



Council of the  
European Union

Brussels, 17 December 2020  
(OR. en)

14077/20

**AGRILEG 172**  
**PESTICIDE 50**

**COVER NOTE**

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From:	European Commission
date of receipt:	14 December 2020
To:	General Secretariat of the Council

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No. Cion doc.:	D067437/05
Subject:	COMMISSION REGULATION (EU) .../... of XXX amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for diclofop, fluopyram, ipconazole and terbuthylazine in or on certain products

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Delegations will find attached document D067437/05.

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Encl.: D067437/05



Brussels, **XXX**  
SANTE/10044/2020  
(POOL/E4/2020/10044/10044-EN.docx)  
D067437/05  
[...](2020) **XXX** draft

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

**of **XXX****

**amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for diclofop, fluopyram, ipconazole and terbuthylazine in or on certain products**

(Text with EEA relevance)

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

of **XXX**

## **amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for diclofop, fluopyram, ipconazole and terbuthylazine 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<sup>1</sup>, and in particular Article 14(1)(a) and Article 49(2) thereof,

Whereas:

- (1) For diclofop, fluopyram, ipconazole and terbuthylazine maximum residue levels (MRLs) were set in Part A of Annex III to Regulation (EC) No 396/2005.
- (2) For diclofop the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005<sup>2</sup>. It proposed to change the residue definition. The Authority concluded that concerning the MRLs for barley and wheat, some information was not available and that further consideration by risk managers was required. As there is no risk for consumers, the MRLs for those products should be set in Annex II to Regulation (EC) No 396/2005 at the existing level or the level identified by the Authority. These MRLs will be reviewed; the review will take into account the information available within two years from the publication of this Regulation.
- (3) For fluopyram the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005<sup>3</sup>. It recommended lowering the MRLs for mulberries (black and white), elderberries, cassava roots/manioc, arrowroots, beetroots, garlic, onions, shallots, chervil, chives, celery leaves, parsley, sage, rosemary, thyme, laurel/bay leaves, tarragon, lentils, buckwheat and other pseudocereals and herbal infusions from roots. For other products, the Authority recommended raising or keeping the existing MRLs. Based on rotational crops studies and taking into account that the uptake of residues in succeeding crops cannot be fully avoided, specific MRLs reflecting uptake of residues from soil were derived for cassava roots/manioc, sweet potatoes, yams, arrowroots, other root and

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<sup>1</sup> OJ L 070, 16.3.2005, p. 1.

<sup>2</sup> European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for diclofop according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2020; 18(1): 5981.

<sup>3</sup> European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for fluopyram according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2020; 18(4): 6059.

tuber vegetables except sugar beets, chicory roots, broccoli, cauliflowers, Brussels sprouts, head cabbages, kales, kohlrabies, watercresses, herbal infusions from roots, root and rhizome spices, sugar beet roots, sweet corn, maize/corn, buckwheat and other pseudocereals and common millet/proso millet. The MRLs for those products should be set in Annex II to Regulation (EC) No 396/2005 at the existing level or the level identified by the Authority. The Authority further concluded that concerning the MRLs for lemons, mandarins, bananas, spring onions/green onions and Welsh onions, tomatoes, melons, watermelons, Chinese cabbage/pe-tsai, escaroles/broad-leaved endives, land cresses, red mustards, spinaches, chards/beet leaves, globe artichokes and leeks some information was not available and that further consideration by risk managers was required. As there is no risk for consumers, the MRLs for those products should be set in Annex II to Regulation (EC) No 396/2005 at the existing level or the level identified by the Authority. These MRLs will be reviewed; the review will take into account the information available within two years from the publication of this Regulation.

- (4) For ipconazole the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005<sup>4</sup>. It recommended keeping the existing MRLs. The MRLs for the products concerned should be set in Annex II to Regulation (EC) No 396/2005 at the existing level or the level identified by the Authority.
- (5) For terbuthylazine the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005<sup>5</sup>. The Authority proposed to change the residue definition for milk. It recommended lowering the MRLs for maize/corn and sorghum. The MRLs for those products should be set in Annex II to Regulation (EC) No 396/2005 at the level identified by the Authority. The Authority further concluded that concerning the MRLs for sweet corn, lupins/lupini beans, sunflower seeds, cotton seeds, bovine (muscle, fat, liver, kidney, milk) and equine (muscle, fat, liver, kidney, milk) some information was not available and that further consideration by risk managers was required. As there is no risk for consumers, the MRLs for those products should be set in Annex II to Regulation (EC) No 396/2005 at the level identified by the Authority. These MRLs will be reviewed; the review will take into account the information available within two years from the publication of this Regulation.
- (6) Existing Codex maximum residue limits (CXLs) were taken into account in the reasoned opinions of the Authority. CXLs, which are safe for consumers in the Union, were considered for MRL setting.
- (7) As regards products on which the use of the plant protection product concerned is not authorised in the EU, and for which no import tolerances or CXLs exist, MRLs should be set at the specific Limit of Determination ('LOD') or the default MRL should apply, as provided for in Article 18(1)(b) of Regulation (EC) No 396/2005.
- (8) The Commission consulted the European Union reference laboratories for residues of pesticides as regards the need to adapt certain LOD. As regards all substances

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<sup>4</sup> European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for ipconazole according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2020; 18(1): 5961.

<sup>5</sup> European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for terbuthylazine according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2020; 18(1): 5980.

concerned by this Regulation, those laboratories concluded that for certain commodities technical development requires the setting of specific LOD.

- (9) Based on the reasoned opinions of the Authority and taking into account the factors relevant to the matter under consideration, the appropriate modifications to the MRLs fulfil the requirements of Article 14(2) of Regulation (EC) No 396/2005.
- (10) 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.
- (11) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (12) In order to allow for the normal marketing, processing and consumption of products, this Regulation should provide for a transitional arrangement for products which have been produced before the modification of the MRLs and for which information shows that a high level of consumer protection is maintained.
- (13) A reasonable period should be allowed to elapse before the modified MRLs become applicable in order to permit Member States, third countries and food business operators to prepare themselves to meet the new requirements which will result from the modification of the MRLs.
- (14) 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 III to Regulation (EC) No 396/2005 are amended in accordance with the Annex to this Regulation.

*Article 2*

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 of application of this Regulation*].

*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 Publication: please insert date 6 months after entry into force*].

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*