

Commission Implementing Decision (EU) 2016/2318 of 16 December 2016
on a derogation from mutual recognition of the authorisations of biocidal
products containing brodifacoum by Spain in accordance with Article 37 of
Regulation (EU) No 528/2012 of the European Parliament and of the Council
(notified under document C(2016) 8414) (Only the Spanish text is authentic)

COMMISSION IMPLEMENTING DECISION (EU) 2016/2318

of 16 December 2016

on a derogation from mutual recognition of the authorisations of biocidal
products containing brodifacoum by Spain in accordance with Article 37 of
Regulation (EU) No 528/2012 of the European Parliament and of the Council

(notified under document C(2016) 8414)

(Only the Spanish text is authentic)

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 37(2)(b) thereof,

Whereas:

- (1) The company Syngenta Crop Protection AG ('the applicant') submitted complete applications to Spain for mutual recognition of authorisations granted by Ireland in respect of rodenticides containing the active substance brodifacoum ('the products'). Ireland authorised the products as a rodenticide for use indoors, outdoors around buildings and in sewers by professionals and trained professionals, as well as for use indoors and outdoors around buildings by the general public.
- (2) Pursuant to Article 37(2) of Regulation (EU) No 528/2012, Spain proposed the applicant to adjust the terms and conditions of the authorisations to be granted in Spain and proposed restricting the use of the products to trained professionals and indoors only. The objective of such restrictions is the protection of the environment referred to in Article 37(1)(a) of Regulation (EU) No 528/2012 by preventing primary and secondary poisoning incidents in non-target animals as a result of the hazardous properties of brodifacoum, which render it potentially persistent, liable to bioaccumulation and toxic, or very persistent and very liable to bioaccumulation.
- (3) The applicant disagreed with the proposed restrictions and considered that those measures are not sufficiently justified on the grounds laid down in Article 37(1) of Regulation (EU) No 528/2012. As a result, on 18 April 2016 Spain informed the Commission in accordance with the second subparagraph of Article 37(2) of that Regulation.

Status: Point in time view as at 16/12/2016.

*Changes to legislation: There are currently no known outstanding effects for the
Commission Implementing Decision (EU) 2016/2318. (See end of Document for details)*

- (4) In line with the conditions imposed on the approval of brodifacoum in Commission Directive 2010/10/EU⁽²⁾, authorisations of biocidal products containing brodifacoum are subject to all appropriate and available risk mitigation measures in order to limit the risk of primary and secondary exposure of non-target animals, as well as the long term effects of the substance on the environment. Those measures may include, amongst others, the restriction to professional use only or restrictions regarding the area of use of the products.
- (5) The Commission notes that the proposal by Spain is part of a national set of risk mitigation measures for anticoagulant rodenticides, which was communicated to the Commission in 2012 in the context of discussions on the risk mitigation measures applied by Member States during the authorisation of anticoagulant rodenticide biocidal products.
- (6) Concerning the restriction to trained professionals only, the Commission notes that that user category is considered to be in possession of the required knowledge, skills and competencies enabling it to consider the risks of using rodenticides to non-target animals. That user category is therefore considered to be able to decide which rodenticide is necessary to control an infestation with the lowest impact on the environment.
- (7) Regarding the proposed restriction to indoors only, it avoids the exposure to brodifacoum of non-target animals such as small mammals living around buildings, resulting in a reduction of primary poisoning incidents. As a consequence, the restriction may contribute to the reduction of secondary poisoning of predators consuming the contaminated animals.
- (8) The proposed derogation is consistent with the specific provisions laid down in Directive 2010/10/EU, which leave to the Member States a certain level of discretion to apply the appropriate and available risk mitigation measures as a condition for the authorisation of products containing brodifacoum. The proposed derogation is justified in order to protect the environment, particularly as it aims to prevent or reduce primary and secondary poisoning of non-target organisms. The Commission therefore considers that the proposed derogation from mutual recognition fulfils the condition referred to in Article 37(1)(a) of Regulation (EU) No 528/2012.
- (9) 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

1 The derogation from mutual recognition proposed by Spain for the products referred to in paragraph 2 is justified on the grounds of the protection of the environment, as referred to in Article 37(1)(a) of Regulation (EU) No 528/2012.

2 Paragraph 1 applies to the products identified by the following case numbers, as provided for by the Register for Biocidal Products:

- a BC-KC011180-73;

Status: Point in time view as at 16/12/2016.

Changes to legislation: There are currently no known outstanding effects for the
Commission Implementing Decision (EU) 2016/2318. (See end of Document for details)

b BC-VM011322-40.

Article 2

This Decision is addressed to the Kingdom of Spain.

Done at Brussels, 16 December 2016.

For the Commission

Vytenis ANDRIUKAITIS

Member of the Commission

Status: Point in time view as at 16/12/2016.

Changes to legislation: There are currently no known outstanding effects for the
Commission Implementing Decision (EU) 2016/2318. (See end of Document for details)

- (1) [OJ L 167, 27.6.2012, p. 1.](#)
- (2) Commission Directive 2010/10/EU of 9 February 2010 amending Directive 98/8/EC of the European Parliament and of the Council to include brodifacoum as an active substance in Annex I thereto ([OJ L 37, 10.2.2010, p. 44](#)).

Status:

Point in time view as at 16/12/2016.

Changes to legislation:

There are currently no known outstanding effects for the Commission Implementing Decision (EU) 2016/2318.