



**COUNCIL OF
THE EUROPEAN UNION**

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AGRILEG 1

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Subject: Draft COMMISSION REGULATION (EU) No .../.. 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 chlorantraniliprole, fludioxonil and prohexadione in or on certain products

Delegations will find attached Commission document D024734/02.

Encl.: D024734/02



Brussels, **XXX**
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[...](2012) **XXX** draft

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

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 chlorantraniliprole, fludioxonil and prohexadione in or on certain products

(Text with EEA relevance)

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

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 chlorantraniliprole, fludioxonil and prohexadione 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) thereof,

Whereas:

- (1) For prohexadione, maximum residue levels (MRLs) were set in Annex II and Part B of Annex III to Regulation (EC) No 396/2005. For chlorantraniliprole and fludioxonil, MRLs were set in Part A of Annex III to Regulation (EC) No 396/2005.
- (2) In the context of a procedure for the authorisation of the use of a plant protection product containing the active substance chlorantraniliprole on carrots, parsnips, parsley root and celeriac an application was made under Article 6(1) of Regulation (EC) No 396/2005 for modification of the existing MRLs.
- (3) As regards fludioxonil, such an application was made for celery, celery leaves and radishes.
- (4) In accordance with Article 6(2) and (4) of Regulation (EC) No 396/2005 an application was made for prohexadione on peanuts. The applicant claims that the authorised use of prohexadione on peanuts in the United States leads to residues exceeding the MRLs in Regulation (EC) No 396/2005 and that higher MRLs are necessary to avoid trade barriers for the importation of this crop.
- (5) In accordance with Article 8 of Regulation (EC) No 396/2005 these applications were evaluated by the Member States concerned and the evaluation reports were forwarded to the Commission.

¹ OJ L 70, 16.3.2005, p. 1.

- (6) The European Food Safety Authority, hereinafter "the Authority", assessed the applications and the evaluation reports, examining in particular the risks to the consumer and where relevant to animals and gave reasoned opinions on the proposed MRLs². It forwarded these opinions to the Commission and the Member States and made them available to the public.
- (7) The Authority concluded in its reasoned opinion that, as regards the use of fludioxonil on radishes, the submitted residue trials were not performed according to the supported Good Agricultural Practice.
- (8) As regards all other applications, the Authority concluded that all requirements with respect to data were met and that the modifications to the MRLs requested by the applicants were acceptable with regard to consumer safety on the basis of a consumer exposure assessment for 27 specific European consumer groups. It took into account the most recent information on the toxicological properties of the substances. Neither the lifetime exposure to these substances via consumption of all food products that may contain these substances, nor the short-term exposure due to extreme consumption of the relevant crops and products showed that there is a risk that the acceptable daily intake (ADI) or the acute reference dose (ARfD) is exceeded.
- (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) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (11) As regards chlorantraniliprole in carrots 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.
- (12) As regards chlorantraniliprole in carrots, a temporary MRL was inserted into Regulation (EC) No 396/2005 by Commission Regulation (EC) No 460/2011³ an MRL which applies until 31 December 2012. In order to avoid obliging Member States and operators to adapt to changing MRLs twice within a few months, it is appropriate to set the MRL for chlorantraniliprole in carrots with effect from 1 January 2013.
- (13) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health and neither the European Parliament nor the Council has opposed them,

² EFSA scientific reports available online: <http://www.efsa.europa.eu>: Reasoned opinion on the modification of the existing MRLs for chlorantraniliprole in carrots, parsnips, parsley root and celeriac. EFSA Journal 2012; 10(11):2988 [24 pp.]. doi:10.2903/j.efsa.2012.2988. Reasoned opinion on the modification of the existing MRLs for fludioxonil in celery, celery leaves and radishes. EFSA Journal 2012; 10(12):3014 [26 pp.]. doi:10.2903/j.efsa.2012.3014.

Reasoned opinion on the setting of a new MRL for prohexadione in peanuts. EFSA Journal 2012; 10(11):2957 [26 pp.]. doi:10.2903/j.efsa.2012.2957.

³ OJ L 124, 13.5.2011, p. 23.

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

As regards chlorantraniliprole in carrots of code number 0213020, 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 1 January 2013.

Article 3

This Regulation shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

It shall however apply from 1 January 2013 as regards the MRL for chlorantraniliprole in carrots of code number 0213020.

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

ANNEX

Annexes II and III to Regulation (EC) No 396/2005 are amended as follows:

- (1) In Annex II, the column for prohexadione is replaced by the following:

[For Official Journal: insert table Annex II existing].

- (2) In Part A of Annex III, the columns for chlorantraniliprole and fludioxonil are replaced by the following:

[For Official Journal: insert table Annex IIIA existing].