



Brussels, **XXX**
PLAN/2022/2310 v2
[...](2023) **XXX** draft

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

of **XXX**

amending Annexes II and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for denatonium benzoate, diuron, etoxazole, methomyl and teflubenzuron in or on certain products

(Text with EEA relevance)

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amending Annexes II and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for denatonium benzoate, diuron, etoxazole, methomyl and teflubenzuron 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 14(1), point (a), Article 18(1), point (b), and Article 49(2) thereof,

Whereas:

- (1) For denatonium benzoate, diuron, etoxazole, methomyl and teflubenzuron, maximum residue levels ('MRLs') were set in Annex II to Regulation (EC) No 396/2005.
- (2) The approval of the active substance denatonium benzoate expired on 30 November 2020² and no application for renewal of its approval had been submitted. All existing authorisations for plant protection products containing that active substance have been revoked. No Codex maximum residue limits ('CXLs') or import tolerances exist for that substance. The MRLs for denatonium benzoate on all products are set at the limit of determination ('LOD'). It is therefore appropriate to delete the MRLs set out for this substance in Annex II to Regulation (EC) No 396/2005 in accordance with Article 17 of Regulation (EC) No 396/2005 in conjunction with Article 14(1), point (a), thereof. MRLs for denatonium benzoate on all products should be set at the product specific LODs in Annex V to Regulation (EC) No 396/2005 in accordance with Article 18(1), point (b), of that Regulation.
- (3) The approval of the active substance diuron expired on 30 September 2020 and no application for renewal of its approval had been submitted. All existing authorisations for plant protection products containing that active substance have been revoked. No CXLs or import tolerances exist for that substance. The MRLs for diuron on all products are currently set at the product specific LODs. It is therefore appropriate to delete the MRLs set out for this substance in Annex II to Regulation (EC) No 396/2005 in accordance with Article 17 of Regulation (EC) No 396/2005 in conjunction with Article 14(1), point (a), thereof. MRLs for diuron on all products should be set at the product specific LODs in Annex V to Regulation (EC) No 396/2005 in accordance with Article 18(1), point (b), of that Regulation. Additionally,

¹ OJ L 70, 16.3.2005, p. 1.

² Commission Implementing Regulation (EU) 2020/1643 of 5 November 2020 amending Implementing Regulation (EU) No 540/2011 as regards the approval periods of the active substances calcium phosphide, denathonium benzoate, haloxyfop-P, imidacloprid, pencycuron and zeta-cypermethrin (OJ L 370, 6.11.2020, p. 18).

for the avoidance of doubt, the respective footnotes indicating lack of information on residue trials should be deleted.

- (4) The approval of the active substance etoxazole was renewed by Commission Implementing Regulation (EU) 2020/2105³ with a specific provision that only uses of plant protection products on ornamental plants in permanent greenhouses shall be authorised by Member States. All existing authorisations for plant protection products containing that active substance for use on edible crops have been revoked. In the context of the procedure for the renewal of approval of that active substance, the European Food Safety Authority ('the Authority') published a conclusion⁴ on the peer review explaining that risks for human health from consumption of edible crops treated with etoxazole could not be excluded. Therefore, existing MRLs based on CXLs cannot be confirmed as being safe for consumers and cannot be maintained. It is therefore appropriate to delete the MRLs set out for this substance in Annex II to Regulation (EC) No 396/2005 in accordance with Article 17 of Regulation (EC) No 396/2005 in conjunction with Article 14(1) point (a) thereof. MRLs for etoxazole on all products should be set at the product specific LODs in Annex V to Regulation (EC) No 396/2005 in accordance with Article 18(1), point (b), of that Regulation. Additionally, for the avoidance of doubt, the footnote indicating lack of information on analytical methods should be deleted.
- (5) The approval of the active substance methomyl expired on 31 August 2019 as no application for renewal of its approval had been submitted. All existing authorisations for plant protection products containing that active substance have been revoked. The MRLs for methomyl on kumquats and gherkins were based on CXLs that the Authority had confirmed are safe for consumers⁵. Those MRLs should therefore be maintained in Annex II to Regulation (EC) No 396/2005 at the existing levels in accordance with Article 14(2), point (e), of Regulation (EC) No 396/2005. The existing MRLs for methomyl on lettuces, beans (dry), soyabeans, cotton seeds, maize/corn, and oat were based on CXLs, for which the Authority concluded that they are not sufficiently supported by data as data is missing on metabolism of methomyl in leafy crops, pulses and oilseeds⁵. Those MRLs should therefore be lowered to product specific LODs in Annex II to Regulation (EC) No 396/2005. For all other products, for which the MRLs were based on uses in the EU which are no longer authorized, it is appropriate to lower the MRLs to product specific LODs in Annex II to Regulation (EC) No 396/2005 in accordance with Article 17 of Regulation (EC) No 396/2005 in conjunction with Article 14(1) point (a) thereof. Additionally, for the avoidance of doubt, the footnotes indicating lack of information on residue trials and crop metabolism should be deleted.
- (6) The approval of the active substance teflubenzuron expired on 30 November 2019 as no application for renewal of its approval had been submitted. The MRLs for teflubenzuron on grapefruits and mandarins are based on import tolerance requests

³ Commission Implementing Regulation (EU) 2020/2105 of 15 December 2020 renewing the approval of the active substance etoxazole as a candidate for substitution 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 425, 16.12.2020, p. 96).

⁴ EFSA Conclusion on the peer review of the pesticide risk assessment of the active substance etoxazole; EFSA Journal 2017;15(10):4988.

⁵ EFSA Reasoned Opinion on the review of the existing maximum residue levels for methomyl according to Article 12 of Regulation (EC) No 396/2005; EFSA Journal 2015;13(10):4277.

from Brazil, which the Authority had confirmed as safe for consumers⁶. The MRLs for teflubenzuron on citrus fruits, grapes, papayas, tomatoes, cucumbers, gherkins, melons, sunflower seeds, soyabeans, and coffee beans result from the implementation of CXLs, which the Authority had confirmed as safe for consumers⁷. Those MRLs should therefore be maintained in Annex II to Regulation (EC) No 396/2005 at the existing levels in accordance with Article 14(2), point (e), of Regulation (EC) No 396/2005. For all other products, for which the MRLs were based on uses in the EU which are no longer authorized, it is appropriate to lower the MRLs to product specific LODs in Annex II to Regulation (EC) No 396/2005 in accordance with Article 17 of Regulation (EC) No 396/2005 in conjunction with Article 14(1) point (a) thereof.

- (7) The Commission consulted the European Union reference laboratories for residues of pesticides as regards the need to adapt certain LODs. For all the active substances covered by this Regulation, those laboratories proposed product specific LODs that are analytically achievable.
- (8) Through the World Trade Organisation, the trading partners of the Union were consulted on the new MRLs and their comments have been taken into account.
- (9) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (10) As regards the active substances denatonium benzoate, diuron, methomyl and teflubenzuron, to allow for the normal marketing, processing and consumption of products, this Regulation should not apply to products, which have been produced in the Union or imported into the Union before the new MRLs become applicable and for which a high level of consumer protection is maintained.
- (11) A reasonable period should be allowed to elapse before the new MRLs become applicable in order to permit Member States, third countries and food business operators to adapt themselves to the requirements which result from the modification of the MRLs.
- (12) 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

Annexes II and V to Regulation (EC) No 396/2005 are amended in accordance with the Annex to this Regulation.

Article 2

As regards the active substances denatonium benzoate, diuron, methomyl and teflubenzuron in and on all products, Regulation (EC) No 396/2005 as it stood before being amended by this Regulation shall continue to apply to products which were produced in the Union or imported into the Union before ... [*Office of publications: please insert date 6 months after the date of entry into force of this Regulation*].

⁶ EFSA Reasoned Opinion on the setting of import tolerances for teflubenzuron in grapefruits, mandarins and broccoli; EFSA Journal 2018;16(11):5474.

⁷ EFSA Scientific support for preparing an EU position in the 49th Session of the Codex Committee on Pesticide Residues (CCPR); EFSA Journal 2017;15(7):4929.

Article 3

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from ... [*Office of publications: please insert date 6 months after the date of entry into force of this Regulation*].

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