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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

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

(Text with EEA relevance)

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(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 coumatetralyl 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 Denmark as the evaluating competent authority.

(3) On 23 March 2016, the evaluating competent authority submitted its recommendation on the renewal of the approval of coumatetralyl 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, coumatetralyl 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. Coumatetralyl therefore meets the exclusion criterion set out in Article 5(1)(c) of Regulation (EU) No 528/2012.

(6) In addition, the use of products containing coumatetralyl raises concerns in relation to instances of primary and secondary poisoning, even where restrictive risk management measures are applied and therefore coumatetralyl also satisfies the criterion to be a candidate for substitution in accordance with Article 10(1)(e) of that Regulation.

(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

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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).

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 coumatetralyl, 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.

(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[4], were discussed with Member States in the Standing Committee on Biocidal Products.

(11) Rodents can carry pathogen organisms 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 proper rodent control cannot rely on those non-chemical controls or prevention methods only, coumatetralyl is considered essential to ensure appropriate rodent control in support of those alternatives. As a consequence the use of coumatetralyl 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) 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 coumatetralyl can be mitigated if they are used according to certain specifications and conditions. Therefore, the non-approval of coumatetralyl 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) is thus also satisfied.

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

(14) Coumatetralyl 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.

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

(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, Implementing Decision (EU) 2015/1737[5] is repealed by Implementing Regulation 2017/XXXX [*OJ please insert reference number and publication details of the Implementing Regulation renewing the approval of chlorophacinone as an active substance for use in biocidal products of product-type 14*].

(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 coumatetralyl 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*.

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

Done at Brussels,

For the Commission
The President
Jean-Claude JUNCKER

[5] 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).