

COMMISSION REGULATION (EU) 2023/1030

of 25 May 2023

amending Annex IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards *Bacillus amyloliquefaciens* strain AH2, *Bacillus amyloliquefaciens* strain IT-45 and *Purpureocillium lilacinum* strain PL11

(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/EEC ⁽¹⁾, and in particular Article 5(1) and Article 14(1) thereof,

Whereas:

- (1) For *Bacillus amyloliquefaciens* strain AH2, *Bacillus amyloliquefaciens* strain IT-45 and *Purpureocillium lilacinum* strain PL11, no specific maximum residue levels ('MRLs') have been set. Therefore, 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) 2021/1455 ⁽²⁾ approved the low-risk active substance *Bacillus amyloliquefaciens* strain AH2. During the peer-review of the pesticide risk assessment of the active substance under Regulation (EC) No 1107/2009 of the European Parliament and of the Council ⁽³⁾, the European Food Safety Authority ('Authority') concluded ⁽⁴⁾, as regards the dietary risk assessment for consumers, some information was not available and further consideration by risk managers was required. As set out in the review report for that substance ⁽⁵⁾ in the context of the risk assessment of the active substance under Regulation (EC) No 1107/2009 *Bacillus amyloliquefaciens* strain AH2 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 *Bacillus amyloliquefaciens* strain AH2, the review report and Article 5 and Article 14(2), point (a), (c) and (d), of Regulation (EC) No 396/2005, there is no need to establish MRLs for this substance and it is therefore appropriate to include *Bacillus amyloliquefaciens* strain AH2 in Annex IV to Regulation (EC) No 396/2005.

⁽¹⁾ OJ L 70, 16.3.2005, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) 2021/1455 of 6 September 2021 approving the low-risk active substance *Bacillus amyloliquefaciens* strain AH2 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 315, 7.9.2021, p. 1).

⁽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⁾ Peer review of the pesticide risk assessment of the active substance *Bacillus amyloliquefaciens* strain AH2. *EFSA Journal* 2020;18(7):6156. Doi: <https://doi.org/10.2903/j.efsa.2020.6156>.

⁽⁵⁾ Review report for the active substance *Bacillus amyloliquefaciens* strain AH2 [finalised in the Standing Committee on Plants, Animals, Food and Feed at its meeting on 5 July 2021] SANTE/11938/2020 Rev. 4, 6 July 2021. <https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/start/screen/active-substances/details/1257>.

- (3) Commission Implementing Regulation (EU) 2022/159 ⁽⁶⁾ approved the low-risk active substance *Bacillus amyloliquefaciens* strain IT-45. During the peer-review of the pesticide risk assessment of the active substance under Regulation (EC) No 1107/2009, the Authority concluded ⁽⁷⁾, as regards the dietary risk assessment for consumers some information was not available and further consideration by risk managers was required. As set out in the review report for that substance ⁽⁸⁾, in the context of the risk assessment of the active substance under Regulation (EC) No 1107/2009 *Bacillus amyloliquefaciens* strain IT-45 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 *Bacillus amyloliquefaciens* strain IT-45, the review report and Article 5 and Article 14(2), point (a), (c) and (d), of Regulation (EC) No 396/2005, there is no need to establish MRLs for this substance and it is therefore appropriate to include *Bacillus amyloliquefaciens* strain IT-45 in Annex IV to Regulation (EC) No 396/2005.
- (4) Commission Implementing Regulation (EU) 2022/4 ⁽⁹⁾ approved the low-risk active substance *Purpureocillium lilacinum* strain PL11. During the peer-review of the pesticide risk assessment of the active substance under Regulation (EC) No 1107/2009 the Authority concluded ⁽¹⁰⁾, as regards the dietary risk assessment for consumers some information was not available and further consideration by risk managers was required. As set out in the review report for that substance ⁽¹¹⁾, in the context of the risk assessment of the active substance under Regulation (EC) No 1107/2009 *Purpureocillium lilacinum* strain PL11 is not pathogenic to humans and the risk to humans through metabolites is negligible. Taking into account the peer review of the pesticide risk assessment of the active substance *Purpureocillium lilacinum* strain PL11, the review report and Article 5 and Article 14(2), point (a), (c) and (d), of Regulation (EC) No 396/2005, there is no need to establish MRLs for this substance and it is therefore appropriate to include *Purpureocillium lilacinum* strain PL11 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: *Bacillus amyloliquefaciens* strain AH2, *Bacillus amyloliquefaciens* strain IT-45 and *Purpureocillium lilacinum* strain PL11.

⁽⁶⁾ Commission Implementing Regulation (EU) 2022/159 of 4 February 2022 approving the low-risk active substance *Bacillus amyloliquefaciens* strain IT-45 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 26, 7.2.2022, p. 7).

⁽⁷⁾ Peer review of the pesticide risk assessment of the active substance *Bacillus amyloliquefaciens* strain IT-45. *EFSA Journal* 2021;19(5):6594. Doi: <https://doi.org/10.2903/j.efsa.2021.6594>.

⁽⁸⁾ Review report for the active substance *Bacillus amyloliquefaciens* strain IT-45 [finalised in the Standing Committee on Plants, Animals, Food and Feed at its meeting on 1-2 December 2021] SANTE/10762/2021 Rev. 1, 1-2 December 2021. <https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/start/screen/active-substances/details/1333>.

⁽⁹⁾ Commission Implementing Regulation (EU) 2022/4 of 4 January 2022 approving the active substance *Purpureocillium lilacinum* strain PL11 as a low-risk substance 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 1, 5.1.2022, p. 5).

⁽¹⁰⁾ Peer review of the pesticide risk assessment of the active substance *Purpureocillium lilacinum* strain PL11. *EFSA Journal* 2022;20(5):6393. Doi: <https://doi.org/10.2903/j.efsa.2022.6393>.

⁽¹¹⁾ Review report for the active substance *Purpureocillium lilacinum* strain PL11 [finalised in the Standing Committee on Plants, Animals, Food and Feed at its meeting on 22 October 2021] SANTE/10418/2021 Rev. 4. <https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/start/screen/active-substances/details/1285>.

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, 25 May 2023.

For the Commission
The President
Ursula VON DER LEYEN
