Commission Implementing Regulation (EU) 2019/676 of 29 April 2019 approving the low-risk active substance ABE-IT 56 (components of lysate of Saccharomyces cerevisiae strain DDSF623), in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2019/676

of 29 April 2019

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC[(1)], and in particular Article 22(1) in conjunction with Article 13(2) thereof,

Whereas:

(1) In accordance with Article 7(1) of Regulation (EC) No 1107/2009, the Task Force ABE-IT 56 submitted to France on 1 April 2016 an application for the approval of the active substance ABE-IT 56 (components of lysate of *Saccharomyces cerevisiae* strain DDSF623) (hereinafter 'ABE-IT 56').

(2) In accordance with Article 9(3) of Regulation (EC) No 1107/2009, France, as rapporteur Member State, notified the applicant, the other Member States, the Commission and the European Food Safety Authority ('the Authority') of the admissibility of the application on 25 May 2016.

(3) On 20 June 2017, the rapporteur Member State submitted a draft assessment report to the Commission, with a copy to the Authority, assessing whether that active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

(4) The Authority complied with Article 12(1) of Regulation (EC) No 1107/2009. In accordance with Article 12(3) of that Regulation, it requested that the applicant supply additional information to the Member States, the Commission and the Authority. The assessment of the additional information by the rapporteur Member State was submitted to the Authority in the format of an updated draft assessment report in May 2018.

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2019/676. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(5) On 26 July 2018, the Authority communicated to the applicant, the Member States and the Commission its conclusion on whether the active substance ABE-IT 56 can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009[(2)]. The Authority made its conclusion available to the public.

(6) On 23 October 2018 the Commission presented to the Standing Committee on Plants, Animals, Food and Feed the review report for ABE-IT 56 and on 22 March 2019 a draft Regulation providing that ABE-IT 56 is approved.

(7) The applicant was given the possibility to submit comments on the review report.

(8) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance, and in particular the uses which were examined and detailed in the review report, that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. It is therefore appropriate to approve ABE-IT 56.

(9) The Commission further considers that ABE-IT 56 is a low-risk active substance pursuant to Article 22 of Regulation (EC) No 1107/2009. ABE-IT 56 is not a substance of concern and fulfils the conditions set in point 5 of Annex II to Regulation (EC) No 1107/2009. ABE-IT 56 is a fractionation product of the lysate of *Saccharomyces cerevisiae* strain DDSF623. *Saccharomyces cerevisiae* is the most widely used yeast in industrial/commercial food and beverage production and is ubiquitous in the environment. It is not pathogenic to humans or animals, nor is it infective to humans. It is in general naturally occurring and does not constitute a distinct risk to any compartment of the environment.

(10) It is therefore appropriate to approve ABE-IT 56 as a low risk substance for a period of 15 years.

(11) In accordance with Article 13(4) of Regulation (EC) No 1107/2009, the Annex to Commission Implementing Regulation (EU) No 540/2011[(3)] should be amended accordingly.

(12) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Approval of active substance

The active substance ABE-IT 56 (components of lysate of *Saccharomyces cerevisiae* strain DDSF623), as specified in Annex I, is approved subject to the conditions laid down in that Annex.

***Changes to legislation:** There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2019/676. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

Article 2

Amendments to Implementing Regulation (EU) No 540/2011

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

Article 3

Entry into force

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, 29 April 2019.

For the Commission

The President

Jean-Claude JUNCKER