



Council of the  
European Union

060187/EU XXVI. GP  
Eingelangt am 02/04/19

Brussels, 1 April 2019  
(OR. en)

8034/19

AGRILEG 70  
PESTICIDE 10

#### COVER NOTE

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From:	European Commission
date of receipt:	27 March 2019
To:	General Secretariat of the Council
No. Cion doc.:	D059757/03
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 bispyribac, denatonium benzoate, fenoxycarb, flurochloridone, quizalofop-P-ethyl, quizalofop-P-tefuryl, propaquizafop, tebufenozide in or on certain products

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Delegations will find attached document D059757/03.

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Encl.: D059757/03



Brussels, **XXX**  
SANTE/10482/2018  
(POOL/E4/2018/10482/10482-EN.doc)  
D059757/03  
[...] (2019) **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 bispyribac, denatonium benzoate, fenoxycarb, flurochloridone, quizalofop-P-ethyl, quizalofop-P-tefuryl, propaquizafop, tebufenozide 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 bispyribac, denatonium benzoate, fenoxycarb, flurochloridone, quizalofop-P-ethyl, quizalofop-P-tefuryl, propaquizafop, tebufenozide 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 fenoxycarb, flurochloridone, propaquizafop and tebufenozide maximum residue levels ("MRLs") were set in Part A of Annex III to Regulation (EC) No 396/2005. For quizalofop-P-ethyl and quizalofop-P-tefuryl, expressed as quizalofop, including quizalofop-P, MRLs were set in Part A of Annex III to Regulation (EC) No 396/2005. For bispyribac and denatonium benzoate no MRLs were set in Regulation (EC) No 396/2005, and as these active substances are not included in Annex IV to that Regulation, the default value of 0.01 mg/kg laid down in Article 18(1)(b) of Regulation (EC) No 396/2005 applies.
- (2) For bispyribac the European Food Safety Authority ("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 recommended setting a MRL for rice. No other authorisations exist for this substance. As there is no risk for consumers, the MRLs for all other commodities should be set in Annex II to Regulation (EC) No 396/2005 at the specific limit of determination (LOD).

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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 bispyribac according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2018;16(1):5142.

- (3) For denatonium benzoate 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>. All existing authorisations for plant protection products containing denatonium benzoate are restricted only to uses as repellent in forestry and are not intended for direct application on edible crops. As there is no risk for consumers, MRLs should be set in Annex II to Regulation (EC) No 396/2005 at the specific LOD.
- (4) For fenoxycarb 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 lowering the MRLs for apples, pears, quinces, medlars, loquats/Japanese medlars, plums, table grapes, wine grapes, bovine (muscle, fat, liver, kidney), sheep (muscle, fat, liver, kidney), goat (muscle, fat, liver, kidney), equine (muscle, fat, liver, kidney) and milk (cattle, sheep, goat, horse). For other products, it recommended keeping the existing MRLs. The Authority concluded that concerning the MRLs for oranges, lemons, mandarins, apricots and table olives 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.
- (5) For flurochloridone 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. It recommended lowering the MRLs for potatoes, carrots, celeriacs/turnip rooted celeries, parsnips, sunflower seeds and cotton seeds. It concluded that concerning the MRLs for parsley roots/Hamburg roots parsley, maize/corn, wheat, swine (muscle, fat, liver, kidney), bovine (muscle, fat, liver, kidney), sheep (muscle, fat, liver, kidney), goat (muscle, fat, liver, kidney), equine (muscle, fat, liver, kidney), milk (sheep, goat) 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) For quizalofop-P-ethyl, quizalofop-P-tefuryl and propaquizafop the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005<sup>6</sup>. The Authority proposed changing the residue definition and lowering the MRLs for grapefruits, oranges, lemons, limes, mandarins, apples, pears, quinces, medlars, loquats/Japanese medlars, apricots, cherries (sweet),

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<sup>3</sup> European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for denatonium benzoate according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2018;16(3):5232.

<sup>4</sup> European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for fenoxycarb according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2018;16(1):5155.

<sup>5</sup> European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for flurochloridone according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2018;16(1):5144.

<sup>6</sup> European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for quizalofop-P-ethyl, quizalofop-P-tefuryl and propaquizafop according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2017;15(12):5050.

peaches, plums, table grapes, wine grapes, strawberries, blackberries, raspberries (red and yellow), blueberries, currants (black, red and white), gooseberries (green, red and yellow), rose hips, elderberries, table olives, kumquats, potatoes, beetroots, carrots, celeriacs/turnip rooted celeries, horseradishes, Jerusalem artichokes, parsnips, parsley roots/Hamburg roots parsley, radishes, salsifies, swedes/rutabagas, turnips, garlic, onions, shallots, sweet peppers/bell peppers, aubergines/eggplants, okra/lady's fingers, cucumbers, gherkins, courgettes, melons, pumpkins, watermelons, Brussels sprouts, Chinese cabbages/pe-tsai, kales, kohlrabies, lettuces, escaroles/broad-leaved endives, witloofs/Belgian endives, chervil, chives, celery leaves, parsley, sage, rosemary, thyme, basil and edible flowers, laurel/Bay leave, tarragon, beans (with pods), beans (without pods), peas (with pods), peas (without pods), lentils (fresh), asparagus, celeries, globe artichokes, leeks, beans (dry), lentils (dry), peas (dry), lupins/lupini beans (dry), cotton seeds, olives for olive oil production, herbal infusions from roots and sugar beet roots. For other products, it proposed raising or keeping the existing MRLs. It concluded that for lamb's lettuces/corn salads, lettuces, escaroles/broad-leaved endives, cresses and other sprouts and shoots, land cresses, roman rocket/rucola, red mustards, baby leaf crops (including brassica species), spinaches, chards/beet leaves, herbal infusions from flowers, herbal infusions from leaves and herbs, seed spices, fruit spices, swine (muscle, fat, liver, kidney), bovine (muscle, fat, liver, kidney), sheep (muscle, fat, liver, kidney), goat (muscle, fat, liver, kidney), equine (muscle, fat, liver, kidney), poultry (muscle, fat, liver), milk (cattle, sheep, goat, horse) and birds' eggs 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.

- (7) In accordance with Article 6(2) and (4) of Regulation (EC) No 396/2005 an application was submitted for quizalofop-P-ethyl used on maize in Canada. In accordance with Article 8 of Regulation (EC) No 396/2005, this application was evaluated by the Member State concerned and the evaluation report was forwarded to the Commission. The Authority assessed the application and the evaluation report, examining in particular the risks to the consumer and, where relevant, to animals and gave a reasoned opinion on the proposed MRL<sup>7</sup>. The Authority concluded that all requirements with respect to data were met and that the modification requested is safe for consumers.
- (8) For tebufenozide the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005<sup>8</sup>. It recommended lowering the MRL for chestnuts. For other products, it proposed raising or keeping the existing MRLs. It concluded that for cherries (sweet), rice, swine (liver, kidney), bovine (liver, kidney), sheep (fat, liver, kidney), goat (fat, liver, kidney), equine (liver, kidney), poultry (muscle, fat, liver), milk (cattle, sheep, goat, horse) and birds' eggs 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

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<sup>7</sup> European Food Safety Authority; Setting of import tolerance for quizalofop-P-ethyl in genetically modified maize. EFSA Journal 2018;16(4):5250.

<sup>8</sup> European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for tebufenozide according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2018;16(2):5190.

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. As regards broccoli, head cabbages, Chinese cabbages/pe-tsai, kales, lamb's lettuces/corn salads, lettuces, escaroles/broad-leaved endives, cresses and other sprouts and shoots, land cresses, roman rocket/rucola, red mustards, baby leaf crops (including Brassica species), spinaches, purslanes, chards/beet leaves, grape leaves and similar species, watercresses, chervil, basil and edible flowers, rapeseeds/canola seeds, sugar canes, swine (muscle, fat), bovine (muscle, fat), sheep (muscle), goat (muscle), equine (muscle, fat) and poultry muscle the Authority concluded that the Codex maximum residue limits (CXL) for those products are safe for consumers. It is therefore appropriate to set the MRLs for those products at the same level in Annex II to Regulation (EC) No 396/2005.

- (9) As regards products on which the use of the plant protection product concerned is not authorised, and for which no import tolerances or CXLs exist, MRLs should be set at the specific LOD or the default MRL should apply, as provided for in Article 18(1)(b) of Regulation (EC) No 396/2005.
- (10) The Commission consulted the European Union reference laboratories for residues of pesticides as regards the need to adapt certain limits of determination. As regards several substances, those laboratories concluded that for certain commodities technical development requires the setting of specific limits of determination.
- (11) 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.
- (12) 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.
- (13) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (14) In order to allow for the normal marketing, processing and consumption of products, this Regulation should provide for transitional measures 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.
- (15) 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.
- (16) 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*  
*Jean-Claude JUNCKER*