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COMMISSION IMPLEMENTING REGULATION (EU) 2025/1248

of 26 June 2025

renewing the approval of epsilon-metofluthrin as an active substance 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(4), point (a), thereof,

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 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'). The application was evaluated by the competent authority of Ireland ('the evaluating competent authority').

(3) During the examination of metofluthrin, the name of that active substance has been changed by the evaluating competent authority and the European Chemicals Agency ('the Agency') to epsilon-metofluthrin.

(4) On 7 March 2024, the evaluating competent authority submitted a recommendation on the renewal of the approval of epsilon-metofluthrin to the Agency.

(5) 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 renewal of approval of active substances. The Biocidal Products Committee adopted the opinion of the Agency on 25 November 2024 ([3]), having regard to the conclusions of the evaluating competent authority.

(6) In its opinion, the Agency concluded that biocidal products of product-type 18 containing epsilon-metofluthrin may be expected to still 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. Therefore, the conditions for renewal set out in Article 12(1), read in conjunction with Article 4(1), of Regulation (EU) No 528/2012 are considered satisfied.

(7) It is therefore appropriate to renew the approval of epsilon-metofluthrin for use in biocidal products of product-type 18, subject to compliance with certain conditions, including a condition for placing on the market of treated articles treated with or incorporating epsilon-metofluthrin. A period of transition should be set for new requirements concerning the placing on the market of treated articles treated with or incorporating epsilon-metofluthrin in order to allow sufficient time for economic operators to adapt.

([1]) OJ L 167, 27.6.2012, p. 1, ELI: http://data.europa.eu/eli/reg/2012/528/oj.
([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, ELI: http://data.europa.eu/eli/dir/1998/8/oj).
([3]) Biocidal Products Committee (BPC) Opinion on the application for renewal of the approval of the active substance: epsilon-Metofluthrin, Product type: 18, ECHA/BPC/446/2024, adopted on 25 November 2024.

(8) In its opinion, the Agency also concludes that epsilon-metofluthrin meets the criteria for being a persistent and toxic substance in accordance with Annex XIII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council [4]. Epsilon-metofluthrin therefore meets the condition laid down in Article 10(1), point (d), of Regulation (EU) No 528/2012 and should, therefore, for the purposes of Article 23(1) of that Regulation, be considered a candidate for substitution. Therefore, the period of renewal should not exceed 7 years, pursuant to Article 10(4) of Regulation (EU) No 528/2012.

(9) In accordance with Article 23(1) of Regulation (EU) No 528/2012 the competent authorities of the Member States are to perform a comparative assessment as part of the evaluation of an application for authorisation or for renewal of authorisation of a biocidal product containing an active substance that is a candidate for substitution.

(10) 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 epsilon-metofluthrin as an active substance for use in biocidal products of product-type 18 is renewed, 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, 26 June 2025.

For the Commission
The President
Ursula VON DER LEYEN

[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, ELI: http://data.europa.eu/eli/reg/2006/1907/oj).

ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance ([1])	Expiry date of approval	Product type	Specific conditions
epsilon-metofluthrin	IUPAC name: 2,3,5,6-tetrafluoro-4-(methoxymethyl) benyzl-(1R,3R)-2,2-dimethyl-3-[(Z)-prop-1-enyl]cyclopropane carboxylate EC No: none CAS No: 240494-71-7	sum of all isomers: 946 g/kg RTZ (1 R, 3R = Trans, Z -2,3,5,6-tetrafluoro-4-(methoxymethyl) benyzl-(1R,3R)-2,2-dimethyl-3-[(Z)-prop-1-enyl] cyclopropane carboxylate) isomer: 870 g/kg	31 May 2032	18	1. Epsilon-metofluthrin is a candidate for substitution in accordance with Article 10(1), point (d), of Regulation (EU) No 528/2012. 2. The authorisation of biocidal products containing epsilon-metofluthrin as an active substance is subject to the following conditions: (a) the product assessment pays 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 assessment of the active substance; (b) for products that may lead to residues in food or feed, it is assessed whether new maximum residue limits or maximum residue levels need to be set or the existing maximum residue limits or maximum residue levels need to be amended respectively in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council ([2]) or Regulation (EC) No 396/2005 of the European Parliament and of the Council ([3]), and any appropriate risk mitigation measures are taken to ensure that such maximum residue limits or maximum residue levels are not exceeded; (c) Member States' competent authorities or, in the case of a Union authorisation, the Commission, specify in the summary of the biocidal product characteristics the relevant instructions for use and precautions to be indicated on the label of the treated articles under Article 58(3), second subparagraph, point (e), of Regulation (EU) No 528/2012.

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance ([1])	Expiry date of approval	Product type	Specific conditions
					3. The placing on the market of treated articles is subject to the following condition: as from 1 December 2025, the person responsible for the placing on the market of a treated article treated with or incorporating epsilon-metofluthrin shall ensure that the label of that treated article provides the information listed in Article 58(3), second subparagraph, of Regulation (EU) No 528/2012.

([1]) The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product made available on the market may be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.

([2]) 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, ELI: http://data.europa.eu/eli/reg/2009/470/oj).

([3]) 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, ELI: http://data.europa.eu/eli/reg/2005/396/oj).

ELI: http://data.europa.eu/eli/reg_impl/2025/1248/oj