Commission Implementing Decision of 18 June 2012 approving restrictions of authorisations of biocidal products containing difethialone notified by Denmark in accordance with Article 4(4) of Directive 98/8/EC of the European Parliament and of the Council (notified under document C(2012) 4025) (Only the Danish text is authentic) (2012/316/EU)

COMMISSION IMPLEMENTING DECISION

of 18 June 2012

approving restrictions of authorisations of biocidal products containing difethialone notified by Denmark in accordance with Article 4(4) of Directive 98/8/EC of the European Parliament and of the Council

(notified under document C(2012) 4025)

(Only the Danish text is authentic)

(2012/316/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. The active substance difethialone was approved for inclusion in products belonging to product-type 14, rodenticides, as defined in Annex V to Directive 98/8/EC, by Commission Directive 2007/69/EC of 29 November 2007 amending Directive 98/8/EC of the European Parliament and of the Council to include difethialone as an active substance in Annex I thereto.[(2)]

(2) Difethialone 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 difethialone and other anticoagulant rodenticides in Annex I to Directive 98/8/EC, thus allowing Member States to authorise difethialone-based products. However, Directive 2007/69/EC obliges Member States to ensure, when granting authorisation of products containing difethialone, 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.

(4) The scientific evaluation leading to the adoption of Directive 2007/69/EC concluded that the most significant reductions in exposure to and risks posed by difethialone are achieved by restricting its use to treatment campaigns of limited duration, limiting access of non-target animals to the bait and removing unused bait and dead and moribund rodents during a baiting campaign in order to minimise the opportunity of primary or secondary exposure of non-target animals. The evaluation also concluded that only professional users are expected to follow such instructions. The risk mitigation measures mentioned in Directive 2007/69/EC therefore include restriction to professional use only.

(5) The company LiphaTech 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 of nine rodenticides containing difethialone ('the products'). The products' names and reference numbers in the Register for Biocidal Products ('R4BP') are indicated in the Annex to this decision.

(6) The United Kingdom granted the authorisations on 20 April 2011 (Generation Pat'), on 26 April 2011 (Generation Block) and on 27 April 2011 (Generation Grain'Tech and Rodilon Trio) ('the first authorisations'). The products were authorised with restrictions to ensure that the conditions of Article 5 of Directive 98/8/EC were met in the United Kingdom. Those restrictions did not include a restriction to trained professional users with a license.

(7) The applicant submitted a complete application to Denmark for mutual recognition of the first authorisations in respect of seven of the products (Rodilon Paste, Kvit Muse-Pasta, Rodilon Block, Generation Korn'Tech, Rodilon Trio and Kvit Røde Musekorn, and the product now referred to as Generation Blok) on 9 June 2011, and in respect of two of the products (Generation Museblok and Generation Musekorn) on 14 October 2011.

(8) On 2 November 2011, Denmark 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. Denmark proposed to impose a restriction on the products to use by trained professionals with a license.

(9) 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.

(10) Only the applicant submitted comments within that deadline. The notification was also discussed between Commission representatives, representatives of Member States' Competent Authorities for biocidal products and the applicant in the meeting of the Product Authorisation and Mutual Recognition Facilitation Group of 6-7 December 2011 and in the meeting of the Competent Authorities for Biocidal Products of 29 February to 2 March 2012.

(11) The applicant has argued that the restriction to use by trained professionals with a license is unjustified and should not be accepted, since its products are also suitable for rodent control by non-trained professionals and non-professionals. Furthermore, the

applicant has put forward the arguments that the products are ready-to-use products; that the active ingredient content in the products is low; that an antidote exists; that the products can easily be kept out of the reach of children and non-target animals; that non-professional users are likely to remove dead rodents and that non-professional users can be trained.

(12) The Commission notes that, in accordance with Directive 2007/69/EC, authorisations of biocidal products containing difethialone 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 2007/69/EC concluded that only professional users could be expected to follow the instructions leading to the most significant reductions in exposure and risk. A restriction to professional users should therefore in principle be considered to be an appropriate risk mitigation measure. The arguments put forward by the applicant do not undermine that conclusion.

(13) In the absence of any indication to the contrary, the Commission therefore considers that a restriction to professional users is an appropriate and available risk mitigation measure for the authorisation of products containing difethialone in Denmark. The fact that the United Kingdom did not consider such a restriction to be appropriate and available for an authorisation in its territory is immaterial for that conclusion. The decision of the United Kingdom to authorise non-professional use was based in particular on the risk of a delay in treatment of household infestations due to the costs involved in hiring trained professionals, and the associated risks to public hygiene. Denmark, however, has explained that that risk is less prevalent in Denmark, thanks to a system of mandatory rat infestation reporting and tax financed controlling by trained professionals, together with the general public's access to alternative methods for control of minor mice infestations.

(14) 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

Denmark 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 professionals with a license.

Article 2

This Decision is addressed to the Kingdom of Denmark.

Done at Brussels, 18 June 2012.

For the Commission

Janez POTOČNIK

Member of the Commission

ANNEX

PRODUCTS FOR WHICH DENMARK MAY RESTRICT THE AUTHORISATIONS GRANTED IN ACCORDANCE WITH ARTICLE 4 OF DIRECTIVE 98/8/EC TO USE BY TRAINED PROFESSIONALS WITH A LICENSE

Product name in the United Kingdom	**United Kingdom application reference number in R4BP**	**Product name in Denmark**	**Danish application reference number in R4BP**
Generation Block	2009/4329/3928/UK/AA/4786	Generation Blok	2011/4329/3928/DK/MA/18746
Generation Block	2009/4329/3928/UK/AA/4786	Rodilon Block	2009/4329/3928/DK/MA/5109
Generation Block	2009/4329/3928/UK/AA/4786	Generation Museblok	2009/4329/3928/DK/MA/5089
Generation Pat’	2009/4329/3926/UK/AA/4788	Rodilon Paste	2009/4329/3926/DK/MA/5111
Generation Pat’	2009/4329/3926/UK/AA/4788	Kvit Muse Pasta	2010/4329/3926/DK/MA/16305
Generation Grain’Tech	2009/4329/3929/UK/AA/4785	Generation Korn’Tech	2011/4329/3929/DK/MA/18745
Generation Grain’Tech	2009/4329/3929/UK/AA/4785	Generation Musekorn	2009/4329/3929/DK/MA/5125
Rodilon Trio	2009/4329/3930/UK/AA/4792	Rodilon Trio	2010/4329/3930/DK/MA/5108
Rodilon Trio	2009/4329/3930/UK/AA/4792	Kvit Røde Musekorn	2010/4329/3930/DK/MA/16306

(**1**) OJ L 123, 24.4.1998, p. 1.

(**2**) OJ L 312, 30.11.2007, p. 23.

Status:
Point in time view as at 18/06/2012.

Changes to legislation:
There are currently no known outstanding effects for the Commission Implementing Decision of 18 June 2012 approving restrictions of authorisations of biocidal products containing difethialone notified by Denmark in accordance with Article 4(4) of Directive 98/8/EC of the European Parliament and of the Council (notified under document C(2012) 4025) (Only the Danish text is authentic) (2012/316/EU).