COMMISSION IMPLEMENTING DECISION (EU) 2016/904

of 8 June 2016

pursuant to Article 3(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council on propan-2-ol containing products used for hand disinfection

(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) In the context of an application under the Union authorisation procedure referred to in Article 41 of Regulation (EU) No 528/2012, on 3 December 2015 Germany requested the Commission to decide, pursuant to Article 3(3) of that Regulation, whether a group of ready to use propan-2-ol containing products ('the products') placed on the market to be used for hand disinfection, including in this instance surgical hand disinfection, and to be authorised as a biocidal product family as defined in Article 3(1)(s) of that Regulation, are biocidal products.

(2) Germany considered that the products are medicinal products in accordance with Directive 2001/83/EC of the European Parliament and of the Council ([2]), arguing that the intended uses of the products show that they aim at preventing diseases in humans, as they can be used in areas and situations where disinfection is medically recommended. According to Germany, this is particularly the case when the products are used by health professionals as a preoperative treatment procedure to prevent the risk of transmission of microorganisms into the surgical wound.

(3) The products are intended to control a number of bacteria, viruses and fungi, which meet the definition of 'harmful organism' provided under Article 3(1)(g) of Regulation (EU) No 528/2012 since they may have a detrimental effect on humans.

(4) Since destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on any harmful organism is a biocidal function, the products meet the definition of a biocidal product provided under Article 3(1)(a) of that Regulation.

(5) In accordance with Article 2(2) of Regulation (EU) No 528/2012 it is important to consider whether the products may fall within the scope of Directive 2001/83/EC if they meet the definition of a medicinal product as provided under Article 1(2) of that Directive.

(6) Where the products are solely intended to reduce the micro-organism load on hands and the associated risk of transmitting micro-organisms from potentially contaminated hands and neither used to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action, nor to make a medical diagnosis in humans, nor presented either as having properties to treat or to prevent any human diseases, the products do not meet the definition of a medicinal product as provided under Article 1(2) of Directive 2001/83/EC and therefore fall under the scope of Regulation (EU) No 528/2012.

(7) Since product-type 1, as defined in Annex V to Regulation (EU) No 528/2012, covers products used for human hygiene purposes, applied on or in contact with human skin or scalps for the primary purpose of disinfecting the skin or scalp, the products belong to product-type 1.

([1]) OJ L 167, 27.6.2012, p. 1.
([2]) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

(8) 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

Propan-2-ol containing products to be used in hand disinfection, including in this instance surgical hand disinfection, for the purpose of reducing the risk of transmission of microorganisms shall be considered as biocidal products in accordance with Article 3(1)(a) of Regulation (EU) No 528/2012 and shall fall within product-type 1 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