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PLAN/1279/2023 ANNEX  
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ANNEX.docx)  
[...] (2023) **XXX** draft

ANNEX

**ANNEX**

**to the**

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

**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**

## 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
Formic acid	Methanoic Acid  EC No: 200-579-1  CAS No: 64-18-6	99 % w/w	1 November 2024	31 October 2034	2	The authorisation of biocidal products is subject to the following conditions:  (1) 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 risk assessment of the active substance;  (2) the product assessment pays particular attention to: (i) professional users; (ii) non-professional users; (iii) secondary exposure of the general public and children.
					3	The authorisation of biocidal products is subject to the following conditions:  (1) 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 risk assessment of the active substance;  (2) the product assessment pays particular attention to professionals users;  (3) for products that may lead to residues in food or feed, it shall be assessed whether new maximum residue levels ('MRLs') need to be set or the

<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.

						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 such MRLs are not exceeded.
					4	<p>The authorisation of biocidal products is subject to the following conditions:</p> <p>(1) 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 risk assessment of the active substance;</p> <p>(2) the product assessment pays particular attention to professional users;</p> <p>(3) for products that may lead to residues in food or feed, it shall be assessed whether new maximum residue levels (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 such MRLs are not exceeded.</p>

<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).

					5	<p>The authorisation of biocidal products is subject to the following conditions:</p> <ol style="list-style-type: none"> <li>(1) 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 risk assessment of the active substance;</li> <li>(2) the product assessment pays particular attention to: <ol style="list-style-type: none"> <li>(i) professional users;</li> <li>(ii) the environment: soil compartment;</li> </ol> </li> <li>(3) for products that may lead to residues in food or feed, it shall be assessed whether new maximum residue levels (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 such MRLs are not exceeded.</li> </ol>
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