COMMISSION IMPLEMENTING REGULATION (EU) 2015/406

of 11 March 2015

approving *Bacillus thuringiensis* subsp. *israelensis* serotype H14, strain SA3A as an active substance for use in biocidal products for product-type 18

(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 active substances to be evaluated with a view to their possible approval for use in biocidal products or inclusion into Annex I to Regulation (EU) No 528/2012. That list includes *Bacillus thuringiensis* subsp. *israelensis* serotype H14.

(2) *Bacillus thuringiensis* subsp. *israelensis* serotype H14 has been evaluated in accordance with Article 90(2) of Regulation (EU) No 528/2012 for use in biocidal products for product-type 18, insecticides, acaricides and products to control other arthropods, as defined in Annex V to Regulation (EU) No 528/2012.

(3) The data submitted for the purpose of the evaluation allowed conclusions to be drawn only regarding a certain form of *Bacillus thuringiensis* subsp. *israelensis* serotype H14, i.e. *Bacillus thuringiensis* subsp. *israelensis* serotype H14, strain SA3A. The evaluation did not allow conclusions to be drawn regarding any other substance complying with the definition of *Bacillus thuringiensis* subsp. *israelensis* serotype H14 in the abovementioned list of active substances in Delegated Regulation (EU) No 1062/2014. Therefore, only *Bacillus thuringiensis* subsp. *israelensis* serotype H14, strain SA3A should be covered by this approval.

(4) Italy was designated as evaluating competent authority and submitted an assessment report, together with its recommendations, to the Commission on 12 June 2009 in accordance with paragraphs 4 and 6 of Article 14 of Commission Regulation (EC) No 1451/2007 ([3]).

(5) The opinion of the European Chemicals Agency was formulated on 19 June 2014 by the Biocidal Product Committee, having regard to the conclusions of the evaluating competent authority.

(6) According to that opinion, biocidal products used for product-type 18 and containing *Bacillus thuringiensis* subsp. *israelensis* serotype H14, strain SA3A may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC of the European Parliament and of the Council ([4]) provided that certain specifications and conditions relating to its use are satisfied.

(7) It is therefore appropriate to approve *Bacillus thuringiensis* subsp. *israelensis* serotype H14, strain SA3A for use in biocidal products for product-type 18 subject to compliance with certain specifications and conditions.

(8) Since the evaluations did not address nanomaterials, the approval should not cover such materials in accordance with Article 4(4) of Regulation (EU) No 528/2012.

([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).
([3]) Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (OJ L 325, 11.12.2007, p. 3).
([4]) Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).

(9) 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.

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

HAS ADOPTED THIS REGULATION:

Article 1

Bacillus thuringiensis subsp. *israelensis* serotype H14, strain SA3A shall be approved as an active substance for use in biocidal products for product-type 18, subject to the specifications and 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, 11 March 2015.

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 (2)
Bacillus thuringiensis subsp. *israelensis* serotype H14, strain SA3A	Not applicable	No relevant impurities	1 July 2016	30 June 2026	18	The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. For biocidal products, authorisations are subject to the following conditions: (1) For professional users, safe operational procedures and appropriate organisational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products shall be used with appropriate personal protective equipment. (2) For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council (3) or Regulation (EC) No 396/2005 of the European Parliament and of the Council (4) shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.

(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 8 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.

(2) For the implementation of the common principles of Annex VI to Regulation (EU) No 528/2012, the content and conclusions of assessment reports are available on the Commission website: http://ec.europa.eu/environment/chemicals/biocides/index_en.htm

(3) Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).

(4) Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).