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⁽¹⁾ Text with EEA relevance.

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

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II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2017/1529

of 7 September 2017

approving the basic substance sodium chloride in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ⁽¹⁾, and in particular Article 23(5) in conjunction with Article 13(2) thereof,

Whereas:

- (1) In accordance with Article 23(3) of Regulation (EC) No 1107/2009, the Commission received on 7 June 2016 an application from the Agriculture and Horticulture Development Board (UK) and the Institut Technique de l'Agriculture Biologique (ITAB) for the approval of salt as a basic substance for use as a fungicide in mushrooms. In addition, the Commission received on 21 July 2016 an application from ITAB for the approval of sea salt as basic substance for use as a fungicide and insecticide in grapes. Since both applications concern the substance sodium chloride of food-grade quality, the applications were merged. The applications were accompanied by the information required by the second subparagraph of Article 23(3) of Regulation (EC) No 1107/2009.
- (2) The Commission asked the European Food Safety Authority (hereinafter 'the Authority') for scientific assistance. The Authority presented to the Commission a Technical Report on sodium chloride on 20 January 2017 ⁽²⁾. The Commission presented the review report ⁽³⁾ and a draft of this Regulation to the Standing Committee on Plants, Animals, Food and Feed on 23 March 2017 and finalised them for the meeting of that Committee on 20 July 2017.
- (3) The documentation provided by the applicant shows that sodium chloride fulfils the criteria of a foodstuff as defined in Article 2 of Regulation (EC) No 178/2002 of the European Parliament and of the Council ⁽⁴⁾. Moreover, it is not predominantly used for plant protection purposes but nevertheless is useful in plant protection in a product consisting of the substance and water. Consequently, it is to be considered as a basic substance.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ European Food Safety Authority, 2016; Outcome of the consultation with Member States and EFSA on the basic substance application for sodium chloride for use in plant protection as fungicide and bactericide in seed treatment and for disinfecting cutting tools. EFSA supporting publication 2016:EN-1091. 39 pp.

⁽³⁾ <http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.selection&language=EN>

⁽⁴⁾ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

- (4) It has appeared from the examinations made that sodium chloride may be expected to satisfy, in general, the requirements laid down in Article 23 of Regulation (EC) No 1107/2009, in particular with regard to the uses which were examined and detailed in the Commission review report. It is therefore appropriate to approve sodium chloride as a basic substance.
- (5) In accordance with Article 13(2) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge, it is, however, necessary to include certain conditions and restrictions.
- (6) In accordance with Article 13(4) of Regulation (EC) No 1107/2009, the Annex to Commission Implementing Regulation (EU) No 540/2011 ⁽¹⁾ should be amended accordingly.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Approval of a basic substance

The substance sodium chloride is approved as a basic substance as laid down in Annex I.

Article 2

Amendments to Implementing Regulation (EU) No 540/2011

Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

Article 3

Entry into force

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, 7 September 2017.

For the Commission
The President
Jean-Claude JUNCKER

⁽¹⁾ Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Specific provisions
Sodium chloride CAS No 7647-14-5	Sodium chloride	970 g/kg Food grade	28 September 2017	Only uses as basic substance being a fungicide and insecticide are approved. Sodium chloride shall be used in accordance with the specific conditions included in the conclusions of the review report on sodium chloride (SANTE/10383/2017) and in particular Appendices I and II thereof.

⁽¹⁾ Further details on identity, specification and manner of use of basic substance are provided in the review report.

ANNEX II

In Part C of the Annex to Implementing Regulation (EU) No 540/2011, the following entry is added:

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Specific provisions
'16	Sodium chloride CAS No 7647-14-5	Sodium chloride	970 g/kg Food grade	28 September 2017	Only uses as basic substance being a fungicide and insecticide are approved. Sodium chloride shall be used in accordance with the specific conditions included in the conclusions of the review report on sodium chloride (SANTE/10383/2017) and in particular Appendices I and II thereof.'

⁽¹⁾ Further details on identity, specification and manner of use of basic substance are provided in the review report.

COMMISSION IMPLEMENTING REGULATION (EU) 2017/1530**of 7 September 2017****amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval period of the active substance quizalofop-p-tefuryl****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ⁽¹⁾, and in particular the first paragraph of Article 17 thereof,

Whereas:

- (1) Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 ⁽²⁾ sets out the active substances deemed to have been approved under Regulation (EC) No 1107/2009.
- (2) In view of the time and resources necessary for completing the assessment of applications for the renewal of approvals of the large number of active substances the approvals of which are expiring between 2019 and 2021, Commission Implementing Decision C/2016/6104 ⁽³⁾ established a work programme grouping together similar active substances and setting priorities on the basis of safety concerns for human and animal health or the environment as provided for in Article 18 of Regulation (EC) No 1107/2009.
- (3) Active substances propaquizafop, quizalofop-p-ethyl and quizalofop-p-tefuryl have approvals which were originally expiring between 2019 and 2021. Considering that the three substances are ester variants of quizalofop, they share similar properties. Taking into account Implementing Decision C/2016/6104, the hazard properties of quizalofop-p-tefuryl ⁽⁴⁾ and the fact that the three substances have important similarities, it is appropriate to group them together in order to align the timing of their assessment and the peer-review process carried out by the European Food Safety Authority. Consequently, the dossiers for the three substances should be submitted to their respective rapporteur Member States within the same time frame.
- (4) The approvals of propaquizafop and quizalofop-p-ethyl expire on 30 November 2021. In order to align the timing of the assessment of the substance quizalofop-p-tefuryl with the assessment of the other two substances the approval period of the substance quizalofop-p-tefuryl should be extended.
- (5) An application for the renewal of the approval of quizalofop-p-tefuryl was submitted in accordance with Commission Implementing Regulation (EU) No 844/2012 ⁽⁵⁾.
- (6) In view of the aim of the first paragraph of Article 17 of Regulation (EC) No 1107/2009, as regards cases where no supplementary dossier in accordance with Implementing Regulation (EU) No 844/2012 is submitted no later than 30 months before the expiry date laid down in Article 1 of this Regulation, the Commission will set the expiry date at the same date as before this Regulation or at the earliest date thereafter.
- (7) In view of the aim of the first paragraph of Article 17 of Regulation (EC) No 1107/2009, as regards cases where the Commission will adopt a Regulation providing that the approval of the active substance referred to in this

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ OJ L 153, 11.6.2011, p. 1.

⁽³⁾ Commission Implementing Decision of 28 September 2016 on the establishment of a work programme for the assessment of applications for the renewal of approvals of active substances expiring in 2019, 2020 and 2021 in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council (OJ C 357, 29.9.2016, p. 9).

⁽⁴⁾ European Chemicals Agency Committee for Risk Assessment (RAC) Opinion proposing harmonised classification and labelling at EU level of Quizalofop-P-tefuryl. Adopted 3 June 2016.

⁽⁵⁾ Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26).

Regulation is not renewed because the approval criteria are not satisfied, the Commission will set the expiry date at the same date as before this Regulation or at the date of the entry into force of the Regulation providing that the approval of the active substance is not renewed, whichever date is later. As regards cases where the Commission will adopt a Regulation providing for the renewal of the active substance referred to in this Regulation, the Commission will endeavour to set, as appropriate under the circumstances, the earliest possible application date.

- (8) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

In the sixth column, 'expiration of approval', of entry 279, in Part A of the Annex to Implementing Regulation (EU) No 540/2011, the date '30 November 2019' relating to Quizalofop-P-tefuryl, is replaced by the date '30 November 2021'.

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, 7 September 2017.

For the Commission
The President
Jean-Claude JUNCKER

COMMISSION IMPLEMENTING REGULATION (EU) 2017/1531**of 7 September 2017****renewing the approval of the active substance imazamox, as a candidate for substitution, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ⁽¹⁾ and in particular Article 24 in conjunction with Article 20(1) thereof,

Whereas:

- (1) Commission Directive 2003/23/EC ⁽²⁾ included imazamox as an active substance in Annex I to Council Directive 91/414/EEC ⁽³⁾.
- (2) Active substances included in Annex I to Directive 91/414/EEC are deemed to have been approved under Regulation (EC) No 1107/2009 and are listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 ⁽⁴⁾.
- (3) The approval of the active substance imazamox, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011 expires on 31 July 2018.
- (4) An application for the renewal of the approval of imazamox was submitted in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012 ⁽⁵⁾ within the time period provided for in that Article.
- (5) The applicant submitted the supplementary dossiers required in accordance with Article 6 of Implementing Regulation (EU) No 844/2012. The application was found to be complete by the rapporteur Member State.
- (6) The rapporteur Member State prepared a renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the European Food Safety Authority ('the Authority') and the Commission on 13 April 2015.
- (7) The Authority communicated the renewal assessment report to the applicant and to the other Member States for comments and forwarded the comments received to the Commission. The Authority also made the supplementary summary dossier available to the public.
- (8) On 15 March 2016 the Authority communicated to the Commission its conclusion ⁽⁶⁾ on whether imazamox can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Commission presented the draft renewal report for imazamox to the Standing Committee on Plants, Animals, Food and Feed on 11 July 2016.
- (9) The applicant was given the opportunity to submit comments on the draft renewal report.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ Commission Directive 2003/23/EC of 25 March 2003 amending Council Directive 91/414/EEC to include imazamox, oxasulfuron, ethoxysulfuron, foramsulfuron, oxadiargyl and cyazofamid as active substances (OJ L 81, 28.3.2003, p. 39).

⁽³⁾ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

⁽⁴⁾ Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

⁽⁵⁾ Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26).

⁽⁶⁾ EFSA Journal 2016;14(4):4432. Available online: www.efsa.europa.eu.

- (10) It has been established with respect to one or more representative uses of at least one plant protection product containing imazamox that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. It is therefore appropriate to renew the approval of imazamox.
- (11) The risk assessment for the renewal of the approval of imazamox is based on a limited number of representative uses, which however do not restrict the uses for which plant protection products containing imazamox may be authorised. It is therefore appropriate to remove the restriction to use only as a herbicide.
- (12) The Commission, however, considers that imazamox is a candidate for substitution pursuant to Article 24 of Regulation (EC) No 1107/2009. Imazamox is a persistent and toxic substance in accordance with points 3.7.2.1 and 3.7.2.3 respectively, of Annex II to Regulation (EC) No 1107/2009, given that the half-life in fresh water and sediment is higher than 120 days and the long term no-observed effect concentration for aquatic plants is 0,0045 mg/l. Imazamox therefore fulfils the condition set in the second indent of point 4 of Annex II to Regulation (EC) No 1107/2009.
- (13) It is therefore appropriate to renew the approval of imazamox as a candidate for substitution.
- (14) In accordance with Article 14(1) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge, it is, however, necessary to include certain conditions and restrictions.
- (15) The Annex to Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (16) Commission Implementing Regulation (EU) 2017/841 ⁽¹⁾ extended the approval period of imazamox to 31 July 2018 in order to allow the renewal process to be completed before the expiry of the approval of that substance. However, given that a decision on renewal has been taken ahead of this extended expiry date, this Regulation should apply from 1 November 2017.
- (17) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Renewal of the approval of the active substance as a candidate for substitution

The approval of the active substance imazamox, as a candidate for substitution, is renewed as set out in Annex I.

Article 2

Amendments to Implementing Regulation (EU) No 540/2011

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

Article 3

Entry into force and date of application

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

It shall apply from 1 November 2017.

⁽¹⁾ Commission Implementing Regulation (EU) 2017/841 of 17 May 2017 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances alpha-cypermethrin, *Ampelomyces quisqualis* strain: aq 10, benalaxyl, bentazone, bifenazate, bromoxynil, carfentrazone ethyl, chlorpropham, cyazofamid, desmedipham, diquat, DPX KE 459 (flupyrsulfuron-methyl), etoxazole, famoxadone, fenamidone, flumioxazine, foramsulfuron, *Gliocladium catenulatum* strain: j1446, imazamox, imazosulfuron, isoxaflutole, laminarin, metalaxyl-m, methoxyfenozide, milbemectin, oxasulfuron, pendimethalin, phenmedipham, pymetrozine, s-metolachlor, and trifloxystrobin (OJ L 125, 18.5.2017, p. 12).

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

Done at Brussels, 7 September 2017.

For the Commission

The President

Jean-Claude JUNKER

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
imazamox CAS No 114311-32-9 CIPAC No 619	2-[(RS)-4-isopropyl-4-methyl-5-oxo-2-imidazolin-2-yl]-5-methoxymethylnicotinic acid	≥ 950 g/kg The impurity cyanide ion (CN ⁻) shall not exceed 5 mg/kg in the technical material.	1 November 2017	31 October 2024	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on imazamox, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of consumers; — the protection of aquatic plants and of non-target terrestrial plants; — the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation shall include risk mitigation measures and monitoring programs shall be initiated to verify potential groundwater contamination from imazamox and metabolites CL 312622 and CL 354825 in vulnerable zones, where appropriate.

⁽¹⁾ Further details on identity and specification of active substance are provided in the review report.

The Annex to Implementing Regulation (EU) No 540/2011 is amended as follows:

- (1) in Part A, entry 41 on imazamox is deleted;
 (2) in Part E, the following entry is added:

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
'8	imazamox CAS No 114311-32-9 CIPAC No 619	2-[(RS)-4-isopropyl-4-methyl-5-oxo-2-imidazolin-2-yl]-5-methoxymethylnicotinic acid	≥ 950 g/kg The impurity cyanide ion (CN ⁻) shall not exceed 5 mg/kg in the technical material.	1 November 2017	31 October 2024	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on imazamox, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of consumers; — the protection of aquatic plants and of non-target terrestrial plants; — the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation shall include risk mitigation measures and monitoring programs shall be initiated to verify potential groundwater contamination from imazamox and metabolites CL 312622 and CL 354825 in vulnerable zones, where appropriate.'

⁽¹⁾ Further details on identity and specification of active substance are provided in the review report.

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2017/1532

of 7 September 2017

addressing questions regarding the comparative assessment of anticoagulant rodenticides in accordance with Article 23(5) of 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 first subparagraph of Article 23(5) thereof,

Whereas:

- (1) At the 60th meeting of representatives of Member States Competent Authorities for the implementation of Regulation (EU) No 528/2012 held on 20 and 21 May 2015, all Member States submitted to the Commission a number of questions to be addressed at Union level in the context of the comparative assessment to be carried out at the renewal of anticoagulant rodenticide biocidal products ('anticoagulant rodenticides').
- (2) The questions submitted were the following: (a) Is the chemical diversity of the active substances in authorised rodenticides in the Union adequate to minimise the occurrence of resistance in the target harmful organisms?; (b) For the different uses specified in the applications for renewal, are alternative authorised biocidal products or non-chemical means of control and prevention methods available?; (c) Do these alternatives present a significantly lower overall risk for human health, animal health and the environment?; d) Are these alternatives sufficiently effective?; (e) Do these alternatives present no other significant economic or practical disadvantages?
- (3) The answers to these questions are relevant for any receiving competent authority for the purpose of deciding whether the criteria in Article 23(3)(a) and (b) of Regulation (EU) No 528/2012 are met and, as a consequence, whether it shall prohibit or restrict the making available on the market or the use of anticoagulant rodenticides.
- (4) Pursuant to Article 75(1)(g) of Regulation (EU) No 528/2012, the Commission requested from the European Chemicals Agency ('Agency') to formulate an opinion addressing the questions for the different uses that may be authorised in anticoagulant rodenticides according to the conditions and risk mitigation measures referred to in the opinions ⁽²⁾ adopted by the Biocidal Products Committee of the Agency at its 16th meeting for the renewal of the active substance approvals.
- (5) On 2 March 2017, the Biocidal Products Committee of the Agency adopted its opinion ⁽³⁾.
- (6) According to that opinion, in the absence of anticoagulant rodenticides, the use of rodenticide biocidal products containing other active substances would lead to an inadequate chemical diversity to minimize the occurrence of resistance in the target harmful organisms. These products also showed some significant practical or economical disadvantages for the relevant uses.
- (7) The opinion also considered a number of non-chemical control or prevention methods ('non-chemical alternatives'), which may provide sufficient efficacy in certain circumstances on their own or in a combination

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ <http://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval>

⁽³⁾ Opinion ECHA/BPC/145/2017, available at https://echa.europa.eu/documents/10162/21680461/bpc_opinion_comparative-assessment_ar_en.pdf/bf81f0a5-3e95-6b7d-d601-37db9bb16fa5

of them. However, there is insufficient scientific evidence to prove that those non-chemical alternatives are sufficiently effective according to the criteria established in agreed Union guidance ⁽¹⁾ with a view to prohibit or restrict the authorised uses of anticoagulant rodenticides.

- (8) Nevertheless the Commission notes the recommendation in the opinion that the use of non-chemical alternatives is a fundamental part of sustainable pest management for rodent control and proper use of anticoagulant rodenticides in accordance with Article 17(5) of Regulation (EU) No 528/2012.
- (9) 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

For the purpose of Article 23(3) of Regulation (EU) No 528/2012, the receiving competent authorities of the Member States shall consider the information addressing the questions referred to the Commission concerning the comparative assessment of anticoagulant rodenticide biocidal products provided in the Annex.

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, 7 September 2017.

For the Commission

The President

Jean-Claude JUNCKER

⁽¹⁾ Technical guidance note on Comparative assessment of biocidal products, available at <https://circabc.europa.eu/w/browse/d309607f-f75b-46e7-acc4-1653cadcaf7e>

ANNEX

Information addressing the questions referred by Member States to the Commission concerning the comparative assessment of anticoagulant rodenticide biocidal products.

For the purpose of those questions, the specified uses referred to in Article 23(3)(a) of Regulation (EU) No 528/2012 are listed in Table 1.

Table 1

Specified uses for anticoagulant rodenticides

Use number	Target organism(s)	Field of use	Category(ies) of users	Application method
#1	<i>Mus musculus</i> (house mice) (Other target organisms may be added)	Indoor	General public	Ready-to-use bait to be used in tamper-resistant bait stations
#2	<i>Rattus norvegicus</i> (brown rat) <i>Rattus rattus</i> (black or roof rat)	Indoor	General public	Ready-to-use bait to be used in tamper-resistant bait stations
#3	<i>Rattus norvegicus</i> (brown rat) <i>Rattus rattus</i> (black or roof rat) (Other target organisms — except house mice — may be added (e.g. voles))	Outdoor around buildings	General public	Ready-to-use bait to be used in tamper-resistant bait stations
#4	<i>Mus musculus</i> (house mice) (Other target organisms may be added)	Indoor	Professionals	Ready-to-use bait to be used in tamper-resistant bait stations
#5	<i>Rattus norvegicus</i> (brown rat) <i>Rattus rattus</i> (black or roof rat)	Indoor	Professionals	Ready-to-use bait to be used in tamper-resistant bait stations
#6	<i>Mus musculus</i> (house mice) <i>Rattus norvegicus</i> (brown rat) <i>Rattus rattus</i> (black or roof rat)	Outdoor around buildings	Professionals	Ready-to-use bait to be used in tamper-resistant bait stations
#7	<i>Mus musculus</i> (house mice) <i>Rattus norvegicus</i> (brown rat) <i>Rattus rattus</i> (black or roof rat)	Indoor	Trained professionals	Ready-to-use bait or Ready-to-use contact formulations
#8	<i>Mus musculus</i> (house mice) <i>Rattus norvegicus</i> (brown rat) <i>Rattus rattus</i> (black or roof rat)	Outdoor around buildings	Trained professionals	Ready-to-use bait
#9	<i>Rattus norvegicus</i> (brown rat) <i>Rattus rattus</i> (black or roof rat)	Outdoor open areas Outdoor waste dumps	Trained professionals	Ready-to-use bait
#10	<i>Rattus norvegicus</i> (brown rat)	Sewers	Trained professionals	Ready-to-use bait

Question (a): Is the chemical diversity of the active substances in authorised rodenticides in the EU adequate to minimise the occurrence of resistance in the target harmful organisms?

There are five approved active substances in biocidal products for product-type 14 with a mode of action different from that of anticoagulant rodenticides (alpha chloralose, aluminium phosphide releasing phosphine, carbon dioxide, hydrogen cyanide and powdered corn cob).

According to the opinion, the minimum requirement in agreed Union guidance of having three different alternatives with a different mode of action is not reached for any of the specified uses listed in Table 1. Therefore, in the absence of anticoagulant rodenticides, the condition in Article 23(3)(b) of Regulation (EU) No 528/2012 that the chemical diversity of the active substances is adequate to minimize the occurrence of resistance in the target harmful organisms is not met.

Question (b): For the different uses specified in the applications for renewal, are alternative authorised biocidal products or non-chemical means of control and prevention methods available?

Tables 2 and 3 provide an overview of the alternatives considered in the opinion in order to address this question.

Table 2

Overview of the alternative authorised biocidal products to the specified uses of anticoagulant rodenticides

Active substance in the alternative biocidal products	Application type	Use number as described in Table 1									
		#1	#2	#3	#4	#5	#6	#7	#8	#9	#10
Alpha chloralose	Bait	yes			yes			Only mice			
Aluminium phosphide releasing phosphine	Fumigant								Only for <i>R. norvegicus</i>	Only for <i>R. norvegicus</i>	
Carbon dioxide	Cannister for trapping device							Only mice			

The alternative authorised biocidal products do not cover all the uses specified for anticoagulant rodenticides (see Table 2). For some uses (uses number #2, #3, #5, #6 and #10), no alternative authorised biocidal products are available. For use #7, there are alternative authorised biocidal products only for mice, and for uses #8 and #9 there are alternative authorised biocidal products only for rats (*R. norvegicus*).

Table 3

Overview of the identified non-chemical alternatives to the specified uses of anticoagulant rodenticides

Reported non-chemical alternative	Mode of action	Uses potentially covered
Curative treatments		
Electrical rodent traps	Traps with electrical current killing the rodent entering the trap.	1, 2, 3, 4, 5, 6, 7, 8, 9, 10
Glue boards	Rodents are captured in glue, killing has to be done separately.	1, 4, 6, 7, 8

Reported non-chemical alternative	Mode of action	Uses potentially covered
Mechanical traps (spring traps or break-back traps)	Traps with mechanical weight are killing the entering rodent.	1, 2, 3, 4, 5, 6, 7, 8, 9, 10
Shooting	Shooting the rodents.	6, 8, 9

Preventive treatments

Habitat modification	Preventing rodent populations from establishing by limiting the supply of food/water/harbourage	1, 2, 3, 4, 5, 6, 7, 8, 9
Rodent proofing	Preventing access of rodents to buildings by blocking entering routes.	1, 2, 4, 5, 7
Ultra-sound	Repelling rodents with an ultrasonic output at 70-140 dB.	1, 2, 3, 4, 5, 6, 7, 8, 9

Question (c) Do these alternatives present a significantly lower overall risk for human health, animal health and the environment?

According to agreed Union guidance, this question should only be addressed if the considered alternatives are sufficiently effective and do not present other significant economic or practical disadvantages (see sections addressing Questions (d) and (e)).

Based on the conclusions reached for questions (a), (b), (d) and (e), the opinion considered that addressing Question (c) was not necessary.

Question (d): Are these alternatives sufficiently effective?

The authorised biocidal products identified under Question (b) include active substances that have been approved and therefore considered effective for the specified uses. Since being sufficiently effective is a criterion for granting an authorisation in Article 19(1)(b)(i) of Regulation (EU) No 528/2012, those products are considered as being sufficiently effective.

Regarding the non-chemical alternatives identified under Question (b), according to the opinion each of the alternatives, on their own or in combination with other alternatives may provide sufficient efficacy in certain, perhaps limited, circumstances. However, there is insufficient scientific evidence to prove that any of the non-chemical alternatives reviewed are sufficiently effective according to agreed Union guidance (i.e. providing similar levels of protection or control of rodent populations under field conditions) to negate the need for anticoagulant rodenticides for the specified uses. As the condition of being sufficiently effective in Article 23(3)(a) of Regulation (EU) No 528/2012 is not met, no further investigation was made for the identified non-chemical alternatives.

Question (e): Do these alternatives present no other significant economic or practical disadvantages?

According to agreed Union guidance, the assessment of the practical and economical disadvantages is to be done with those alternatives meeting the eligibility criteria. Therefore, only the authorised biocidal products identified in table 2 were assessed for the purpose of this question.

According to the opinion, the use of aluminium phosphide releasing phosphine and carbon dioxide leads to significant practical or economical disadvantages compared to anticoagulant rodenticides, as the control of target organisms would be at very high efforts and/or disproportionate cost. Therefore, the condition of presenting no other significant economic or practical disadvantage in Article 23(3)(a) of Regulation (EU) No 528/2012 is not met for the above-mentioned authorised biocidal products.

Concerning alpha chloralose products, their temperature-dependent efficacy would compromise the use of this alternative in locations where the temperature cannot be controlled, resulting in a practical disadvantage for use in warm environments. Moreover, considering the lack of chemical diversity (see section addressing Question (a), replacing or restricting the use of anticoagulant rodenticides with only this substance would not be advised in order to minimize the occurrence of resistance.

