency[4] was adopted on 10 December 2019 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.

(5) It can be derived from Article 90(2) of Regulation (EU) No 528/2012 that substances for which the Member States' evaluation has been completed by 1 September 2013 should be evaluated in accordance with the provisions of Directive 98/8/EC. Following the opinion of the Agency, biocidal products of product-type 19 containing icaridin may be expected to satisfy the requirements of Article 5 of Directive 98/8/EC, provided that certain specifications and conditions concerning their use are complied with.

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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 582/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1)

3 Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).

4 Biocidal Products Committee Opinion on the application for approval of the active substance Icaridin, Product type: 19, ECHA/BPC/229/2019, adopted on 10 December 2019.

(6) It is therefore appropriate to approve icaridin for use in biocidal products of product-type 19, subject to compliance with certain specifications and conditions.

(7) Since it can be derived from Article 90(2) of Regulation (EU) No 528/2012 that substances for which the Member States' evaluation has been completed by 1 September 2013 should be approved under the terms of Directive 98/8/EC, the period of approval should be 10 years, in accordance with the practice established under that Directive.

(8) A reasonable period should be allowed to elapse before an active substance is approved in order to permit interested parties to take the preparatory measures necessary to meet the new requirements.

(9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

Icaridin is approved as an active substance for use in biocidal products of product-type 19, subject to the specifications and conditions set out in the Annex.

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,

For the Commission
The President
Ursula VON DER LEYEN

EUROPEAN
COMMISSION

Brussels, XXX
SANTE/10334/2020 ANNEX
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to the

COMMISSION IMPLEMENTING REGULATION (EU) .../...

approving icaridin as an existing active substance for use in biocidal products of product-type 19

ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance[1]	Date of approval	Expiry date of approval	Product type	Specific conditions
Icaridin	IUPAC name: (RS)-sec-butyl (RS)-2-(2-hydroxyethyl)piperidine-1-carboxylate EC No: 423-210-8 CAS No: 119515-38-7	97% w/w	1 February 2022	31 January 2032	19	The authorisations of biocidal products are subject to the following conditions: (a) the product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance; (b) for products that may lead to residues in food and feed, the need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council[2] or Regulation (EC) No 396/2005 of the European Parliament and of the Council[3] shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded; (c) in view of the risks identified for the uses assessed, the product assessment shall pay particular attention to children younger than two years following dermal and secondary exposure.

[1] The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.

[2] Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).

[3] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).