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COMMISSION IMPLEMENTING REGULATION (EU) 2025/1043

of 26 May 2025

approving formic acid as an existing active substance for use in biocidal products of product-type 6 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 89(1), third subparagraph, thereof,

Whereas:

(1) Commission Delegated Regulation (EU) No 1062/2014 ([2]) establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That list includes formic acid (EC No: 200-579-1; CAS No: 64-18-6) for product-type 6.

(2) Formic acid has been evaluated for use in biocidal products of product-type 6 (in-can preservatives), as described in Annex V to Directive 98/8/EC of the European Parliament and of the Council ([3]), which corresponds to product-type 6 (preservatives for products during storage), as described in Annex V to Regulation (EU) No 528/2012.

(3) Belgium was designated as the rapporteur Member State and its evaluating competent authority submitted the assessment report together with its conclusions to the European Chemicals Agency ('the Agency') on 15 September 2021. The Agency discussed the assessment report and the conclusions in technical meetings.

(4) 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 approval of active substances. In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014 read in conjunction with Article 75(1) and (4) of Regulation (EU) No 528/2012, the Biocidal Products Committee adopted the opinion of the Agency on 8 June 2022 ([4]), having regard to the conclusions of the evaluating competent authority. In its opinion, the Agency concluded that formic acid may be approved as an active substance for use in biocidal products of product-type 6.

(5) On 18 July 2023, pursuant to Article 75(1), second subparagraph, point (g), of Regulation (EU) No 528/2012, the Commission requested the Agency ([5]) to revise its opinion as the efficacy of the representative biocidal product has not been appropriately assessed in accordance with the applicable Agency's guidance document ([6]) on efficacy, and since that efficacy issue was not adequately identified by the evaluating competent authority during the evaluation nor during the review by the Agency. In particular, the Commission requested the examination of tier 2 efficacy data representing real-life conditions.

([1]) OJ L 167, 27.6.2012, p. 1, ELI: http://data.europa.eu/eli/reg/2012/528/oj.

([2]) Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1, ELI: http://data.europa.eu/eli/reg_del/2014/1062/oj).

([3]) 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).

([4]) Biocidal Products Committee Opinion on the application for approval of the active substance formic acid; Product-type: 6; ECHA/BPC/329/2022, adopted on 8 June 2022.

([5]) Mandate requesting ECHA opinions under Article 75(1)(g) of the BPR – 'Examination of efficacy tier 2 data on specific active substances acting as preservatives (product-types 6-13)'.

([6]) ECHA Guidance on the Biocidal Products Regulation: Volume II Efficacy, Assessment + Evaluation (Parts B+C); Version 3.0, April 2018.

(6) The Biocidal Products Committee adopted the revised opinion of the Agency for approval of the active substance formic acid for product-type 6 on 18 September 2024 ([7]). In that opinion, the Agency concluded that biocidal products of product-type 6 containing formic acid may be expected to 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.

(7) Taking into account the opinion of the Agency, it is appropriate to approve formic acid as an active substance for use in biocidal products of product-type 6 subject to compliance with certain conditions, including conditions for placing on the market of treated articles treated with or incorporating formic acid in accordance with Article 4(3) of Regulation (EU) No 528/2012 read in conjunction with Article 58(3) of that Regulation.

(8) A reasonable period should be allowed to elapse before an active substance is approved in order to permit interested parties to take the preparatory measures necessary to meet the new requirements.

(9) 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

Formic acid is approved as an active substance for use in biocidal products of product-type 6, 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 May 2025.

For the Commission
The President
Ursula VON DER LEYEN

([7]) Biocidal Products Committee Opinion on the application for approval of the active substance formic acid; Product-type: 6; ECHA/BPC/444/2024, adopted on 18 September 2024.

ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance [1]	Date of approval	Expiry date of approval	Product type	Specific conditions
Formic acid	Methanoic Acid EC No: 200-579-1 CAS No: 64-18-6	99 % weight/weight	1 October 2026	30 September 2036	6	1. The authorisation of biocidal products containing formic acid 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) the product assessment pays particular attention to professional users; (c) for products that may lead to residues in food or feed, it is assessed whether new maximum residue limits need to be set or the existing maximum residue limits need to be amended in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council [2] or whether new maximum residue levels need to be set or the existing maximum residue levels needs to be amended in accordance with 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; (d) Member States' competent authorities or, in the case of a Union authorisation the Commission, specify in the summary of the biocidal product characteristics for a biocidal product containing formic acid, the relevant instructions for use and precautions to be

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance ([1])	Date of approval	Expiry date of approval	Product type	Specific conditions
						indicated on the label of the treated articles under Article 58(3), second subparagraph, point (e), of Regulation (EU) No 528/2012. 2. The placing on the market of treated articles is subject to the following condition: the person responsible for the placing on the market of a treated article treated with or incorporating formic acid ensures 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 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.

([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).

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