COMMISSION IMPLEMENTING DECISION (EU) 2015/1751

of 29 September 2015

on the terms and conditions of the authorisation of a biocidal product containing bromadiolone 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(2015) 6516)

(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 Rentokil Initial 1927 plc ('the applicant') submitted on 8 April 2014 a complete application to Germany ('the concerned Member State') for mutual recognition of an authorisation granted by the United Kingdom ('the reference Member State') in respect of a rodenticide biocidal product containing the active substance bromadiolone as a wax block formulation ('the contested product').

(2) The reference Member State authorised the contested product on 17 February 2014 for use in and around buildings against mice and rats and in sewers against rats. The authorisation has subsequently been mutually recognised by Estonia, Ireland, Luxembourg, the Netherlands and Norway.

(3) In accordance with Article 35(2) of Regulation (EU) No 528/2012, the concerned Member State referred to the Coordination Group established under Article 35 of that Regulation on 9 September 2014 three points of disagreement indicating that the contested product does not meet the conditions laid down in Article 19 of that Regulation.

(4) The concerned Member State considers that (a) regarding the use in and around buildings against rats, the efficacy has not been demonstrated since the results of two out of the three field trials submitted by the applicant did not demonstrate an acceptable level of efficacy; (b) regarding the use in sewers against rats, the approach followed by the reference Member State to establish the efficacy of the product is not acceptable as a consequence of the first point of disagreement; (c) regarding the use against mice, the set of laboratory studies and one out of the two field trials submitted by the applicant failed to fulfil the criteria to demonstrate efficacy.

(5) The Coordination Group Secretariat invited the other Member States and the applicant to submit written comments to the referral and comments were submitted by Belgium, Denmark, France, Germany, the Netherlands, Spain and the United Kingdom. The referral was also discussed between the Member States' Competent Authorities for biocidal products in the meeting of the Coordination Group of 11 November 2014.

(6) As no agreement was reached within the Coordination Group, in accordance with Article 36(1) of Regulation (EU) No 528/2012 the reference Member State referred to the Commission on 13 March 2015 a detailed statement of the matters on which Member States were unable to reach agreement and the reasons for their disagreement. A copy of this statement was also forwarded to the Member States concerned referred to in Article 35(2) of that Regulation and the applicant.

(7) Concerning the efficacy against rats in and around buildings, the results of the laboratory tests and of one of the field trials submitted by the applicant demonstrate an acceptable level of efficacy against the criteria established in

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

the EU guidance on efficacy evaluation of rodenticides (hereafter 'the EU guidance') ([1]). In addition, the availability of at least one valid field trial was deemed to be in line with the EU guidance and acceptable to demonstrate the efficacy of a rodenticide by the Coordination Group in a previous similar case ([2]).

(8) Concerning the efficacy against rats in sewers, the reference Member State used the results of one of the field trials submitted by the applicant demonstrating an acceptable level of efficacy to overcome the inconclusive results of the palatability studies. The same approach was used previously by the concerned Member State during the evaluation of a similar product, but with positive results from three field trials.

(9) Concerning the use against mice, the laboratory studies do not fulfil the criteria established in the EU guidance. However, that EU guidance also establishes that results of field trials might outweigh those of laboratory trials. In the present case, the results of one of the field trials demonstrate an acceptable level of efficacy against the criteria established in the available EU guidance.

(10) In the light of the elements referred to in recitals 7 to 9, the Commission considers the conclusions reached by the reference Member State on the three points of disagreement to be valid.

(11) The Commission also notes that the conclusions reached by the reference Member State on the basis of these elements and of the judgement of its experts, as provided for by paragraph 12 of Annex VI to Regulation (EU) No 528/2012, were supported by those Member States having authorised the contested product through mutual recognition.

(12) Since the legal basis for this Decision is Article 36(3) of that Regulation, this decision should be addressed to all Member States by virtue of Article 36(4) of that Regulation.

(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-0005252-0000, as provided for by the Register for Biocidal Products.

Article 2

The product meets the condition laid down in Article 19(1)(b)(i) of Regulation (EU) No 528/2012 of being sufficiently effective for use in and around buildings against mice and rats and in sewers against rats.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 29 September 2015.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

([1]) See Technical Notes for Guidance on Product Evaluation. Appendices to Chapter 7. Product Type 14: Efficacy Evaluation of Rodenticidal Biocidal Products, available on the website http://echa.europa.eu/documents/10162/16960215/bpd_guid_revised_appendix_chapter_7_pt14_2009_en.pdf

([2]) See the agreement reached at the 10th Coordination Group meeting regarding the efficacy of a rodenticide biocidal product containing coumatetralyl against mice, available at https://circabc.europa.eu/sd/a/0ca55b45-1c74-4c78-b125-de52fd53c08c/Racumin%20Paste_disagreement%20to%20CG_formal_with%20outcome_public.pdf