COMMISSION IMPLEMENTING REGULATION (EU) 2018/1278

of 21 September 2018

approving the low-risk active substance *Pasteuria nishizawae* Pn1 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 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 in conjunction with Article 13(2) thereof,

Whereas:

(1) In accordance with Article 7(1) of Regulation (EC) No 1107/2009 Syngenta Crop Protection AG submitted to Denmark on 27 February 2015 an application for the approval of the active substance *Pasteuria nishizawae* Pn1.

(2) In accordance with Article 9(3) of that Regulation, Denmark, 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 3 July 2015.

(3) On 19 December 2016, 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 on 23 May 2017 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 17 October 2017.

(5) On 11 January 2018 the Authority communicated to the applicant, the Member States and the Commission its conclusion ([2]) on whether the active substance *Pasteuria nishizawae* Pn1 can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Authority made its conclusion available to the public.

(6) On 11 March 2018, the Commission presented to the Standing Committee on Plants, Animals, Food and Feed the review report for *Pasteuria nishizawae* Pn1 and a draft Regulation providing that *Pasteuria nishizawae* Pn1 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 *Pasteuria nishizawae* Pn1.

(9) The Commission further considers that *Pasteuria nishizawae* Pn1 is a low-risk active substance pursuant to Article 22 of Regulation (EC) No 1107/2009. *Pasteuria nishizawae* Pn1 is not a substance of concern and fulfils the conditions set in point 5 of Annex II to Regulation (EC) No 1107/2009. *Pasteuria nishizawae* Pn1 is a wild-type strain of a micro-organism naturally occurring in the environment. It is an obligate parasite of cyst nematodes. *Pasteuria nishizawae* Pn1 spores only germinate when in contact with a cyst nematode. Infectivity to any other organism, including humans and immunocompromised patients can be excluded. Therefore as the micro-organism cannot develop outside the obligate host, its resistance to antimicrobials used in human or veterinary medicines can be excluded: the criterion set in point 5.2.1 of Annex II of Regulation (EC) No 1107/2009 is considered fulfilled.

([1]) OJ L 309, 24.11.2009, p. 1.

([2]) EFSA (European Food Safety Authority), 2018. Conclusion on the peer review of the pesticide risk assessment of the active substance *Pasteuria nishizawae* Pn1. EFSA Journal 2018;16(1):5159, 19 pp. doi:10.2903/j.efsa.2018.5159.

(10) It is therefore appropriate to approve *Pasteuria nishizawae* Pn1 for a period of 15 years.

(11) In accordance with Article 13(2) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge, it is, however, necessary to include certain generic conditions as *Pasteuria nishizawae* Pn1 is a micro-organism.

(12) 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.

(13) 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 *Pasteuria nishizawae* Pn1, 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

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, 21 September 2018.

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
Pasteuria nishizawae Pn1 Culture collection: ATCC Safe Deposit (SD-5833) CIPAC No Not allocated	Not applicable	minimum concentration 1×10^{11} spores/g	14 October 2018	14 October 2033	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 *Pasteuria nishizawae* Pn1, 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 *Pasteuria nishizawae* Pn 1 is to be considered as a potential sensitizer. Conditions of use shall include risk mitigation measures, where appropriate. Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be ensured by the producer.

[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:

	Common Name, Identification Numbers	IUPAC Name	Purity [1]	Date of approval	Expiration of approval	Specific provisions
'13	*Pasteuria nishizawae* Pn1 Culture collection: ATCC Safe Deposit (SD-5833) CIPAC No Not allocated	Not applicable	minimum concentration 1×10^{11} spores/g	14 October 2018	14 October 2033	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 *Pasteuria nishizawae* Pn1, 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 *Pasteuria nishizawae* Pn 1 is to be considered as a potential sensitizer. Conditions of use shall include risk mitigation measures, where appropriate. Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer.'

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