EUROPEAN
COMMISSION

Brussels, XXX
PLAN/2022/1833 Rev1
(POOL/E4/2022/1833/1833R1-EN.docx)
[…](2023) XXX draft

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

not approving cyanamide as an existing active substance for use in biocidal products of product-types 3 and 18 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

not approving cyanamide as an existing active substance for use in biocidal products of product-types 3 and 18 in accordance with 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 Article 89(1), third subparagraph, 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 cyanamide (EC No: 206-992-3; CAS No: 420-04-2).

(2) Cyanamide has been evaluated for use in biocidal products of product-type 3, veterinary hygiene biocidal products, and product-type 18, insecticides, acaricides and products to control other arthropods, as described in Annex V to Directive 98/8/EC of the European Parliament and of the Council[3], which correspond respectively to product-types 3 and 18 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 Commission on 30 July 2013. After the submission of the assessment report, discussions took place in technical meetings organised by the European Chemicals Agency ('the Agency').

(4) It follows 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.

(5) In accordance with Article 75(1), point (a), of Regulation (EU) No 528/2012, the Biocidal Products Committee is responsible for preparing the opinion of the Agency regarding applications for approval of active substances. In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the Biocidal Products Committee

[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).

adopted the opinions of the Agency on 16 June 2016 ("the opinions of 16 June 2016")[4], having regard to the conclusions of the evaluating competent authority.

(6) According to the opinions of 16 June 2016, cyanamide met the criteria to be classified as carcinogen category 2 and toxic for reproduction category 2 in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council[5], and was therefore considered as also having endocrine-disrupting properties in accordance with Article 5(3) of Regulation (EU) No 528/2012, pending the adoption of delegated acts specifying the scientific criteria for the determination of endocrine-disrupting properties. The opinions of 16 June 2016 also considered that the risks to human health and the environment of using the representative biocidal products presented in the application for approval of cyanamide for product-types 3 and 18 were acceptable subject to appropriate risk mitigation measures. However, the risk assessment presented in those opinions did not take into account the risks resulting from the endocrine-disrupting properties of cyanamide.

(7) Commission Delegated Regulation (EU) 2017/2100[6] setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 entered into force on 7 December 2017 and came into effect on 7 June 2018.

(8) In anticipation of the application of the new scientific criteria set out in Delegated Regulation (EU) 2017/2100, and to provide clarity as regards the hazard properties and the risks resulting from the use of cyanamide, on 26 April 2018, pursuant to Article 75(1), point (g), of Regulation (EU) No 528/2012, the Commission requested the Agency[7] to revise its opinions of 16 June 2016 and to clarify whether cyanamide has also endocrine-disrupting properties on the basis of the scientific criteria laid down in that Delegated Regulation. The Agency was requested to update only that part of the opinions relating to the assessment of the endocrine-disrupting properties, unless the conclusion of that assessment affected the results of the risk assessment already performed or the recommendations for approval. In the latter case, such assessment and recommendations were also to be updated. For the preparation of the revised opinions of the Agency, the evaluating competent authority of Germany invited the applicant to submit additional information as regards the assessment of the endocrine-disrupting properties of cyanamide in accordance with the criteria laid down in Delegated Regulation (EU) 2017/2100.

(9) The Biocidal Products Committee adopted the revised opinions of the Agency on 10 December 2019 ("the opinions of 10 December 2019")[8], having regard to the conclusions of the evaluating competent authority.

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4 Biocidal Products Committee Opinion on the application for approval of the active substance: Cyanamide, Product type: 3, ECHA/BPC/116/2016, adopted on 16 June 2016; Biocidal Products Committee Opinion on the application for approval of the active substance: Cyanamide, Product type: 18, ECHA/BPC/117/2016, adopted on 16 June 2016.

5 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).

6 Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council (OJ L 301, 17.11.2017, p. 1).

7 Mandate requesting ECHA opinions under Article 75(1)(g) of the BPR - "Evaluation of the Endocrine disrupting properties of certain biocidal actives substances according to the new scientific criteria"

8 Biocidal Products Committee Opinion on the application for approval of the active substance: Cyanamide, Product type: 3, ECHA/BPC/230/2019, adopted on 10 December 2019; Biocidal Products

(10) According to the opinions of 10 December 2019, cyanamide has endocrine-disrupting properties that may cause adverse effects in humans and the environment (non-target organisms) on the basis of the criteria laid down in Delegated Regulation (EU) 2017/2100. The opinions remarked that there is no agreed methodology for undertaking a risk assessment of endocrine-disrupting properties and that, given the exposure to cyanamide of humans and the environment, a risk related to endocrine-disrupting properties cannot be excluded.

(11) The opinions of 10 December 2019 did not contain any information as to whether a safe threshold can be derived in relation to endocrine-disrupting properties of cyanamide, and, if so, whether the risks of using the representative biocidal products presented in the application for approval of cyanamide for product-types 3 and 18 could be considered acceptable or not, in relation to the endocrine-disrupting properties of cyanamide.

(12) On 2 September 2020, pursuant to Article 75(1), point (g), of Regulation (EU) No 528/2012, the Commission requested the Agency[9] to revise its opinions of 10 December 2019 and to clarify whether a safe threshold may be derived in relation to the endocrine-disrupting properties of cyanamide, and to conclude whether the risks for human health and for the environment could be considered acceptable or not.

(13) The Biocidal Products Committee adopted the new revised opinions of the Agency on 30 November 2021 ("the opinions of 30 November 2021")[10], having regard to the conclusions of the evaluating competent authority. According to those opinions, since it was not possible to derive a safe threshold with respect to the endocrine-disrupting properties of cyanamide, it is not possible to conclude whether risks for both human health for the general public and the environment for the representative biocidal product used for product-type 3 (for the disinfection by professional users against *Brachyspira hyodysenteriae* of the liquid manure stored underneath the slatted floor in pig stables in order to protect fattening pigs against the pig disease dysenteria) and product-type 18 (for the control by professional users of *Musca domestica* in liquid manure in pig stables) are acceptable or not. Therefore, no conclusion could be drawn whether cyanamide fulfils the approval conditions.

(14) Therefore, given that the opinions of 30 November 2021 of the Agency do not provide either a positive or a negative conclusion on whether cyanamide fulfils the approval conditions, the Commission considers that it has ultimately not been demonstrated based on the data available in the application submitted for the approval that the representative biocidal product containing cyanamide for product-types 3 and 18 may be expected to not have unacceptable effects itself, or as a result of its residues, on human health and on the environment.

(15) Taking into account the opinions of 30 November 2021, it has not been demonstrated that biocidal products of product-types 3 and 18 containing cyanamide meet the criteria laid down in Article 5(1), points (b) (iii) and (iv), read in conjunction with

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Committee Opinion on the application for approval of the active substance: Cyanamide, Product type: 18, ECHA/BPC/231/2019, adopted on 10 December 2019.

9 Mandate requesting ECHA opinions under Article 75(1)(g) of the BPR - "Evaluation of the level of the risks for human health and for the environment of cyanamide used in biocidal products of product types 3 and 18".

10 Biocidal Products Committee Opinion on the application for approval of the active substance: Cyanamide, Product type: 3, ECHA/BPC/301/2021, adopted on 30 November 2021; Biocidal Products Committee Opinion on the application for approval of the active substance: Cyanamide, Product type: 18, ECHA/BPC/302/2021, adopted on 30 November 2021.

Article 10(1) of Directive 98/8/EC. It is therefore appropriate not to approve cyanamide for use in biocidal products of product-types 3 and 18.

(16) 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

Cyanamide (EC No: 206-992-3; CAS No: 420-04-2) is not approved as an active substance for use in biocidal products of product-types 3 and 18.

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
PLAN/2022/2574 Rev2
(POOL/E4/2022/2574/2574R2-EN.docx)
[…](2023) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

approving (13*Z*)-hexadec-13-en-11-yn-1-yl acetate as an active substance for use in biocidal products of product-type 19 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

approving (13*Z*)-hexadec-13-en-11-yn-1-yl acetate as an active substance for use in biocidal products of product-type 19 in accordance with 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 Article 9(1), point (a), thereof,

Whereas:

(1) On 13 March 2018, the European Chemicals Agency ('the Agency') received an application, in accordance with Article 7(1) of Regulation (EU) No 528/2012, for the approval of (13*Z*)-hexadec-13-en-11-yn-1-yl acetate as an active substance for use in biocidal products of product-type 19, repellents and attractants, as described in Annex V to that Regulation. The application was evaluated by the competent authority of France ('the evaluating competent authority').

(2) On 1 June 2021, the evaluating competent authority submitted the assessment report together with the conclusions of its evaluation to the Agency. The Agency discussed the assessment report and the conclusions of the evaluating competent authority in technical meetings.

(3) In accordance with Article 75(1), second subparagraph, point (a), of Regulation (EU) No 528/2012, the Biocidal Products Committee prepares the opinion of the Agency regarding the applications for approval of active substances. In accordance with Article 8(4) of Regulation (EU) No 528/2012, the Biocidal Products Committee adopted the opinion of the Agency[2] on 8 March 2022, having regard to the conclusions of the evaluating competent authority.

(4) In that opinion the Agency concludes that biocidal products of product-type 19 containing (13*Z*)-hexadec-13-en-11-yn-1-yl acetate may be expected to satisfy the criteria laid down in Article 19(1), point (b), of Regulation (EU) No 528/2012, provided that certain conditions concerning their use are complied with.

(5) In its opinion the Agency recommends that (13*Z*)-hexadec-13-en-11-yn-1-yl acetate be approved subject to the conditions that only biocidal products consisting of a passive non-retrievable dispenser (for example a wax emulsion inserted into a ball) to be applied using a compressed air gun may be authorised, and that biocidal products may

[1] OJ L 167, 27.6.2012, p. 1.

[2] Biocidal Products Committee Opinion on the application for approval of the active substance (13*Z*)-hexadec-13-en-11-yn-1-yl acetate; Product-type: 19; ECHA/BPC/323/2022, adopted on 8 March 2022.

only be authorised for professional use ('the conditions proposed by the Agency'). These conditions correspond to the representative biocidal product and category of user submitted in the application for approval of the active substance. The Agency proposed to impose those conditions as a consequence of the acceptance by the evaluating competent authority of certain adaptations in the data submitted for the approval of the active substance, in accordance with Annex IV to Regulation (EU) No 528/2012. The evaluating competent authority accepted the adaptations because (13*Z*)-hexadec-13-en-11-yn-1-yl acetate is a pheromone, which is a class of substances generally recognised as being of low concern to human and animal health and the environment, and because of the very low exposure of humans and the environment to the active substance due to use of the representative biocidal product.

(6) However, restrictive conditions for the making available on the market or the use of biocidal products containing an active substance are usually established in the approval of an active substance when risks are identified during the examination of approval of the active substance and no other suitable risk mitigation measures can be identified on a specific use. No risks to human health, animal health or the environment have been identified by the Agency in its opinion which would necessitate the conditions proposed by the Agency. The approval of an active substance is also usually not restricted only to the representative product and user category presented in the application for approval. Moreover, the imposition of the conditions proposed by the Agency would limit innovation in the development of products containing a pheromone, which is a class of substances generally recognised as being of low concern to human and animal health and the environment.

(7) The Commission therefore considers it not necessary to include the conditions proposed by the Agency in this Regulation. However, in order to emphasise the possible need for additional data on the active substance to demonstrate the safety for human health, animal health or the environment of other uses in the case of an application for authorisation of products other than the representative product, it is appropriate to lay down that the product assessment needs to pay particular attention to the exposures, the risks and the efficacy linked to any of the uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. In addition, for uses leading to higher exposure of the users, bystanders or the environment compared to the Union level risk assessment of the active substance, applications for product authorisation need to contain all data required for active substances in accordance with Annex II to Regulation (EU) No 528/2012, subject to the possibilities of adaptation of the data requirements in accordance with Annex IV to that Regulation.

(8) Taking into account the opinion of the Agency, it is appropriate to approve (13*Z*)-hexadec-13-en-11-yn-1-yl acetate as an active substance for use in biocidal products of product-type 19 subject to compliance with certain conditions.

(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

(13*Z*)-hexadec-13-en-11-yn-1-yl acetate is approved as an active substance for use in biocidal products of product-type 19 subject to the 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
PLAN/2022/2574 ANNEX Rev2
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to the

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

approving (13*Z*)-hexadec-13-en-11-yn-1-yl acetate as an active substance for use in biocidal products of product-type 19 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

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
(13*Z*)-Hexadec-13-en-11-yn-1-yl acetate	IUPAC name: (13*Z*)-hexadec-13-en-11-yn-1-yl acetate EC No: Not allocated CAS No: 78617-58-0	970 g/kg dry weight	1 June 2023	31 May 2033	19	The authorisation of biocidal products is subject to the following conditions: The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any of the uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. For uses leading to higher exposure of the users, by-standers or the environment compared to the Union level risk assessment of the active substance, applications for product authorisation shall contain all data required for active substances in accordance with Annex II to Regulation (EU) No 528/2012, subject to the possibilities of adaptation of the data requirements in accordance with Annex IV to that Regulation.

[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.

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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

approving ozone generated from oxygen as an active substance for use in biocidal products of product-types 2, 4, 5 and 11 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

approving ozone generated from oxygen as an active substance for use in biocidal products of product-types 2, 4, 5 and 11 in accordance with 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 Article 9(1), point (a), thereof,

Whereas:

(1) On 5 June 2015 and 22 August 2016, the European Chemicals Agency ('the Agency') received applications, in accordance with Article 7(1) of Regulation (EU) No 528/2012, for the approval of ozone generated from oxygen as an active substance for use in biocidal products of product-type 2, disinfectants and algaecides not intended for direct application to humans or animals, product-type 4, food and feed area, product-type 5, drinking water, and product-type 11, preservatives for liquid-cooling and processing systems, as described in Annex V to Regulation (EU) No 528/2012. These applications were evaluated by the competent authority of Germany ('the evaluating competent authority of Germany') and the competent authority of the Netherlands ('the evaluating competent authority of the Netherlands').

(2) On 9 September 2020, the evaluating competent authority of Germany submitted the assessment report on the applications together with the conclusions of its evaluation to the Agency. The Agency discussed the assessment report and the conclusions in technical meetings.

(3) On 28 October 2021, the evaluating competent authority of the Netherlands submitted the assessment report on the applications together with the conclusions of its evaluation to the Agency. The Agency discussed the assessment report and the conclusions in technical meetings.

(4) In accordance with Article 75(1), second subparagraph, point (a), of Regulation (EU) No 528/2012, the Biocidal Products Committee prepares the opinion of the Agency regarding the applications for approval of active substances. In accordance with Article 8(4) of Regulation (EU) No 528/2012, the Biocidal Products Committee adopted the opinions of the Agency on 1 December 2021[2], having regard to the conclusions of the evaluating competent authority of Germany, and on 26 September

[1] OJ L 167, 27.6.2012, p. 1.

[2] Biocidal Products Committee Opinions on the application for approval of the active substance ozone generated from oxygen; Product types: 2, 4, 5 and 11; ECHA/BPC/303/2021, ECHA/BPC/304/2021, ECHA/BPC/305/2021 and ECHA/BPC/306/2021; adopted on 1 December 2021.

2022[3], having regard to the conclusions of the evaluating competent authority of the Netherlands.

(5) In the opinions the Agency concludes that biocidal products of product-types 2, 4, 5 and 11 using ozone generated from oxygen may be expected to satisfy the criteria laid down in Article 19(1), point (b), of Regulation (EU) No 528/2012, provided that certain conditions concerning their use are complied with.

(6) Taking into account the opinions of the Agency, it is appropriate to approve ozone generated from oxygen as an active substance for use in biocidal products of product-types 2, 4, 5 and 11 subject to compliance with certain 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

Ozone generated from oxygen is approved as an active substance for use in biocidal products of product-types 2, 4, 5 and 11 subject to the 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

[3] Biocidal Products Committee Opinions on the application for approval of the active substance ozone generated from oxygen; Product types: 2, 4, 5 and 11; ECHA/BPC/350/2022, ECHA/BPC/351/2022, ECHA/BPC/352/2022 and ECHA/BPC/353/2022; adopted on 26 September 2022.

EUROPEAN
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to the

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

approving ozone generated from oxygen as an active substance for use in biocidal products of product-types 2, 4, 5 and 11 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

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
Ozone generated from oxygen	IUPAC name: Ozone EC No: not applicable CAS No: not applicable	For ozone generated from the precursor oxygen supplied in containers, the following specifications apply: The purity of oxygen shall be at least 90% by volume fraction and the hydrocarbons content reported as methane equivalents (methane index) shall not exceed a volume fraction of 50 ppm. Depending on the production route of oxygen, oxygen may contain quantities of the following impurities: water, nitrogen, argon, carbon dioxide and other rare gases.	1 July 2024	30 June 2034	2	The authorisation of biocidal products is 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: (i) professional users; (ii) non-professional users; (iii) the secondary exposure of the general public.
					4	The authorisation of biocidal products is 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: (i) professional users; (ii) the secondary exposure of the general public; (c) for products that may lead to residues in food or feed, it shall be assessed whether new maximum residue levels (MRLs) need to be set or the existing MRLs

[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.

						need to be amended in accordance with Regulation (EC) No 396/2005[2] or Regulation (EC) No 470/2009[3] of the European Parliament and of the Council, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.
					5	The authorisation of biocidal products is 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: (i) professional users; (ii) the secondary exposure of the general public; (c) for products that may lead to residues in food or feed, it shall be assessed whether new maximum residue levels (MRLs) need to be set or the existing MRLs need to be amended in accordance with Regulation (EC) No 396/2005 or Regulation (EC) No 470/2009 of the European Parliament and of the Council, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.
					11	The authorisation of biocidal products is subject to the following conditions:

[2] 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).

[3] 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).

						(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: (i) professional users; (ii) surface water following direct discharge of treated cooling water.

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COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

postponing the expiry date of the approval of deltamethrin for use in biocidal products of product-type 18 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

postponing the expiry date of the approval of deltamethrin for use in biocidal products of product-type 18 in accordance with 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 Article 14(5) thereof,

After consulting the Standing Committee on Biocidal Products,

Whereas:

(1) Deltamethrin was included in Annex I to Directive 98/8/EC of the European Parliament and of the Council[2] as an active substance for use in biocidal products of product-type 18. Pursuant to Article 86 of Regulation (EU) No 528/2012, it is therefore considered approved under that Regulation subject to the conditions set out in Annex I to Directive 98/8/EC.

(2) The approval of deltamethrin for use in biocidal products of product-type 18 ('the approval') is to expire on 30 September 2023. On 27 and 29 March 2022, two applications were submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval ('the applications').

(3) On 21 June 2022, the evaluating competent authority of Sweden informed the Commission that it had decided, pursuant to Article 14(1) of Regulation (EU) No 528/2012, that a full evaluation of the applications was necessary. Pursuant to Article 8(1) of that Regulation, 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, require the applicants to provide sufficient data to carry out the evaluation, in accordance with Article 8(2) of Regulation (EU) No 528/2012. In that event, 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 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 applicants, the approval is likely to expire before a decision has been taken on its renewal. It is therefore appropriate to postpone the expiry date of the approval for a period of time sufficient to enable the examination of the applications. Taking into account the time-limits for evaluations by the evaluating competent authority and for preparation and submission by the European Chemicals Agency of its opinion, and the time needed to decide whether the approval of deltamethrin for use in biocidal products for product-type 18 may be renewed, the expiry date should be postponed to 31 March 2026.

(7) After the postponement of the expiry date of the approval, deltamethrin remains approved for use in biocidal products of product-type 18 subject to the conditions set out in Annex I to Directive 98/8/EC,

HAS ADOPTED THIS DECISION:

Article 1

The expiry date of the approval of deltamethrin for use in biocidal products of product-type 18 set out in Annex I to Directive 98/8/EC is postponed to 31 March 2026.

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
PLAN/2023/331
(POOL/E4/2023/331/331-EN.doc)
[…](2023) XXX draft

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

postponing the expiry date of the approval of lambda-cyhalothrin for use in biocidal products of product-type 18 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

postponing the expiry date of the approval of lambda-cyhalothrin for use in biocidal products of product-type 18 in accordance with 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 Article 14(5) thereof,

After consulting the Standing Committee on Biocidal Products,

Whereas:

(1) Lambda-cyhalothrin was included in Annex I to Directive 98/8/EC of the European Parliament and of the Council[2] as an active substance for use in biocidal products of product-type 18. Pursuant to Article 86 of Regulation (EU) No 528/2012, it is therefore considered approved under that Regulation subject to the conditions set out in Annex I to Directive 98/8/EC.

(2) The approval of lambda-cyhalothrin for use in biocidal products of product-type 18 ('the approval') is to expire on 30 September 2023. On 24 March 2022, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval ('the application').

(3) On 16 September 2022, the evaluating competent authority of Greece 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 that Regulation, 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, require the applicant to provide sufficient data to carry out the evaluation, in accordance with Article 8(2) of Regulation (EU) No 528/2012. In that event, 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 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 is likely to expire before a decision has been taken on its renewal. It is therefore appropriate to postpone the expiry date of the approval for a period of time sufficient to enable the examination of the application. Taking into account the time-limits for evaluation by the evaluating competent authority and for preparation and submission by the European Chemicals Agency of its opinion, and the time needed to decide whether the approval of lambda-cyhalothrin for use in biocidal products for product-type 18 may be renewed, the expiry date should be postponed to 31 March 2026.

(7) After the postponement of the expiry date of the approval, lambda-cyhalothrin remains approved for use in biocidal products of product-type 18 subject to the conditions set out in Annex I to Directive 98/8/EC,

HAS ADOPTED THIS DECISION:

Article 1

The expiry date of the approval of lambda-cyhalothrin for use in biocidal products of product-type 18 set out in Annex I to Directive 98/8/EC is postponed to 31 March 2026.

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
PLAN/2023/391
(POOL/E4/2023/391/391-EN.docx)
[…](2023) XXX draft

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

postponing the expiry date of the approval of metofluthrin for use in biocidal products of product-type 18 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

postponing the expiry date of the approval of metofluthrin for use in biocidal products of product-type 18 in accordance with 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 Article 14(5) thereof,

After consulting the Standing Committee on Biocidal Products,

Whereas:

(1) Metofluthrin was included in Annex I to Directive 98/8/EC of the European Parliament and of the Council[2] as an active substance for use in biocidal products of product-type 18. Pursuant to Article 86 of Regulation (EU) No 528/2012, it was therefore considered approved until 30 April 2021 under that Regulation subject to the conditions set out in Annex I to Directive 98/8/EC.

(2) 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 for use in biocidal products of product-type 18 ('the application').

(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 that Regulation, 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, require the applicant to provide sufficient data to carry out the evaluation, in accordance with Article 8(2) of Regulation (EU) No 528/2012. In that event, 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) Commission Implementing Decision (EU) 2021/327[3] postponed the expiry date of the approval of metofluthrin for use in biocidal products of product-type 18 to 31 October 2023 in order to allow sufficient time for the examination of the application.

(7) On 2 February 2023, the evaluating competent authority informed the Commission that the evaluation is delayed due to the need to assess additional data requested from the applicant. The evaluating competent authority expects to submit the renewal assessment report to the Agency in the fourth quarter of 2023.

(8) Consequently, for reasons beyond the control of the applicant, the approval is likely to expire before a decision has been taken on its renewal. It is therefore appropriate to further postpone the expiry date of the approval for a period of time sufficient to enable the examination of the application. Taking into account the time-limits for evaluation by the evaluating competent authority, for preparation and submission by the Agency of its opinion and for the Commission to decide whether to renew the approval of metofluthrin for use in biocidal products for product-type 18, the expiry date should be postponed to 31 October 2024.

(9) After the further postponement of the expiry date of the approval, metofluthrin remains approved for use in biocidal products of product-type 18 subject to the conditions set out in Annex I to Directive 98/8/EC,

HAS ADOPTED THIS DECISION:

Article 1

The expiry date of the approval of metofluthrin for use in biocidal products of product-type 18 set out in Implementing Decision (EU) 2021/327 is postponed to 31 October 2024.

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

[3] Commission Implementing Decision (EU) 2021/327 of 23 February 2021 postponing the expiry date of approval of metofluthrin for use in biocidal products of product-type 18 (OJ L 64, 24.2.2021, p. 10).

EUROPEAN
COMMISSION

Brussels, XXX
PLAN/2023/593
(POOL/E4/2023/593/593-EN.docX)
[…](2023) XXX draft

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

postponing the expiry date of the approval of *Bacillus thuringiensis* subsp. *israelensis* Serotype H14, Strain AM65-52 for use in biocidal products of product-type 18 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

postponing the expiry date of the approval of *Bacillus thuringiensis* subsp. *israelensis* Serotype H14, Strain AM65-52 for use in biocidal products of product-type 18 in accordance with 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 Article 14(5) thereof,

After consulting the Standing Committee on Biocidal Products,

Whereas:

(1) *Bacillus thuringiensis* subsp. *israelensis* Serotype H14, Strain AM65-52 was included in Annex I to Directive 98/8/EC of the European Parliament and of the Council[2] as an active substance for use in biocidal products of product-type 18. Pursuant to Article 86 of Regulation (EU) No 528/2012, it is therefore considered approved under that Regulation subject to the conditions set out in Annex I to Directive 98/8/EC.

(2) The approval of *Bacillus thuringiensis* subsp. *israelensis* Serotype H14, Strain AM65-52 for use in biocidal products of product-type 18 ('the approval') is to expire on 30 September 2023. On 30 March 2022, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval ('the application').

(3) On 2 February 2023, the evaluating competent authority of Italy 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 that Regulation, 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, require the applicant to provide sufficient data to carry out the evaluation, in accordance with Article 8(2) of Regulation (EU) No 528/2012. In that event, 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 is to prepare and submit to the

[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).

Commission an opinion on renewal of the approval of the active substance in accordance with Article 14(3) of Regulation (EU) No 528/2012.

(6) Consequently, for reasons beyond the control of the applicant, the approval is likely to expire before a decision has been taken on its renewal. It is therefore appropriate to postpone the expiry date of the approval for a period of time sufficient to enable the examination of the application. Taking into account the time-limits for evaluation by the evaluating competent authority and for preparation and submission by the European Chemicals Agency of its opinion, and the time needed to decide whether the approval of *Bacillus thuringiensis* subsp. *israelensis* Serotype H14, Strain AM65-52 for use in biocidal products for product-type 18 may be renewed, the expiry date should be postponed to 31 March 2026.

(7) After the postponement of the expiry date of the approval, *Bacillus thuringiensis* subsp. *israelensis* Serotype H14, Strain AM65-52 remains approved for use in biocidal products of product-type 18 subject to the conditions set out in Annex I to Directive 98/8/EC,

HAS ADOPTED THIS DECISION:

Article 1

The expiry date of the approval of *Bacillus thuringiensis* subsp. *israelensis* Serotype H14, Strain AM65-52 for use in biocidal products of product-type 18 set out in Annex I to Directive 98/8/EC is postponed to 31 March 2026.

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
PLAN/2022/2092
(POOL/E4/2022/2092/2092-EN.docx)
[…](2023) XXX draft

COMMISSION IMPLEMENTING DECISION

of XXX

on the unresolved objections regarding the conditions for granting an authorisation for the biocidal product A-Quasan in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION

of XXX

on the unresolved objections regarding the conditions for granting an authorisation for the biocidal product A-Quasan in accordance with 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 Article 36(3) thereof,

Whereas:

(1) On 15 June 2021, the company Menno Chemie-Vertrieb GMBH ('the applicant') submitted an application to the competent authority of the Netherlands for the mutual recognition in sequence, in accordance with Article 33 of Regulation (EU) No 528/2012, of the national authorisation of the biocidal product A-Quasan ('the biocidal product') already granted in Germany. The biocidal product, containing benzoic acid as active substance, has been authorised as a disinfectant of product-type 3, veterinary hygiene, to be used for disinfection in the veterinary healthcare area, including veterinary clinics and operating rooms, surfaces, equipment, and objects for companion animals.

(2) On 24 October 2021, the Netherlands referred objections to the coordination group indicating that the biocidal product does not meet the condition laid down in Article 19(1), point (a), of Regulation (EU) No 528/2012 for the use in operating rooms in the veterinary healthcare area, as such use corresponds to product-type 2, disinfectants and algaecides not intended for direct application to humans or animals, and benzoic acid is not approved for that product-type. To support their position, the Netherlands referred to the Guidance on the Biocidal Products Regulation Volume II Efficacy - Assessment and Evaluation (Parts B+C) ('the efficacy guidance') of the European Chemicals Agency, version of April 2018[2], which indicates in its chapter 5.4.3.1 that biocidal products applied for general disinfection of surfaces in the medical area (medical practices, hospitals) as well as of surfaces in veterinary practices associated with examination and operation/treatment of the animals are assigned to product-type 2, whereas products for specific veterinary hygiene purposes (e.g. products with specific claims against a target organism only relevant in the veterinary area) are

[1] OJ L 167, 27.6.2012, p. 1

[2] European Chemicals Agency, Guidance on the Biocidal Products Regulation, Volume II Efficacy - Assessment and Evaluation (Parts B+C), Version 3.0, April 2018 https://echa.europa.eu/documents/10162/23036412/bpr_guidance_assessment_evaluation_part_vol_ii_part_bc_en.pdf/950efefa-f2bf-0b4a-a3fd-41c86daae468

considered to be in product-type 3. The efficacy guidance follows the note for guidance CA-May15-Doc8.3[3] ('the CA document') presented by the Commission services and agreed by the competent authorities of the Member States for the implementation of Regulation (EU) No 528/2012.

(3) Germany is of the opinion that the agreement presented in the CA document does not make it mandatory to assign biocidal products used for the disinfection of surfaces in the veterinary health care area exclusively to product-type 2. In their opinion, the CA document provides the possibility to assign, to product-type 2, biocidal products for general surface disinfection in veterinary health care area when the products are used both in human and veterinary clinics, while the biocidal product is not intended to be used in the human medical area. Germany is of the opinion that it is not the purpose of the efficacy guidance and the CA document to establish a description of the product-type, as such a description is established in Annex V to Regulation (EU) No 528/2012. For those reasons, Germany considers the use in veterinary healthcare as appropriate for product-type 3 for the biocidal product.

(4) As no agreement was reached in the coordination group, on 24 August 2022 Germany referred the unresolved objection to the Commission, pursuant to Article 36(1) of Regulation (EU) No 528/2012. It thereby provided the Commission with a detailed statement of the matter on which Member States were unable to reach agreement and the reasons for their disagreement. That statement was forwarded to the Member States concerned and to the applicant.

(5) Article 2(1) of Regulation (EU) No 528/2012 states that a list of the types of biocidal products covered by that Regulation and their descriptions is set out in Annex V to that Regulation.

(6) Article 19(1), point (a), of Regulation (EU) No 528/2012 provides that one of the conditions for granting an authorisation is that the active substances contained in the biocidal product are included in Annex I to that Regulation or approved for the relevant product-type and any conditions specified for those active substances are met.

(7) Annex V to Regulation (EU) No 528/2012 provides that product-type 2, disinfectants and algaecides not intended for direct application to humans or animals, includes products used for the disinfection of surfaces, materials, equipment and furniture which are not used for direct contact with food or feeding stuffs; usage areas include, inter alia, swimming pools, aquariums, bathing and other waters; air conditioning systems; and walls and floors in private, public, and industrial areas and in other areas for professional activities; products used for disinfection of air, water not used for human or animal consumption, chemical toilets, waste water, hospital waste and soil; products used as algaecides for treatment of swimming pools, aquariums and other waters and for remedial treatment of construction materials; products used to be incorporated in textiles, tissues, masks, paints and other articles or materials with the purpose of producing treated articles with disinfecting properties. Annex V to Regulation (EU) No 528/2012 provides that product-type 3, veterinary hygiene, includes products used for veterinary hygiene purposes such as disinfectants,

[3] European Commission, Health and Food Safety Directorate General, Safety of the food chain, Pesticides and Biocides - Note for Guidance, Assignment of products used for general disinfection in veterinary practices or hospitals to product type 2 or 3 under the BPR, May 2015 https://circabc.europa.eu/ui/group/e947a950-8032-4df9-a3f0-f61eefd3d81b/library/0015a899-662d-4b86-ab1d-d73b42bf1888/details

disinfecting soaps, oral or corporal hygiene products or with anti-microbial function; products used to disinfect the materials and surfaces associated with the housing or transportation of animals.

(8) After having carefully examined all the available information, the Commission concurs with the views of Germany that the use of the biocidal product should be assigned to product-type 3 as described in Annex V to Regulation (EU) No 528/2012, as the product is to be used for disinfection in the veterinary health care area, including veterinary clinics and operating rooms, surfaces, equipment and objects for companion animals. Product-type 3 includes products used for veterinary hygiene purposes such as disinfectants, disinfecting soaps, oral or corporal hygiene products or with anti-microbial function, products used to disinfect the materials and surfaces associated with the housing or transportation of animals. Therefore, as the biocidal product is intended to be used for disinfection in the veterinary health care area, it should be considered as a disinfectant used for veterinary hygiene purposes.

(9) The CA document reflects the agreement reached by the Commission services and competent authorities for the implementation of Regulation (EU) No 528/2012 to harmonise practices on the allocation of the product-types for disinfectants used in the medical area and in veterinary health care. The CA document indicates that it is feasible to assign to product-type 2 biocidal products for disinfection of surfaces in veterinary practices or hospitals associated with examination and operation/treatment of the animals, whereas products for specific veterinary hygiene purposes (e.g., products with specific claims against a target organism only relevant in the veterinary area) should be assigned to product-type 3. The CA document thus provides for flexibility on the allocation of such products to either product-type 2 or product-type 3 and does not preclude the allocation of the biocidal product to product-type 3.

(10) The wording of the efficacy guidance, chapter 5.4.3.1, has been updated by the European Chemicals Agency[4] to accurately reflect the agreement reached by the Commission services and competent authorities for the implementation of Regulation (EU) No 528/2012, contained in the CA document.

(11) Taking into account those arguments and the fact that benzoic acid has been approved for use in biocidal products of product-type 3 by Commission Implementing Regulation (EU) No 1035/2013[5], the Commission considers that the biocidal product meets the condition laid down in Article 19(1), point (a), of Regulation (EU) No 528/2012, for the disinfection of surfaces in the veterinary health care area, including operating rooms.

(12) On 4 October 2022, the Commission provided the applicant with the opportunity to provide written comments in accordance with Article 36(2) of Regulation (EU) No 528/2012. The applicant did not provide comments.

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[4] European Chemicals Agency, Guidance on the Biocidal Products Regulation, Volume II Efficacy - Assessment and Evaluation (Parts B+C), Version 5.0, November 2022 https://echa.europa.eu/documents/10162/2324906/bpr_guidance_assessment_evaluation_part_vol_ii_part_bc_en.pdf/ae2e9a18-82ee-2340-9354-d82913543fb9?t=1667389376408

[5] Commission Implementing Regulation (EU) No 1035/2013 of 24 October 2013 approving benzoic acid as an existing active substance for use in biocidal products for product-types 3 and 4 (OJ L 283, 25.10.2013, p. 31).

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

HAS ADOPTED THIS DECISION:

Article 1

The biocidal product identified by the case number BC-FG047486-40 in the Register for Biocidal Products meets the condition laid down in Article 19(1), point (a), of Regulation (EU) No 528/2012 for the disinfection of surfaces in the veterinary health care area, including operating rooms.

Article 2

This Decision is addressed to the Member States.

Done at Brussels,

For the Commission
Stella KYRIAKIDES
Member of the Commission

EUROPEAN
COMMISSION

Brussels, XXX
PLAN/2364/2022 Rev1
(POOL/E4/2022/2364/2364-R1-EN.docx)
[…](2023) XXX draft

COMMISSION IMPLEMENTING DECISION

of XXX

on the unresolved objections regarding the terms and conditions of the authorisation of the biocidal product Rapid Pro referred by France in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION

of XXX

on the unresolved objections regarding the terms and conditions of the authorisation of the biocidal product Rapid Pro referred by France in accordance with 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 Article 36(3) thereof,

Whereas:

(1) On 7 October 2016, the biocidal product Rapid Pro ('the biocidal product') was authorised in France by mutual recognition in parallel of an authorisation granted by Belgium in accordance with Article 34 of Regulation (EU) No 528/2012. The biocidal product is a rodenticide, falling under product-type 14 and is placed on the market in pre-filled tamper-resistant bait boxes used for indoor control of mice by professionals. The biocidal product contains the approved active substance alphachloralose. The authorisation holder of the biocidal product is Rentokil Initial.

(2) In 2019, France was informed by the Netherlands and Finland that in 2018 a significant increase of cases of primary and secondary poisonings of cats and dogs with symptoms of alphachloralose poisoning had been reported by poison centres, pet owners and veterinary clinics. In France, the French veterinary poisoning centres had also reported an increase of alphachloralose poisoning of companion animals, mainly primary poisoning of dogs, in 2017 and 2018.

(3) On 9 December 2019, France amended the authorisation of the biocidal product in accordance with Article 48(1), point (a), of Regulation (EU) No 528/2012 to address the primary poisoning incidents involving dogs and secondary poisoning incidents involving cats.

(4) France amended the authorisation by requiring additional labelling on the biocidal product to indicate the risk for humans and non-target organisms and on the packaging to indicate the obligation to use the biocidal product only in bait boxes.

(5) Pursuant to Article 48(3), third subparagraph, read in conjunction with Article 35(2) of Regulation (EU) No 528/2012, on 15 April 2020, Germany referred to the coordination group objections to the amendment of the authorisation of the biocidal product made by France.

(6) The objection from Germany related to the legal basis under which the product can be authorised, as according to Germany, the product does not fully meet the conditions of

[1] OJ L 167, 27.6.2012, p. 1.

Article 19(1) of Regulation (EU) No 528/2012 due to the risk of primary and secondary poisoning of animals and may therefore be authorised only under Article 19(5). France considered that the biocidal product complies with Article 19(1) of Regulation (EU) No 528/2012 and that therefore Article 19(1) is the correct legal basis for the amended authorisation.

(7) On 6 June 2020, the secretariat of the coordination group invited the other concerned Member States and the authorisation holder to submit written comments on the referral. The authorisation holder submitted written comments on 30 June 2020, 6 July 2020 and 23 July 2020. The referral was discussed in the coordination group on 6 and 23 July 2020 with the participation of the authorisation holder.

(8) As no agreement was reached in the coordination group, on 21 October 2020, France, as a reference Member State for the purposes of amending the authorisation under Article 48(1), first subparagraph, of Regulation (EU) No 528/2012, referred the unresolved objections to the Commission pursuant to Article 36(1) of that Regulation and provided the Commission with a detailed statement of the matter on which Member States were unable to reach an agreement and the reasons for their disagreement. That statement was forwarded to the Member States concerned and to the authorisation holder.

(9) In May 2021, the Finnish Safety and Chemical Agency requested an opinion from the Finnish Food Authority and the Finnish Veterinary Association on the effects of biocidal products containing alphachloralose on pets and the need to restrict the use of such products. That opinion, which Finland shared with the Commission, stated that biocidal products containing alphachloralose cause significant harm and suffering to both pets and wildlife and that the number of pet poisonings reported to the Finnish Safety and Chemical Agency and the Finnish Food Authority is significant.

(10) In addition, the Swedish Chemical Agency obtained additional information in the form of blood sample analyses from the University Animal Hospital in Uppsala, Sweden, which confirmed the presence of alphachloralose in the blood of poisoned animals.

(11) According to Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012, it is a condition for granting an authorisation that the biocidal product has no immediate or delayed unacceptable effects itself, or as a result of its residues, on the health of humans, including that of vulnerable groups, or animals, directly or through drinking water, food, feed, air, or through other indirect effects.

(12) Article 19(5), first subparagraph, of Regulation (EU) No 528/2012 provides that a biocidal product may be authorised when the conditions laid down in Article 19(1), point (b)(iii), are not fully met, where not authorising the biocidal product would result in disproportionate negative impacts for society when compared to the risks to human health, animal health or the environment arising from the use of the biocidal product under the conditions laid down in the authorisation. Furthermore, Article 19(5), second subparagraph, states that the use of a biocidal product authorised pursuant to that provision is to be subject to appropriate risk mitigation measures to ensure that exposure of humans and the environment to that biocidal product is minimised. The use of a biocidal product authorised pursuant to that paragraph is to be restricted to Member States in which the condition set out in Article 19(5), first subparagraph, is met.

(13) The Commission has carefully examined the information submitted by the Member States and by the authorisation holder of the biocidal product, including the fact that

incidents of animal poisoning by products containing alphachloralose were also reported in other Member States and in Norway. The Commission also takes into account the opinion from the Finnish Food Authority and the Finnish Veterinary Association, as well as the reports from the University Animal Hospital in Uppsala and the Swedish Veterinary Association, which strongly indicate that the biocidal product has unacceptable effects on animal health, and which confirm, by analytical tests conducted on the poisoned animals, that a significant number of incidents of secondary poisoning by alphachloralose involving cats had occurred, as well as all the information provided and the discussions held in the context of disagreements for other biocidal products containing alphachloralose that were referred to the Commission pursuant to Article 36(1) of Regulation (EU) No 528/2012.

(14) The Commission recognises that it is technically and scientifically impossible to link the reported secondary poisoning cases to a specific biocidal product, as it is not possible to identify which of the specific products was ingested by the mouse that was ingested by the cat. It is only possible to detect the presence of the active substance alphachloralose in the tissue of the animals and sometimes in the carcases of dead rodents in the stomach of poisoned cats. However, it is clear that those poisoning incidents were linked to biocidal products containing alphachloralose, including the biocidal product.

(15) Based on similar considerations, the Commission has recently adopted, in respect of similar products containing alphachloralose, Commission Implementing Decisions (EU) 2022/1005, (EU) 2022/1006 and (EU) 2022/1388[2].

(16) The Commission considers that, while the conditions laid down in Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012 are not fully met due to the unacceptable risks for animal health arising from the use of the biocidal product, no objection was referred to the coordination group on the rest of the conditions laid down in Article 19(1), point (b), and, regarding the risks to animal health identified, the risk mitigation measures applied by Member States are likely to reduce the risk of primary and secondary poisoning.

(17) The Commission therefore considers that, due to the risk of primary and secondary poisoning of dogs in France and of cats in several Member States, the biocidal product does not fully meet the conditions laid down in Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012.

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[2] Commission Implementing Decision (EU) 2022/1005 of 23 June 2022 on the unresolved objections regarding the terms and conditions of the authorisation of the biocidal product family Alphachloralose Grain referred by France and Sweden in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (notified under document C(2022) 4193), (OJ L 168, 27.6.2022, p. 86); Commission Implementing Decision (EU) 2022/1006 of 24 June 2022 on the unresolved objections regarding the terms and conditions of the authorisation of the biocidal product family Alphachloralose Pasta referred by France and Sweden in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (notified under document C(2022) 4226) (OJ L 168, 27.6.2022, p. 90); Commission Implementing Decision (EU) 2022/1388 of 23 June 2022 on the unresolved objections regarding the terms and conditions of the authorisation of the biocidal product Pat'Appât Souricide Canadien Foudroyant referred by France and Sweden in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (notified under document C(2022) 4220) C/2022/4220, (OJ L 208, 10.8.2022, p. 7).

(18) Therefore, in accordance with Article 19(5) of Regulation (EU) No 528/2012, the biocidal product may only be authorised in Member States who consider that not authorising it would result in disproportionate negative impacts for society when compared to the risks to human health, animal health or the environment arising from the use of the biocidal product under the conditions laid down in the authorisation.

(19) Also, in accordance with Article 19(5) of Regulation (EU) No 528/2012, the use of the biocidal product is to be subject to appropriate risk mitigation measures to ensure that exposure of humans and the environment to that biocidal product is minimised. The active substance alphachloralose was included in Annex I to Directive 98/8/EC for use in biocidal products of product-type 14, and is therefore, pursuant to Article 86 of Regulation (EU) No 528/2012, deemed to have been approved under that Regulation, subject to the specifications and conditions set out in Annex I to Directive 98/8/EC.

(20) On 24 December 2019, pursuant to Article 13(1) of Regulation (EU) No 528/2012, an application for renewal of the approval of the active substance alphachloralose was submitted to the European Chemicals Agency. On 15 October 2020, the evaluating competent authority of Poland informed the Commission that it had decided, pursuant to Article 14(1) of that Regulation, that a full evaluation of the application for renewal was necessary.

(21) For reasons beyond the control of the applicants, the approval of alphachloralose for use in biocidal products of product-type 14, which was to expire on 30 June 2021, would have expired before a decision would have been taken on its renewal. Therefore, the expiry date of the approval of alphachloralose was postponed to 31 December 2023 by Commission Implementing Decision (EU) 2021/333[3], to enable the examination of the application.

(22) The risk of primary and secondary poisoning of animals due to the use of biocidal products containing alphachloralose, the differences in the occurrence of primary and secondary poisoning incidents among Member States and the necessary risk mitigation measures to be applied to reduce that risk to an acceptable level should be also assessed in the context of the evaluation of the application for renewal of the approval of alphachloralose and should subsequently be duly taken into account by Member States in the authorisation of biocidal products containing alphachloralose.

(23) The Commission therefore considers that risk mitigation measures to address the risk of primary and secondary poisoning from the use of the biocidal product should, exceptionally, until the conclusion of the evaluation of the application for renewal of the approval of alphachloralose, take into account the particular circumstances and available scientifically validated evidence of the occurrence of primary and secondary poisoning incidents in the individual Member States.

(24) On 26 October 2022, the Commission provided the authorisation holder with the opportunity to provide written comments in accordance with Article 36(2) of Regulation (EU) No 528/2012. The authorisation holder provided comments, which have been considered by the Commission.

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

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[3] Commission Implementing Decision (EU) 2021/333 of 24 February 2021 postponing the expiry date of approval of alphachloralose for use in biocidal products of product-type 14 (OJ L 65, 25.2.2021, p. 58).

HAS ADOPTED THIS DECISION:

Article 1

The biocidal product identified by the asset numbers AT-0016213-0000, BE-0011978-0000, CH-0016234-0000, DE-0015430-0000, DK-0012634-0000, ES-0014035-0000, FR-0012648-0000, IE-0014481-0000, IT-0014977-0000, LU-0012652-0000, LT-0018189-0000, NL-0016288-0000, NO-0015333-0000, PT-0020295-0000 in the Register for Biocidal Products ('the biocidal product') does not fully meet the conditions laid down in Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012.

The biocidal product may only be authorised in accordance with Article 19(5) of Regulation (EU) No 528/2012 in Member States who consider that not authorising it would result in disproportionate negative impacts for society when compared to the risks to human health, animal health or the environment arising from the use of the biocidal product under the conditions laid down in the authorisation.

The use of the biocidal product shall be subject to appropriate risk mitigation measures, as referred to in Article 19(5) of Regulation (EU) No 528/2012, which shall be adopted in each Member State based on the particular circumstances and available evidence of the occurrence of primary and secondary poisoning incidents in that Member State.

Article 2

This Decision is addressed to the Member States.

Done at Brussels,

For the Commission
Stella KYRIAKIDES
Member of the Commission

EUROPEAN
COMMISSION

Brussels, XXX
PLAN/2022/2363 Rev1
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[…](2023) XXX draft

COMMISSION IMPLEMENTING DECISION

of XXX

on the unresolved objections regarding the terms and conditions of the authorisation of the biocidal product Virazan referred by France in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION

of XXX

on the unresolved objections regarding the terms and conditions of the authorisation of the biocidal product Virazan referred by France in accordance with 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 Article 36(3) thereof,

Whereas:

(1) On 8 January 2016, the biocidal product Virazan was authorised in France by mutual recognition in sequence of an authorisation granted by United Kingdom in accordance with Article 33 of Regulation (EU) No 528/2012 of the European Parliament and of the Council. The biocidal product is a rodenticide, falling under product-type 14 and is placed on the market in pre-filled tamper-resistant bait boxes used for indoor control of mice by professionals. The biocidal product contains the approved active substance alphachloralose. The authorisation holder of the biocidal products is SBM Développement SAS.

(2) In 2019, France was informed by the Netherlands and Finland that in 2018 a significant increase of cases of primary and secondary poisonings of cats and dogs with symptoms of alphachloralose poisoning had been reported by poison centres, pet owners and veterinary clinics. In France, the French veterinary poisoning centres had also reported an increase of alphachloralose poisoning of companion animals, mainly primary poisoning of dogs, in 2017 and 2018.

(3) On 9 December 2019, France amended the authorisation of the biocidal product in accordance with Article 48(1), point (a), of Regulation (EU) No 528/2012 to address the primary poisoning incidents involving dogs and secondary poisoning incidents involving cats.

(4) France amended the authorisation by requiring additional labelling on the biocidal product to indicate the risk for humans and non-target organisms and on the packaging to indicate the obligation to use the biocidal product only in bait boxes.

(5) Pursuant to Article 48(3), third subparagraph, read in conjunction with Article 35(2) of Regulation (EU) No 528/2012, on 15 April 2020, Germany referred to the coordination group objections to the amendment of the authorisation of the biocidal product made by France.

[1] OJ L 167, 27.6.2012, p. 1.

(6) The objection from Germany related to the legal basis under which the product can be authorised, as according to Germany, the product does not fully meet the conditions of Article 19(1) of Regulation (EU) No 528/2012 due to the risk of primary and secondary poisoning of animals and may therefore be authorised only under Article 19(5). France considered that the biocidal product complies with Article 19(1) of Regulation (EU) No 528/2012 and that therefore Article 19(1) is the correct legal basis for the amended authorisation.

(7) On 6 June 2020, the secretariat of the coordination group invited the other concerned Member States and the authorisation holder to submit written comments on the referral. The authorisation holder submitted written comments on 30 June 2020, 6 July 2020 and 23 July 2020. The referral was discussed in the coordination group on 6 and 23 July 2020 with the participation of the authorisation holder.

(8) As no agreement was reached in the coordination group, on 21 October 2020, France, as a reference Member State for the purposes of amending the authorisation under Article 48(1), first subparagraph, of Regulation (EU) No 528/2012, referred the unresolved objections to the Commission pursuant to Article 36(1) of that Regulation and provided the Commission with a detailed statement of the matter on which Member States were unable to reach an agreement and the reasons for their disagreement. That statement was forwarded to the Member States concerned and to the authorisation holder.

(9) In May 2021, the Finnish Safety and Chemical Agency requested an opinion from the Finnish Food Authority and the Finnish Veterinary Association on the effects of biocidal products containing alphachloralose on pets and the need to restrict the use of such products. That opinion, which Finland shared with the Commission, stated that biocidal products containing alphachloralose cause significant harm and suffering to both pets and wildlife and that the number of pet poisonings reported to the Finnish Safety and Chemical Agency and the Finnish Food Authority is significant.

(10) In addition, the Swedish Chemical Agency obtained additional information in the form of blood sample analyses from the University Animal Hospital in Uppsala, Sweden, which confirmed the presence of alphachloralose in the blood of poisoned animals.

(11) According to Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012, it is a condition for granting an authorisation that the biocidal product has no immediate or delayed unacceptable effects itself, or as a result of its residues, on the health of humans, including that of vulnerable groups, or animals, directly or through drinking water, food, feed, air, or through other indirect effects.

(12) Article 19(5), first subparagraph, of Regulation (EU) No 528/2012 provides that a biocidal product may be authorised when the conditions laid down in Article 19(1), point (b)(iii), are not fully met, where not authorising the biocidal product would result in disproportionate negative impacts for society when compared to the risks to human health, animal health or the environment arising from the use of the biocidal product under the conditions laid down in the authorisation. Furthermore, Article 19(5), second subparagraph, states that the use of a biocidal product authorised pursuant to that provision is to be subject to appropriate risk mitigation measures to ensure that exposure of humans and the environment to that biocidal product is minimised. The use of a biocidal product authorised pursuant to that paragraph is to be restricted to Member States in which the condition set out in Article 19(5), first subparagraph, is met.

(13) The Commission has carefully examined the information submitted by the Member States and by the authorisation holder of the biocidal product, including the fact that incidents of animal poisoning by products containing alphachloralose were also reported in other Member States and in Norway. The Commission also takes into account the opinion from the Finnish Food Authority and the Finnish Veterinary Association, as well as the reports from the University Animal Hospital in Uppsala and the Swedish Veterinary Association, which strongly indicate that the biocidal product has unacceptable effects on animal health, and which confirm, by analytical tests conducted on the poisoned animals, that a significant number of incidents of secondary poisoning by alphachloralose involving cats had occurred, as well as all the information provided and the discussions held in the context of disagreements for other biocidal products containing alphachloralose that were referred to the Commission pursuant to Article 36(1) of Regulation (EU) No 528/2012.

(14) The Commission recognises that it is technically and scientifically impossible to link the reported secondary poisoning cases to a specific biocidal product, as it is not possible to identify which of the specific products was ingested by the mouse that was ingested by the cat. It is only possible to detect the presence of the active substance alphachloralose in the tissue of the animals and sometimes in the carcases of dead rodents in the stomach of poisoned cats. However, it is clear that those poisoning incidents were linked to biocidal products containing alphachloralose, including the biocidal product.

(15) Based on similar considerations, the Commission has recently adopted, in respect of similar products containing alphachloralose, Commission Implementing Decisions (EU) 2022/1005, (EU) 2022/1006 and (EU) 2022/1388[2].

(16) The Commission considers that, while the conditions laid down in Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012 are not fully met due to the unacceptable risks for animal health arising from the use of the biocidal product, no objection was referred to the coordination group on the rest of the conditions laid down in Article 19(1), point (b), and, regarding the risks to animal health identified, the risk mitigation measures applied by Member States are likely to reduce the risk of primary and secondary poisoning.

(17) The Commission therefore considers that, due to the risk of primary and secondary poisoning of dogs in France and of cats in several Member States, the biocidal product does not fully meet the conditions laid down in Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012.

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[2] Commission Implementing Decision (EU) 2022/1005 of 23 June 2022 on the unresolved objections regarding the terms and conditions of the authorisation of the biocidal product family Alphachloralose Grain referred by France and Sweden in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (notified under document C(2022) 4193), (OJ L 168, 27.6.2022, p. 86); Commission Implementing Decision (EU) 2022/1006 of 24 June 2022 on the unresolved objections regarding the terms and conditions of the authorisation of the biocidal product family Alphachloralose Pasta referred by France and Sweden in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (notified under document C(2022) 4226) (OJ L 168, 27.6.2022, p. 90); Commission Implementing Decision (EU) 2022/1388 of 23 June 2022 on the unresolved objections regarding the terms and conditions of the authorisation of the biocidal product Pat'Appât Souricide Canadien Foudroyant referred by France and Sweden in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (notified under document C(2022) 4220) C/2022/4220, (OJ L 208, 10.8.2022, p. 7).

(18) Therefore, in accordance with Article 19(5) of Regulation (EU) No 528/2012, the biocidal product may only be authorised in Member States who consider that not authorising it would result in disproportionate negative impacts for society when compared to the risks to human health, animal health or the environment arising from the use of the biocidal product under the conditions laid down in the authorisation.

(19) Also, in accordance with Article 19(5) of Regulation (EU) No 528/2012, the use of the biocidal product is to be subject to appropriate risk mitigation measures to ensure that exposure of humans and the environment to that biocidal product is minimised. The active substance alphachloralose was included in Annex I to Directive 98/8/EC for use in biocidal products of product-type 14, and is therefore, pursuant to Article 86 of Regulation (EU) No 528/2012, deemed to have been approved under that Regulation, subject to the specifications and conditions set out in Annex I to Directive 98/8/EC.

(20) On 24 December 2019, pursuant to Article 13(1) of Regulation (EU) No 528/2012, an application for renewal of the approval of the active substance alphachloralose was submitted to the European Chemicals Agency. On 15 October 2020, the evaluating competent authority of Poland informed the Commission that it had decided, pursuant to Article 14(1) of that Regulation, that a full evaluation of the application for renewal was necessary.

(21) For reasons beyond the control of the applicants, the approval of alphachloralose for use in biocidal products of product-type 14, which was to expire on 30 June 2021, would have expired before a decision would have been taken on its renewal. Therefore, the expiry date of the approval of alphachloralose was postponed to 31 December 2023 by Commission Implementing Decision (EU) 2021/333[3], to enable the examination of the application.

(22) The risk of primary and secondary poisoning of animals due to the use of biocidal products containing alphachloralose, the differences in the occurrence of primary and secondary poisoning incidents among Member States and the necessary risk mitigation measures to be applied to reduce that risk to an acceptable level should be also assessed in the context of the evaluation of the application for renewal of the approval of alphachloralose and should subsequently be duly taken into account by Member States in the authorisation of biocidal products containing alphachloralose.

(23) The Commission therefore considers that risk mitigation measures to address the risk of primary and secondary poisoning from the use of the biocidal product should, exceptionally, until the conclusion of the evaluation of the application for renewal of the approval of alphachloralose, take into account the particular circumstances and available scientifically validated evidence of the occurrence of primary and secondary poisoning incidents in the individual Member States.

(24) On 26 October 2022, the Commission provided the authorisation holder with the opportunity to provide written comments in accordance with Article 36(2) of Regulation (EU) No 528/2012. The authorisation holder provided comments, which the Commission subsequently considered.

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

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[3] Commission Implementing Decision (EU) 2021/333 of 24 February 2021 postponing the expiry date of approval of alphachloralose for use in biocidal products of product-type 14 (OJ L 65, 25.2.2021, p. 58).

HAS ADOPTED THIS DECISION:

Article 1

The biocidal product identified by the asset numbers in the Register for Biocidal Products BE-0003002-0000, CH-0009788-0000, DE-0011801-0000, DK-0007141-0000, FR-0005302-0000, IE-0007441-0000, IT-0012826-0000, NL-0005019-0000, PT-0010276-0000 does not fully meet the conditions laid down in Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012.

The biocidal product may only be authorised in accordance with Article 19(5) of Regulation (EU) No 528/2012 in Member States who consider that not authorising it would result in disproportionate negative impacts for society when compared to the risks to human health, animal health or the environment arising from the use of the biocidal product under the conditions laid down in the authorisation.

The use of the biocidal product shall be subject to appropriate risk mitigation measures, as referred to in Article 19(5) of Regulation (EU) No 528/2012, which in each Member State shall be adopted based on the particular circumstances and available evidence of the occurrence of secondary poisoning incidents in that Member State.

Article 2

This Decision is addressed to the Member States.

Done at Brussels,

For the Commission
Stella KYRIAKIDES
Member of the Commission