COMMISSION IMPLEMENTING REGULATION (EU) 2016/1085

of 5 July 2016

approving *Bacillus amyloliquefaciens* strain ISB06 as an existing active substance for use in biocidal products of product-type 3

(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 *Bacillus subtilis*.

(2) As a result of the evaluation of the active substance originally notified, it became apparent that it belonged in fact to the species *Bacillus amyloliquefaciens* strain ISB06. The evaluation did not allow for conclusions to be drawn regarding any other substance complying with the definition of *Bacillus subtilis* in the abovementioned list of active substances in Delegated Regulation (EU) No 1062/2014. Therefore, only *Bacillus amyloliquefaciens* strain ISB06 should be covered by this approval.

(3) *Bacillus amyloliquefaciens* strain ISB06 has been evaluated for use in products of product-type 3, veterinary hygiene as described in Annex V to Regulation (EU) No 528/2012.

(4) Germany was designated as evaluating competent authority and submitted the assessment report together with its recommendations on 22 September 2014.

(5) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the opinion of the European Chemicals Agency was formulated on 10 December 2015 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.

(6) According to that opinion, biocidal products of product-type 3 and containing *Bacillus amyloliquefaciens* strain ISB06 may be expected to satisfy the criteria of Article 19(1)(b) of Regulation (EU) No 528/2012, provided that certain specifications and conditions concerning their use are complied with.

(7) It is therefore appropriate to approve *Bacillus amyloliquefaciens* strain ISB06 for use in biocidal products of product-type 3, subject to compliance with certain specifications and conditions.

(8) A reasonable period should be allowed to elapse before an active substance is approved in order to permit interested parties to take the preparatory measures necessary to meet the new requirements.

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

([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).

HAS ADOPTED THIS REGULATION:

Article 1

Bacillus amyloliquefaciens strain ISB06 is approved as an active substance for use in biocidal products of product-type 3, subject to the conditions set out in the Annex.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 5 July 2016.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance ([1])	Date of approval	Expiry date of approval	Product type	Specific conditions
Bacillus amyloliquefaciens strain ISB06	Not applicable	No relevant impurities	1 January 2018	31 December 2027	3	The authorisations of biocidal products are subject to the following conditions: 1. The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any use covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. 2. In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to professional users.

([1]) The purity indicated in this column was the minimum degree of purity of the active substance used for the evaluation made in accordance with Article 89(1) of Regulation (EU) No 528/2012. The active substance in the product placed on the market can be of equal or different purity if it has been proven technically equivalent with the evaluated active substance.