COMMISSION IMPLEMENTING REGULATION (EU) 2023/199

of 30 January 2023

approving the low-risk active substance *Trichoderma atroviride* AT10 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 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 13(2) in conjunction with Article 22(1) thereof,

Whereas:

(1) On 30 October 2018, France received an application pursuant to Article 7(1) of Regulation (EC) No 1107/2009 from Agrotecnologías Naturales S.L. for the approval of the active substance *Trichoderma atroviride* AT10.

(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') on 15 February 2019 of the admissibility of the application.

(3) On 18 September 2020, after assessing whether that active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009, the rapporteur Member State submitted a draft assessment report to the Commission with a copy to the Authority.

(4) Pursuant to Article 12(1) of Regulation (EC) No 1107/2009, the Authority circulated the draft assessment report to the applicant and the other Member States.

(5) In accordance with Article 12(3) of Regulation (EC) No 1107/2009, it requested the applicant to supply additional information to the Member States, the Commission and the Authority.

(6) The assessment of the additional information by the rapporteur Member State was submitted to the Authority in the form of an updated draft assessment report.

(7) On 20 January 2022, the Authority communicated to the applicant, the Member States and the Commission its conclusion ([2]) on whether the active substance *Trichoderma atroviride* AT10 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.

(8) On 14 July 2022, the Commission presented a review report regarding *Trichoderma atroviride* AT10 and a draft of this Regulation to the Standing Committee on Plants, Animals, Food and Feed.

(9) The Commission invited the applicant to submit its comments on the review report. The applicant submitted its comments, which have been carefully examined.

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

([2]) Conclusion on the peer review of the pesticide risk assessment of the active substance *Trichoderma atroviride* strain AT10. https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2022.7200. EFSA Journal 2022;7200. DOI: 10.2903/j.efsa.2022.7200.

(10) It has been established, with respect to one representative use of at least one plant protection product containing the active substance, which was examined and detailed in the review report, that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.

(11) The Commission further considers that *Trichoderma atroviride* AT10 is a low-risk active substance pursuant to Article 22 of Regulation (EC) No 1107/2009. *Trichoderma atroviride* AT10 is not a microorganism of concern and fulfils the conditions set in Annex II point 5.2 to Regulation (EC) No 1107/2009.

(12) It is therefore appropriate to approve *Trichoderma atroviride* AT10 as a low-risk active substance.

(13) 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 necessary to include certain conditions.

(14) In accordance with Article 13(4) of Regulation (EC) No 1107/2009 in conjunction with Article 22(2) thereof, Commission Implementing Regulation (EU) No 540/2011 ([3]) should therefore be amended accordingly.

(15) 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 the active substance

The active substance *Trichoderma atroviride* AT10, is approved subject to the conditions set out in Annex I to this Regulation.

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, 30 January 2023.

For the Commission
The President
Ursula VON DER LEYEN

([3]) 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
Trichoderma atroviride AT10	n.a.	The nominal content of *Trichoderma atroviride* AT10 in the technical product should be Minimal: 1 x 10^{11} CFU/kg Nominal: 5 x 10^{11}CFU/kg Maximal: 1 x 10^{12} CFU/kg No relevant impurities	20 February 2023	20 February 2038	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 *Trichoderma atroviride* AT10 and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the specification of the technical material as commercially manufactured used in plant protection products, including full characterisation of relevant secondary metabolites; — the protection of operators and workers, taking into account that microorganisms are per se considered as potential sensitizers. Use of PPE/RPE might be considered to reduce dermal and inhalation exposure.

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

ANNEX II

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

No	Common Name, Identification Numbers	IUPAC Name	Purity [1]	Date of approval	Expiration of approval	Specific provisions
'43	*Trichoderma atroviride* AT10	n.a.	The nominal content of *Trichoderma atroviride* AT10 in the technical product and formulation is Minimal: 1 x 10^{11} CFU/kg Nominal: 5 x 10^{11}CFU/kg Maximal: 1 x 10^{12} CFU/kg No relevant impurities	20 February 2023	20 February 2038	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 *Trichoderma atroviride* AT10 and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the specification of the technical material as commercially manufactured used in plant protection products, including full characterisation of relevant secondary metabolites; — the protection of operators and workers, taking into account that microorganisms are per se considered as potential sensitizers. Use of PPE/RPE might be considered to reduce dermal and inhalation exposure.

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