Commission Regulation (EU) 2015/401 of 25 February 2015 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 acetamiprid, chromafenozide, cyazofamid, dicamba, difenoconazole, fenpyrazamine, fluazinam, formetanate, nicotine, penconazole, pymetrozine, pyraclostrobin, tau-fluvalinate and tebuconazole in or on certain products (Text with EEA relevance)

COMMISSION REGULATION (EU) 2015/401

of 25 February 2015

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 acetamiprid, chromafenozide, cyazofamid, dicamba, difenoconazole, fenpyrazamine, fluazinam, formetanate, nicotine, penconazole, pymetrozine, pyraclostrobin, tau-fluvalinate and tebuconazole 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 acetamiprid, cyazofamid, formetanate, pymetrozine, pyraclostrobin and tebuconazole maximum residue levels (MRLs) were set in Annex II to Regulation (EC) No 396/2005. For penconazole MRLs were set in Annex II and Part B of Annex III to Regulation (EC) No 396/2005. For chromafenozide, dicamba, difenoconazole, fenpyrazamine, fluazinam, nicotine and tau-fluvalinate 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 chromafenozide on pome fruit and grapes, an application was submitted in accordance with Article 6(1) of Regulation (EC) No 396/2005 for modification of the existing MRLs.

(3) As regards cyazofamid, such an application was made for grapes. As regards difenoconazole, such an application was made for peppers and aubergines. As regards fenpyrazamine, such an application was made for apricots, cherries, peaches and plums. As regards formetanate, such an application was made for strawberries. As regards penconazole, such an application was made for blackberries and raspberries. As regards pymetrozine, such an application was made for azarole. As regards pyraclostrobin, such an application was made for chicory roots. As regards tau-fluvalinate, such an

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application was made for pome fruits, peaches, apricots, grapes, tomatoes, aubergines, melons, broccoli, Brussels sprouts, kohlrabi, globe artichokes, lettuce and other salad plants. As regards tebuconazole, such an application was made for poppy seed.

(4) In accordance with Article 6(2) and (4) of Regulation (EC) No 396/2005 an application was submitted for acetamiprid on apricots and tree nuts. The applicant claims that the authorised uses of that substance on such crops in the United States lead 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 those crops.

(5) Such applications were also submitted as regards dicamba on genetically modified soya bean and as regards fluazinam on ginseng root. The applicants claim that the authorised uses of those substances on such crops in the United States lead 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 those crops.

(6) 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.

(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 the use of fenpyrazamine on peaches, no modification of the existing MRL is required. As regards the use of tau-fluvalinate on pome fruit, apricots, peaches and tomatoes, the submitted data were not sufficient to set new MRLs. The existing MRLs should therefore remain unchanged.

(9) As regards dicamba, no residues were detected at harvest in dicamba-tolerant soya bean. The Authority concluded that the relevant component of the residues identified in dicamba-tolerant soya bean was the metabolite 3,6-dichlorosalicylic acid (DCSA).

(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 them, nor the short-term exposure due to high 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) As regards nicotine, by Commission Regulation (EU) No 897/2012[(3)] temporary MRLs were set for wild mushrooms until 30 November 2014 pursuant to Article 16(1)(a) of Regulation (EC) No 396/2005, pending the submission and evaluation of new data and information on the natural occurrence or formation of nicotine in the concerned

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products. The Commission was informed of a research project which is being carried out to investigate on the sources of nicotine occurring in those crops. In view of the expected duration of the study and in order to provide the necessary time for the Commission to take its decision, it is appropriate to extend the validity of these MRLs until 19 October 2016.

(12) As regards formetanate, several MRLs were modified by Commission Regulation (EU) No 61/2014[(4)]. That Regulation lowers the MRL for strawberries to the limit of determination as of 14 August 2014. In the interest of legal certainty, it is appropriate for the MRL provided for by this Regulation, to apply from the same date.

(13) 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.

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

(15) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

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 day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 November 2014. However, it shall apply from 14 August 2014 for the MRL for formetanate in strawberries.

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

Done at Brussels, 25 February 2015.

For the Commission

The President

Jean-Claude JUNCKER

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ANNEX

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

(1) In Annex II, the columns for acetamiprid, cyazofamid, formetanate, penconazole, pymetrozine, pyraclostrobin and tebuconazole 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[c]**	**Acetamiprid (R)**	**Cyazofamid**	**Sum of formetanate and its salts expressed as formetanate(hydrochloride)**	**Penconazole (F)**	**Pymetrozine (A) (R)**	**Pyraclostrobin (F)**	**Tebuconazole (R)**
0100000	1. **FRESH OR FROZEN NUTS**	**FRUIT**						
0110000	(i) **fruit**	0,9 **Citrus**	0,01[a]	0,01[a]	0,05[a]	0,3 (+)		
0110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo (except mineola), ugli and other hybrids)						1	5
0110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)						2	0,9
0110030	Lemons (Citron, lemon,						1	5

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	Buddha's hand (Citrus medica var. sarcodactylis))							
0110040	Limes						1	5
0110050	Mandarins (Clementine, tangerine, mineola and other hybrids tangor (Citrus reticulata × sinensis))						1	5
0110990	Others						1	5
0120000	(ii) **nuts**	**0,07 Tree**	0,02[a]	0,01[a]	0,05[a]			0,05
0120010	Almonds					0,02[a]	0,02[a]	
0120020	Brazil nuts					0,02[a]	0,02[a]	
0120030	Cashew nuts					0,02[a]	0,02[a]	
0120040	Chestnuts					0,05	0,02[a]	
0120050	Coconuts					0,02[a]	0,02[a]	
0120060	Hazelnuts (Filbert)					0,05	0,02[a]	
0120070	Macadamia					0,02[a]	0,02[a]	
0120080	Pecans					0,02[a]	0,02[a]	
0120090	Pine nuts					0,02[a]	0,02[a]	
0120100	Pistachios					0,02[a]	1	
0120110	Walnuts					0,05	0,02[a]	
0120990	Others					0,02[a]	0,02[a]	
0130000	(iii) **fruit**	0,8 **Pome**	0,01[a]	0,01[a]	0,2	0,02[a]	0,5	