Commission Regulation (EU) 2018/1514 of 10 October 2018 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 abamectin, acibenzolar-S-methyl, clopyralid, emamectin, fenhexamid, fenpyrazamine, fluazifop-P, isofetamid, Pasteuria nishizawae Pn1, talc E553B and tebuconazole in or on certain products (Text with EEA relevance)

COMMISSION REGULATION (EU) 2018/1514

of 10 October 2018

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 abamectin, acibenzolar-S-methyl, clopyralid, emamectin, fenhexamid, fenpyrazamine, fluazifop-P, isofetamid, *Pasteuria nishizawae* Pn1, talc E553B 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 5(1) and Article 14(1)(a) thereof,

Whereas:

(1) For abamectin, acibenzolar-S-methyl, fenhexamid, fluazifop-P, isofetamid and tebuconazole, maximum residue levels (MRLs) were set in Annex II to Regulation (EC) No 396/2005. For clopyralid, emamectin and fenpyrazamine, MRLs were set in Part A of Annex III to that Regulation. For *Pasteuria nishizawae* Pn1 and talc E553B, no specific MRLs were set nor were those substance 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 abamectin 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 acibenzolar-S-methyl, such an application was submitted for aubergines and cucurbits. As regards clopyralid, such an application was submitted for spring onions and leeks. As regards emamectin, such an application was submitted for leafy brassica, beans (with pods) and peas (with pods). As regards fenhexamid, such an application was submitted for plums, blueberries, cranberries, currants, gooseberries and beans (with pods). As regards fenpyrazamine, such an application was submitted for lettuces,

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salad plants, spinaches and similar leaves. As regards fluazifop-P, such an application was submitted for tomatoes. As regards isofetamid, such an application was submitted for tomatoes, peppers, aubergines, okra and cucurbits (with edible peel). As regards tebuconazole, such an application was submitted for olives, rice, 'herbs and edible flowers' and herbal infusions from flowers, leaves and herbs.

(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 ('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)]. The Authority forwarded those opinions to the applicants, the Commission and the Member States and made them available to the public.

(6) As regards all 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. The Authority 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.

(7) As regards abamectin, the applicant also submitted validated analytical methods for crop matrices with high acid and water content. As regards tebuconazole, the applicant also submitted validated analytical methods for all crop matrices. The relevant footnotes should therefore be deleted from Annex II to Regulation (EC) No 396/2005.

(8) In the context of the approval of the active substance *Pasteuria nishizawae* Pn1, an MRL application was included in the summary dossier in accordance with Article 8(1)(g) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council[(3)]. Such application was evaluated by the Member State concerned in accordance with Article 11(2) of that Regulation. The Authority assessed the application and delivered a conclusion on the peer review of the pesticide risk assessment of the active substance, where it recommended the inclusion of *Pasteuria nishizawae* Pn1 in Annex IV to Regulation (EC) No 396/2005.[(4)].

(9) Talc E553B is approved as basic substance by Commission Implementing Regulation (EU) 2018/691[(5)]. The conditions of use of that substance 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 to include that substance in Annex IV to Regulation (EC) No 396/2005.

(10) 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

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modifications to the MRLs fulfil the requirements of Article 14(2) of Regulation (EC) No 396/2005.

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

(12) 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, 10 October 2018.

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 abamectin, acibenzolar-S-methyl, fenhexamid, fluazifop-P, isofetamid 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[b]**	**Abamectin (sum of avermectin B1a, avermectin B1b and delta-8,9 isomer of avermectin B1a, expressed as avermectin B1a) (F) (R)**	**Acibenzolar-S-methyl (sum of acibenzolar-S-methyl and acibenzolar acid (free and conjugated), expressed as acibenzolar-S-methyl)**	**Fenhexamid (F)**	**Fluazifop-P (sum of all the constituent isomers of fluazifop, its esters and its conjugates, expressed as fluazifop)**	**Isofetamid**	**Tebuconazole (R)**
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
0100000	**FRUITS, FRESH or FROZEN; TREE NUTS**						
0110000	**Citrus fruits**	**0,04**	0,01[a]	0,01[a]	0,01[a]	0,01[a]	
0110010	Grapefruits						5
0110020	Oranges						0,9
0110030	Lemons						5
0110040	Limes						5
0110050	Mandarins						5
0110990	Others (2)						5
0120000	**Tree nuts**			0,02[a]	0,01[a]	0,01[a]	0,05
0120010	Almonds	0,02 (+)	0,01[a]				

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0120020	Brazil nuts	0,01[a]	0,01[a]				
0120030	Cashew nuts	0,01[a]	0,01[a]				
0120040	Chestnuts	0,01[a]	0,01[a]				
0120050	Coconuts	0,01[a]	0,01[a]				
0120060	Hazelnuts/ cobnuts	0,02 (+)	0,1				
0120070	Macadamias	0,01[a]	0,01[a]				
0120080	Pecans	0,01[a]	0,01[a]				
0120090	Pine nut kernels	0,01[a]	0,01[a]				
0120100	Pistachios	0,01[a]	0,01[a]				
0120110	Walnuts	0,02 (+)	0,01[a]				
0120990	Others (2)	0,01[a]	0,01[a]				
0130000	**Pome fruits**	0,03 (+)		0,01[a]	0,01[a]	0,01[a]	
0130010	Apples		0,3				0,3
0130020	Pears		0,2				0,3
0130030	Quinces		0,2				0,5
0130040	Medlars		0,2				0,5
0130050	Loquats/ Japanese medlars		0,2				0,5
0130990	Others (2)		0,2				0,5
0140000	**Stone fruits**				0,01[a]	0,01[a]	
0140010	Apricots	**0,02**	0,2	10			0,6
0140020	Cherries (sweet)	0,01[a]	0,01[a]	7			1 (+)
0140030	Peaches	**0,02**	0,2	10			0,6
0140040	Plums	**0,01**[a]	0,01[a]	**2**			1
0140990	Others (2)	0,01[a]	0,01[a]	0,01[a]			0,02[a]
0150000	**Berries and**						