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[...] (2023) **XXX** draft

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

approving formic acid as an existing active substance for use in biocidal products of product-types 2, 3, 4 and 5 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(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 products¹, and in particular Article 89(1), third subparagraph, thereof,

Whereas:

- (1) Commission Delegated Regulation (EU) No 1062/2014² establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That list includes formic acid for product-types 2, 3, 4 and 5.
- (2) Formic acid has been evaluated for use in biocidal products of product-types 2 (disinfectants and algacides not intended for direct application to humans or animals), 3 (veterinary hygiene), 4 (food and feed area) and 5 (drinking water), 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 reports together with the conclusions of its evaluation to the European Chemicals Agency (the ‘Agency’) on 15 September 2021. The Agency discussed the assessment reports 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 opinions of the Agency³ on 8 June 2022, having regard to the conclusions of the evaluating competent authority.

¹ OJ L 167, 27.6.2012, p. 1.

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).

³ Biocidal Products Committee Opinions on the application for approval of the active substance *formic acid*, Product-types 2, 3, 4 and 5; ECHA/BPC/325/2022, ECHA/BPC/326/2022, ECHA/BPC/327/2022 and ECHA/BPC/328/2022.

- (5) In those opinions, the Agency concludes that biocidal products of product-types 2, 3, 4 and 5 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.
- (6) Taking into account the opinions of the Agency, it is appropriate to approve formic acid as an active substance for use in biocidal products of product-types 2, 3, 4 and 5 subject to compliance with certain conditions.
- (7) 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.
- (8) 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-types 2, 3, 4 and 5, 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,

For the Commission
The President
Ursula VON DER LEYEN