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Delegations will find attached document D039941/02.

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**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 abamectin, desmedipham, dichlorprop-P, haloxyfop-P, oryzalin and phenmedipham 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 abamectin, desmedipham, dichlorprop-P, haloxyfop-P, oryzalin and phenmedipham 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 dichlorprop-P, haloxyfop-P and oryzalin, maximum residue levels (MRLs) were set in Part A of Annex III to Regulation (EC) No 396/2005. For abamectin, desmedipham and phenmedipham, MRLs were set in Annex II and Part B of Annex III to that Regulation.
- (2) For abamectin, the European Food Safety Authority, hereinafter "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 and recommended lowering the MRLs for bovine muscle and kidney. For other products it recommended raising or keeping the existing MRLs. It concluded that concerning the MRLs for citrus fruits, almonds, hazelnuts, walnuts, apples, pears, quinces, medlar, loquat, peaches, plums, table grapes, wine grapes, strawberries, blackberries, raspberries, currants (red, black and white), gooseberries, papaya, potatoes, radishes, garlic, onions, shallots, spring onions, tomatoes, peppers, aubergines, cucumbers, gherkins, courgettes, melons, pumpkins, watermelons, Chinese cabbage, lamb's lettuce, lettuce, scarole, rocket, leaves and sprouts of brassica, witloof, chervil, chives, celery leaves, parsley, sage, rosemary, thyme, basil, bay leaves, tarragon, beans (fresh, with pods), peas (fresh, with pods) and leek 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

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<sup>1</sup> OJ L 70, 16.3.2005, p. 1.

<sup>2</sup> European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for abamectin according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2014;12(9):3823.

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 cherries, avocados, peas (fresh, without pods) and globe artichokes no information was available and that for cress and celery the information available was insufficient to derive a tentative MRL and that further consideration by risk managers was required. The MRLs for these products should be set at the specific limit of determination. Taking into account additional information on the good agricultural practice provided by France after publication of the reasoned opinion and as there is no risk for consumers, the MRL for apricots should be set in Annex II to Regulation (EC) No 396/2005 at the existing level.

- (3) For desmedipham, 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>3</sup>. It concluded that concerning the MRLs for beetroot, beet leaves, sugar beet (root), swine muscle, fat, liver and kidney, bovine muscle, fat, liver and kidney, sheep muscle, fat, liver and kidney, goat muscle, fat, liver and kidney 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 dichlorprop-P, 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. It recommended lowering the MRLs for apples, pears, cherries, plums, barley grain, oats grain, rye grain and wheat grain. For oranges it recommended raising the existing MRL. It concluded that concerning the MRLs for swine muscle, fat, liver and kidney, bovine muscle, fat, liver and kidney, sheep muscle, fat, liver and kidney, goat muscle, fat, liver and kidney, cattle milk, sheep milk and goat 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 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 haloxyfop-P, 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>. It proposed to change the residue definition. It concluded that concerning the MRLs for carrots,

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<sup>3</sup> European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for desmedipham according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2014;12(7):3803.

<sup>4</sup> European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for dichlorprop-P according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2014;12(2):3552.

<sup>5</sup> European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for haloxyfop-P according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2014;12(10):3861.

onions, beans (dry), peas (dry), sunflower seed, sugar beet (root), swine muscle, fat, liver and kidney, bovine muscle, fat, liver and kidney, sheep muscle, fat, liver and kidney, goat muscle, fat, liver and kidney, poultry muscle, fat and liver, cattle milk, sheep milk, goat milk 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 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 spring onions and rape seed the information available was insufficient to derive a tentative MRL and that further consideration by risk managers was required. The MRL for spring onions should be set at the specific limit of determination. Taking into account additional information on the good agricultural practice provided by Australia after publication of the reasoned opinion and as there is no risk for consumers, the MRL for rape seed should be set in Annex II to Regulation (EC) No 396/2005 at the existing level. This MRL will be reviewed; the review will take into account the information available within two years from the publication of this Regulation.

- (6) For oryzalin, 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>. It recommended lowering the MRL for table grapes. For other products it recommended keeping the existing MRL. It concluded that concerning the MRLs for kiwi and asparagus 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 MRL for banana the information available was insufficient to derive a tentative MRL and that further consideration by risk managers was required. The MRL for this product should be set at the specific limit of determination.
- (7) For phenmedipham, 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>7</sup>. It proposed to change the residue definition. The Authority concluded that concerning the MRLs for strawberries, beetroot, spinach, beet leaves, chervil, chives, celery leaves, parsley, sage, rosemary, thyme, basil, bay leaves and tarragon 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 MRL for sugar beet (root) some information was not available and that further consideration by risk managers was required. Taking into account

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<sup>6</sup> European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for oryzalin according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2014;12(8):3819.

<sup>7</sup> European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for phenmedipham according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2014;12(8):3807.

additional information on the residue trials provided by Finland after publication of the reasoned opinion, the MRL for sugar beet (root) should be set in Annex II to Regulation (EC) No 396/2005 at 0.05\* mg/kg. This MRL 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 swine muscle, fat, liver and kidney, bovine muscle, fat, liver and kidney, sheep muscle, fat, liver and kidney, goat muscle, fat, liver and kidney, cattle milk, sheep milk and goat milk, poultry muscle, fat and liver and birds' eggs the information available was not sufficient to derive a tentative MRL and that further consideration by risk managers was required. The MRLs for these products should be set at the specific limit of determination.

- (8) 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 limit of determination or the default MRL should apply, as provided for in Article 18(1)(b) of Regulation (EC) No 396/2005.
- (9) 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.
- (10) 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.
- (11) 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.
- (12) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (13) 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.
- (14) 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.
- (15) 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 by *[Office of Publications please insert day before the 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**