COMMISSION IMPLEMENTING DECISION (EU) 2018/1985

of 13 December 2018

not approving Willaertia magna c2c maky as an active substance for use in biocidal products of product-type 11

(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 9(1)(b) thereof,

Whereas:

- (1) The evaluating competent authority of France received on 17 March 2014 an application for the approval of the microorganism *Willaertia magna c2c maky* for use as an active substance in biocidal products of product-type 11, preservatives for liquid cooling and processing systems, as described in Annex V to Regulation (EU) No 528/2012.
- (2) The evaluating competent authority of France submitted the assessment report together with its conclusions on 15 March 2017 in accordance with Article 8(1) of Regulation (EU) No 528/2012.
- (3) The opinion of the European Chemicals Agency was formulated on 26 April 2018 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority (²).
- (4) According to that opinion, biocidal products of product-type 11 containing Willaertia magna c2c maky may not be expected to meet the criteria laid down in Article 19(1)(b) of Regulation (EU) No 528/2012. In particular, the scenarios evaluated in the human health risk assessment identified unacceptable risks and no safe use could be identified. Moreover, the innate efficacy of Willaertia magna c2c maky to control Legionella pneumophila was not sufficiently demonstrated.
- (5) Taking into account the opinion of the European Chemicals Agency, the Commission considers it not appropriate to approve Willaertia magna c2c maky for use in biocidal products of product-type 11.
- (6) 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

Willaertia magna c2c maky is not approved as an active substance for use in biocidal products of product-type 11.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ Biocidal Products Committee (BPC) Opinion on the application for approval of the active substance: Willaertia magna c2c maky, product-type 11, ECHA/BPC/206/2018, adopted on 26 April 2018.

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, 13 December 2018.

For the Commission
The President
Jean-Claude JUNCKER