COMMISSION IMPLEMENTING DECISION (EU) 2018/1305

of 26 September 2018

on the terms and conditions of the authorisation of a biocidal product family containing deltamethrin referred by Sweden in accordance with Article 36 of Regulation (EU) No 528/2012 of the European Parliament and of the Council

(notified under document number C(2018) 5503)

(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 29 August 2013, the company Bayer CropScience Deutschland GmbH ('the applicant') submitted an application to Germany ('the Member State concerned') for the mutual recognition of an insecticide biocidal product family containing the active substance deltamethrin ('the contested product family'). Applications for mutual recognition of the contested product family were also submitted to a number of other Member States. The competent authority of Sweden acted as the Member State responsible for the evaluation of the application 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 an objection to the coordination group on 23 February 2017, indicating that the contested product family does not meet the conditions laid down in Article 19(1)(c) of that Regulation.

(3) Germany considers that the determination of the quantity of active substance in the contested product family made by the reference Member State, and indicated in the draft summary of the product characteristics established pursuant to Article 22(2)(e) of Regulation (EU) No 528/2012, is not correct. Germany argues that excluding the impurities of the active substance when expressing the quantitative composition in terms of the main constituent of that substance, is inconsistent with the definition of an active substance laid down in Article 3(1)(c) of that Regulation, which in turn refers to the definition of a substance laid down in Article 3(1) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([2]). Since the definition of a substance in Article 3(1) of Regulation (EC) 1907/2006 refers to a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, the quantitative composition should, according to the objection referred by Germany, not refer only to the content of the active substance without impurities.

(4) The coordination group secretariat invited the other Member States and the applicant to submit written comments about the referral. Austria, Belgium, Denmark, France, the Member State concerned, Hungary, Norway, the reference Member State, the United Kingdom and the applicant submitted comments. The referral was also discussed in the coordination group's meetings of 14 March 2017 and 10 May 2017.

(5) As no agreement was reached in the coordination group, the reference Member State referred the unresolved objection to the Commission pursuant to Article 36(1) of Regulation (EU) No 528/2012 on 18 May 2017. It hereby 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) The reference Member State, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Finland, France, Latvia, Luxembourg, Norway, Slovenia and Switzerland authorised the contested product family in the period from 29 June 2017 to 19 December 2017 pursuant to Article 34(7) of Regulation (EU) No 528/2012.

([1]) OJ L 167, 27.6.2012, p. 1.

([2]) 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).

(7) According to the definition laid down in Article 3(1)(c) of Regulation (EU) No 528/2012, an active substance means a substance that has an action on or against harmful organisms. Pursuant to Article 3(2) of that Regulation, the definition in Article 3(1) of Regulation (EC) No 1907/2006 is to apply for the term 'substance'. According to that definition, a substance also includes any additive necessary to preserve its stability and any impurity deriving from the process used. The risk assessment and the efficacy assessment carried out for the approval of deltamethrin as an active substance in accordance with Article 4 of Regulation (EU) No 528/2012 were based on the active substance including its impurities, and the approval itself sets a minimum degree of purity to be observed by any source of that active substance.

(8) Therefore, a reference to the content of the active substance in the contested product family should not relate to the concentration of the main constituent of the active substance on its own without impurities.

(9) On 30 April 2018, the Commission provided the applicant with the opportunity to provide written comments in accordance with Article 36(2) of Regulation (EU) No 528/2012. The Commission took into account the comments provided by the applicant.

(10) 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 asset number SE-0017809-0000 in the Register for Biocidal Products.

Article 2

The minimum and maximum percentage for the concentration of the active substance in the biocidal product family referred to in Article 1, as referred to in Article 22(2)(e) of Regulation (EU) No 528/2012, shall be expressed by considering the active substance as it was approved, which includes the main constituent of the active substance and any additives or impurities.

Under the terms and conditions set out in paragraph 1, the biocidal product family referred to in Article 1 meets the conditions laid down in Article 19(1)(c) of Regulation (EU) No 528/2012.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 26 September 2018.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission