



2025/2473

8.12.2025

COMMISSION REGULATION (EU) 2025/2473

of 5 December 2025

**amending Annex IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council
as regards maximum residue levels for *Betabaculovirus phoperculellae*, elemental iron and rape seed
oil in or on certain products**

(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, thereof,

Whereas:

- (1) For the active substances *Betabaculovirus phoperculellae* and elemental iron, 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. Since no MRLs were required for the active substance rape seed oil, that active substance was temporarily included in Annex IV to that Regulation.
- (2) The Commission approved *Betabaculovirus phoperculellae* as a low-risk active substance ⁽²⁾ in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council ⁽³⁾. According to the European Food Safety Authority ('the Authority'), exposure to that substance does not pose health risks to consumers ⁽⁴⁾. It is therefore appropriate to include this substance in Annex IV to Regulation (EC) No 396/2005.
- (3) The Commission approved elemental iron as a low-risk active substance ⁽⁵⁾ in accordance with Regulation (EC) No 1107/2009. The Authority concluded that the natural exposure of plants to elemental iron through soil is expected to be higher than the exposure linked to its use as plant protection product ⁽⁶⁾. It is therefore appropriate to include this substance in Annex IV to Regulation (EC) No 396/2005.

⁽¹⁾ OJ L 70, 16.3.2005, p. 1, ELI: <http://data.europa.eu/eli/reg/2005/396/oj>.

⁽²⁾ Commission Implementing Regulation (EU) 2025/103 of 22 January 2025 approving the active substance *Betabaculovirus phoperculellae* as a low-risk active substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) No 540/2011 (OJ L, 2025/103, 23.1.2025, ELI: http://data.europa.eu/eli/reg_impl/2025/103/oj).

⁽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, ELI: <http://data.europa.eu/eli/reg/2009/1107/oj>).

⁽⁴⁾ Peer review of the pesticide risk assessment of the active substance *Phthorimaea operculella* granulovirus. *EFSA Journal* 2024;22(8): e8976. <https://doi.org/10.2903/j.efsa.2024.8976>.

⁽⁵⁾ Commission Implementing Regulation (EU) 2025/845 of 5 May 2025 approving the active substance elemental iron as a low-risk active substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) No 540/2011 (OJ L, 2025/845, 6.5.2025, ELI: http://data.europa.eu/eli/reg_impl/2025/845/oj).

⁽⁶⁾ Peer review of the pesticide risk assessment of the active substance elemental iron. *EFSA Journal* 2024;22(10): e9056. <https://doi.org/10.2903/j.efsa.2024.9056>.

- (4) Rape seed oil is an approved active substance already included in Annex IV to Regulation (EC) No 396/2005 on a temporary basis ⁽⁷⁾. According to the Authority, the substance is not expected to possess hazardous properties, and exposure from uses as plant protection product is unlikely to be higher than exposure via food ⁽⁸⁾. It is therefore appropriate to maintain this active substance in Annex IV to Regulation (EC) No 396/2005 and to delete the reference to the footnote indicating its temporary inclusion in Annex IV.
- (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

Annex IV to Regulation (EC) No 396/2005 is amended in accordance with the Annex to this Regulation.

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, 5 December 2025.

For the Commission
The President
Ursula VON DER LEYEN

⁽⁷⁾ Commission Regulation (EC) No 839/2008 of 31 July 2008 amending Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards Annexes II, III and IV on maximum residue levels of pesticides in or on certain products (OJ L 234, 30.8.2008, p. 1, ELI: <http://data.europa.eu/eli/reg/2008/839/oj>).

⁽⁸⁾ Peer review of the pesticide risk assessment of the active substance rape seed oil. EFSA Journal 2022;20(5): e07305. <https://doi.org/10.2903/j.efsa.2022.7305>.

ANNEX

Annex IV to Regulation (EC) No 396/2005 is amended as follows:

- (1) the reference to footnote 1 after the entry 'Plant oils/Rapeseed oil' is deleted;
 - (2) the following entries are added:
'*Betabaculovirus phoperculellae*;
Elemental iron'.
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