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Subject: 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 *Allium fistulosum*, processed; lysate of *Willaertia magna*; magnesium hydroxide E528; *Onobrychis viciifolia* (sainfoin) dried pellets and *Vitis vinifera* L. seed extract (grape seed extract) in or on certain products

Delegations will find attached document D109998/02.

Encl.: D109998/02



Brussels, **XXX**
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D109998/02
[...] (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 *Allium fistulosum*, processed; lysate of *Willaertia magna*; magnesium hydroxide E528; *Onobrychis viciifolia* (sainfoin) dried pellets and *Vitis vinifera* L. seed extract (grape seed extract) in or on certain products

(Text with EEA relevance)

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amending Annex IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for *Allium fistulosum*, processed; lysate of *Willaertia magna*; magnesium hydroxide E528; *Onobrychis viciifolia* (sainfoin) dried pellets and *Vitis vinifera* L. seed extract (grape seed extract) 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(1) thereof,

Whereas:

- (1) For the active substances *Allium fistulosum*, processed; lysate of *Willaertia magna*; magnesium hydroxide E528; *Onobrychis viciifolia* (sainfoin) dried pellets and *Vitis vinifera* L. seed extract (grape seed extract), 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) On 11 November 2024, the Commission approved *Allium fistulosum*, processed, as a basic substance² in accordance with Regulation (EC) No 1107/2009³. The conditions of use of this substance are not expected to lead to the presence of residues in food or feed commodities that may pose a risk to the consumer and, therefore, no MRLs are required. It is therefore appropriate to include this substance in Annex IV to Regulation (EC) No 396/2005.
- (3) On 17 June 2025, the Commission approved Lysate of *Willaertia magna* as a low-risk active substance in accordance with Regulation (EC) No 1107/2009⁴. The European

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

² Commission Implementing Regulation (EU) 2024/2878 of 8 November 2024 approving the basic substance *Allium fistulosum*, processed, 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, 2024/2878, 11.11.2024, ELI: http://data.europa.eu/eli/reg_impl/2024/2878/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 Commission Implementing Regulation (EU) 2025/1177 of 16 June 2025 approving the active substance lysate of *Willaertia magna* 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

Food Safety Authority ('the Authority') concluded that toxicological reference values were not necessary for this substance as it does not exhibit any hazardous properties⁵. It is therefore appropriate to include this substance in Annex IV to Regulation (EC) No 396/2005.

- (4) On 13 March 2024, the Commission approved magnesium hydroxide E528 as a basic substance in accordance with Regulation (EC) No 1107/2009⁶. The conditions of use of this substance are not expected to lead to the presence of residues in food or feed commodities that may pose a risk to the consumer and, therefore, no MRLs are required. It is therefore appropriate to include this substance in Annex IV to Regulation (EC) No 396/2005.
- (5) On 27 June 2024, the Commission approved *Onobrychis viciifolia* (sainfoin) dried pellets as a basic substance in accordance with Regulation (EC) No 1107/2009⁷. The conditions of use of this substance are not expected to lead to the presence of residues in food or feed commodities that may pose a risk to the consumer and, therefore, no MRLs are required. It is therefore appropriate to include this substance in Annex IV to Regulation (EC) No 396/2005.
- (6) On 22 January 2025, the Commission approved *Vitis vinifera* L. seed extract (grape seed extract) as a basic substance in accordance with Regulation (EC) No 1107/2009⁸. The conditions of use of this substance are not expected to lead to the presence of residues in food or feed commodities that may pose a risk to the consumer and, therefore, no MRLs are required. It is therefore appropriate to include this substance in Annex IV to Regulation (EC) No 396/2005.
- (7) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (8) 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: *Allium fistulosum*, processed; Lysate of *Willaertia magna*; Magnesium hydroxide E528; *Onobrychis viciifolia* (sainfoin) dried pellets; *Vitis vinifera* L. seed extract (grape seed extract).

Regulation (EU) No 540/2011 (OJ L, 2025/1177, 17.6.2025, p. 1, ELI: http://data.europa.eu/eli/reg_impl/2025/1177/oj).

⁵ Peer review of the pesticide risk assessment of the active substance lysate of *Willaertia magna* C2c Maky. EFSA Journal 2025;23(1): e9194. <https://doi.org/10.2903/j.efsa.2025.9194>.

⁶ Commission Implementing Regulation (EU) 2024/836 of 12 March 2024 approving the basic substance magnesium hydroxide E528 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, 2024/836, 13.3.2024, ELI: http://data.europa.eu/eli/reg_impl/2024/836/oj).

⁷ Commission Implementing Regulation (EU) 2024/1768 of 26 June 2024 approving the basic substance *Onobrychis viciifolia* (sainfoin) dried pellets 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, 2024/1768, 27.6.2024, ELI: http://data.europa.eu/eli/reg_impl/2024/1768/oj).

⁸ Commission Implementing Regulation (EU) 2025/96 of 21 January 2025 approving the basic substance *Vitis vinifera* L. seed extract (grape seed extract) 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, 2025/96, 22.1.2025, ELI: http://data.europa.eu/eli/reg_impl/2025/96/oj).

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