EUROPEAN
COMMISSION

Brussels, XXX
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COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

not approving empenthrin as an existing active substance for use in biocidal products of product-type 18

(Text with EEA relevance)

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not approving empenthrin as an existing active substance for use in biocidal products of product-type 18

(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) 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 empenthrin (EC No: n.a., CAS No: 54406-48-3).

(2) Empenthrin has been evaluated for use in 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) Belgium was designated as evaluating competent authority and submitted the assessment reports together with its recommendations on 24 June 2016.

(4) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the opinion of the European Chemicals Agency was formulated on 13 December 2017 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority[3].

(5) According to that opinion, biocidal products used for product-type 18 containing empenthrin may not be expected to satisfy the requirements laid down in Article 19(1)(b) of Regulation (EU) No 528/2012.

(6) In particular, according to Article 6(2) of Regulation (EU) No 528/2012, sufficient data is to be provided by the applicant in order to make it possible to determine whether an active substance meets the exclusion criteria referred to in Article 5(1) of that Regulation. The applicant has been requested on several occasions by the evaluating competent authority to provide data on carcinogenicity to perform this assessment, and failed to provide sufficient data in due time, making it impossible to assess the exclusion criterion set out in Article 5(1)(a) of that Regulation.

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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 (BPC), Opinion on the application for approval of the active substance Empenthrin, Product type: 18, ECHA/BPC/182/2017, Adopted on 13 December 2017.

(7) In addition, the scenarios evaluated in the human health and environmental risk assessments identified unacceptable risks and no safe use could be identified.

(8) It is therefore not appropriate to approve empenthrin for use in biocidal products of product-type 18.

(9) 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

Empenthrin (EC No: n.a., CAS No: 54406-48-3) 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
Jean-Claude JUNCKER