COMMISSION IMPLEMENTING DECISION (EU) 2016/1174

of 15 July 2016

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

(notified under document C(2016) 4380)

(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 Will Kill S.A. ('the applicant') submitted a complete application to France ('the Member State concerned') on 20 December 2013 for the mutual recognition of an authorisation granted by Spain ('the reference Member State') in respect of a rodenticide biocidal product containing the active substance difenacoum as a liquid formulation ('the contested product').

(2) The reference Member State authorised the contested product for use against mice and the rat species *Rattus norvegicus* ('rats') for use indoors and in and around buildings by professional users, and outdoors by trained professional users only. The contested product is supplied in non-reusable bottles together with a roll-on dispenser and a bait station ('the device') in order to avoid primary and secondary poisoning. After use, the whole device is to be disposed of in order to avoid exposure to the user.

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

(4) The coordination group secretariat invited the other Member States and the applicant to submit written comments about the referral. Austria, France, Germany, Italy, the Netherlands, Norway, Portugal, Spain, Sweden, the United Kingdom and the applicant submitted comments. The identified points of disagreement were discussed by the Member States' competent authorities for biocidal products in the coordination group's meetings of 23 January and 17 March 2015.

(5) Pursuant to Article 36(1) of Regulation (EU) No 528/2012, the reference Member State 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 on 30 June 2015. A copy of that statement was also forwarded to the Member States concerned and the applicant.

(6) The unresolved objections referred to the Commission concerned the efficacy of the contested product against rats and mice, which was insufficiently demonstrated in well-documented field trials; the efficacy in Member States with wet climates, which might be reduced as a result of the target organisms having easier access to water; the efficiency of the device as a risk mitigation measure to avoid leaching; and an unacceptable risk to the health of users during the cleaning of bait stations.

(7) Pursuant to paragraph 12 of Annex VI to Regulation (EU) No 528/2012, the reference Member State considered the contested product to be sufficiently effective on the basis of field data generated by using a prototype device and the judgment of its experts. That conclusion was conditional, however, on the submission of field data corroborating those findings.

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

(8) The reference Member State concluded that the results of the field trials submitted by the applicant demonstrate an acceptable level of efficacy in accordance with the criteria established in the Union guidance on efficacy evaluation of rodenticides ([1]).

(9) Concerning efficacy in wet climates, the indoor use of the product in areas where abundant food or feed is available to rodents shows no significant difference across Member States. Regarding use in and around buildings and outdoors, the product authorisation already includes a condition to restrict the use of the product to situations where it is difficult to access water. Given that the product was sufficiently effective in field trials in areas with full access to water, the product authorisation should not be subject to any restriction on the grounds of specific weather conditions.

(10) The reference Member State considered the device to be a suitable risk mitigation measure to prevent spillage and avoid primary and secondary poisoning compared to the application of the contested product in open trays. This conclusion was confirmed in the field trials where spillage only occurred twice due to an accident with agriculture machinery or vandalism. In order to limit accidental spillage as much as possible, the product authorisation should include additional instructions for use such as fixing the bait station to the ground and a recommendation that in the event of an accidental spillage, the bait station is to be disposed of as hazardous waste.

(11) The reference Member State assessed the health risk to users of the product by using a model developed for solid bait formulations and by using very conservative parameters under a worst case scenario. As an unacceptable risk to the user was identified, a risk mitigation measure was introduced stating that the device was to be disposed of after use in order to prevent any potential exposure during the cleaning of the bait stations.

(12) The product authorisation has been subject to an agreed change based on a recalculation of the risk to human health as a result of exposure to the contested product based on a product-specific dermal absorption study and new parameters generated by the applicant based on the real use of the contested product (for example the number of splashes to which the user may be exposed as well as the droplet size of the splash).

(13) Given the risk of accidental splash, additional risk mitigation measures should be included in the authorisation. Those measures should include restricting use to trained professional users only and the specification that users wear protective gloves. Taking into account that trained professional users are expected to follow the instructions for use closely, the contested product is expected to be safe for this category of user under the proposed terms and conditions.

(14) In order to avoid unnecessary plastic waste, the current condition of the authorisation to supply the product and the roll-on dispenser together with the bait station as a single device and to dispose of the whole device, including the bait station, after use should be removed from the authorisation.

(15) 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 ES-0000196-0000, as provided for by the Register for Biocidal Products.

Article 2

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

([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. The condition restricting the use of the product to situations where it is difficult to access water shall be removed from the product authorisation.

Article 3

1. The user category in the authorised uses of the product shall be restricted to trained professional users only.

2. The product authorisation shall include the following risk mitigation measure: 'Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information)'.

3. The condition to supply the product and the roll-on dispenser together with the bait station as a single device and to dispose of the bait station as part of the whole device after use of the product shall be removed from the product authorisation.

4. Under the terms and conditions set out in paragraphs 1, 2 and 3, the product meets the conditions laid down in Article 19(1)(b)(iii) of Regulation (EU) No 528/2012.

Article 4

1. The following instructions for use shall be included in the product authorisation:

— 'Fix the bait station to the ground'.

— 'In case of accidental spillage of the liquid, dispose of the bait station as hazardous waste'.

2. Under the terms and conditions set out in paragraph 1, the product meets the conditions laid down in Article 19(1)(b)(iv) of Regulation (EU) No 528/2012.

Article 5

This Decision is addressed to the Member States.

Done at Brussels, 15 July 2016.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission