EUROPEAN
COMMISSION

Brussels, XXX
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COMMISSION IMPLEMENTING DECISION

of XXX

pursuant to Article 3(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council on a permethrin containing topical insecticide used for the purpose of controlling insects on livestock

(Text with EEA relevance)

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(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 3(3) thereof,

Whereas:

(1) On 9 March 2017, the Netherlands requested the Commission to decide, pursuant to Article 3(3) of Regulation (EU) No 528/2012, whether a permethrin containing product ("the product") placed on the market to be used to control a number of insects on the skin of livestock (cattle, sheep, horses and donkeys) is a biocidal product or a treated article or neither.

(2) According to the information provided by the Netherlands, the product is intended to be authorised as an insecticide under product-type 18, as defined in Annex V to Regulation (EU) No 528/2012. The product consists of a solution for external use only, being directly applied on the back of the animal from head till tail. The target organisms in the application are adult stable flies (*Stomoxys* spp.) and midges (*Culicoides* spp.), which will be killed when landing on the animal.

(3) The product is currently placed on the market of Belgium and the Netherlands according to the systems referred to in Article 89(2) of that Regulation as a biocidal product.

(4) The product meets the definition of a mixture referred to in Article 3(2)(b) of Regulation (EU) No 528/2012.

(5) The product contains permethrin, which meets the definition of an active substance as provided under Article 3(1)(c) of that Regulation.

(6) The target organisms in the application meet the definition of harmful organism as provided under Article 3(1)(g) of Regulation (EU) No 528/2012 since they may have a detrimental effect on animals or humans.

(7) In accordance with Article 3(1)(a) of that Regulation, destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on any harmful organism is a biocidal function.

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

(8) Therefore, the product as it is supplied to the user meets the definition of a biocidal product provided under the first indent of Article 3(1)(a) of Regulation (EU) No 528/2012.

(9) In accordance with Article 2(2) of Regulation (EU) No 528/2012 it is also important to consider whether the product may fall within the scope of Directive 2001/82/EC of the European Parliament and of the Council[2] if it meets the definition of a veterinary medicinal product as provided under Article 1(2) of that Directive.

(10) Since i) the product is applied as a topical insecticide in order to kill the target organisms present on the animal; ii) the target organisms infesting the animal are ecto-parasites and may cause an animal disease; iii) the application of the product may either eliminate or limit the development of infestations, the product could be seen by the user as having properties for treating or preventing the above mentioned infestations. As a consequence, the product could be considered as meeting the definition of a veterinary medicinal product as provided under Article 1(2) of Directive 2001/82/EC.

(11) A withdrawal period, as provided for under Article 1(9) of that Directive, sets the period necessary between the last administration of a veterinary medicinal product to animals and the production of foodstuffs from such animals. It is one of the essential requirements towards the use of veterinary medicinal products in food-producing animals in order to ensure food safety. The Commission notes that the product, as currently placed on the market of Belgium and the Netherlands, is presented as having a withdrawal period for meat.

(12) Pursuant to Article 2(2) of Directive 2001/82/EC, in cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a veterinary medicinal product and within the definition of a product covered by other Community legislation, the provisions of that Directive shall apply.

(13) Therefore, in accordance with Article 2(2)(c) of Regulation (EU) No 528/2012, the product does not fall under the scope of that Regulation.

(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

A permethrin containing topical insecticide used for the purpose of controlling insects on livestock shall not be considered as a biocidal product falling under the scope of Regulation (EU) No 528/2012.

Article 2

This Decision shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

[2] Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1).

Done at Brussels,

For the Commission
The President
Jean-Claude JUNCKER