COMMISSION IMPLEMENTING DECISION

of 4 October 2013

rejecting a refusal of the authorisation of a biocidal product containing difenacoum notified by the Netherlands in accordance with Directive 98/8/EC of the European Parliament and of the Council

(notified under document C(2013) 6409)

(Only the Dutch text is authentic)

(2013/501/EU)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market [1], and in particular Article 4(4) thereof,

Whereas:

(1) Annex I to Directive 98/8/EC contains the list of active substances approved at Union level for inclusion in biocidal products. Commission Directive 2008/81/EC of 29 July 2008 amending Directive 98/8/EC of the European Parliament and of the Council to include difenacoum as an active substance in Annex I thereto [2] added the active substance difenacoum for use in products belonging to product-type 14, Rodenticides, as defined in Annex V to Directive 98/8/EC.

(2) The company Edialux France submitted an application to France for authorisation of a product containing difenacoum as a paraffin block formulation ('the contested product') in accordance with Article 8 of Directive 98/8/EC. The name and reference numbers of the contested product in the Register for Biocidal Products ('R4BP') are indicated in the Annex to this Decision.

(3) France authorised the contested product on 23 February 2012. The authorisation has subsequently been mutually recognised by Germany, Luxembourg, Belgium and Switzerland.

(4) On 3 July 2012, Denka Registrations BV ('the applicant') submitted a complete application to the Netherlands for mutual recognition of the French authorisation of the contested product.

(5) On 24 January 2013, the Netherlands notified the Commission, the other Member States and the applicant of its proposal to refuse the authorisation in accordance with Article 4(4) of Directive 98/8/EC. The Netherlands considered that the contested product does not meet the requirement of being sufficiently effective in accordance with Article 5(1) of Directive 98/8/EC, as its efficacy was not demonstrated in field or semi-field trials. According to the notification, efficacy of rodenticide products is a matter of particular concern for the Netherlands, as resistance problems have been reported both in rats and mice.

(6) The Commission invited the other Member States and the applicant to submit comments to the notification in writing within 90 days in accordance with Article 27(1) of Directive 98/8/EC. Comments were submitted within that deadline by France, Belgium and the applicant. The notification was also discussed between Commission representatives and representatives of Member States' Competent Authorities for biocidal products in the meeting of the Product Authorisation and Mutual Recognition Facilitation Group of 25-26 February 2013, where the applicant was present.

(7) From the comments received, it follows that France assessed the product's efficacy in accordance with the available EU guidance on efficacy evaluation of rodenticidal biocidal products [3]. Although both laboratory and field studies performed with the product to be authorised are normally required when applying for authorisation of a rodenticide, field trials can be waived by read-across to data generated with another product authorised in accordance with Directive 98/8/EC containing the same active substance and already authorised for the same field of use.

(8) The conclusions on the efficacy of the contested product were therefore based on the read-across to data generated with another grain formulation rodenticide (Sorkil Avoine Speciale [4]) meeting the characteristics required by the abovementioned guidance document, for which field and semi-field tests on the target species proved the efficacy of the product.

(9) As requested by the guidance document, bait choice tests also demonstrated that palatability was not affected by

[1] OJ L 123, 24.4.1998, p. 1.
[2] OJ L 201, 30.7.2008, p. 46.
[3] 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://ihcp.jrc.ec.europa.eu/our_activities/public-health/risk_assessment_of_Biocides/doc/TNsG/TNsG_PRODUCT_EVALUATION/Revised_Appendix_Chapter_7_PT14_2009.pdf
[4] French application reference number in the Register for Biocidal Products: 2010/6309/6308/FR/AA/7742. Date of authorisation: 1 October 2011.

the bait formulation and that the contested product was more palatable for mice and equally palatable for rats than the product Sorkil Avoine Speciale.

(10) In the light of the above arguments, the Commission supports the conclusions of the assessment carried out by France and the other Member States having mutually recognised the French authorisation, considering the contested product sufficiently effective as required by Article 5(1) of Directive 98/8/EC. The Commission therefore considers that the request by the Netherlands to refuse the authorisation cannot be justified on the grounds put forward.

(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

The proposal by the Netherlands to refuse the authorisation granted by France on 23 February 2012 of the product mentioned in the Annex, is rejected.

Article 2

This Decision is addressed to the Kingdom of the Netherlands.

Done at Brussels, 4 October 2013.

For the Commission
Janez POTOČNIK
Member of the Commission

ANNEX

Product for which the proposal by the Netherlands, to refuse the authorisation granted in accordance with Article 4 of Directive 98/8/EC, is rejected:

Product name in France	French application reference number in the Register for Biocidal Products	Product name in the Netherlands	Dutch application reference number in the Register for Biocidal Products
Sorkil Bloc	2010/6309/6327/FR/AA/7767	Sorkil Bloc	2012/6309/6327/NL/MA/31585