

Brussels, XXX
PLAN/2025/985
[...] (2025) XXX draft

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

of XXX

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)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.

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

of **XXX**

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/EEC¹, 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 these 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. For the active substance rape seed oil, it was concluded that no MRLs were required. This active substance was therefore temporarily included in Annex IV to that Regulation.
- (2) *Betabaculovirus phoperculellae* was approved as a low-risk substance². According to the European Food Safety Authority, hereinafter 'the Authority', exposure to the substance does not pose health risks for consumers³. It is therefore appropriate to include this substance in Annex IV to Regulation (EC) No 396/2005.
- (3) Elemental iron was approved as a low-risk substance⁴ in accordance with Regulation (EC) No 1107/2009⁵. The Authority concluded that the natural exposure of plants to

-

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, p. 1, ELI: http://data.europa.eu/eli/reg_impl/2025/103/oj)

³ Peer review of the pesticide risk assessment of the active substance Peer review of the pesticide risk assessment of the active substance *Phthorimaea operculella* granulovirus. EFSA Journal 2024;22(8): e9194. <https://doi.org/10.2903/j.efsa.2024.8976>.

⁴ 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).

⁵ 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

elemental iron through soil is expected to be higher than the exposure linked to the use as plant protection product⁶. It is therefore appropriate to include this substance in Annex IV to Regulation (EC) No 396/2005.

- (4) Rape seed oil is an approved active substance already included in Annex IV to Regulation (EC) No 396/2005 on a temporary basis. According to the Authority⁷, 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. It is therefore appropriate to maintain this active substance in Annex IV to Regulation (EC) No 396/2005 and to delete the footnote referring to 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,

For the Commission
The President
Ursula VON DER LEYEN

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>).

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>.

⁷ 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>.