



Council of the
European Union

Brussels, 8 November 2016
(OR. en)

14188/16

AGRILEG 167

COVER NOTE

From:	European Commission
date of receipt:	8 November 2016
To:	General Secretariat of the Council

No. Cion doc.:	D047111/02
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Subject:	COMMISSION REGULATION (EU) .../... of XXX amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bifenthrin, carbetamide, cinidon-ethyl, fenpropimorph and triflurosulfuron in or on certain products
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Delegations will find attached Commission document D047111/02.

Encl.: D047111/02



Brussels, **XXX**
SANTE/11418/2015
(POOL/E4/2015/11418/11418-EN.doc)
D047111/02
[...](2016) **XXX** draft

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

of **XXX**

amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bifenthrin, carbetamide, cinidon-ethyl, fenpropimorph and triflurosulfuron in or on certain products

(Text with EEA relevance)

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

of **XXX**

amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bifenthrin, carbetamide, cinidon-ethyl, fenpropimorph and triflusal 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)(a), Article 18(1)(b) and Article 49(2) thereof,

Whereas:

- (1) For carbetamide and triflusal maximum residue levels (MRLs) were set in Part A of Annex III to Regulation (EC) No 396/2005. For bifenthrin, cinidon-ethyl and fenpropimorph MRLs were set in Annex II and Part B of Annex III to that Regulation.
- (2) For bifenthrin 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 396/2005². It identified concerning the MRL for Chinese cabbage a risk for consumers. It is therefore appropriate to lower this MRL. The Authority proposed to change the residue definition and recommended lowering the MRLs for papaya, Brussels sprouts, head cabbage, rape seed, barley grain, maize grain, fruit spices, root and rhizome spices, muscle from swine, bovine, sheep and goat and poultry liver. For other products it recommended raising or keeping the existing MRLs. It concluded that concerning the MRLs for citrus fruit, cherries, peaches, plums, strawberries, blackberries, dewberries, raspberries 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 apples, pears,

¹ OJ L 70, 16.3.2005, p. 1.

² European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels (MRLs) for bifenthrin according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2015;13(4):4081.

currants, garlic, cucumbers, courgettes, melons, watermelons, beans with pods, beans without pods, peas with pods and peas 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. Taking into account comments by European stakeholder associations and trading partners, as there is no risk for consumers MRLs for herbal infusions should be set in Annex II to Regulation (EC) No 396/2005 at the existing level.

- (3) For carbetamide the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005³. It proposed to change the residue definition and recommended lowering the MRLs for sunflower seed and rape seed. It concluded that concerning the MRLs for apples, pears, quinces, stone fruit, table and wine grapes, lettuce, scarole, witloof, lentils (dry), peas (dry), chicory roots and milk from cattle, sheep and 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 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 salsify, kale, chive, celery leaves, parsley, tarragon, beans (dry), safflower, herbal infusions (dried flowers), herbal infusions (dried roots), spices (fruits and berries), sugar beet (root), muscle, fat, liver and kidney from swine, bovine, sheep and goat 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.
- (4) For cinidon-ethyl the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005⁴. The approval of cinidon-ethyl has not been renewed in accordance with Commission Implementing Regulation (EU) No 1134/2011⁵. Considering that the use of cinidon-ethyl is no longer authorised within the Union and no authorised uses in third countries have been notified, residues of cinidon-ethyl are not expected to occur in any plant or animal commodity. Nevertheless the Authority considers appropriate establishing the MRLs of cinidon-ethyl at the specific limit of determination or at the default MRL as set out in Article 18(1)(b) of Regulation (EC) No 396/2005.
- (5) For fenpropimorph the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005⁶. It identified

³ European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels (MRLs) for carbetamide according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2015;13(7):4192.

⁴ European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels (MRLs) for cinidon-ethyl according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2015;13(7):4166.

⁵ Commission Implementing Regulation (EU) No 1134/2011 of 9 November 2011 concerning the non-renewal of the approval of the active substance cinidon-ethyl, 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 Commission Implementing Regulation (EU) No 540/2011 (OJ L 292, 10.11.2011, p. 1).

⁶ European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels (MRLs) for fenpropimorph according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2015;13(3):4050.

concerning the MRLs for strawberries, blackberries and leek a risk for consumers. It is therefore appropriate to lower these MRLs. The Authority proposed to change the residue definition and recommended lowering the MRLs for banana, carrots, horseradish, parsnips, parsley root, salsifies, barley, oats, rye and wheat. For other products it recommended raising or keeping the existing MRLs. It concluded that concerning the MRLs for dewberries, raspberries, blueberries, cranberries, currants, gooseberries and hops 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 sugar beet (root) some information was not available and that further consideration by risk managers was required. The MRLs for this product should be set at the specific limit of determination.

- (6) For triflurosulfuron the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005⁷. It proposed to change the residue definition and recommended lowering the MRLs for beetroot, witloof, sugar beet (root) and chicory roots.
- (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.
- (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. Because a risk to consumers cannot be excluded at the current MRLs, the value for bifenthrin of 0.01 mg/kg for Chinese cabbage and the value for fenpropimorph of 0.01 mg/kg for strawberries,

⁷ European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels (MRLs) for triflurosulfuron according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2015;13(7):4190.

blackberries and leeks should apply to all products from the date of application of this Regulation.

- (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, III 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 carbetamide, cinidon-ethyl and triflusaluron 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 before [*Office of Publications please insert date 6 months after entry into force of this Regulation*].

As regards the active substances bifenthrin in and on all products except Chinese cabbage and fenpropimorph in and on all products except strawberries, blackberries and leek, 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 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