

COMMISSION IMPLEMENTING DECISION (EU) 2016/903**of 8 June 2016****pursuant to Article 3(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council on a horse rug impregnated with permethrin used for the purpose of controlling nuisance insects in the environment of the horse****(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 21 September 2015, Ireland requested the Commission to decide, pursuant to Article 3(3) of Regulation (EU) No 528/2012, whether a horse rug placed on the market to be used for the protection of horses and their environment from insects (horse and stable flies) is a biocidal product or a treated article or neither.
- (2) According to the information provided by Ireland, the horse rug consists of two separate layers of fabric, of which the outer layer is impregnated with permethrin and separated from the horses' skin by a non-impregnated inner layer. The treatment with permethrin is claimed to further enhance the physical protection function of the rug against nuisance insects in the environment of the horse, as insects will be killed when landing on the outer layer of the rug.
- (3) The horse rug is intended to control insects, which 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.
- (4) 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.
- (5) The horse rug meets the definition of an article as provided under Article 3(2)(c) of Regulation (EU) No 528/2012, since it has a special shape, surface or design which determines its function to a greater degree than does its chemical composition.
- (6) The rug meets the definition of a treated article as provided under Article 3(1)(l) of Regulation (EU) No 528/2012, as permethrin is intentionally incorporated into it with the aim to control insects in the environment of the horse.
- (7) It is therefore essential to establish whether or not the horse rug has a primary biocidal function according to agreed Union guidance ⁽²⁾, in order to define whether it is a treated article or a biocidal product.
- (8) Since: (i) nuisance insects in the environment of the horse are not harmful to the rug itself; (ii) the concentration of permethrin in the rug is comparable to that in biocidal products and higher than the concentration used to control keratin feeding textile pests ⁽³⁾; (iii) the mode of action of permethrin in the rug is identical to that of a biocidal product; and (iv) greater prominence and first importance is given in the product's information to the biocidal function of controlling insects than to other functions of the horse rug (in particular to mitigate cold weather conditions or UV-protection), the horse rug can be considered to have a primary biocidal function and to meet the definition of a biocidal product provided under Article 3(1)(a) of Regulation (EU) No 528/2012.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ Note for guidance on Frequently asked questions on treated articles (Question 11), available at <https://circabc.europa.eu/w/browse/d7363efd-d8fb-43e6-8036-5bcc5e87bf22>

⁽³⁾ Assessment report of the evaluation of the active substance permethrin for product-type 18 (Section 2.1.2.1. Field of use envisaged/ Function and organism(s) to be controlled), available at http://dissemination.echa.europa.eu/Biocides/ActiveSubstances/1342-18/1342-18_Assessment_Report.pdf

- (9) In accordance with Article 2(2) of Regulation (EU) No 528/2012 it is also important to consider whether the horse rug may fall within the scope of Directive 2001/82/EC of the European Parliament and of the Council ⁽¹⁾ if it meets the definition of a veterinary medicinal product as provided under Article 1(2) of that Directive.
- (10) When the horse rug is not designed to be applied as a topical insecticide and is not used with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis in horses, and when the horse rug is not presented either as having properties for treating or preventing any horse diseases but to control insects that may be present in the environment of the horse and may disturb the animal, the horse rug does not meet the definition of a veterinary medicinal product as provided under Article 1(2) of Directive 2001/82/EC and therefore falls under the scope of Regulation (EU) No 528/2012.
- (11) Since product-type 18, as defined in Annex V to Regulation (EU) No 528/2012, covers products used for the control of arthropods (e.g. insects, arachnids and crustaceans), by means other than repulsion or attraction, the horse rug should be deemed to belong to product-type 18. Furthermore, as permethrin is not under assessment nor approved ⁽²⁾ for use in biocidal products of product-type 19, the horse rug should not be claimed to have any repellent function.
- (12) 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 horse rug impregnated with permethrin for the purpose of controlling nuisance insects in the environment of the horse, by means other than repulsion or attraction, shall be considered as a biocidal product in accordance with Article 3(1)(a) of Regulation (EU) No 528/2012 and shall fall within product-type 18 as defined in Annex V to that Regulation.

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*.

Done at Brussels, 8 June 2016.

For the Commission
The President
Jean-Claude JUNCKER

⁽¹⁾ 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).

⁽²⁾ Commission Implementing Regulation (EU) No 1090/2014 of 16 October 2014 approving permethrin as an existing active substance for use in biocidal products for product-types 8 and 18 (OJ L 299, 17.10.2014, p. 10).