Commission Implementing Regulation (EU) 2016/952 of 15 June 2016 approving the low-risk active substance Saccharomyces cerevisiae strain LAS02 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) 2016/952

of 15 June 2016

approving the low-risk active substance *Saccharomyces cerevisiae* strain LAS02 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)

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, France received on 9 April 2013 an application from Agrolevures et Dérivés for the approval of the active substance *Saccharomyces cerevisiae* strain LAS02. In accordance with Article 9(3) of that Regulation, France, as rapporteur Member State, notified the applicant, the other Member States, the Commission and the European Food Safety Authority (hereinafter 'the Authority') of the admissibility of the application on 15 October 2013.

(2) On 4 December 2014, 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.

(3) The Authority complied with Article 12(1) of Regulation (EC) No 1107/2009. In accordance with Article 12(3) of Regulation (EC) No 1107/2009, 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 on 14 September 2015.

(4) On 3 December 2015, the Authority communicated to the applicant, the Member States and the Commission its conclusion on whether the active substance *Saccharomyces*

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2016/952. 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*

cerevisiae strain LAS02 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.

(5) On 7 March 2016, the Commission presented to the Standing Committee on Plants, Animals, Food and Feed the review report for *Saccharomyces cerevisiae* strain LAS02 and a draft Regulation providing that *Saccharomyces cerevisiae* strain LAS02 is approved as a low-risk active substance.

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

(7) 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. Those approval criteria are therefore deemed to be satisfied. It is therefore appropriate to approve *Saccharomyces cerevisiae* strain LAS02.

(8) The Commission further considers that *Saccharomyces cerevisiae* strain LAS02 is a low-risk active substance pursuant to Article 22 of Regulation (EC) No 1107/2009. *Saccharomyces cerevisiae* strain LAS02 is not a substance of concern and fulfils the conditions set in point 5 of Annex II to Regulation (EC) No 1107/2009. *Saccharomyces cerevisiae* strain LAS02 is a naturally occurring yeast, which is widely used in food. It is also widely present in the environment. The additional exposure of humans, animals and the environment by the uses approved under Regulation (EC) No 1107/2009 is expected to be negligible compared to exposure expected through realistic natural situations.

(9) It is therefore appropriate to approve *Saccharomyces cerevisiae* strain LAS02 as a low-risk substance for a period of 15 years. 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.

(10) 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 a low-risk active substance

The active substance *Saccharomyces cerevisiae* strain LAS02, as specified in Annex I, is approved subject to the conditions laid down in that Annex.

Article 2

Amendment 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.

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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, 15 June 2016.

For the Commission

The President

Jean-Claude JUNCKER

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ANNEX I

Common Name, Identification Numbers	**IUPAC Name**	**Purity**[a]	**Date of approval**	**Expiration of approval**	**Specific provisions**
Saccharomyces cerevisae strain LAS02 Accession number in the collection of the 'Collection Nationale de Cultures de Microorganismes' (CNCM) of the Pasteur Institute: CNCM I-3936	Not applicable	Minimum concentration: 1×10^{13} CFU/kg	6 July 2016	6 July 2031	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on *Saccharomyces cerevisiae* strain LAS02, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection of operators and workers, taking into account that *Saccharomyces cerevisiae* strain LAS02 is to be considered as a potential sensitizer. Conditions of use shall include risk mitigation

a Further details on identity and specification of active substance are provided in the review report.