COMMISSION IMPLEMENTING REGULATION (EU) 2015/553

of 7 April 2015

approving the active substance cerevisane, 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 5 March 2012 an application from Agro-Levures et Dérivés SAS for the approval of the active substance cerevisane. In accordance with Article 9(3) of that Regulation, France, as rapporteur Member State, notified the Commission on 14 May 2012 of the admissibility of the application.

(2) On 22 February 2013, the rapporteur Member State submitted a draft assessment report to the Commission, with a copy to the European Food Safety Authority (hereinafter '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 in January 2014.

(4) On 5 May 2014, the Authority communicated to the applicant, the Member States and the Commission its conclusion on whether the active substance cerevisane 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) The applicant was given the possibility to submit comments on the review report.

(6) On 11 December 2014 the Commission presented to the Standing Committee on Plants, Animals, Food and Feed the review report for cerevisane and a draft Regulation providing that cerevisane is approved.

(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 cerevisane.

(8) The Commission further considers that cerevisane is a low-risk active substance pursuant to Article 22 of Regulation (EC) No 1107/2009. Cerevisane is not a substance of concern and fulfils the conditions set in point 5 of Annex II to Regulation (EC) No 1107/2009. The main constituent for cerevisane are cell walls of *Saccharomyces cerevisiae*, a yeast which is widespread in nature and commonly used in food production (baking, alcoholic beverages, nutritional supplement) and which is regularly consumed without any evidence of harmful potential. 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.

([1]) OJ L 309, 24.11.2009, p. 1.
([2]) EFSA Journal 2014;12(6):3583.

(9) It is therefore appropriate to approve cerevisane as a low risk substance. In accordance with Article 13(4) of Regulation (EC) No 1107/2009, the Annex to Commission Implementing Regulation (EU) No 540/2011 [1] 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 active substance

The active substance cerevisane, as specified in Annex I, is approved subject to the conditions laid down in that Annex.

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 and date of application

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, 7 April 2015.

For the Commission
The President
Jean-Claude JUNCKER

[1] Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
Cerevisane (no ISO name adopted) CAS No: not allocated CIPAC No: 980	Not relevant	≥ 924 g/kg	23 April 2015	23 April 2030	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 cerevisane, and in particular Appendices I and II thereof, shall be taken into account.

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

ANNEX II

In Part D of the Annex to Implementing Regulation (EU) No 540/2011, the following entry is added:

Number	Common Name, Identification Numbers	IUPAC Name	Purity (*)	Date of approval	Expiration of approval	Specific provisions
'3	Cerevisane (no ISO name adopted) CAS No: not allocated CIPAC No: 980	Not relevant	≥ 924 g/kg	23 April 2015	23 April 2030	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 cerevisane, and in particular Appendices I and II thereof, shall be taken into account.'

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