



Council of the  
European Union

082580/EU XXV. GP  
Eingelangt am 05/11/15

Brussels, 4 November 2015  
(OR. en)

13706/15

AGRILEG 208

## COVER NOTE

From:	European Commission
date of receipt:	30 October 2015
To:	General Secretariat of the Council
No. Cion doc.:	D041471/02
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 boscalid, clothianidin, thiamethoxam, folpet and tolclofos-methyl in or on certain products

Delegations will find attached document D041471/02.

Encl.: D041471/02



EUROPEAN  
COMMISSION

Brussels, **XXX**  
SANTE/10530/2015  
(POOL/E3/2015/10530/10530-EN.doc)  
D041471/02  
[...](2015) **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 boscalid, clothianidin, thiamethoxam, folpet and tolclofos-methyl 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 boscalid, clothianidin, thiamethoxam, folpet and tolclofos-methyl 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), Article 18(1)(b) and Article 49(2) thereof,

Whereas:

- (1) For boscalid, clothianidin, thiamethoxam and tolclofos-methyl maximum residue levels (MRLs) were set in Part A of Annex III to Regulation (EC) No 396/2005. For folpet, MRLs are set in Annex II and Part B of Annex III to that Regulation.
- (2) For boscalid, the European Food Safety Authority, hereinafter "the Authority", submitted a reasoned opinion on the existing MRLs in accordance with Article 12(2) of Regulation (EC) No 396/2005 in conjunction with Article 12(1) thereof<sup>2</sup>. It proposed to change the residue definition. It concluded that concerning all the MRLs under evaluation some information was not available and that further consideration by risk managers was required. It indicated that a potential for accumulation of boscalid residues in crops grown in rotation is expected. It calculated MRLs which take or do not take this potential for accumulation into account and left it to risk managers to choose the required option. As there is no risk for consumers, the MRLs should be set in Annex II to Regulation (EC) No 396/2005 at the level identified by the Authority which considers the potential for accumulation. 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 clothianidin, the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(2) of Regulation (EC) No 396/2005 in conjunction with

---

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

<sup>2</sup> EFSA (European Food Safety Authority), 2014. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for boscalid according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2014;12(7):3799, 127 pp.

Article 12(1) thereof<sup>3</sup>. It recommended lowering the MRLs for pecans, papaya, potatoes, tomatoes, peppers, aubergines, sweet corn, cauliflower, leafy brassica, lettuce, chervil, beans (fresh, without pods), peas (fresh, without pods), fresh lentils, cotton seed, sorghum grain, cocoa and chicory roots. For other products it recommended raising or keeping the existing MRLs. It concluded that concerning the MRLs for citrus fruits, cherries, table and wine grapes, strawberries, pineapples, melons, watermelons, kohlrabi and scarole 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 thiamethoxam, the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(2) of Regulation (EC) No 396/2005 in conjunction with Article 12(1) thereof<sup>4</sup>. It proposed to change the residue definition and recommended lowering the MRLs for pecans, pome fruits, peaches, table olives, bananas, papaya, potatoes, swedes, sweet corn, cauliflower, Brussels sprouts, head cabbage, leafy brassica, beans (fresh, with and without pods), peas (fresh, without pods), fresh lentils, pulses, linseed, peanuts, poppy seed, sesame seed, sunflower seed, rape seed, soya bean, mustard seed, cotton seed, pumpkin seeds, safflower, borage, gold of pleasure, hempseed, castor bean, olives for oil production, oats grain, rye grain, cocoa, sugar beet (roots), swine (muscle, liver, kidney), bovine (muscle, liver, kidney), sheep (muscle, liver, kidney) and goat (muscle, liver, kidney). For other products it recommended raising or keeping the existing MRLs. It concluded that concerning the MRLs for citrus fruits, apricots, cherries, table and wine grapes, strawberries, pineapples, melons, watermelons and scarole 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.
- (5) For folpet, the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(2) of Regulation (EC) No 396/2005 in conjunction with Article 12(1) thereof<sup>5</sup>. It proposed to change the residue definition. It recommended raising or keeping the existing MRLs for certain products. It concluded that concerning the MRLs for strawberries, table olives, potatoes, radishes, salsify, tomatoes, melons, olives for oil production, barley grain, wheat grain, hops (dried), poultry (meat, fat, liver) 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)

---

<sup>3</sup> EFSA (European Food Safety Authority), 2014. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for clothianidin and thiamethoxam according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2014;12(12):3918, 120 pp. doi:10.2903/j.efsa.2014.3918.

<sup>4</sup> EFSA (European Food Safety Authority), 2014. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for clothianidin and thiamethoxam according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2014;12(12):3918, 120 pp. doi:10.2903/j.efsa.2014.3918.

<sup>5</sup> EFSA (European Food Safety Authority), 2014. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for folpet according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2014;12(5):3700, 55 pp.

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. The Authority concluded that concerning the MRLs for garlic, onions, shallots, spring onions, kohlrabi, lettuce, scarole, spinach and beans (fresh, without pods) no information was available and that further consideration by risk managers was required. The MRLs for these products should be set at the specific limit of determination.

- (6) For tolclofos-methyl, the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(2) of Regulation (EC) No 396/2005 in conjunction with Article 12(1) thereof<sup>6</sup>. The Authority recommended keeping the MRL for potatoes. It concluded that concerning the MRLs for radishes, broccoli, cauliflower, Brussels sprouts, head cabbage, lamb's lettuce, lettuce, scarole (broad-leave endive), cress, land cress, rocket (rucola), red mustard and leaves and sprouts of Brassica spp. 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. The Authority concluded that concerning the MRLs for swedes, turnips, Chinese cabbage, kale, kohlrabi, celery, swine (muscle, fat, liver, kidney), bovine (muscle, fat, liver, kidney), sheep (muscle, fat, liver, kidney), goat (muscle, fat, liver, kidney), poultry (muscle, fat, liver), milk (cattle, sheep, goat) and birds' eggs no information was available and that further consideration by risk managers was required. The MRLs for these products should be set at the specific limit of determination.
- (7) As regards products on which the use of the plant protection product concerned is not authorised, and for which no import tolerances or Codex maximum residue limits (CXLs) exist, MRLs should be set at the specific limit of determination 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 limits of determination. As regards several substances, those laboratories concluded that for certain commodities technical development requires the setting of specific limits of determination.
- (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.

---

<sup>6</sup> European Food Safety Authority, 2014. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for tolclofos-methyl according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2014;12(12):3920, 42 pp.

- (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 before [*Office of Publications: please insert date 6 months after entry into force 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 Publications: 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*