



Council of the
European Union

Brussels, 6 August 2014
(OR. en)

12379/14

AGRILEG 165

COVER NOTE

From:	European Commission
date of receipt:	4 August 2014
To:	Mr Uwe CORSEPIUS, Secretary-General of the Council of the European Union

No. Cion doc.:	D033904/02
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 asulam, cyanamide, dicloran, flumioxazin, flupyr-sulfuron-methyl, picolinafen and propisochlor in or on certain products (Text with EEA relevance)

Delegations will find attached document D033904/02.

Encl.: D033904/02



Brussels, **XXX**
SANCO/11781/2013 Rev. 1
(POOL/E3/2013/11781/11781R1-
EN.doc) D033904/02
[...](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 asulam,
cyanamide, dicloran, flumioxazin, flupyrsulfuron-methyl, picolinafen and propisochlor
in or on certain products**

(Text with EEA relevance)

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 asulam, cyanamide, dicloran, flumioxazin, flupyrulfuron-methyl, picolinafen and propisochlor 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 asulam, cyanamide, dicloran and propisochlor, maximum residue levels (MRLs) were set in Part A of Annex III to Regulation (EC) No 396/2005. For flumioxazin, flupyrulfuron-methyl and picolinafen, MRLs were set in Annex II and Part B of Annex III to that Regulation.
- (2) The non-inclusion of asulam in Annex I to Directive 91/414/EEC is provided for in Commission Implementing Regulation (EU) No 1045/2011². All existing authorisations for plant protection products containing the active substance asulam have been revoked.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.
- (3) The non-inclusion of cyanamide in Annex I to Directive 91/414/EEC is provided for in Commission Decision No 2008/745/EC³. All existing authorisations for plant protection products containing the active substance cyanamide have been revoked. In

¹ OJ L 070, 16.3.2005, p. 1.

² Commission Implementing Regulation (EU) No 1045/2011 of 19 October 2011 concerning the non-approval of the active substance asulam, 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 275, 20.10.2011, p. 23).

³ Commission Decision No 2008/745/EC of 18 September 2008 concerning the non-inclusion of cyanamide in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance (OJ L 251, 19.9.2008, p. 45).

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 dicloran in Annex I to Directive 91/414/EEC is provided for in Commission Implementing Decision No 2011/329/EU⁴. All existing authorisations for plant protection products containing the active substance dicloran 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 this 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.
- (5) For dicloran, 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 identified concerning the CXLs for peaches, table grapes, wine grapes and carrots a risk for consumers. It is therefore appropriate to set these 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. The Authority concluded that concerning the CXL for onions, some information was not available and that further consideration by risk managers was required. As there is no risk for consumers, the MRL for this product should be set in Annex II to Regulation (EC) No 396/2005 at the existing level or the level identified by the Authority. 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 flumioxazin, 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) thereof⁶. It recommended lowering the MRLs for apples, pears, stone fruits, potatoes, carrots, parsnips, peas (without pods), sunflower seed, soya bean, maize grain, oat grain, sorghum grain and wheat grain. For other products it recommended keeping the existing MRLs. It concluded that concerning the MRL for onions some information was not available and that further consideration by risk managers was required. As there is no risk for consumers, the MRL for this product should be set in Annex II to Regulation (EC) No 396/2005 at the existing level or the level identified by the Authority. This MRL will be reviewed; the review will take into account the information available within two years from the publication of this Regulation.
- (7) For flupyrsulfuron-methyl, the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(2) of Regulation (EC) No 396/2005 in

⁴ Commission Implementing Decision No 2011/329/EU of 1 June 2011 concerning the non-inclusion of dicloran in Annex I to Council Directive 91/414/EEC (OJ L 153, 11.6.2011, p. 194).

⁵ European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for dicloran according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2013;11(6):3274. [30 pp.].

⁶ European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for flumioxazin according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2013;11(5):3225. [35 pp.].

conjunction with Article 12(1) thereof⁷. It concluded that concerning the MRLs for linseed, barley grain, wheat grain, oat grain and rye grain 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. As the availability of the missing information was reported by France, no footnote requesting the submission of this information will be added.

- (8) For picolinafen, 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 concluded that concerning the MRLs for barley grain, oats grain, rye grain, wheat grain, bovine meat, fat, liver and kidney; sheep meat, fat, liver, kidney and milk; goat meat, fat, liver, kidney and milk and cattle 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 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.
- (9) The non-inclusion of propisochlor in Annex I to Directive 91/414/EEC is provided for in Commission Implementing Decision No 2011/262/EU⁹. All existing authorisations for plant protection products containing the active substance propisochlor 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 this active substance in Annex III should therefore be deleted.
- (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.

⁷ European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for flupyr-sulfuron-methyl according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2013;11(5):3226. [28 pp.].

⁸ European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for picolinafen according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2013;11(5):3222. [34 pp.].

⁹ Commission Implementing Decision No 2011/262/EU of 27 April 2011 concerning the non-inclusion of propisochlor in Annex I to Council Directive 91/414/EEC and amending Commission Decision 2008/941/EC (OJ L 111, 30.4.2011, p. 19).

- (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 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 the Food Chain and Animal Health,

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*