



Brussels, **XXX**  
SANTE/12069/2017 CIS  
(POOL/E4/2017/12069/12069-EN  
CIS.doc)  
[...] (2018) **XXX** draft

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

**of **XXX****

**approving cyphenothrin as an existing active substance for use in biocidal products of  
product-type 18**

(Text with EEA relevance)

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

**of XXX**

**approving cyphenothrin 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<sup>1</sup>, and in particular the third subparagraph of Article 89(1) thereof,

Whereas:

- (1) Commission Delegated Regulation (EU) No 1062/2014<sup>2</sup> establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That list includes cyphenothrin.
- (2) Cyphenothrin 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 Directive 98/8/EC of the European Parliament and of the Council<sup>3</sup>, which corresponds to product-type 18 as described in Annex V to Regulation (EU) No 528/2012.
- (3) Greece was designated as a rapporteur Member State and its evaluating competent authority submitted the assessment report together with its recommendations on 11 April 2013.
- (4) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the opinion of the European Chemicals Agency was formulated on 14 December 2017 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority<sup>4</sup>.
- (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 while taking into account the conditions set out in Article 5 of Directive 98/8/EC. Following the opinion of the European Chemicals Agency, biocidal products of product-type 18 containing cyphenothrin may be expected to

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<sup>1</sup> OJ L 167, 27.6.2012, p. 1.

<sup>2</sup> 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).

<sup>3</sup> Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).

<sup>4</sup> Biocidal Products Committee (BPC) Opinion on the application for approval of the active substance Cyphenothrin, Product type: 18, ECHA/BPC/183/2017, Adopted on 14 December 2017.

satisfy the requirements of Article 5 of Directive 98/8/EC, provided that certain specifications and conditions concerning their use are complied with.

- (6) It is therefore appropriate to approve cyphenothrin for use in biocidal products of product-type 18, subject to compliance with certain specifications and conditions.
- (7) The opinion of the European Chemicals Agency concludes that cyphenothrin meets the criteria for being a persistent (P) and toxic (T) substance in accordance with Annex XIII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council<sup>5</sup>.
- (8) For the purposes of Regulation (EU) No 528/2012, cyphenothrin meets the conditions set out in point (d) of Article 10(1) of Regulation (EU) No 528/2012 and should be therefore considered a candidate for substitution. The receiving competent authority or, in the case of an evaluation of an application for a Union authorisation, the evaluating competent authority, should perform a comparative assessment as part of the evaluation of an application for authorisation or for renewal of authorisation of a biocidal product containing cyphenothrin.
- (9) Since 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 approved under the terms of Directive 98/8/EC, the period of approval should be 10 years, in accordance with the practice established under that Directive.
- (10) 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.
- (11) 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*

Cyphenothrin is approved as an active substance for use in biocidal products of product-type 18, subject to the specifications and conditions set out in the Annex.

#### *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.

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<sup>5</sup> Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

Done at Brussels,

*For the Commission*  
*The President*  
*Jean-Claude JUNCKER*