EUROPEAN
COMMISSION

Brussels, XXX
SANTE/11658/2020 Rev. 1
(POOL/E4/2020/11658/11658R1-EN.docx)
[…](2020) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

approving active chlorine released from hypochlorous acid as an active substance for use in biocidal products of product-type 1

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

approving active chlorine released from hypochlorous acid as an active substance for use in biocidal products of product-type 1

(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 9(1)(a) thereof,

Whereas:

(1) On 31 July 2007, the competent authority of Slovakia ('the evaluating competent authority') received an application, in accordance with Article 11(1) of Directive 98/8/EC of the European Parliament and of the Council[2], for the inclusion of the active substance active chlorine released from hypochlorous acid in Annex I to that Directive for use in biocidal products of product-type 1, human hygiene, as defined in Annex V to that Directive, which corresponds to product-type 1 as defined in Annex V to Regulation (EU) No 528/2012.

(2) On 19 November 2010, the evaluating competent authority submitted the assessment report together with its conclusions to the Commission in accordance with Article 11(2) of Directive 98/8/EC.

(3) On 16 June 2020, the Biocidal Products Committee adopted the opinion of the European Chemicals Agency[3] ('the Agency'), having regard to the conclusions of the evaluating competent authority.

(4) According to that opinion, biocidal products of product-type 1 using active chlorine released from hypochlorous acid may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC, provided that certain specifications and conditions concerning their use are complied with.

(5) Taking into account the opinion of the Agency, it is appropriate to approve active chlorine released from hypochlorous acid as an active substance for use in biocidal products of product-type 1 subject to compliance with certain specifications and conditions.

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

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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 Biocidal Products Committee Opinion on the application for approval of the active substance active chlorine released from hypochlorous acid, Product type:1, ECHA /BPC/255 adopted on 16 June 2020.

HAS ADOPTED THIS REGULATION:

Article 1

Active chlorine released from hypochlorous acid is approved as an active substance for use in biocidal products of product-type 1 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/11658/2020 ANNEX Rev1
(POOL/E4/2020/11658/11658-EN
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[…](2020) XXX draft

ANNEX

ANNEX

to the

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

approving active chlorine released from hypochlorous acid as an active substance for use in biocidal products of product-type 1

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
Active chlorine released from hypochlorous acid	IUPAC name: Hypochlorous acid EC No: 232-232-5 CAS No: 7790-92-3	Specification established for hypochlorous acid (as dry weight min. 90,87% w/w) releasing active chlorine. Hypochlorous acid is the predominant species at pH 3,0 – 7,4.	1 July 2021	30 June 2031	1	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.

[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.

EUROPEAN
COMMISSION

Brussels, XXX
SANTE/11468/2020 Rev. 1
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[…](2020) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

approving active chlorine released from hypochlorous acid as an active substance for use in biocidal products of product-types 2, 3, 4 and 5

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

approving active chlorine released from hypochlorous acid as an active substance for use in biocidal products of product-types 2, 3, 4 and 5

(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 active chlorine released from hypochlorous acid.

(2) Active chlorine released from hypochlorous acid has been evaluated for use in biocidal products of product-type 2, private area and public health area disinfectants and other biocidal products, product-type 3, veterinary hygiene biocidal products, product-type 4, food and feed area disinfectants, and product-type 5, drinking water disinfectants as defined in Annex V to Directive 98/8/EC of the European Parliament and of the Council[3], which correspond respectively to product-types 2, 3, 4 and 5 as defined in Annex V to Regulation (EU) No 528/2012.

(3) Slovakia was designated as the rapporteur Member State and its evaluating competent authority submitted the assessment reports together with its conclusions to the Commission on 19 November 2010.

(4) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the Biocidal Products Committee adopted the opinions of the European Chemicals Agency[4] ('the Agency') on 16 June 2020, having regard to the conclusions of the evaluating competent authority.

(5) According to those opinions, biocidal products of product-types 2, 3, 4 and 5 using active chlorine released from hypochlorous acid may be expected to satisfy the

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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 active chlorine released from hypochlorous acid, Product type: 2, 3, 4 and 5, ECHA /BPC/256, 257, 258, 259 adopted on 16 June 2020

requirements laid down in Article 5 of Directive 98/8/EC, provided that certain specifications and conditions concerning their use are complied with.

(6) Taking into account the opinions of the Agency, it is appropriate to approve active chlorine released from hypochlorous acid for use in biocidal products of product-types 2, 3, 4 and 5 subject to compliance with certain specifications and conditions.

(7) 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.

(8) 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

Active chlorine released from hypochlorous acid is approved as an active substance for use in biocidal products of product-types 2, 3, 4 and 5 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/11468/2020 ANNEX Rev2
(POOL/E4/2020/11468/11468-EN
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[…](2021) XXX draft

ANNEX

ANNEX

to the

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

approving active chlorine released from hypochlorous acid as an active substance for use in biocidal products of product-types 2, 3, 4 and 5

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
Active chlorine released from hypochlorous acid	IUPAC name: Hypochlorous acid EC No: 232-232-5 CAS No: 7790-92-3	Specification established for hypochlorous acid (as dry weight min 90.87% w/w) releasing active chlorine. Hypochlorous acid is the predominant species at pH 3.0 - 7.4.	1 July 2022	30 June 2032	2	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. (a) the product assessment shall pay particular attention to the protection of professional users for hard surface disinfection via mopping or wiping.
					3	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 or feed, the need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/2009[2] or Regulation (EC)

[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).

						No 396/2005[3] shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.
					4	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 or feed, the need to set new or to amend existing MRLs in accordance with Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005 shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.
					5	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 or feed, the need to set new or to amend existing MRLs in accordance with Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005 shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable

[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).

						MRLs are not exceeded.

EUROPEAN
COMMISSION

Brussels, XXX
SANTE/11656/2020
(POOL/E4/2020/11656/11656-EN.docx)
[…](2020) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

approving active chlorine generated from sodium chloride by electrolysis as an active substance for use in biocidal products of product-type 1

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

approving active chlorine generated from sodium chloride by electrolysis as an active substance for use in biocidal products of product-type 1

(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 9(1)(a) thereof,

Whereas:

(1) On 31 July 2007, the competent authority of Slovakia ("the evaluating competent authority") received an application, in accordance with Article 11(1) of Directive 98/8/EC of the European Parliament and of the Council[2], for the inclusion of the active substance active chlorine generated from sodium chloride by electrolysis in Annex I to that Directive for use in biocidal products of product-type 1, human hygiene, as defined in Annex V to that Directive, which corresponds to product-type 1 as defined in Annex V to Regulation (EU) No 528/2012.

(2) On 19 November 2010, the evaluating competent authority submitted the assessment report together with its conclusions to the Commission in accordance with Article 11(2) of Directive 98/8/EC.

(3) On 16 June 2020, the Biocidal Products Committee adopted the opinion of the European Chemicals Agency[3] ('the Agency'), having regard to the conclusions of the evaluating competent authority.

(4) According to that opinion, biocidal products of product-type 1 using active chlorine generated from sodium chloride by electrolysis may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC, provided that certain specifications and conditions concerning their use are complied with.

(5) Taking into account the opinion of the Agency, it is appropriate to approve active chlorine generated from sodium chloride by electrolysis as an active substance for use in biocidal products of product-type 1 subject to compliance with certain specifications and conditions.

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

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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 Biocidal Products Committee Opinion on the application for approval of the active substance active chlorine generated from sodium chloride by electrolysis, Product type:1, ECHA /BPC/250 adopted on 16 June 2020.

HAS ADOPTED THIS REGULATION:

Article 1

Active chlorine generated from sodium chloride by electrolysis is approved as an active substance for use in biocidal products of product-type 1 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/11656/2020 ANNEX Rev3
(POOL/E4/2020/11656/11656-EN
ANNEX R3.docx)
[…](2021) XXX draft

ANNEX

ANNEX

to the

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

approving active chlorine generated from sodium chloride by electrolysis as an active substance for use in biocidal products of product-type 1

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
Active chlorine generated from sodium chloride by electrolysis	IUPAC name: not applicable EC No: not applicable CAS No: not applicable Precursor : IUPAC Name: Sodium Chloride EC No 231-598-3 CAS No 7647-14-5	The specifications for active chlorine generated from sodium chloride by electrolysis in situ are dependent on the precursor sodium chloride which must comply with purity requirements of one of the following standards: NF Brand, EN 973 A, EN 973 B, EN 14805 Type 1, EN 14805 Type 2, EN 16370 Type 1, EN 16370 Type 2, EN 16401 Type 1, EN 16401 Type 2, CODEX STAN 150-1985 or European Pharmacopoeia 9.0.	1 July 2021	30 June 2031	1	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.

[1] The purity requirements for the precursor indicated in this column are those provided in the application for the approval of the active substance evaluated.

EUROPEAN
COMMISSION

Brussels, XXX
SANTE/11466/2020
(POOL/E4/2020/11466/11466-EN.docx)
[…](2020) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

approving active chlorine generated from sodium chloride by electrolysis as an active substance for use in biocidal products of product types 2, 3, 4 and 5

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

approving active chlorine generated from sodium chloride by electrolysis as an active substance for use in biocidal products of product types 2, 3, 4 and 5

(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 active chlorine generated from sodium chloride by electrolysis.

(2) Active chlorine generated from sodium chloride by electrolysis has been evaluated for use in biocidal products of product-type 2, private area and public health area disinfectants and other biocidal products, product-type 3, veterinary hygiene biocidal products, product-type 4, food and feed area disinfectants, and product-type 5, drinking water disinfectants as defined in Annex V to Directive 98/8/EC of the European Parliament and of the Council[3], which correspond respectively to product-types 2, 3, 4 and 5 as defined in Annex V to Regulation (EU) No 528/2012.

(3) Slovakia was designated as the rapporteur Member State and its evaluating competent authority submitted the assessment reports together with its conclusions to the Commission on 19 November 2010.

(4) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the Biocidal Products Committee adopted the opinions of the European Chemicals Agency[4] ('the Agency') on 16 June 2020, having regard to the conclusions of the evaluating competent authority.

(5) According to those opinions, biocidal products of product-types 2, 3, 4 and 5 using active chlorine generated from sodium chloride by electrolysis may be expected to

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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 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 active chlorine generated from sodium chloride by electrolysis, Product type: 2, 3, 4 and 5, ECHA /BPC/251, 252, 253, 254, adopted on 16 June 2020.

satisfy the requirements laid down in Article 5 of Directive 98/8/EC, provided that certain specifications and conditions concerning their use are complied with.

(6) Taking into account the opinions of the Agency, it is appropriate to approve active chlorine generated from sodium chloride by electrolysis for use in biocidal products of product-types 2, 3, 4 and 5 subject to compliance with certain specifications and conditions.

(7) 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.

(8) 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

Active chlorine generated from sodium chloride by electrolysis is approved as an active substance for use in biocidal products of product-types 2, 3, 4 and 5 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/11466/2020 ANNEX Rev2
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[…](2021) XXX draft

ANNEX

ANNEX

to the

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

approving active chlorine generated from sodium chloride by electrolysis as an active substance for use in biocidal products of product types 2, 3, 4 and 5

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
Active chlorine generated from sodium chloride by electrolysis	IUPAC name: not applicable EC No: not applicable CAS No: not applicable Precursor : IUPAC Name: Sodium Chloride EC No 231-598-3 CAS No 7647-14-5	The specification for active chlorine generated in situ is dependent on the precursor sodium chloride which must comply with purity requirements of one of the following standards: NF Brand, EN 973 A, EN 973 B, EN 14805 Type 1, EN 14805 Type 2, EN 16370 Type 1, EN 16370 Type 2, EN 16401 Type 1, EN 16401 Type 2, CODEX STAN 150-1985 or European Pharmacopoeia 9.0.	1 July 2022	30 June 2032	2	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) the product assessment shall pay particular attention to the protection of professional users for hard surface disinfection via mopping or wiping.
					3	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 or feed, the need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/2009[2] or Regulation (EC) No 396/2005[3] shall be verified, and any appropriate

[1] The purity requirements for the precursor indicated in this column are those provided in the application for the approval of the active substance evaluated.

[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).

						risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.
					4	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 or feed, the need to set new or to amend existing MRLs in accordance with Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005 shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.
					5	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 or feed, the need to set new or to amend existing MRLs in accordance with Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005 shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.

EUROPEAN
COMMISSION

Brussels, XXX
SANTE/10388/2020 Rev1
(POOL/E4/2020/10388/10388 R1-EN.docx)
[…](2021) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

approving carbendazim as an existing active substance for use in biocidal products of product-types 7 and 10

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

approving carbendazim as an existing active substance for use in biocidal products of product-types 7 and 10

(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 , and in particular the third subparagraph of Article 89(1) thereof,

Whereas:

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

(2) Carbendazim has been evaluated for use in biocidal products of product-type 7, film preservatives, and product-type 10, masonry preservatives, as described in Annex V to Directive 98/8/EC of the European Parliament and of the Council , which correspond respectively to product-types 7 and 10 as described in Annex V to Regulation (EU) No 528/2012.

(3) The evaluating competent authority of Germany submitted the assessment reports together with its conclusions to the Commission on 2 August 2013.

(4) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the opinions of the European Chemicals Agency[1] (the 'Agency') were 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.

(6) According to the opinions of the Agency, biocidal products of product-types 7 and 10 containing carbendazim 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.

[1] Biocidal Products Committee (BPC) opinion on the application for approval of the active substance Carbendazim, Product type: 7, ECHA/BPC/234/2019, adopted on 10 December 2019; Biocidal Products Committee (BPC) opinion on the application for approval of the active substance Carbendazim, Product type: 10, ECHA/BPC/235/2019, adopted on 10 December 2019.

(7) It is therefore appropriate to approve carbendazim for use in biocidal products of product-types 7 and 10, subject to compliance with certain specifications and conditions.

(8) The opinions of the Agency conclude that carbendazim meets the criteria for classification as mutagen category 1B and reproductive toxicant category 1B in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council[2].

(9) Since carbendazim should be approved under the terms of Directive 98/8/EC, taking into account those properties, the period of approval should be considerably shorter than 10 years in accordance with the latest practice established under that Directive. In addition, since carbendazim has benefitted from the transitional period provided for in Article 89 of Regulation (EU) No 528/2012 since 14 May 2000 and has been under peer review since 2 August 2013, and with the view to examine at Union level as soon as possible in the context of a potential renewal of approval whether the conditions of Article 5(2) of Regulation (EU) No 528/2012 can be satisfied for carbendazim, the period of approval should be three years.

(10) Furthermore, pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the competent authorities of the Member States should evaluate whether the conditions of Article 5(2) of that Regulation can be satisfied in their territories in order to decide whether a biocidal product containing carbendazim can be authorised.

(11) The opinions of the Agency also conclude that carbendazim meets the criteria for being a persistent and toxic substance in accordance with Annex XIII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council[3].

(12) For the purposes of Article 23 of Regulation (EU) No 528/2012, carbendazim meets the condition laid down in points (a) and (d) of Article 10(1) of that Regulation and should therefore be considered a candidate for substitution. The competent authorities of the Member States should therefore perform a comparative assessment as part of the evaluation of an application for authorisation or for renewal of authorisation of a biocidal product containing carbendazim.

(13) The opinions of the Agency also conclude that the outdoor use of paints and plasters treated with or incorporating carbendazim poses unacceptable risks for surface water and sediment during their service life. No adequate risk mitigation measure could be identified to avoid releases of carbendazim in sewers during service-life of such treated articles when used outdoors. Consequently, in addition to the recommendations in the opinions of the Agency, the Commission considers appropriate that biocidal products containing carbendazim should not be authorised for use in paints and plasters which are intended to be used outdoors. Furthermore, paints and plasters treated with or incorporating carbendazim should not be allowed to be placed on the

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[2] 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 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

[3] 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).

market for outdoor use. Lastly, paints and plasters treated with or incorporating carbendazim should be labelled to indicate that they are not to be used outdoors.

(14) Since, as concluded by the Agency, carbendazim meets the criteria for classification as mutagen category 1B, reproductive toxicant category 1B, and as skin sensitiser category 1 in accordance with Annex I to Regulation (EC) No 1272/2008, treated articles treated with or incorporating carbendazim should be appropriately labelled when placed on the market.

(15) This Regulation does not affect the application of Union law in the area of health and safety at work, in particular Council Directives 89/391/EEC[4] and 98/24/EC[5], and Directive 2004/37/EC of the European Parliament and of the Council [6].

(16) 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.

(17) 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

Carbendazim is approved as an active substance for use in biocidal products of product-types 7 and 10, 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

[4] 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, 29.06.1989, p. 1).

[5] 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, 05.5.1998, p. 11).

[6] Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004).

EUROPEAN
COMMISSION

Brussels, XXX
SANTE/10388/2020 Rev1 ANNEX
(POOL/E4/2020/10388/10388 R1-EN
ANNEX.docx)
[…](2020) XXX draft

ANNEX

ANNEX

to the

COMMISSION IMPLEMENTING REGULATION (EU) …/...

approving carbendazim as an existing active substance for use in biocidal products of product-types 7 and 10

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
Carbendazim	IUPAC Name: Methyl-benzimidazol-2-ylcarbamate EC No: 234-232-0 CAS No: 10605-21-7	99,0% w/w	1 February 2022	31 January 2025	7	Carbendazim is considered a candidate for substitution in accordance with points (a) and (d) of Article 10(1) of Regulation (EU) No 528/2012. The authorisations of biocidal products are subject to the following conditions: 1) 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. In addition, pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the product assessment shall include an evaluation as to whether the conditions of Article 5(2) of Regulation (EU) No 528/2012 can be satisfied. 2) Products shall only be authorised for use in Member States where at least one of the conditions laid down in Article 5(2) of Regulation (EU) No 528/2012 is met. 3) Products shall not be authorised for use in paints which are intended to be used outdoors. The placing on the market of treated articles is subject to the following conditions: 1) Paints treated with or incorporating carbendazim shall not be placed on the market for outdoor use. 2) The person responsible for the placing on the market of a paint treated with or incorporating carbendazim shall ensure that the label of that paint indicates that it shall not

[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.

						be used outdoors. 3) The person responsible for the placing on the market of a treated article treated with or incorporating carbendazim shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012.
					10	Carbendazim is considered a candidate for substitution in accordance with points (a) and (d) of Article 10(1) of Regulation (EU) No 528/2012. The authorisations of biocidal products are subject to the following conditions: 1) 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. In addition, pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the product assessment shall include an evaluation as to whether the conditions of Article 5(2) of Regulation (EU) No 528/2012 can be satisfied. 2) Products shall only be authorised for use in Member States where at least one of the conditions laid down in Article 5(2) of Regulation (EU) No 528/2012 is met. 3) Products shall not be authorised for use in plasters which are intended to be used outdoors.. The placing on the market of treated articles is subject to the following conditions: 1) Plasters treated with or incorporating carbendazim shall not be placed on the market for outdoor use. 2) The person responsible for the placing on the market of a plaster treated with or incorporating carbendazim shall ensure that the label of that plaster indicates that it shall not be used outdoors. 3) The person responsible for the placing on the market of a

						treated article treated with or incorporating carbendazim shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012.

EUROPEAN
COMMISSION

Brussels, XXX
SANTE/12418/2020
(POOL/E4/2020/12418/12418-EN.doc)
[…](2020) XXX draft

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

postponing the expiry date of approval of propiconazole 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 propiconazole 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 propiconazole 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 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 1 October 2018, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval of propiconazole.

(3) On 8 February 2019, the evaluating competent authority of Finland 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. The evaluating competent authority has requested the applicant to provide sufficient data to carry out the evaluation in accordance with Article 8(2) of that Regulation.

(4) As the competent authority is carrying out a full evaluation of the application, in accordance with Article 14(3) of Regulation (EU) No 528/2012, 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 within 270 days of receipt of the recommendation from the evaluating competent authority.

(5) Considering that propiconazole is classified as toxic for reproduction category 1B in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council[3], and therefore meets the exclusion criterion set out in point (c) of Article 5(1)

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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 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

of Regulation (EU) No 528/2012, further examination is 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 propiconazole may therefore be renewed.

(6) The expiry date of approval of propiconazole has been postponed to 31 March 2021 by Commission Implementing Decision (EU) 2020/27[4] in order to allow sufficient time for the examination of the application. This examination is still not finalised and the evaluating competent authority has not yet submitted its assessment report and the conclusions of its evaluation to the Agency.

(7) Consequently, for reasons beyond the control of the applicant, the approval of propiconazole 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 postpone the expiry date of approval of propiconazole for use in biocidal products of product-type 8 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 assess 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 propiconazole may therefore be renewed, it is appropriate to postpone the expiry date of approval to 31 December 2022.

(9) Except for the expiry date of approval, propiconazole remains approved for use in biocidal products of product-type 8 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 propiconazole for use in biocidal products of product-type 8 is postponed to 31 December 2022.

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

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

[4] Commission Implementing Decision (EU) 2020/27 of 13 January 2020 postponing the expiry date of approval of propiconazole for use in biocidal products of product-type 8 (OJ L 8, 14.1.2020, p. 40).

EUROPEAN
COMMISSION

Brussels, XXX
SANTE/12402/2020
(POOL/E4/2020/12402/12402-EN.doc)
[…](2020) XXX draft

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

postponing the expiry date of approval of alphachloralose for use in biocidal products of product-type 14

(Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

postponing the expiry date of approval of alphachloralose for use in biocidal products of product-type 14

(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 alphachloralose 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 14, 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 alphachloralose for use in biocidal products of product-type 14 will expire on 30 June 2021. On 24 December 2019, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval of alphachloralose.

(3) On 15 October 2020, the evaluating competent authority of Poland 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 an 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 alphachloralose for use in biocidal products of product-type 14 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 alphachloralose for use in biocidal products of product-type 14 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 31 December 2023.

(7) Except for the expiry date of approval, alphachloralose remains approved for use in biocidal products of product-type 14 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 alphachloralose for use in biocidal products of product-type 14 is postponed to 31 December 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/12400/2020
(POOL/E4/2020/12400/12400-EN.doc)
[…](2020) XXX draft

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

postponing the expiry date of approval of metofluthrin for use in biocidal products of product-type 18

(Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

postponing the expiry date of approval of metofluthrin for use in biocidal products of product-type 18

(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 metofluthrin 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 18, 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 metofluthrin for use in biocidal products of product-type 18 will expire on 30 April 2021. On 25 October 2019, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval of metofluthrin.

(3) On 15 October 2020, the evaluating competent authority of Ireland 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 an 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 metofluthrin for use in biocidal products of product-type 18 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 metofluthrin for use in biocidal products of product-type 18 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 31 October 2023.

(7) Except for the expiry date of approval, metofluthrin remains approved for use in biocidal products of product-type 18 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 metofluthrin for use in biocidal products of product-type 18 is postponed to 31 October 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

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2021/98

of 28 January 2021

not approving esbiothrin as an existing active substance for use in biocidal products of product-type 18

(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 lists includes esbiothrin (EC No: Not available; CAS No: 260359-57-7).

(2) Esbiothrin has been evaluated for use in biocidal products of product-type 18, insecticides, acaricides and products to control other arthropods, as described in Annex V to Regulation (EU) No 528/2012.

(3) Germany was designated as the rapporteur Member State and its evaluating competent authority submitted the assessment report together with its conclusions to the European Chemicals Agency ('the Agency') on 11 January 2017.

(4) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the Biocidal Products Committee adopted the opinion of the Agency on 16 June 2020 ([3]), having regard to the conclusions of the evaluating competent authority.

(5) According to that opinion, biocidal products of product-type 18 containing esbiothrin may not be expected to meet the criteria laid down in Article 19(1)(b) of Regulation (EU) No 528/2012 as the human health risk assessment identified unacceptable risks.

(6) Taking into account the opinion of the Agency, the Commission considers it not appropriate to approve esbiothrin for use in biocidal products of product-type 18.

(7) 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

Esbiothrin (EC No: Not available; CAS No: 260359-57-7) is not approved as an active substance for use in biocidal products of product-type 18.

([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]) Biocidal Products Committee Opinion on the application for approval of the active substance: Esbiothrin, Product type: 18, ECHA/BPC/260/2020, adopted on 16 June 2020.

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, 28 January 2021.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING DECISION (EU) 2021/103

of 29 January 2021

not approving carbon dioxide 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 carbon dioxide (EC No: 204-696-9; CAS No: 124-38-9). That list also includes carbon dioxide generated from propane, butane or a mixture of both by combustion. The latter is not covered by this Implementing Decision.

(2) All the participants have withdrawn their support for carbon dioxide for use in biocidal products of product-type 19, repellents and attractants. The European Chemicals Agency published an open invitation to take over the role of participant in accordance with point (a) of Article 14(1) of Delegated Regulation (EU) No 1062/2014. No notification has been submitted pursuant to Article 17 of that Regulation. In accordance with point (b) of the first paragraph of Article 20 of Delegated Regulation (EU) No 1062/2014, a non-approval decision should be adopted for active substances no longer supported in the review programme for the product-type concerned.

(3) Carbon dioxide (EC No: 204-696-9; CAS No: 124-38-9) should therefore not be approved as an active substance for use in biocidal products of product-type 19.

(4) Existing biocidal products of product-type 19 and containing carbon dioxide may continue to be made available on the market and used before the dates set in the second subparagraph of Article 89(2) of Regulation (EU) No 528/2012.

(5) In any case, carbon dioxide is listed in category 6 of Annex I to Regulation (EU) No 528/2012. Biocidal products of product-type 19 containing carbon dioxide may be therefore made available on the market and used provided that they are authorised in accordance with that Regulation and comply with the conditions and specifications set in Annex I for carbon dioxide.

(6) 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

Carbon dioxide (EC No: 204-696-9; CAS No: 124-38-9) is not approved as an active substance for use in biocidal products of product-type 19.

([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).

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, 29 January 2021.

For the Commission
The President
Ursula VON DER LEYEN