EUROPEAN
COMMISSION

Brussels, XXX
PLAN/2158/2022
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[…](2022) XXX draft

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

not approving d-Allethrin as an existing active substance for use in biocidal products of product-type 18 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 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 (RS)-3-Allyl-2-methyl-4-oxocyclopent-2- enyl-(1R,3R;1R,3S)-2,2-dimethyl-3-(2-methylprop-1-enyl)-cyclopropanecarboxylate (mixture of 4 isomers 1R trans, 1R: 1R trans, 1S: 1R cis, 1R: 1R cis, 1S 4:4:1:1) ('d-Allethrin') (CAS No: 231937-89-6).

(2) D-Allethrin has been evaluated for use in biocidal products of product-type 18, (insecticides, acaricides and products to control other arthropods), as described in Annex V to Regulation (EU) No 528/2012.

(3) Germany 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 11 January 2017. After the submission of the assessment report, discussions took place in technical meetings organised by the Agency.

(4) In accordance with Article 75(1), 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, the Biocidal Products Committee adopted the opinion of the Agency on 12 October 2021[3], having regard to the conclusions of the evaluating competent authority.

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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 Opinion on the application for approval of the active substance: d-Allethrin, Product type: 18, ECHA/BPC/293/2021, adopted on 12 October 2021.

(5) According to the opinion of the Agency, biocidal products of product-type 18 containing d-Allethrin cannot be expected to meet the criteria laid down in Article 19(1), points (b)(iii), and (iv), of Regulation (EU) No 528/2012.

(6) In its opinion, the Agency noted that the proposed reference specifications, established on the basis of data provided by one of the applicants, are not in line with the composition of the material that was used for testing to generate the toxicological data provided by the applicants. As a result, on the basis of the data provided in the applications, it could not be established whether the representative biocidal products could fulfil the criteria referred to in Article 19(1), point (b) of Regulation (EU) No 528/2012.

(7) According to the opinion of the Agency, based on the available toxicological data, an unacceptable risk has been identified for the general public due to secondary exposure to genotoxic photometabolites formed after the application of the representative products.

(8) In addition, according to the opinion of the Agency, an unacceptable risk to the environment has been identified for the aquatic compartment (surface water and sediment) and for soil.

(9) In conclusion, no safe use could be identified when considering the risks to human health and the environment for each of the representative biocidal products submitted in the applications.

(10) The conditions for approval of d-Allethrin laid down in Article 4(1) of Regulation (EU) No 528/2012 are therefore not met.

(11) Taking into account the opinion of the Agency, it is not appropriate to approve d-Allethrin for use in biocidal products of product-type 18.

(12) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DECISION:

Article 1

D-Allethrin (CAS No: 231937-89-6) is not approved as an active substance for use in biocidal products of product-type 18.

Article 2

This Decision shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN