COMMISSION IMPLEMENTING DECISION (EU) 2015/1985

of 4 November 2015

pursuant to Article 3(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council on an anti-viral tissue impregnated with citric acid

(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 28 April 2015, Belgium requested the Commission to decide, pursuant to Article 3(3) of Regulation (EU) No 528/2012, whether an anti-viral tissue placed on the market with the claim 'kills 99,9 % of cold & flu viruses in the tissue' is a biocidal product or a treated article and, if considered a biocidal product, whether it would belong to product-type 1 (human hygiene) or 2 (disinfectants and algaecides not intended for direct application to humans or animals).

(2) According to the information provided by Belgium, the tissue is a 3-ply tissue of which the middle layer is impregnated with citric acid. Citric acid is stated to be irreversibly bound into the tissue's matrix and to remain in the product throughout its lifecycle. After the tissue has been used, i.e. when moisture after sneezing, coughing or blowing of the nose into the tissue hits the middle layer, citric acid is claimed to deactivate the viral load within the tissue in order to prevent transfer back to the hands, transmittance of the virus from hand to hand contact and transmittance to surfaces with which the tissue comes into contact.

(3) The tissue meets the definition of an article as provided under Article 3(2)(c) of Regulation (EU) No 528/2012.

(4) The tissue meets the definition of a treated article as provided under Article 3(1)(l) of Regulation (EU) No 528/2012, as citric acid is intentionally incorporated into it with the aim to deactivate viruses and to limit cross-contamination with these viruses.

(5) Viruses 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 humans.

(6) Destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on any harmful organism is a biocidal function.

(7) It is therefore essential to establish whether the tissue has a primary biocidal function or not, in order to define whether the tissue is a treated article or a biocidal product.

(8) The claim made on the tissue packaging and advertising is 'kills 99,9 % of cold & flu viruses in the tissue'. Through such a claim, greater prominence and first importance is given to the biocidal function of the tissue than to its other functions (for example to blow the nose). The anti-viral tissue has therefore a primary biocidal function.

(9) Since product-type 1 covers biocidal products used to disinfect the skin or the scalp and product-type 2 covers biocidal products used for wider purposes, such as the disinfection of surfaces, materials or air, the use of the tissue would rather correspond to the latter product-type.

(10) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

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

HAS ADOPTED THIS DECISION:

Article 1

An anti-viral tissue impregnated with citric acid and placed on the market with the claim 'kills 99,9 % of cold & flu viruses in the tissue' 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 2 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, 4 November 2015.

For the Commission

The President

Jean-Claude JUNCKER