Commission Implementing Decision (EU) 2019/641 of 17 April 2019 on the terms and conditions of the authorisation of a biocidal product family containing 1R-trans phenothrin referred by Ireland in accordance with Article 36 of Regulation (EU) No 528/2012 of the European Parliament and of the Council (notified under document C(2019) 2837) (Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) 2019/641

of 17 April 2019

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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 36(3) thereof,

Whereas:

(1) On 20 August 2015, the company CSI-Europe ('the applicant') submitted an application to the competent authorities of a number of Member States, including Germany, ('the Member States concerned') for mutual recognition in parallel of a biocidal product family of bait-based insecticides against ants containing the active substance 1R-trans phenothrin ('the contested product family'). Ireland acted as the Member State responsible for the evaluation of the application as referred to in Article 34(1) of Regulation (EU) No 528/2012 ('the reference Member State').

(2) Pursuant to Article 35(2) of Regulation (EU) No 528/2012, Germany referred objections to the coordination group on 30 June 2017 and to the applicant, indicating that the contested product family does not meet the condition laid down in Article 19(1)(b)(i) of that Regulation.

(3) Germany considers that the efficacy data provided by the applicant and evaluated by the reference Member State are not acceptable. Germany questions whether the palatability of the bait products was sufficiently demonstrated in the laboratory tests. It also questions the validity of the field study, since it was not performed during spring time, as well as the validity of the statistical analysis performed by the applicant. Moreover, Germany disagrees with the judgments made by the reference Member State based on expert advice, as referred to in point 12 of Annex VI to Regulation (EU) No 528/2012.

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Decision (EU) 2019/641. (See end of Document for details)*

(4) The coordination group secretariat invited the Member States concerned and the applicant to submit written comments about the referral. Belgium, Germany, Luxembourg, the Netherlands, the United Kingdom and the applicant submitted comments. The referral was also discussed in the meeting of the coordination group on 26 September 2017.

(5) As no agreement was reached in the coordination group, the reference Member State referred the unresolved objections to the Commission pursuant to Article 36(1) of Regulation (EU) No 528/2012 on 16 January 2018. The reference Member State thereby provided the Commission with a detailed statement of the matters on which Member States were unable to reach agreement and the reasons for their disagreement. A copy of that statement was forwarded to the Member States concerned and the applicant.

(6) On 16 February 2018, the Commission requested an opinion from the European Chemicals Agency ('the Agency') pursuant to Article 36(2) of Regulation (EU) No 528/2012 on a number of questions concerning the unresolved objections.

(7) The Agency adopted its opinion[(2)] on 18 October 2018.

(8) According to the Agency, the palatability of the bait products covered by the contested product family is sufficiently demonstrated for the claimed use.

(9) Furthermore, the Agency indicates in its opinion that the field study is valid, since it shows a greater reduction in ant population in the treated nests compared to the control nests. Moreover, the Agency considers that the statistical analysis of the results of the field study performed by the applicant is acceptable. Taking into account the agreed Union guidance[(3)] applicable at the time of submission of the application, the Agency concludes that the efficacy of the contested product family for the claimed use is sufficiently demonstrated by the field data provided by the applicant.

(10) In light of the opinion of the Agency, the contested product family is sufficiently effective as required under Article 19(1)(b)(i) of Regulation (EU) No 528/2012.

(11) 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

This Decision applies to the biocidal product family identified by the case number BC-LR019221-36 in the Register for Biocidal Products.

Article 2

The biocidal product family referred to in Article 1 meets the condition laid down in Article 19(1)(b)(i) of Regulation (EU) No 528/2012.

Article 3

This Decision is addressed to the Member States.