



**COUNCIL OF
THE EUROPEAN UNION**

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AGRILEG 2

COVER NOTE

from:	European Commission
date of receipt:	10 January 2013
to:	General Secretariat of the Council
No Cion doc.:	D024728/02
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 emamectin benzoate, etofenprox, etoxazole, flutriafol, glyphosate, phosmet, pyraclostrobin, spinosad and spirotetramat in or on certain products

Delegations will find attached Commission document D024728/02.

Encl.: D024728/02



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D024728/02
[...](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 emamectin benzoate, etofenprox, etoxazole, flutriafol, glyphosate, phosmet, pyraclostrobin, spinosad and spirotetramat in or on certain products

(Text with EEA relevance)

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

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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

(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 etoxazole, glyphosate and pyraclostrobin maximum residue levels (MRLs) were set in Annex II and Part B of Annex III to Regulation (EC) No 396/2005. For emamectin benzoate, etofenprox, flutriafol, phosmet, prothioconazole, spinosad and spirotetramat 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 prothioconazole on rape seed, linseed, poppy seed and mustard seed an application was made in accordance with Article 6(1) of Regulation (EC) No 396/2005 for modification of the existing MRL.
- (3) As regards phosmet, such an application was made for table olives, potatoes and rape seeds.
- (4) 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.
- (5) 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

¹ OJ L 70, 16.3.2005, p. 1.

MRLs². It forwarded these opinions to the Commission and the Member States and made them available to the public.

- (6) The Authority concluded in its reasoned opinions that, as regards the use of prothioconazole on rape seed, linseed, poppy seed and mustard seed, further data are necessary to address the stability of residues included in the plant risk assessment residue definition. Furthermore, the Authority highlighted that the good agricultural practice (GAP) concerns a product containing bixafen as well as prothioconazole. Consequently, the available data for raising MRLs for bixafen should also be considered. The existing MRLs should therefore remain unchanged.
- (7) 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.
- (8) On 7 July 2012 the Codex Alimentarius Commission (CAC)³ adopted CXLs for emamectin benzoate, etofenprox, etoxazole, flutriafol, glyphosate, pyraclostrobin, spinosad and spirotetramat. These CXLs should be included in Regulation (EC) No 396/2005 as MRLs, with the exception of those CXLs which are not safe for a European consumer group and for which the Union presented a reservation to the CAC⁴.
- (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) 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.
- (11) A reasonable period should be allowed to elapse before the modified MRLs become applicable in order to permit Member States and interested parties to prepare themselves to meet the new requirements which will result from the modification of the MRLs.

² EFSA scientific reports available online: <http://www.efsa.europa.eu>: Reasoned opinion on the modification of the existing MRLs for phosmet in various crops. EFSA Journal 2012;10(2):2582 [27 pp.]. doi:10.2903/j.efsa.2012.2582.

Reasoned opinion on the modification of the existing MRLs for prothioconazole in rape seed, linseed, poppy seed and mustard seed. EFSA Journal 2012;10(11):2952 [35 pp.]. doi:10.2903/j.efsa.2012.2952.

³ Codex Committee on Pesticide Residues reports available on: http://www.codexalimentarius.org/download/report/777/REP12_PRe.pdf

Joint FAO/WHO food standards programme Codex Alimentarius Commission. Appendix II and III. Thirty-Fifth Session. Rome, Italy, 2 - 7 July 2012.

⁴ Scientific support for preparing an EU position in the 44th Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal 2012;10(7):2859 [155 pp.]. doi:10.2903/j.efsa.2012.2859.

- (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) 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,

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 lawfully produced before [*Office of Publications please insert date of application of this Regulation*].

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 [*Office of Publication: please insert date 6 months after entry into force*], as regards the MRLs for phosmet in table olives and rape seed of code numbers 0161030 and 0401060 respectively.

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 columns for etoxazole, glyphosate and pyraclostrobin are replaced by the following:

[Office of Publication: please insert table Annex II existing].

- (2) Annex III is amended as follows:

- (a) In Part A, the columns for emamectin benzoate, etofenprox, flutriafol, phosmet, spinosad and spirotetramat are replaced by the following:

[Office of Publication: please insert table Annex IIIA existing].

- (b) In Part B, the columns for etoxazole and glyphosate are replaced by the following:

[Office of Publication: please insert table Annex IIIB existing].