Commission Regulation (EU) No 592/2012 of 4 July 2012 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 bifenazate, captan, cyprodinil, fluopicolide, hexythiazox, isoprothiolane, metaldehyde, oxadixyl and phosmet in or on certain products (Text with EEA relevance)

COMMISSION REGULATION (EU) No 592/2012

of 4 July 2012

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 bifenazate, captan, cyprodinil, fluopicolide, hexythiazox, isoprothiolane, metaldehyde, oxadixyl and phosmet 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/EEC[(1)], and in particular Article 14(1)(a) thereof,

Whereas:

(1) For bifenazate and captan maximum residue levels (MRLs) were set in Annex II and Part B of Annex III to Regulation (EC) No 396/2005. For cyprodinil, fluopicolide, hexythiazox, metaldehyde, oxadixyl and phosmet MRLs were set in Part A of Annex III to Regulation (EC) No 396/2005. For isoprothiolane no MRLs were set before in any of the Annexes 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 bifenazate on currants (red, black and white), raspberries and blackberries an application was made under Article 6(1) of Regulation (EC) No 396/2005 for modification of the existing MRLs.

(3) As regards captan, such an application was made on blackberries, raspberries, blueberries, currants (red, black and white) and gooseberries. As regards cyprodinil, such an application was made in fresh herbs, spinach and beet leaves, lettuce, lamb's lettuce, cress, scarole, rocket/rucola and leaves and sprouts of Brassica *spp*. As regards fluopicolide, such an application was made for in radishes, onions, potatoes and kale. As regards hexythiazox, such an application was made for tea. As regards metaldehyde such an application was made for strawberries, potatoes, kohlrabi, lettuce and other salad plants, the whole group of spinach and similar, the whole group of herbs and rape seed. As regards phosmet, such an application was made for potatoes, apricots, peaches, table olives, olives for oil production and rape seed.

Changes to legislation: *There are outstanding changes not yet made to Commission Regulation (EU) No 592/2012. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(4) In accordance with Article 6(2) and (4) of Regulation (EC) No 396/2005 an application was made for isoprothiolane on rice. The authorised use of isoprothiolane on rice in Japan leads to a higher residue than the MRL in Regulation (EC) No 396/2005. To avoid trade barriers for the importation of this crop, a higher MRL are necessary.

(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.

(6) The Commission received information from Belgium about residues of oxadixyl on parsley, celery and leeks which exceed the current MRLs. According to the Belgium authorities, the unexpected presence of oxadixyl in these crops is due to the persistence of the active substance in soil. Belgium submitted an application in accordance with Article 6(3) of Regulation (EC) No 396/2005 for modifications to those MRLs.

(7) 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 MRLs[(2)]. It forwarded these opinions to the Commission and the Member States and made them available to the public.

(8) The Authority concluded in its reasoned opinions that, as regards use of fluopicolide in onion, the submitted data are not sufficient to derive a new MRL. As regards use of metaldehyde in strawberries and kohlrabi, the submitted data are not sufficient to derive a new MRL. As regards phosmet in apricots, the submitted data is not sufficient to derive a new MRL.

(9) As regards use of bifenazate on raspberries and blackberries, no modification of the MRLs is necessary, since the MRLs set out in Annex II to Regulation (EC) No 396/2005 are identical with those requested.

(10) 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.

(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) Regulation (EC) No 396/2005 should therefore be amended accordingly.

(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,

***Changes to legislation:** There are outstanding changes not yet made to Commission Regulation (EU) No 592/2012. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

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

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

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 4 July 2012.

For the Commission

The President

José Manuel BARROSO

Changes to legislation: *There are outstanding changes not yet made to Commission Regulation (EU) No 592/2012. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

ANNEX

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

(1) In Annex II, the columns for bifenazate and captan are replaced by the following:

PESTICIDE RESIDUES AND MAXIMUM RESIDUE LEVELS (MG/KG)

Code number	**Groups and examples of individual products to which the MRLs apply**[a]	**Bifenazate**	**Captan (R)**
(1)	(2)	(3)	(4)
0100000	1. **FRUIT FRESH OR FROZEN; NUTS**		
0110000	(i) **Citrus fruit**	0,01[b]	0,02[b]
0110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo (except mineola), ugli and other hybrids)		
0110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)		
0110030	Lemons (Citron, lemon)		
0110040	Limes		
0110050	Mandarins (Clementine, tangerine, mineola and other hybrids)		
0110990	Others		

a For the complete list of products of plant and animal origin to which MRLs apply, reference should be made to Annex I.

b Indicates lower limit of analytical determination

c Pesticide-code combination for which the MRL as set in Annex III Part B applies.

Captan (R)

Captan : The enforcement residue definition for the following codes is "the sum of captan and folpet": 0130000; 0152000; 0153010; 0153030; 0154030; 0154040; 0231010; 0260010; 0260020;

***Changes to legislation:** There are outstanding changes not yet made to Commission Regulation (EU) No 592/2012. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

0120000	(ii) **Tree nuts (shelled or unshelled)**	0,01[b]	
0120010	Almonds		0,3
0120020	Brazil nuts		0,02[b]
0120030	Cashew nuts		0,02[b]
0120040	Chestnuts		0,02[b]
0120050	Coconuts		0,02[b]
0120060	Hazelnuts (Filbert)		0,02[b]
0120070	Macadamia		0,02[b]
0120080	Pecans		0,02[b]
0120090	Pine nuts		0,02[b]
0120100	Pistachios		0,02[b]
0120110	Walnuts		0,02[b]
0120990	Others		0,02[b]
0130000	(iii) **Pome fruit**	0,01[b]	**3**
0130010	Apples (Crab apple)		
0130020	Pears (Oriental pear)		
0130030	Quinces		
0130040	Medlar	[c]	[c]
0130050	Loquat	[c]	[c]
0130990	Others		
0140000	(iv) **Stone fruit**	0,01[b]	
0140010	Apricots		4

a For the complete list of products of plant and animal origin to which MRLs apply, reference should be made to Annex I.

b Indicates lower limit of analytical determination

c Pesticide-code combination for which the MRL as set in Annex III Part B applies.

Captan (R)

Captan : The enforcement residue definition for the following codes is "the sum of captan and folpet": 0130000; 0152000; 0153010; 0153030; 0154030; 0154040; 0231010; 0260010; 0260020;