Official Journal
of the European Union

EN
L series

2024/734

29.2.2024

COMMISSION IMPLEMENTING DECISION (EU) 2024/734

of 27 February 2024

postponing the expiry date of the approval of brodifacoum, bromadiolone, chlorophacinone, coumatetralyl, difenacoum, difethialone and flocoumafen for use in biocidal products of product-type 14 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) Brodifacoum, bromadiolone, chlorophacinone, coumatetralyl, difenacoum, difethialone and flocoumafen are approved as active substances for use in biocidal products of product-type 14 (rodenticides) under Regulation (EU) No 528/2012 by Commission Implementing Regulation (EU) 2017/1381 ([2]), Commission Implementing Regulation (EU) 2017/1380 ([3]), Commission Implementing Regulation (EU) 2017/1377 ([4]), Commission Implementing Regulation (EU) 2017/1378 ([5]), Commission Implementing Regulation (EU) 2017/1379 ([6]), Commission Implementing Regulation (EU) 2017/1382 ([7]) and Commission Implementing Regulation (EU) 2017/1383 ([8]) ('the approvals').

(2) The approvals are to expire on 30 June 2024. In accordance with Article 13(1) of Regulation (EU) No 528/2012, applications were submitted to the European Chemicals Agency ('the Agency') for the renewal of the approvals ('the applications'). The applications are evaluated by the competent authorities of Denmark, Finland, France, the Netherlands, Norway and Spain as the evaluating competent authorities.

([1]) OJ L 167, 27.6.2012, p. 1, ELI: http://data.europa.eu/eli/reg/2012/528/oj
([2]) Commission Implementing Regulation (EU) 2017/1381 of 25 July 2017 renewing the approval of brodifacoum as an active substance for use in biocidal products of product-type 14 (OJ L 194, 26.7.2017, p. 39, ELI: http://data.europa.eu/eli/reg_impl/2017/1381/oj).
([3]) 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 (OJ L 194, 26.7.2017, p. 33, ELI: http://data.europa.eu/eli/reg_impl/2017/1380/oj).
([4]) 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 (OJ L 194, 26.7.2017, p. 15, ELI: http://data.europa.eu/eli/reg_impl/2017/1377/oj).
([5]) Commission Implementing Regulation (EU) 2017/1378 of 25 July 2017 renewing the approval of coumatetralyl as an active substance for use in biocidal products of product-type 14 (OJ L 194, 26.7.2017, p. 21, ELI: http://data.europa.eu/eli/reg_impl/2017/1378/oj).
([6]) Commission Implementing Regulation (EU) 2017/1379 of 25 July 2017 renewing the approval of difenacoum as an active substance for use in biocidal products of product-type 14 (OJ L 194, 26.7.2017, p. 27, ELI: http://data.europa.eu/eli/reg_impl/2017/1379/oj).
([7]) Commission Implementing Regulation (EU) 2017/1382 of 25 July 2017 renewing the approval of difethialone as an active substance for use in biocidal products of product-type 14 (OJ L 194, 26.7.2017, p. 45, ELI: http://data.europa.eu/eli/reg_impl/2017/1382/oj).
([8]) Commission Implementing Regulation (EU) 2017/1383 of 25 July 2017 renewing the approval of flocoumafen as an active substance for use in biocidal products of product-type 14 (OJ L 194, 26.7.2017, p. 51, ELI: http://data.europa.eu/eli/reg_impl/2017/1383/oj).

(3) The evaluating competent authorities informed the Commission ([9]) that they had decided, pursuant to Article 14(1) of Regulation (EU) No 528/2012, that full evaluations of the applications were 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 authorities, 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.

(6) On 25 October 2023, the Agency informed the Commission that the evaluating competent authorities intend to submit their assessment reports and the conclusions of their evaluations to the Agency in the third quarter of 2024.

(7) Brodifacoum, bromadiolone, chlorophacinone, coumatetralyl, difenacoum, difethialone and flocoumafen are classified in Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([10]) as toxic for reproduction category 1A or 1B, and thus they meet the exclusion criterion set out in Article 5(1), point (c), of Regulation (EU) No 528/2012. The substances brodifacoum, bromadiolone, difenacoum, difethialone and flocoumafen also meet the criteria in Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([11]) for being persistent, bioaccumulative and toxic, and thus they meet the exclusion criterion set out in of Article 5(1), point (e), of Regulation (EU) No 528/2012. The substances difethialone and flocoumafen also meet the criteria in Regulation (EC) No 1907/2006 of the European Parliament and of the Council for being very persistent and very bioaccumulative, and thus they meet the exclusion criterion set out in of Article 5(1), point (e), of Regulation (EU) No 528/2012.

(8) Pursuant to Article 12(1) of Regulation (EU) No 528/2012, the approval of brodifacoum, bromadiolone, chlorophacinone, coumatetralyl, difenacoum, difethialone and flocoumafen, may only be renewed if the active substances still meet the conditions laid down in Article 4(1) and the conditions for derogation set out in Article 5(2) of that Regulation.

(9) Discussions need to take place with Member States representatives to decide whether the condition set out in Article 5(2), first subparagraph, of Regulation (EU) No 528/2012 is still met, and whether the approval of brodifacoum, bromadiolone, chlorophacinone, coumatetralyl, difenacoum, difethialone and flocoumafen may therefore be renewed.

([9]) The evaluating competent authority of Denmark informed the Commission on 9 November 2023 for coumatetralyl, of Finland on 27 March 2023 for difenacoum, of France on 25 May 2023 for bromadiolone, of the Netherlands on 23 October 2023 for brodifacoum and flocoumafen, of Norway on 1 November 2023 for difethialone, of Spain on 18 October 2023 for chlorophacinone.

([10]) 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, ELI: http://data.europa.eu/eli/reg/2008/1272/oj).

([11]) 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, ELI: http://data.europa.eu/eli/reg/2006/1907/2014-04-10).

(10) Consequently, for reasons beyond the control of the applicants, the approvals are likely to expire before decisions have been taken on their renewals. It is therefore appropriate to postpone the expiry date of the approvals 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 authorities, the preparation and submission by the Agency of its opinions and the time needed for the Commission to decide whether to renew the approval of these active substances for use in biocidal products of product-type 14, the expiry dates should be postponed to 31 December 2026.

(11) After the postponement of the expiry dates of the approvals, brodifacoum, bromadiolone, chlorophacinone, coumatetralyl, difenacoum, difethialone and flocoumafen remain approved for use in biocidal products of product-type 14 subject to the conditions set out in the Annexes to their approvals,

HAS ADOPTED THIS DECISION:

Article 1

The expiry date of the approval of brodifacoum set out in the Annex to Implementing Regulation (EU) 2017/1381, of bromadiolone set out in the Annex to Implementing Regulation (EU) 2017/1380, of chlorophacinone set out in the Annex to Implementing Regulation (EU) 2017/1377, of coumatetralyl set out in Annex to Implementing Regulation (EU) 2017/1378, of difenacoum set out in Annex to Implementing Regulation (EU) 2017/1379, of difethialone set out in Annex to Implementing Regulation (EU) 2017/1382, and of flocoumafen set out in Annex to Implementing Regulation (EU) 2017/1383, for use in biocidal products of product-type 14 is postponed to 31 December 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, 27 February 2024.

For the Commission
The President
Ursula VON DER LEYEN