Commission Regulation (EU) 2016/1 of 3 December 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 bifenazate, boscalid, cyazofamid, cyromazine, dazomet, dithiocarbamates, fluazifop-P, mepanipyrim, metrafenone, picloram, propamocarb, pyridaben, pyriofenone, sulfoxaflor, tebuconazole, tebufenpyrad and thiram in or on certain products (Text with EEA relevance)

COMMISSION REGULATION (EU) 2016/1

of 3 December 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 bifenazate, boscalid, cyazofamid, cyromazine, dazomet, dithiocarbamates, fluazifop-P, mepanipyrim, metrafenone, picloram, propamocarb, pyridaben, pyriofenone, sulfoxaflor, tebuconazole, tebufenpyrad and thiram 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, cyazofamid, cyromazine, mepanipyrim, metrafenone, propamocarb and tebuconazole maximum residue levels (MRLs) were set in Annex II to Regulation (EC) No 396/2005. For dithiocarbamates and thiram MRLs were set in Annex II and Part B of Annex III to Regulation (EC) No 396/2005. For boscalid, dazomet, fluazifop-P, picloram, pyridaben, pyriofenone and tebufenpyrad MRLs were set in Part A of Annex III to that Regulation. For sulfoxaflor no specific MRLs were set nor was the substance included in Annex IV to that Regulation, so the default value of 0,01 mg/kg laid down in Article 18(1)(b) applies.

(2) In the context of a procedure for the authorisation of the use of a plant protection product containing the active substance bifenazate on blueberries, cranberries, gooseberries and azaroles, 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 boscalid, such an application was submitted for beans and peas (with pods). As regards cyazofamid, such an application was submitted for aubergines. As regards cyromazine, such an application was submitted for ‘lettuces and salad plants’, ‘spinaches and similar leaves’ and ‘herbs and edible flowers’. As regards dazomet, such an application was submitted for fruits of code number 0100000, carrots,

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radishes, fruiting vegetables (except sweetcorn), leafy brassica, 'lettuces and salad plants' and 'spinaches and similar leaves'. As regards fluazifop-P, such an application was submitted for celeriac, Jerusalem artichokes, peas (without pods), globe artichokes, dry beans, lentils, lupins, linseeds, poppy seeds, safflower seeds, herbal infusion (dried roots) and spices (roots or rhizome). As regards mepanipyrim, such an application was submitted for strawberries, tomatoes, aubergines and cucumbers. As regards metrafenone, such an application was submitted for hops. As regards picloram, such an application was submitted for borage. As regards propamocarb, such an application was submitted for garlic, onions and shallots. As regards pyridaben, such an application was submitted for cucurbits (edible peel). As regards pyriofenone, such an application was submitted for table grapes. As regards tebuconazole, such an application was submitted for cucumbers and courgettes. As regards tebufenpyrad, such an application was submitted for citrus fruits, plums, strawberries, tomatoes, peppers, aubergines, gherkins, melons and watermelons.

(4) In accordance with Article 6(2) and (4) of Regulation (EC) No 396/2005 an application was submitted for thiram used on avocados. The applicant claims that the authorised uses of that substance on such crop in Australia and New Zealand lead to residues exceeding the MRL contained in Regulation (EC) No 396/2005 and that a higher MRL is necessary to avoid trade barriers for the importation of that 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.

(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 MRLs[(2)]. 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 opinions that, as regards the use of cyromazine on scarole and the use of tebufenpyrad on peppers, a risk to the consumer cannot be excluded. The existing MRLs should therefore remain unchanged.

(8) As regards the use of cyromazine on lamb's lettuce and fresh herbs, the use of dazomet on fruits and the use of tebufenpyrad on plums, gherkins, melons and watermelons, the submitted data support lower MRLs than the existing ones. However, since it needs to be verified whether these lower MRLs adequately reflect the critical Good Agricultural Practices (GAP) used in the EU and given that the existing MRLs are safe to the consumer, it is appropriate not to lower the existing MRLs in the framework of the current Regulation, but to use the information derived from the submitted data when reviewing all existing MRLs for those substances.

(9) For dithiocarbamates, the Authority concluded that a new MRL for avocados needs to be set at the level of 7 mg/kg to adequately address the use of thiram on such a crop. The proposed MRL is considered safe to the consumer.

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(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) For sulfoxaflor, the Authority submitted a conclusion on the peer review of the pesticide risk assessment of the active substance sulfoxaflor[(3)]. In that framework, it recommended to set MRLs covering both the representative uses according to GAPs in the Union and import tolerance requests from several third countries. The Commission consulted the European Union reference laboratories on the appropriate limits of determination (LODs).

(12) 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.

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

(14) 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 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, 3 December 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 bifenazate, cyazofamid, cyromazine, dithiocarbamates, mepanipyrim, metrafenone, propamocarb, tebuconazole and thiram 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]	**Bifenazate (sum of bifenazate plus bifenazate-diazene expressed as bifenazate) (F)**	**Cyazofamid**	**Cyromazine**	**Dithiocarbamates (dithiocarbamates expressed as CS2, including maneb, mancozeb, metiram, propineb, thiram and ziram)**	**Mepanipyrim**	**Metrafenone (F)**	**Propamocarb (Sum of propamocarb and its salts, expressed as propamocarb) (R)**	**Tebuconazole (R)**	**Thiram (expressed as thiram)**
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
0100000	**FRUITS, FRESH or FROZEN; TREE NUTS**			0,05[a]				0,01[a]		
0110000	**Citrus fruits**	0,9	0,01[a]		**5 (+)**	0,01[a]	0,01[a]			0,1[a]
0110010	Grapefruits								5	
0110020	Oranges								0,9	
0110030	Lemons								5	
0110040	Limes								5	
0110050	Mandarins								5	
0110990	Others								5	
0120000	**Tree nuts**	0,2	0,02[a]			0,02[a]	0,01[a]		0,05	0,1[a]
0120010	Almonds				0,05[a]					
0120020	Brazil nuts				0,05[a]					
0120030	Cashew nuts				0,05[a]					

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0120040	Chestnuts				0,05[a]					
0120050	Coconuts				0,05[a]					
0120060	Hazelnuts/ cobnuts				0,05[a]					
0120070	Macadamias				0,05[a]					
0120080	Pecans				0,05[a]					
0120090	Pine nut kernels				0,05[a]					
0120100	Pistachios				0,05[a]					
0120110	Walnuts				**0,1 (+)**					
0120990	Others				0,05[a]					
0130000	**Pome fruits**	0,7 (+)	0,01[a]		**5 (+)**	0,01[a]	0,01[a]			
0130010	Apples								0,3	5
0130020	Pears								0,3	5
0130030	Quinces								0,5	0,1[a]
0130040	Medlars				[b]		[b]		0,5	[b]
0130050	Loquats/ Japanese medlars				[b]		[b]		0,5	[b]
0130990	Others								0,5	0,1[a]
0140000	**Stone fruits**	2	0,01[a]			0,01[a]	0,01[a]			
0140010	Apricots				2 (+)				0,6	3
0140020	Cherries (sweet)				2 (+)				1 (+)	3
0140030	Peaches				2 (+)				0,6	3
0140040	Plums				2 (+)				1	2
0140990	Others				0,05[a]				0,02[a]	0,1[a]
0150000	**Berries and small fruits**									
0151000	(a)	0,7 *grapes*	**2**		5 (+)	2	7			