COMMISSION IMPLEMENTING DECISION (EU) 2016/109

of 27 January 2016

not to approve PHMB (1600; 1.8) as an existing active substance for use in biocidal products for product-types 1, 6 and 9

(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 the third subparagraph of Article 89(1) thereof,

Whereas:

(1) Commission Delegated Regulation (EU) No 1062/2014 ([2]) establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That list includes PHMB (1600; 1.8).

(2) PHMB (1600; 1.8) has been evaluated for use in product-type 1, human hygiene, product-type 6, preservatives for products during storage, and product-type 9, fibre, leather, rubber and polymerised materials preservatives, as defined in Annex V to Regulation (EU) No 528/2012.

(3) France was designated as evaluating competent authority and submitted the assessment reports, together with its recommendations, on 5 September 2013, 8 October 2013 and 14 February 2014, respectively.

(4) In accordance with Article 7(1)(b) of Delegated Regulation (EU) No 1062/2014, the opinions of the European Chemicals Agency were formulated on 16 and 17 June 2015 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.

(5) According to those opinions, biocidal products used for product-types 1, 6 and 9 and containing PHMB (1600; 1.8) may not be expected to satisfy the requirements laid down in Article 19(1)(b) of Regulation (EU) No 528/2012. For these product-types, the scenarios evaluated in the human health risk assessments and the environmental risk assessments identified unacceptable risks.

(6) It is therefore not appropriate to approve PHMB (1600; 1.8) for use in biocidal products for product-types 1, 6 and 9.

(7) 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

PHMB (1600; 1.8) (EC No: n.a., CAS No 27083-27-8 and 32289-58-0) is not approved as an active substance for use in biocidal products for product-types 1, 6 and 9.

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

([2]) Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).

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, 27 January 2016.

For the Commission
The President
Jean-Claude JUNCKER