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To:	General Secretariat of the Council
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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 2,4-D, beflubutamid, cyclanilide, diniconazole, florasulam, metolachlor and S-metolachlor, and milbemectin in or on certain products (Text with EEA relevance)

Delegations will find attached document D027518/03.

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COMMISSION

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[…](2013) XXX draft

COMMISSION REGULATION (EU) No …/..

of XXX

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(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/EEC[1], and in particular Article 14(1)(a), Article 18(1)(b) and Article 49(2) thereof,

Whereas:

(1) For 2,4-D, cyclanilide, florasulam, metolachlor and S-metolachlor, and milbemectin, maximum residue levels (MRLs) are set in Annex II and Part B of Annex III to Regulation (EC) No 396/2005. For beflubutamid and diniconazole, MRLs are set in Part A of Annex III to that Regulation.

(2) Certain technical adaptations should be made, in particular the name of the active substance 'metholachlor and metholachlor-S' should be replaced by 'metolachlor and S-metolachlor'.

[1] OJ L 70, 16.3.2005, p. 1.

(3) For 2,4-D, the European Food Safety Authority, hereinafter "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) thereof[2]. The Authority proposed to change the residue definition. It recommended raising or keeping the existing MRLs for certain products. It concluded that concerning the MRLs for almonds, brazil nuts, cashew nuts, coconuts, hazelnuts, macadamia, pecans, pine nuts, pistachios, walnuts, soya bean and buckwheat grain some information was not available and that further consideration by risk managers was required. As there is no risk for consumers, 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.

(4) For beflubutamid, 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) thereof[3]. It recommended lowering the MRL for wheat grain. For other products it recommended keeping the existing MRLs.

(5) For cyclanilide, 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) thereof[4]. It recommended raising the existing MRL for cotton seed. However, as the approval of the active substance cyclanilide expired on 31 October 2011[5] and all existing authorisations for plant protection products containing cyclanilide have been revoked, it is appropriate to set the MRLs at the specific limit of determination.

(6) For diniconazole, the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005[6]. It proposed to change the residue definition. All existing authorisations for plant protection products containing diniconazole-M have been revoked. It is therefore appropriate to set the MRLs at the specific limit of determination.

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2 European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for 2,4-D according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2011;9(11):2431. [52 pp.]

3 European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for beflubutamid according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2012;10(2):2585. [28 pp.]

4 European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for cyclanilide according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2012;10(2):2568. [27 pp.]

5 Commission Implementing Regulation (EU) No 1022/2011 of 14 October 2011 concerning the non-renewal of the approval of the active substance cyclanilide 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 Implementing Regulation (EU) No 540/2011. OJ L 270, 15.10.2011, p. 20.

6 European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for diniconazole-M according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2012;10(2):2590. [19 pp.]

(7) For florasulam, 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) thereof[7]. It recommended keeping the existing MRLs for certain products. It concluded that concerning the MRLs for meat, fat, liver and kidney of bovine animals, sheep and goat, as well as for cattle milk, sheep milk and goat milk some information was not available and that further consideration by risk managers was required. As there is no risk for consumers, MRLs for those products should be set in Annex II to Regulation (EC) No 396/2005 at 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.

(8) For metolachlor and S-metolachlor, 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) thereof[8]. It recommended lowering the MRLs for linseed, sunflower seed, rape seed, soya bean, cotton seed and pumpkin seeds. For other products it recommended keeping the existing MRLs or setting MRLs at the level identified by the Authority. It concluded that concerning the MRLs for strawberries and pineapple some information was not available and that further consideration by risk managers was required. As there is no risk for consumers, 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.

(9) For milbemectin, 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) thereof[9]. It proposed to change the residue definition. It recommended lowering the MRLs for pome fruits and strawberries. For hops it recommended raising the MRLs.

(10) As regards products for which no relevant authorisations or import tolerances were reported at European Union level and no Codex MRL was 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.

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7 European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels (MRLs) for florasulam according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2012;10(3):2626. [29 pp.]

8 European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for S-metolachlor according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2012;10(2):2586. [42 pp.]

9 European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels (MRLs) for milbemectin according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2012;10(3):2629. [32 pp.]

(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) 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.

(13) 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.

(14) Annex II to Regulation (EC) No 396/2005, Part A and B of Annex III, and Annex V to that Regulation should therefore be amended accordingly.

(15) 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.

(16) 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, 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

ANNEX

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

(1) Annex II is amended as follows:

(a) The columns for 2,4-D, florasulam, metholachlor and metholachlor-S, and milbemectin are replaced by the following:

[Office of Publication: please insert table Annex II-1]

(b) The following column for beflubutamid is added:

[Office of Publication: please insert table Annex II-2]

(c) The column for cyclanilide is deleted.

(2) In Annex III, the columns for 2,4-D, beflubutamid, cyclanilide, diniconazole, florasulam, metholachlor and metholachlor-S, and milbemectin are deleted.

(3) In Annex V, the columns for cyclanilide and for diniconazole are added:

[Office of Publication: please insert table Annex V]