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)

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:

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Decision (EU) 2018/1985. (See end of Document for details)*

Article 1

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

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