Commission Implementing Regulation (EU) 2020/1763 of 25 November 2020 approving formaldehyde as an existing active substance for use in biocidal products of product-types 2 and 3 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1763

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approving formaldehyde as an existing active substance for use in biocidal products of product-types 2 and 3

(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 the third subparagraph of Article 89(1) 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 lists includes formaldehyde.

(2) Formaldehyde has been evaluated for use in biocidal products of product-type 2, private area and public health area disinfectants and other biocidal products, and product-type 3, veterinary hygiene biocidal products, as described in Annex V to Directive 98/8/EC of the European Parliament and of the Council[(3)], which correspond respectively to product-types 2 and 3 as described in Annex V to Regulation (EU) No 528/2012.

(3) The evaluating competent authority of Germany submitted the assessment reports together with its conclusions to the Commission on 29 July 2013.

(4) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the opinions of the European Chemicals Agency[(4)] (the 'Agency') were adopted on 10 December 2019 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.

(5) It can be derived from Article 90(2) of Regulation (EU) No 528/2012 that substances for which the Member States' evaluation has been completed by 1 September 2013 should be evaluated in accordance with the provisions of Directive 98/8/EC.

(6) According to the opinions of the Agency, biocidal products of product-types 2 and 3 containing formaldehyde may be expected to satisfy the requirements of Article 5 of Directive 98/8/EC, provided that certain specifications and conditions concerning their use are complied with.

(7) It is therefore appropriate to approve formaldehyde for use in biocidal products of product-types 2 and 3, subject to compliance with certain specifications and conditions.

(8) The opinions of the Agency conclude that formaldehyde meets the criteria for classification as carcinogen category 1B in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council[(5)].

(9) Since formaldehyde should be approved under the terms of Directive 98/8/EC, taking into account that property, the period of approval should be considerably shorter than 10 years, in accordance with the latest practice established under that Directive. In addition, since formaldehyde has benefitted from the transitional period provided for in Article 89 of Regulation (EU) No 528/2012 since 14 May 2000 and has been under peer review since 29 July 2013, and with the view to examine at Union level as soon as possible in the context of a potential renewal of approval whether the conditions of Article 5(2) of Regulation (EU) No 528/2012 can be satisfied for formaldehyde, the period of approval should be three years.

(10) Furthermore, pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the competent authorities of the Member States should evaluate whether the conditions of Article 5(2) of that Regulation can be satisfied in their territories in order to decide whether a biocidal product containing formaldehyde can be authorised.

(11) For the purposes of Article 23 of Regulation (EU) No 528/2012, formaldehyde meets the conditions laid down in point (a) of Article 10(1) of that Regulation and should therefore be considered a candidate for substitution. The competent authorities of the Member States should therefore perform a comparative assessment as part of the evaluation of an application for authorisation or for renewal of authorisation of a biocidal product containing formaldehyde.

(12) Since, as concluded by the Agency, formaldehyde meets the criteria for classification as carcinogen category 1B and as skin sensitiser category 1 in accordance with Annex I to Regulation (EC) No 1272/2008, treated articles treated with or incorporating formaldehyde should be appropriately labelled when placed on the market.

(13) This Regulation does not affect the application of Union law in the area of health and safety at work, in particular Council Directives 89/391/EEC[(6)] and 98/24/EC[(7)], and Directive 2004/37/EC of the European Parliament and of the Council[(8)].

(14) 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.

(15) 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

Formaldehyde is approved as an active substance for use in biocidal products of product-types 2 and 3, subject to the specifications and conditions set out in the Annex.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1763. (See end of Document for details)*

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, 25 November 2020.

For the Commission

The President

Ursula VON DER LEYEN

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1763. (See end of Document for details)*

ANNEX

Common Name	IUPAC NameIdentification Numbers	Minimum degree of purity of the active substance[a]	Date of approval	Expiry date of approval	Product type	Specific conditions
Formaldehyde	IUPAC Name: Methanal EC No: 200-001-8 CAS No: 50-00-0	25–55,5 % formaldehyde in aqueous solution (minimum purity 87,5 % w/w with regard to formaldehyde)	1 February 2022	31 January 2025	2	Formaldehyde is considered a candidate for substitution in accordance with point (a) of Article 10(1) of Regulation (EU) No 528/2012. The authorisations of biocidal products are subject to the following conditions: 1. The product assessment shall pay particular attention to the exposures, the risks

a 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.

b 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).

c 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).

						and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. In addition, pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the product assessment

a	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.
b	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).
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