COMMISSION IMPLEMENTING DECISION (EU) 2016/1175

of 15 July 2016

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

(notified under document C(2016) 4385)

(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) The company Scotts Celaflor GmbH ('the applicant') submitted a complete application to Germany ('the Member State concerned') on 29 June 2015 for the mutual recognition of an authorisation granted by the United Kingdom ('the reference Member State') in respect of an insecticide biocidal product containing the active substance spinosad as a granular solid bait formulation to be applied directly or to be diluted and applied as liquid drench ('the contested product').

(2) The reference Member State authorised the contested product on 23 April 2015 for use by the general public against ants outdoors by means of direct application to ant nests. The authorisation has subsequently been mutually recognised by Ireland.

(3) Pursuant to Article 35(2) of Regulation (EU) No 528/2012, the Member State concerned referred a point of disagreement to the coordination group on 26 October 2015 indicating that the contested product does not meet the conditions laid down in Article 19(1)(b)(iv) of that Regulation.

(4) The Member State concerned considers that the contested product does not fulfil the requirement set out in paragraph 66 of Annex VI to Regulation (EU) No 528/2012 as the PEC/PNEC ratio for the soil compartment is greater than 1 and as a result the contested product poses an unacceptable risk to the environment, albeit in very small areas and for very short periods of time.

(5) The coordination group secretariat invited the other Member States and the applicant to submit written comments about the referral. Belgium, France, the Netherlands, the United Kingdom and the applicant submitted comments. The referral was also discussed by the Member States' competent authorities for biocidal products in the coordination group's meetings of 17 November 2015 and 20 January 2016.

(6) As no agreement was reached by the coordination group, the reference Member State provided the Commission on 5 February 2016 with a detailed statement of the matters on which Member States were unable to reach agreement and the reasons for their disagreement, pursuant to Article 36(1) of Regulation (EU) No 528/2012. A copy of that statement was also forwarded to the Member States concerned and the applicant.

(7) As regards the unresolved objection referred to the Commission, paragraph 66 of Annex VI to Regulation (EU) No 528/2012 sets out that where the PEC/PNEC ratio is greater than 1, the evaluating body is to judge, on a case-by-case basis, the elements or the risk mitigation measures to be considered in order to conclude whether the biocidal product complies with Article 19(1)(b)(iv).

(8) From the discussions within the coordination group, it seems that there is a lack of agreed Union guidance to assist the evaluating body in making such a judgment.

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

(9) From those discussions it also follows that the unacceptable risk identified is limited because of the use pattern of the product, which is only applied to small areas (for example on ant nests) and is expected to break down in a short period of time so that non-target species can recolonise the treated area after use.

(10) In the absence of agreed Union guidance, the conclusion of the reference Member State was based on the available information and on the judgement of its experts, pursuant to paragraph 12 of Annex VI to Regulation (EU) No 528/2012.

(11) Against this background and until such agreed guidance is formally adopted, the conclusion reached by the reference Member State on the point of disagreement is considered to be valid until the renewal of the product authorisation.

(12) From the discussions within the coordination group it also follows that the current terms and conditions of the product authorisation should better describe the field of use of the contested product and should provide some information on its application. Those terms and conditions should therefore be amended accordingly.

(13) 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 product identified by the asset number UK-0008829-0000, as provided for by the Register for Biocidal Products.

Article 2

The product meets the conditions laid down in Article 19(1)(b)(iv) of Regulation (EU) No 528/2012.

Article 3

1. The field of use in the product authorisation is amended as follows: 'Outdoor use (only for direct application to ant nests around domestic premises)'.

2. The sentence 'Apply directly to the nest only' listed in the product authorisation as both an instruction for use and as a risk mitigation measure is replaced by the following: 'Apply this biocidal product directly to ant nests only. Do not scatter dry granules or pour liquid onto hard surfaces or bare soil used as ant runways'.

Article 4

This Decision is addressed to the Member States.

Done at Brussels, 15 July 2016.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission