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COMMISSION REGULATION (EU) .../...

of XXX

amending Annex IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards *Pythium oligandrum* strain M1, *Trichoderma atroviride* strain AGR2 and *Trichoderma atroviride* strain AT10

(Text with EEA relevance)

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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 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC¹, and in particular Article 5(1) and Article 14(1) thereof,

Whereas:

- (1) For *Pythium oligandrum* strain M1, *Trichoderma atroviride* strain AGR2 and *Trichoderma atroviride* strain AT10, no specific maximum residue levels ('MRLs') have been set. Therefore, for those active substances the default value of 0,01 mg/kg laid down in Article 18(1), point (b), of Regulation (EC) No 396/2005 applies.
- (2) Commission Implementing Regulation (EU) 2022/2314² renewed the approval of the active substance *Pythium oligandrum* strain M1. During the peer review of the pesticide risk assessment of the active substance under Regulation (EC) No 1107/2009³, the European Food Safety Authority ('the Authority') concluded⁴ that some information was not available as regards the dietary risk assessment for consumers and that further consideration by risk managers was required. As set out in the renewal report for that active substance⁵ in the context of the risk assessment under Regulation (EC) No 1107/2009, *Pythium oligandrum* strain M1 is not pathogenic to humans, is not expected to produce toxins that are relevant for human health and the risk to humans through metabolites is negligible. Taking into account the peer review

¹ OJ L 70, 16.3.2005, p. 1.

² Commission Implementing Regulation (EU) 2022/2314 of 25 November 2022 renewing the approval of the active substance *Pythium oligandrum* strain M1 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 (OJ L 307, 28.11.2022, p. 47).

³ 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 (OJ L 309, 24.11.2009, p. 1).

⁴ Conclusion on the peer review of the pesticide risk assessment of the active substance *Pythium oligandrum* strain M1. EFSA Journal 2020;18(11):6296.

⁵ Renewal report for the active substance *Pythium oligandrum* strain M1 finalised in the Standing Committee on Plants, Animals, Food and Feed at its meeting on 14 October 2022 in view of the renewal of the approval of *Pythium oligandrum* strain M1 in accordance with Regulation (EC) No 1107/2009. <https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/start/screen/active-substances/details/1102> .

of the pesticide risk assessment of the active substance *Pythium oligandrum* strain M1, the renewal report and Article 5 and Article 14(2), points (a), (c) and (d), of Regulation (EC) No 396/2005, there is no need to establish MRLs for this active substance and it is therefore appropriate to include *Pythium oligandrum* strain M1 in Annex IV to Regulation (EC) No 396/2005.

- (3) Commission Implementing Regulation (EU) 2023/216⁶ approved the low-risk active substance *Trichoderma atroviride* strain AGR2. During the peer review of the pesticide risk assessment of the active substance under Regulation (EC) No 1107/2009, the Authority concluded⁷ that some information was not available as regards the dietary risk assessment for consumers and that further consideration by risk managers was required. As set out in the review report for that active substance⁸ in the context of the risk assessment under Regulation (EC) No 1107/2009, *Trichoderma atroviride* strain AGR2 is not pathogenic to humans, is not expected to produce toxins that are relevant for human health and the risk to humans through metabolites is negligible. Taking into account the peer review of the pesticide risk assessment of the active substance *Trichoderma atroviride* strain AGR2, the review report and Article 5 and Article 14(2), points (a), (c) and (d), of Regulation (EC) No 396/2005, there is no need to establish MRLs for this active substance and it is therefore appropriate to include *Trichoderma atroviride* strain AGR2 in Annex IV to Regulation (EC) No 396/2005.
- (4) Commission Implementing Regulation (EU) 2023/199⁹ approved the low-risk active substance *Trichoderma atroviride* strain AT10. During the peer review of the pesticide risk assessment of the active substance under Regulation (EC) No 1107/2009, the Authority concluded¹⁰ that some information was not available as regards the dietary risk assessment for consumers and that further consideration by risk managers was required. As set out in the review report for that active substance¹¹ in the context of the risk assessment under Regulation (EC) No 1107/2009, *Trichoderma atroviride* strain AT10 is not pathogenic to humans, is not expected to produce toxins that are relevant for human health and the risk to humans through metabolites is negligible. Taking into

⁶ Commission Implementing Regulation (EU) 2023/216 of 1 February 2023 approving the low-risk active substance *Trichoderma atroviride* AGR2 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 (OJ L 30, 2.2.2023, p. 7).

⁷ Conclusion on the peer review of the pesticide risk assessment of the active substance *Trichoderma atroviride* strain AGR2. EFSA Journal 2022;20(3).

⁸ Review report for the active substance *Trichoderma atroviride* strain AGR2 as a low-risk substance Finalised in the Standing Committee on Plants, Animals, Food and Feed Animals, Food and Feed at its meeting on 9 December 2022 in view of the approval of *Trichoderma atroviride* strain AGR2 in accordance with Regulation (EC) No 1107/2009. <https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/start/screen/active-substances/details/1231>.

⁹ 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 (OJ L 27, 31.1.2023, p. 22).

¹⁰ Conclusion on the peer review of the pesticide risk assessment of the active substance *Trichoderma atroviride* strain AT10. EFSA Journal 2022; 20(4):7200.

¹¹ Review report for the active substance *Trichoderma atroviride* strain AT10 as low-risk substance Finalised in the Standing Committee on Plants, Animals, Food and Feed at its meeting on 9 December 2022 in view of the approval of *Trichoderma atroviride* strain AT10 in accordance with Regulation (EC) No 1107/2009. <https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/start/screen/active-substances/details/1268>.

account the peer review of the pesticide risk assessment of the active substance *Trichoderma atroviride* strain AT10, the review report and Article 5 and Article 14(2), points (a), (c) and (d), of Regulation (EC) No 396/2005, there is no need to establish MRLs for this active substance and it is therefore appropriate to include *Trichoderma atroviride* strain AT10 in Annex IV to Regulation (EC) No 396/2005.

- (5) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (6) 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

In Annex IV to Regulation (EC) No 396/2005, the following entries are inserted in alphabetical order: *Pythium oligandrum* strain M1, *Trichoderma atroviride* strain AGR2 and *Trichoderma atroviride* strain AT10.

Article 2

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,

For the Commission
The President
Ursula VON DER LEYEN