

COMMISSION IMPLEMENTING DECISION

of 19 February 2013

regarding restrictions of authorisations of biocidal products containing difenacoum notified by Germany in accordance with Directive 98/8/EC of the European Parliament and of the Council*(notified under document C(2013) 780)***(Only the German text is authentic)**

(2013/96/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 to belonging to product type 14, rodenticides, as defined in Annex V to Directive 98/8/EC.

(2) Difenacoum is an anticoagulant rodenticide known to pose risks of accidental incidents with children, as well as risks for animals and the environment. It has been identified as potentially persistent, liable to bioaccumulate and toxic ('PBT'), or very persistent and very liable to bioaccumulate ('vPvB').

(3) For reasons of public health and hygiene, it was nevertheless found to be justified to include difenacoum and other anticoagulant rodenticides in Annex I to Directive 98/8/EC, thus allowing Member States to authorise difenacoum-based products. However, Directive 2008/81/EC obliges Member States to ensure, when granting authorisation of products containing difenacoum, that primary as well as secondary exposure of humans, non-target animals and the environment is minimised, by considering and applying all appropriate and available risk mitigation measures. The risk mitigation measures mentioned in Directive 2008/81/EC therefore include, amongst others, restriction to professional use only.

(4) The company Kwizda France S.A.S. ('the applicant') has, in accordance with Article 8 of Directive 98/8/EC,

submitted an application to the United Kingdom for authorisation for six rodenticides containing difenacoum ('the products').

(5) The United Kingdom granted the authorisations to five products on 3 November 2011 and to another one on 14 November 2011. The products were authorised for general use against rats and mice for the protection of stored products, food, health and material. The restrictions to ensure that the conditions of Article 5 of Directive 98/8/EC were met in the United Kingdom included a requirement to indicate 'Keep away from food, drink and animal feedingstuffs' on the label, but did not include restriction to trained or licensed professional users.

(6) On 31 March 2010, the applicant submitted a complete application to Germany for mutual recognition of the first authorisations in respect of the products.

(7) On 8 June 2012, Germany notified the Commission, the other Member States and the applicant of its proposal to restrict the first authorisations in accordance with Article 4(4) of Directive 98/8/EC. Germany proposed to impose a restriction on the products to use by trained or licensed professionals, as well as by excluding food protection from the authorised intended uses of the contested products if the food consists of plants or plant products within the meaning of Article 3 points 5 and 6 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ⁽³⁾.

(8) 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. No comments were submitted within that deadline. The notification was also discussed between the Commission and Member States' Competent Authorities for biocidal products in the meeting of the Product Authorisation and Mutual Recognition Facilitation Group of 3-4 July 2012.

⁽¹⁾ OJ L 123, 24.4.1998, p. 1.

⁽²⁾ OJ L 201, 30.7.2008, p. 46.

⁽³⁾ OJ L 309, 24.11.2009, p. 1.

- (9) Concerning the restriction on the products to use by trained or licensed professionals, in accordance with Directive 2008/81/EC, authorisations of biocidal products containing difenacoum are to be subject to all appropriate and available risk mitigation measures, including the restriction to professional use only. The scientific evaluation leading to the adoption of Directive 2008/81/EC concluded that only professional users could be expected to follow the instructions minimising the risk of secondary poisoning of non-target animals, and to use products in a way that prevents the development and spreading of resistance. A restriction to professional users should therefore in principle be considered to be an appropriate risk mitigation measure, in particular in Member States where resistance to difenacoum occurs.
- (10) In the absence of any indication to the contrary, restriction to professional users is therefore an appropriate and available risk mitigation measure for the authorisation of products containing difenacoum in Germany. This conclusion is reinforced by the arguments put forward by Germany that resistance against difenacoum in rats has been found and is thought to be developing in the country. Furthermore, Germany has a well-functioning infrastructure of trained pest control operators and licensed professionals, such as farmers, gardeners and foresters who received professional training, which means that the proposed restriction does not hinder infection prevention.
- (11) Regarding the exclusion of food protection from the authorised intended uses, Germany argued that products used for food of plant origin protection are covered, for this purpose, by Regulation (EC) No 1107/2009 and hence excluded from the scope of Directive 98/8/EC if the protected food consists of plants or plant products within the meaning of Article 3 points 5 and 6 of Regulation (EC) No 1107/2009.
- (12) The Commission notes that it is undisputed that the contested products are covered by the definition of a biocidal product in Article 2(1)(a) of Directive 98/8/EC. It therefore merely should be examined whether the products are nevertheless excluded from the scope of Directive 98/8/EC by virtue of Article 1(2)(r) of that Directive for the purpose of certain uses, in which case those particular uses would require additional authorisations in accordance with Regulation (EC) No 1107/2009.
- (13) It follows from Article 2(1)(a) of Regulation (EC) No 1107/2009 that that Regulation does not apply to products whose main purpose is considered to be hygiene rather than the protection of plants or plant products.
- (14) The contested products are, inter alia, intended for use as rodenticides against mice and rats to protect food, and food can constitute plants or plant products as defined in Article 3 points 5 and 6 of Regulation (EC) No 1107/2009.
- (15) However, the contested products are also intended for a number of other purposes than food protection, and most food does not constitute plants or plant products. Furthermore, the labelling requirements in the authorisations of the contested products ensure that the products are not directly applied on food ⁽¹⁾. The application of the products referred to as 'food protection' in the authorisation should be seen as primarily intended to avoid food contamination from rodents and the consequent danger for transmission of zoonotic diseases, in line with the general hygiene requirements for all stages of production, processing and distribution according to Annex II to Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs ⁽²⁾.
- (16) As the main purpose of the contested products is hygiene rather than the protection of plants or plant products, the products are not excluded from the scope of Directive 98/8/EC by virtue of Article 1(2)(r) of that Directive for the purpose of its use. The restriction requested by Germany in this respect cannot be justified on the grounds put forward.
- (17) 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

Germany may restrict the authorisations granted in accordance with Article 4 of Directive 98/8/EC for the products mentioned in the Annex to this Decision to use by trained or licensed professionals, without excluding food protection from the authorised intended uses of the products.

⁽¹⁾ See, in this respect, a published guidance document agreed between the Commission services and the competent authorities of Member States for the biocidal products Directive 98/8/EC and for the plant protection products Directive 91/414/EEC entitled 'Borderline between Directive 98/8/EC concerning the placing on the market of Biocidal product and Directive 91/414/EEC concerning the placing on the market of plant protection products', available on the website http://ec.europa.eu/food/plant/protection/evaluation/borderline_en.htm

⁽²⁾ OJ L 139, 30.4.2004, p. 1.

Article 2

This Decision is addressed to the Federal Republic of Germany.

Done at Brussels, 19 February 2013.

For the Commission
Janez POTOČNIK
Member of the Commission

ANNEX

Products for which Germany may restrict the authorisations granted in accordance with Article 4 of Directive 98/8/EC to use by trained or licensed professionals:

Product name in UK	UK application reference number in the Register for Biocidal Products	Product name in Germany	German application reference number in the Register for Biocidal Products
Murabloc LM	2010/1329/5686/UK/AA/7269	Murablock	2010/1329/5686/DE/MA/8105
Souribloc	2010/1329/5706/UK/AA/7465	Souriblock	2010/1329/5706/DE/MA/8109
Raticide VK	2010/1329/5726/UK/AA/7468	MUSCIDAN Haferköder	2010/1329/5726/DE/MA/8113
Le Souriquois	2010/1329/5728/UK/AA/7470	MUSCIDAN Weizenköder	2010/1329/5728/DE/MA/8120
Ratigum	2010/1329/5707/UK/AA/7466	Ratigum	2010/1329/5707/DE/MA/8110
Super Pellets	2010/1329/5708/UK/AA/7467	Super Pellets	2010/1329/5708/DE/MA/8112