



Council of the
European Union

Brussels, 25 July 2016
(OR. en)

11434/16

AGRILEG 112

COVER NOTE

From:	European Commission
date of receipt:	19 July 2016
To:	General Secretariat of the Council

No. Cion doc.:	D045753/02
----------------	------------

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 cymoxanil, phosphane and phosphide salts and sodium 5-nitroguaiacolate, sodium o-nitrophenolate and sodium p-nitrophenolate in or on certain products
----------	--

Delegations will find attached document D045753/02.

Encl.: D045753/02



Brussels, **XXX**
SANTE/10104/2016
(POOL/E4/2016/10104/10104-EN.doc)
D045753/02
[...](2016) **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 cymoxanil, phosphane and phosphide salts and sodium 5-nitroguaiacolate, sodium o-nitrophenolate and sodium p-nitrophenolate 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 cymoxanil, phosphane and phosphide salts and sodium 5-nitroguaiacolate, sodium o-nitrophenolate and sodium p-nitrophenolate 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) and Article 49(2) thereof,

Whereas:

- (1) For cymoxanil and phosphines and phosphides, maximum residue levels (MRLs) were set in Part A of Annex III to Regulation (EC) No 396/2005. For hydrogen phosphide MRLs were set in Annex II and Part B of Annex III to that Regulation. For sodium 5-nitroguaiacolate, sodium o-nitrophenolate and sodium p-nitrophenolate no MRLs are set in Regulation (EC) No 396/2005, and as those 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 that Regulation applies.
- (2) For cymoxanil, 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 recommended lowering the MRLs for potatoes, garlic, onions, cucumbers, gherkins, courgettes, broccoli, cauliflower, peas (fresh, with pods), globe artichokes and leek. For other products it recommended raising or keeping the existing MRLs. It concluded that concerning the MRLs for table grapes, wine grapes, lettuce, spinach, beans (dry), lentils (dry), peas (dry), lupins (dry), herbal infusions (dried, flowers) and hops some information was not available and that further consideration by risk managers was required.

¹ OJ L 070, 16.3.2005, p. 1.

² European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for cymoxanil according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2015;13(12):4355.

- (3) 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 sunflower seed and soya bean 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 phosphane and phosphide salts 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 herbs, beans (dry), lentils (dry), peas (dry), lupins (dry), tea, herbal infusions, cocoa and spices. For coffee beans it recommended raising the existing MRL. It concluded that concerning the MRLs for almonds, brazil nuts, cashew nuts, chestnuts, coconuts, hazelnuts, macadamia, pecans, pine nuts, pistachios, walnuts, 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, barley grain, buckwheat grain, maize grain, millet grain, oats grain, rice grain, rye grain, sorghum grain, wheat grain and commodities of animal origin 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 sodium 5-nitroguaiacolate, sodium o-nitrophenolate and sodium p-nitrophenolate the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005⁴. It proposed a residue definition and recommended setting MRLs for tomatoes, aubergines, melons and watermelons. It concluded that concerning the MRLs for table grapes, wine grapes, strawberries, raspberries, currants, maize grain, rice grain, wheat grain 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 table olives and olives for oil production 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.

³ European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for phosphane and phosphide salts according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2015;13(12):4325.

⁴ European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for sodium 5-nitroguaiacolate, sodium o-nitrophenolate and sodium p-nitrophenolate according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2015;13(12):4356.

- (6) 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.
- (7) 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.
- (8) 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.
- (9) 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.
- (10) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (11) 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.
- (12) 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.
- (13) 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 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