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**[...]**(2020) **XXX** draft  
ANNEX

## **ANNEX**

**to the**

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

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

## ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance <sup>1</sup>	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 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 shall include an evaluation as to whether the conditions of Article 5(2) of Regulation (EU) No 528/2012 can be satisfied. 2) Products shall only be authorised for use in Member States where at least one of the conditions set in Article 5(2) of Regulation (EU) No 528/2012 is met. 3) In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to: i) professional users for products used for disinfection by mopping and wiping of surfaces; ii) secondary exposure of the general public and children; iii) the aquatic environment for products used for room disinfection by fumigation in epidemic cases.

<sup>1</sup> 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.

						<p>The placing on the market of treated articles is subject to the following condition that the person responsible for the placing on the market of a treated article treated with or incorporating formaldehyde shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012.</p>
					3	<p>Formaldehyde is considered a candidate for substitution in accordance with point (a) of Article 10(1) of Regulation (EU) No 528/2012.</p> <p>The authorisations of biocidal products are subject to the following conditions:</p> <ol style="list-style-type: none"> <li>1) The product assessment shall pay 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 risk assessment of the active substance. In addition, pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the product assessment shall include an evaluation as to whether the conditions of Article 5(2) of Regulation (EU) No 528/2012 can be satisfied.</li> <li>2) Products shall only be authorised for use in Member States where at least one of the conditions set in Article 5(2) of Regulation (EU) No 528/2012 is met.</li> <li>3) In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to: <ol style="list-style-type: none"> <li>i) professional users for products used for disinfection by spraying of animal housing and of vehicles in epidemic cases;</li> <li>ii) secondary exposure of the general public;</li> <li>iii) surface water, sediment, soil and groundwater following use of products for disinfection of vehicles and disinfection of animal's feet by bathing or dipping.</li> </ol> </li> <li>4) For products that may lead to residues in food or feed, it shall be verified whether new maximum residue levels</li> </ol>

						<p>(MRLs) need to be set or the existing MRLs need to be amended in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council<sup>2</sup> or Regulation (EC) No 396/2005 of the European Parliament and of the Council<sup>3</sup>, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.</p> <p>The placing on the market of treated articles is subject to the condition that the person responsible for the placing on the market of a treated article treated with or incorporating formaldehyde shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012.</p>
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<sup>2</sup> 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).

<sup>3</sup> 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).