



Council of the
European Union

Brussels, 14 January 2015
(OR. en)

5238/15

AGRILEG 6

COVER NOTE

From: European Commission
date of receipt: 9 January 2015
To: Mr Uwe CORSEPIUS, Secretary-General of the Council of the European Union

No. Cion doc.: D035771/02

Subject: 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 1,3-dichloropropene, bifenox, dimethenamid-P, prohexadione, tolylfluand and trifluralin in or on certain products

Delegations will find attached document D035771/02.

Encl.: D035771/02



Brussels, **XXX**
SANCO/10224/2014 Rev. 1
(POOL/E3/2014/10224/10224R1-
EN.doc) D035771/02
[...](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 1,3-dichloropropene, bifenox, dimethenamid-P, prohexadione, tolyfluanid and trifluralin in or on certain products

(Text with EEA relevance)

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

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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 1,3-dichloropropene, bifenoX, dimethenamid-P, prohexadione, tolylfluanid and trifluralin 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 dimethenamid-P and prohexadione, maximum residue levels (MRLs) were set in Annex II and Part B of Annex III to Regulation (EC) No 396/2005. For 1,3-dichloropropene and bifenoX, MRLs were set in Part A of Annex III to that Regulation. For tolylfluanid and trifluralin, MRLs were set in Annex V to that Regulation.
- (2) The non-inclusion of 1,3-dichloropropene in Annex I to Directive 91/414/EEC is provided for in Commission Decision 2011/36/EU². All existing authorisations for plant protection products containing the active substance 1,3-dichloropropene have been revoked. In accordance with Article 17 of Regulation (EC) No 396/2005 in conjunction with Article 14(1) thereof the MRLs set out for that active substance in Annex III should therefore be deleted. This should not apply to those MRLs corresponding to CXLs based on uses in third countries provided that they are acceptable with regard to consumer safety. Nor should it apply in cases where MRLs have been specifically set as import tolerances.
- (3) For bifenoX, the European Food Safety Authority, hereinafter "the Authority" submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1)

¹ OJ L 70, 16.3.2005, p. 1.

² Commission Decision 2011/36/EU of 20 January 2011 concerning the non-inclusion of 1,3-dichloropropene in Annex I to Council Directive 91/414/EEC (OJ L 18, 21.1.2011, p. 42).

of Regulation (EC) No 396/2005³. It recommended lowering the MRLs for barley grain, oats grain, rye grain and wheat grain. It concluded that concerning the MRLs for sunflower seed and rape seed 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. Those 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 swine (meat, fat, liver, kidney), bovine (meat, fat, liver, kidney), sheep (meat, fat, liver, kidney), goat (meat, fat, liver, kidney), and milk (cattle, sheep, goat) no information was available and that further consideration by risk managers was required. The MRLs for these commodities 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.

- (4) For dimethenamid-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) thereof⁴. It proposed to change the residue definition. It recommended lowering the MRLs for peanuts, sunflower seed, rape seed, soya bean, pumpkin seeds and sugar beet (root). For other products it recommended keeping the existing MRLs. It concluded that concerning the MRLs for spring onions, lettuce and herbs 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. Those MRLs will be reviewed; the review will take into account the information available within two years from the publication of this Regulation.
- (5) For prohexadione, 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) thereof⁵. It recommended lowering the MRLs for table and wine grapes, strawberries, cane fruit, other small fruit and berries, barley, wheat, hops, swine (meat, fat, liver, kidney), bovine (meat, fat, liver, kidney), sheep (meat, fat, liver, kidney) and goat (meat, fat, liver, kidney). For other products it recommended raising or keeping the existing MRLs.
- (6) The removal of tolylfluanid from Annex I to Directive 91/414/EEC is provided for in Commission Directive 2010/20/EU⁶. All existing authorisations for plant protection products containing the active substance tolylfluanid have been revoked.

³ 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 2013;11(4):3215. [36 pp.].

⁴ European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels (MRLs) for dimethenamid-P according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2013;11(4):3216. [53 pp.].

⁵ European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for prohexadione according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2013;11(4):3192. [36 pp.].

⁶ Commission Directive 2010/20/EU of 9 March 2010 amending Council Directive 91/414/EEC to remove tolylfluanid as active substance and on the withdrawal of authorisations for plant protection products containing that substance (OJ L 60, 10.3.2010, p. 20).

- (7) For tolylfluanid, 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. It concluded that further consideration by risk managers was required. Taking into account the current scientific and technical knowledge, MRLs 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.
- (8) The non-inclusion of trifluralin in Annex I to Directive 91/414/EEC is provided for in Commission Decision 2010/355/EU⁸. All existing authorisations for plant protection products containing the active substance trifluralin have been revoked.
- (9) For trifluralin, the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005⁹. 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.
- (10) 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.
- (11) 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.
- (12) 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.
- (13) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (14) 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.
- (15) 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

⁷ European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels (MRLs) for tolylfluanid according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2013;11(7):3300. [37 pp.].

⁸ Commission Decision 2010/355/EU of 25 June 2010 concerning the non-inclusion of trifluralin in Annex I to Council Directive 91/414/EEC (OJ L 160, 26.6.2010, p. 30).

⁹ European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels (MRLs) for trifluralin according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2013;11(4):3193. [16 pp.].

operators to prepare themselves to meet the new requirements which will result from the modification of the MRLs.

- (16) 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.
- (17) 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

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 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