COMMISSION IMPLEMENTING REGULATION (EU) 2017/1380

of 25 July 2017

renewing the approval of bromadiolone as an active substance for use in biocidal products of product-type 14

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([1]), and in particular Article 14(4)(a) thereof,

Whereas:

(1) The active substance bromadiolone is approved for use in biocidal products of product-type 14 as a rodenticide under Regulation (EU) No 528/2012.

(2) In accordance with Article 13(1) of Regulation (EU) No 528/2012, an application was submitted to the European Chemicals Agency ('the Agency') for the renewal of the approval of that active substance. This application was evaluated by the competent authority of Italy as the evaluating competent authority.

(3) On 25 March 2016, the evaluating competent authority submitted its recommendation on the renewal of the approval of bromadiolone to the Agency.

(4) On 16 June 2016, the opinion of the Agency was formulated by its Biocidal Products Committee ([2]), having regard to the conclusions of the evaluating competent authority.

(5) According to that opinion, bromadiolone meets the criteria in Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([3]) to be classified as toxic for reproduction category 1B. The substance also meets the criteria in Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([4]) for being persistent, bioaccumulative and toxic. Bromadiolone therefore meets the exclusion criteria set out in points (c) and (e) of Article 5(1) of Regulation (EU) No 528/2012.

(6) In addition, the use of products containing bromadiolone raises concerns in relation to instances of primary and secondary poisoning, even where restrictive risk management measures are applied and therefore bromadiolone also satisfies the criterion to be a candidate for substitution in accordance with Article 10(1)(e) of Regulation (EU) No 528/2012.

(7) Pursuant to Article 12 of Regulation (EU) No 528/2012, the approval of active substances meeting the exclusion criteria may only be renewed when at least one of the conditions for derogation set out in Article 5(2) of that Regulation continues to be satisfied.

(8) In accordance with Article 10(3) of Regulation (EU) No 528/2012, the Agency organised a public consultation in order to collect relevant information on bromadiolone, including information on available substitutes.

(9) The Commission also carried out a specific public consultation in order to gather information as to whether the conditions for derogation set out in Article 5(2) of Regulation (EU) No 528/2012 were satisfied. The Commission made the contributions to that consultation publicly available.

([1]) OJ L 167, 27.6.2012, p. 1.
([2]) https://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval
([3]) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).
([4]) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

(10) The contributions to the two above-mentioned public consultations, as well as the information regarding the availability of alternatives to anticoagulant rodenticides included in Annex 1 to the Commission report on risk mitigation measures for anticoagulant rodenticides ([1]), were discussed with Member States in the Standing Committee on Biocidal Products.

(11) Rodents can carry pathogens that are responsible for many zoonoses, which can pose serious dangers for human or animal health. Non-chemical controls or prevention methods for rodent control, such as mechanical, electrical or glue traps, may not be sufficiently efficient and may raise further questions as to whether they are humane or whether they cause unnecessary suffering to rodents. Alternative active substances approved for use as rodenticides may not be suitable for all user categories or efficient for all rodent species. As effective rodent control cannot rely on those non-chemical controls or prevention methods only, bromadiolone is considered essential to ensure appropriate rodent control in support of those alternatives. As a consequence the use of bromadiolone would be to prevent or control a serious danger to human and animal health in which rodents are involved. Therefore, the condition set out in Article 5(2)(b) of Regulation (EU) No 528/2012 is satisfied.

(12) Rodent control currently relies largely on the use of anticoagulant rodenticides, the non-approval of which could lead to insufficient rodent control. This may not only cause significant negative impacts on human or animal health or the environment, but also affect the public's perception of its safety with regard to exposure to rodents or the security of a number of economic activities that could be vulnerable to rodents, resulting in economic and social consequences. On the other hand, the risks to human health, animal health or the environment arising from use of products containing bromadiolone can be mitigated if they are used according to certain specifications and conditions. Therefore, the non-approval of bromadiolone as an active substance would have a disproportionate negative impact on society in comparison to the risks arising from the use of the substance. The condition set out in Article 5(2)(c) of Regulation (EU) No 528/2012 is thus also satisfied.

(13) It is therefore appropriate to renew the approval of bromadiolone for use in biocidal products of product-type 14, subject to compliance with certain specifications and conditions.

(14) Bromadiolone is a candidate for substitution in accordance with points (a) and (e) of Article 10(1) of Regulation (EU) No 528/2012 and therefore the period of renewal set out in Article 10(4) of that Regulation should apply.

(15) As the examination of the applications for the renewal of the approval of bromadiolone, chlorophacinone and coumatetralyl for use in biocidal products of product-type 14 is now finalised, Commission Implementing Decision (EU) 2015/1737 ([2]) is repealed by Implementing Regulation (EU) 2017/1377 ([3]).

(16) 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

The approval of bromadiolone as an active substance for use in biocidal products of product-type 14 is renewed, subject to the specifications and conditions set out in the Annex.

Article 2

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

([1]) Risk mitigation measures for anticoagulant rodenticides — Final Report. European Commission (2014), Brussels, Belgium. 100 pp. ISBN 978-92-79-44992-5.

([2]) Commission Implementing Decision (EU) 2015/1737 of 28 September 2015 postponing the expiry date of approval of bromadiolone, chlorophacinone and coumatetralyl for use in biocidal products for product-type 14 (OJ L 252, 29.9.2015, p. 58).

([3]) Commission Implementing Regulation (EU) 2017/1377 of 25 July 2017 renewing the approval of chlorophacinone as an active substance for use in biocidal products of product-type 14 (see page 15 of this Official Journal).

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

Done at Brussels, 25 July 2017.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (1)	Expiry date of approval	Product type	Specific conditions
Bromadiolone	IUPAC Name: 3-[(1RS,3RS;1RS,3SR)-3-(4′-bromobiphenyl-4-yl)-3-hydroxy-1-phenyl-propyl]-4-hydroxy-coumarin EC No: 249-205-9 CAS No: 28772-56-7	969 g/kg	30 June 2024	14	Bromadiolone is considered a candidate for substitution in accordance with points (a) and (e) of Article 10(1) of Regulation (EU) No 528/2012. The authorisations of biocidal products are subject to the following general conditions: (1) the product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. In addition, pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the product assessment shall include an evaluation as to whether the conditions of Article 5(2) of Regulation (EU) No 528/2012 can be satisfied; (2) products shall only be authorised for use in Member States where at least one of the conditions set out in Article 5(2) of Regulation (EU) No 528/2012 is satisfied; (3) the nominal concentration of bromadiolone in the products shall not exceed 50 mg/kg; (4) products shall contain an aversive agent and a dye; (5) products shall not be authorised in the form of tracking powder; (6) products in the form of contact formulations, other than tracking powder, shall only be authorised for use by trained professionals indoors in places not accessible to children or non-target animals; (7) only ready-to-use products shall be authorised; (8) primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include for example the restriction to professional or trained professional use when possible and setting additional specific conditions per user category; (9) dead bodies and uneaten bait shall be disposed of in accordance with local requirements. The method of disposal shall be described specifically in the summary of the product characteristics of the national authorisation and be reflected on the product label.

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (1)	Expiry date of approval	Product type	Specific conditions
					In addition to the general conditions, the authorisations of biocidal products to be used by the general public are subject to the following conditions: (1) products shall only be authorised for use in tamper-resistant bait stations; (2) products shall only be supplied with a maximum quantity of bait per pack of: (a) for products against mice only: (i) for grain, pellet or paste baits: 50 g; (ii) for wax block baits: 100 g; (b) for products against rats only, or mice and rats: (i) for grain, pellet or paste baits: 150 g; (ii) for wax block baits: 300 g; (3) products against *Rattus norvegicus* and *Rattus rattus* shall only be authorised for use indoors or in and around buildings; (4) products against *Mus musculus* shall only be authorised for use indoors; (5) products shall not be authorised for use in permanent or pulse baiting treatments; (6) persons making products available on the market shall ensure that the products are accompanied by information on the risks associated with anticoagulant rodenticides in general, measures to limit their use to the minimum necessary and appropriate precautionary steps to be taken; (7) products in the form of loose bait formulations, such as grain or pellets, shall only be authorised in formulations that are supplied in sachets or other packaging to reduce exposure to humans and the environment. In addition to the general conditions, the authorisations of biocidal products to be used by professionals are subject to the following conditions: (1) products shall not be authorised for use in sewers, open area or waste dumps; (2) products shall not be authorised for use in permanent or pulse baiting treatments;

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (1)	Expiry date of approval	Product type	Specific conditions
					(3) products shall only be authorised for use in tamper-resistant bait stations; (4) persons making products for professional users available on the market shall make sure that these products are not supplied to the general public. In addition to the general conditions, the authorisations of biocidal products to be used by trained professionals are subject to the following conditions: (1) products may be authorised for use in sewers, open area or waste dumps; (2) products may be authorised for use in covered and protected bait points as long as they provide the same level of protection for non-target species and humans as tamper-resistant bait stations; (3) products shall not be authorised for use in pulse baiting treatments; (4) products may only be authorised for use in permanent baiting treatments at those sites with a high potential for reinvasion when other methods of control have proven insufficient; (5) persons making products for trained professional users available on the market shall make sure that the products are not supplied to other persons than trained professionals.

(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.