



EUROPEAN
COMMISSION

Brussels, **XXX**
SANCO/10045/2014 Rev 1
[...] (2014) **XXX** draft

COMMISSION REGULATION (EU) No .../..

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 2-
naphthyloxyacetic acid, acetochlor, chloropicrin, diflufenican, flurprimidol, flutolanil
and spinosad in or on certain products**

(Text with EEA relevance)



**amending Annexes
Parliament and
naphthyloxyacetic ac**

Slettet:

EN

EN

COMMISSION REGULATION (EU) No .../..

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 2-naphthyloxyacetic acid, acetochlor, chloropicrin, diflufenican, flurprimidol, flutolanil and spinosad 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 acetochlor, chloropicrin, diflufenican, flurprimidol, flutolanil and spinosad, maximum residue levels (MRLs) were set in Part A of Annex III to Regulation (EC) No 396/2005. For 2-naphthyloxyacetic acid no MRLs are set in Regulation (EC) No 396/2005, and as that active substance is 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) The non-inclusion of 2-naphthyloxyacetic acid in Annex I to Directive 91/414/EEC is provided for in Commission Implementing Regulation (EU) No 1127/2011². All existing authorisations for plant protection products containing the active substance 2-naphthyloxyacetic acid have been revoked. It is therefore appropriate to set the MRLs 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.

Slettet: is

¹ OJ L 070, 16.3.2005, p. 1
² Commission Implementing Regulation (EU) No 1127/2011 of 7 November 2011 concerning the non-approval of the active substance 2-naphthyloxyacetic acid, 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 (OJ L 289, 8.11.2011, p. 26).

Slettet: ¶

- (3) The non-inclusion of acetochlor in Annex I to Directive 91/414/EEC is provided for in Commission Implementing Regulation (EU) No 1372/2011³. All existing authorisations for plant protection products containing the active substance acetochlor have been revoked. In accordance with Article 17 of Regulation (EC) No 396/2005 in conjunction with Article 14(1)(a) thereof the MRLs set out for that active substance in Annex III should therefore be deleted.
- (4) The non-inclusion of chloropicrin in Annex I to Directive 91/414/EEC is provided for in Commission Implementing Regulation (EU) No 1381/2011⁴. All existing authorisations for plant protection products containing the active substance chloropicrin have been revoked. In accordance with Article 17 of Regulation (EC) No 396/2005 in conjunction with Article 14(1)(a) thereof the MRLs set out for that active substance in Annex III should therefore be deleted.
- (5) For diflufenican, 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 396/2005⁵. It recommended lowering the MRLs for table olives, barley grain, oats grain, rye grain and wheat grain. For another product it recommended raising the existing MRL. It concluded that concerning the MRLs for citrus fruit, almonds, walnuts, pome fruit, stone fruit, table grapes, wine grapes, kiwi, bovine muscle, fat, liver and kidney, sheep muscle, fat, liver and kidney, goat muscle, fat, liver and kidney and cattle, sheep 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. The Authority concluded that concerning the MRLs for strawberries, cane fruits, other small fruits and berries, peas (with pods), peas (without pods), peas (dry) and millet grain 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 or at the default MRL as set out in Article 18(1)(b) of Regulation (EC) No 396/2005.
- (6) The non-inclusion of flurprimidol in Annex I to Directive 91/414/EEC is provided for in Commission Implementing Decision No 2011/328/EU⁶. All existing authorisations for plant protection products containing the active substance flurprimidol have been

Slettet: these

³ Commission Implementing Regulation (EU) No 1372/2011 of 21 December 2011 concerning the non-approval of the active substance acetochlor, 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 Decision 2008/934/EC (OJ L 341, 22.12.2011, p. 45).

⁴ Commission Implementing Regulation (EU) No 1381/2011 of 22 December 2011 concerning the non-approval of the active substance chloropicrin, 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 Decision 2008/934/EC (OJ L 343, 23.12.2011, p. 26).

⁵ European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for diflufenican according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2013;11(6):3281. [42 pp.].

⁶ Commission Implementing Decision No 2011/328/EU of 1 June 2011 concerning the non-inclusion of flurprimidol in Annex I to Council Directive 91/414/EEC (OJ L 153, 11.06.2011, p. 192).

Slettet: ¶

Slettet: ¶

Slettet: ¶

Formateret: Skrifffarve: Automatisk

revoked. In accordance with Article 17 of Regulation (EC) No 396/2005 in conjunction with Article 14(1)(a) thereof the MRLs set out for that active substance in Annex III should therefore be deleted.

- (7) For flutolanil, the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005⁷. It recommended lowering the MRL for potatoes. For another product it recommended keeping the existing MRL. It concluded that concerning the MRLs for peppers, beans (fresh, with pods), globe artichokes, 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, sheep and 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 these 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.
- (8) For spinosad, 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) thereof⁸. It recommended lowering the MRLs for almonds, brazil nuts, cashew nuts, chestnuts, coconuts, hazelnuts, macadamia, pecans, pine nuts, pistachios, walnuts, apples, pears, quinces, medlar, loquat, apricots, cherries, peaches, plums, kiwi, garlic, onions, shallots, tomatoes, aubergines (egg plants), cucumbers, beans (fresh, with pods), peas (fresh, with pods), and leek. For other products it recommended keeping or raising the existing MRLs. It concluded that concerning the MRLs for flowering brassica, spinach, globe artichokes, cereals grain, poultry muscle, fat and 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 these 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 and turnips 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 or at the default MRL as set out in Article 18(1)(b) of Regulation (EC) No 396/2005. As regards blackberries, raspberries, other small fruit and berries, celery, fennel, swine muscle and liver, bovine muscle, sheep muscle, fat and liver, goat muscle, fat and liver and poultry muscle, after submitting the opinion referred to in the first sentence, the Authority submitted further opinions concerning the MRLs^{9,10,11}. It is appropriate to take those opinions

⁷ European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for flutolanil according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2013;11(9):3360. [44 pp.]

⁸ European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for spinosad according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2012;10(3):2630. [89 pp.]

⁹ European Food Safety Authority; Modification of the existing MRLs for spinosad in small fruits and berries and several commodities of animal origin. EFSA Journal 2013; 11(11):3447. [27 pp.]

¹⁰ European Food Safety Authority; Modification of the existing MRLs for spinosad in raspberries. EFSA Journal 2012; 10(5):2751 [26 pp.]

Slettet: ¶

Formateret: Skriftfarve: Automatisk

Slettet: ¶

Formateret: Skriftfarve: Automatisk

Slettet: ¶

into account. As regards tree nuts, dewberries, passion fruit and spring onions, after the Authority submitted the opinion referred to in the first sentence, [by Regulation \(EU\) No 293/2013](#)¹², CXLs were included as MRLs in Reg. (EC) No 396/2005. It is appropriate to take those MRLs into account.

Slettet: according to

(9) As regards products of plant and animal origin for which neither relevant authorisations or import tolerances were reported at Union level nor [CXLs](#) were available, the Authority concluded that further consideration by risk managers was required. Taking into account the current scientific and technical knowledge, MRLs for those products should be set at the specific limit of determination or at the default MRL in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005.

Slettet: Codex MRLs

(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) 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 lawfully 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) 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.

(16) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on [Plants, Animals, Food and Feed](#),

Slettet: the Food Chain and Animal Health

¹¹ European Food Safety Authority; Modification of the existing MRLs for spinosad in celery, fennel, raspberries and blackberries . EFSA Journal 2012;10(6):2770. [27 pp.].

¹² Commission Regulation (EU) No 293/2013 of 20 March 2013 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 emamectin benzoate, etofenprox, etoxazole, flutriafol, glyphosate, phosmet, pyraclostrobin, spinosad and spirotetramat in or on certain products (OJ L 96, 5.4.2013, p. 1).

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

Regulation (EC) No 396/2005 as it stood before being amended by this Regulation shall continue to apply to products which were lawfully produced 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
José Manuel BARROSO