Commission Regulation (EU) 2017/1777 of 29 September 2017 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for Bacillus amyloliquefaciens strain FZB24, Bacillus amyloliquefaciens strain MBI 600, clayed charcoal, dichlorprop-P, ethephon, etridiazole, flonicamid, fluazifop-P, hydrogen peroxide, metaldehyde, penconazole, spinetoram, tau-fluvalinate and Urtica spp. in or on certain products (Text with EEA relevance)

COMMISSION REGULATION (EU) 2017/1777

of 29 September 2017

amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for *Bacillus amyloliquefaciens* strain FZB24, *Bacillus amyloliquefaciens* strain MBI 600, clayed charcoal, dichlorprop-P, ethephon, etridiazole, flonicamid, fluazifop-P, hydrogen peroxide, metaldehyde, penconazole, spinetoram, tau-fluvalinate and *Urtica* spp. 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 5(1) and Article 14(1)(a) thereof,

Whereas:

(1) For dichlorprop-P, ethephon, flonicamid, fluazifop-P and metaldehyde, 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 that Regulation. For etridiazole, spinetoram and tau-fluvalinate, MRLs were set in Part A of Annex III to that Regulation. For *Bacillus amyloliquefaciens* strain FZB24, *Bacillus amyloliquefaciens* strain MBI 600, clayed charcoal, hydrogen peroxide and *Urtica* spp., no specific MRLs were set nor were those substances included in Annex IV to that Regulation, so the default value of 0,01 mg/kg laid down in Article 18(1)(b) thereof applies.

(2) In the context of a procedure for the authorisation of the use of a plant protection product containing the active substance dichlorprop-P on citrus fruits, 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 ethephon, such an application was submitted for Japanese persimmons. As regards etridiazole, such an application was submitted for cucurbits with edible peel. As regards flonicamid, such an application was submitted for apricots, head cabbage, beans

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and peas (with pods) and sugar beet roots. As regards fluazifop-P, such an application was submitted for carrots and courgettes. As regards metaldehyde, such an application was submitted for leeks. As regards penconazole, such an application was submitted for grapes. As regards spinetoram, such an application was submitted for cherries, cane fruit, 'other small fruits and berries', 'lettuces and salad plants', 'spinaches and similar leaves', 'herbs and edible flowers', leeks and herbal infusions from leaves and herbs. As regards tau-fluvalinate, such an application was submitted for citrus fruits.

(4) In accordance with Article 8 of Regulation (EC) No 396/2005, those 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 MRLs[(2)]. It forwarded those opinions to the applicants, the Commission and the Member States and made them available to the public.

(6) The Authority concluded in its reasoned opinion on spinetoram that, as regards its use on scarole, a risk to the consumer could not be excluded. The existing MRL should therefore be kept.

(7) As regards flonicamid, the Authority recommended increasing the existing MRLs for several products of animal origin in order to accommodate for the intended uses of that active substance on sugar beet.

(8) As regards etridiazole, the Authority could not conclude on the dietary risk assessment for consumers as some information was not available and further consideration by risk managers was required. The Standing Committee on Plants, Animals, Food and Feed noted at its meeting on 29 May 2015 that the substance concerned does not produce relevant metabolites of significant toxicity or at levels leading to an exposure higher than negligible[(3)]. It is therefore appropriate to set the MRL for cucurbits with edible peel in Regulation (EC) No 396/2005 at the level of 0,4 mg/kg, which reflects the Good Agricultural Practice.

(9) 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 products showed that there is a risk that the acceptable daily intake or the acute reference dose is exceeded.

(10) For *Bacillus amyloliquefaciens* strain FZB24 and *Bacillus amyloliquefaciens* strain MBI 600, the Authority submitted conclusions on the peer review of the pesticide risk assessment of those active substances[(4)]. For all of these substances, the Authority could not conclude on the dietary risk assessment for consumers as some information was

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not available and further consideration by risk managers was required. Such further consideration was reflected in the respective review reports[(5)] which concluded that the risk to humans through metabolites from these substances is negligible. In view of those conclusions, the Commission considers that the inclusion of those substances in Annex IV to Regulation (EC) No 396/2005 is appropriate.

(11) Clayed charcoal, hydrogen peroxide and Urtica spp. are approved as basic substances by Commission Implementing Regulation (EU) 2017/428[(6)], Commission Implementing Regulation (EU) 2017/409[(7)] and Commission Implementing Regulation (EU) 2017/419[(8)], respectively. The conditions of use of those active substances are not expected to lead to the presence of residues in food or feed commodities that may pose a risk to the consumer. It is therefore appropriate that those substances are included in Annex IV to Regulation (EC) No 396/2005.

(12) Based on the reasoned opinions and the conclusions 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, III and IV 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, 29 September 2017.

For the Commission

The President

Jean-Claude JUNCKER

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ANNEX

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

(1) in Annex II, the columns for dichlorprop-P, ethephon, flonicamid, fluazifop-P, metaldehyde and penconazole 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]**	**Dichlorprop (Sum of dichlorprop (including dichlorprop-P), its salts, esters and conjugates, expressed as dichlorprop (R)**	**Ethephon**	**Flonicamid (sum of flonicamid, TFNA and TFNG expressed as flonicamid (R)**	**Fluazifop-P (sum of all the constituent isomers of fluazifop, its esters and its conjugates, expressed as fluazifop)**	**Metaldehyde**	**Penconazole (F)**
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
0100000	**FRUITS, FRESH or FROZEN; TREE NUTS**					0,05[a]	
0110000	**Citrus fruits**	**0,3**	0,05[a]	0,15 (+)	0,01[a]		0,05[a]
0110010	Grapefruits						
0110020	Oranges						
0110030	Lemons						
0110040	Limes						
0110050	Mandarins						
0110990	Others						
0120000	**Tree nuts**	0,02[a]		0,06[a]	0,01[a]		0,05[a]
0120010	Almonds		0,1				
0120020	Brazil nuts		0,1				
0120030	Cashew nuts		0,1				

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0120040	Chestnuts		0,1				
0120050	Coconuts		0,1				
0120060	Hazelnuts/ cobnuts		0,2				
0120070	Macadamias		0,1				
0120080	Pecans		0,1				
0120090	Pine nut kernels		0,1				
0120100	Pistachios		0,1				
0120110	Walnuts		0,5				
0120990	Others		0,1				
0130000	**Pome fruits**	0,02[a]		0,3	0,01[a]		0,2
0130010	Apples		0,8				
0130020	Pears		0,05[a]				
0130030	Quinces		0,05[a]				
0130040	Medlars		0,05[a]				[b]
0130050	Loquats/ Japanese medlars		0,05[a]				[b]
0130990	Others		0,05[a]				
0140000	**Stone fruits**	0,02[a]			0,01[a]		
0140010	Apricots		0,05[a]	**0,3**			0,1
0140020	Cherries (sweet)		5	0,4 (+)			0,05[a]
0140030	Peaches		0,05[a]	0,4			0,1
0140040	Plums		0,05[a]	0,3 (+)			0,05[a]
0140990	Others		0,05[a]	0,03[a]			0,05[a]
0150000	**Berries and small fruits**	0,02[a]		0,03[a]			
0151000	(a)	*grapes*			0,01[a]		**0,4**
0151010	Table grapes		1				