Commission Regulation (EU) 2018/685 of 3 May 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, beer, fluopyram, fluxapyroxad, maleic hydrazide, mustard seeds powder and tefluthrin in or on certain products (Text with EEA relevance)

COMMISSION REGULATION (EU) 2018/685

of 3 May 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, beer, fluopyram, fluxapyroxad, maleic hydrazide, mustard seeds powder and tefluthrin 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 and maleic hydrazide, maximum residue levels (MRLs) were set in Annex II to Regulation (EC) No 396/2005. For fluopyram, fluxapyroxad and tefluthrin, MRLs were set in Part A of Annex III to that Regulation. For beer and mustard seeds powder, 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 abamectin on bananas, 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 fluopyram, such an application was submitted for purslanes. As regards fluxapyroxad, such an application was submitted for ‘tropical root and tuber vegetables’, ‘other root and tuber vegetables except sugar beets’, spring onions, ‘flowering brassica’, Brussels sprouts, head cabbages, ‘lettuces and salad plants’, ‘spinaches and similar leaves’, witloofs, ‘herbs and edible flowers’, globe artichokes, leeks, ‘herbal infusions from roots’, ‘root and rhizome spices’ and chicory roots. As regards tefluthrin, such an application was submitted for carrots.

(4) In accordance with Article 6(2) and (4) of Regulation (EC) No 396/2005 an application was submitted for fluxapyroxad used on citrus fruits. The applicant claims that the

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authorised uses of that substance on such crops in Brazil lead to residues exceeding the MRLs contained in Regulation (EC) No 396/2005 and that higher MRLs are necessary to avoid trade barriers for the importation of those crops.

(5) 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.

(6) 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.

(7) The Authority concluded in its reasoned opinions that, as regards the use of fluxapyroxad on citrus fruits, the submitted data were not sufficient to set a new MRL for the entire group. However, in accordance with the existing Union guidelines on extrapolation of MRLs, it is appropriate to set the MRL for grapefruits at the value of the existing MRL for oranges. The existing MRLs for citrus fruits should therefore be kept at the current values except for grapefruits for which the MRL should be increased to 0,3 mg/kg.

(8) 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. 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.

(9) For maleic hydrazide, the Authority submitted a conclusion on the peer review of the pesticide risk assessment of the active substance[(3)]. In that framework, it recommended increasing the MRLs for potatoes, garlic, shallots and milk.

(10) Beer and mustard seeds powder are approved as basic substances by Commission Implementing Regulation (EU) 2017/2090[(4)] and Commission Implementing Regulation (EU) 2017/2066[(5)], respectively. The conditions of use of those 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 to include those substances in Annex IV to Regulation (EC) No 396/2005.

(11) Based on the reasoned opinions and the conclusion 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.

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(13) 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, 3 May 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 and maleic hydrazide 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)**	**Maleic hydrazide**
(1)	(2)	(3)	(4)
0100000	**FRUITS, FRESH OR FROZEN; TREE NUTS**		**0,2**[a]
0110000	**Citrus fruits**	0,015 (+)	
0110010	Grapefruits		
0110020	Oranges		
0110030	Lemons		
0110040	Limes		
0110050	Mandarins		
0110990	Others		
0120000	**Tree nuts**		
0120010	Almonds	0,02 (+)	
0120020	Brazil nuts	0,01[a]	
0120030	Cashew nuts	0,01[a]	
0120040	Chestnuts	0,01[a]	
0120050	Coconuts	0,01[a]	
0120060	Hazelnuts/cobnuts	0,02 (+)	
0120070	Macadamias	0,01[a]	
0120080	Pecans	0,01[a]	
0120090	Pine nut kernels	0,01[a]	
0120100	Pistachios	0,01[a]	
0120110	Walnuts	0,02 (+)	

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0120990	Others	0,01[a]	
0130000	**Pome fruits**	0,03 (+)	
0130010	Apples		
0130020	Pears		
0130030	Quinces		
0130040	Medlars		
0130050	Loquats/Japanese medlars		
0130990	Others		
0140000	**Stone fruits**		
0140010	Apricots	0,02 (+)	
0140020	Cherries (sweet)	0,01[a]	
0140030	Peaches	0,02 (+)	
0140040	Plums	0,01[a] (+)	
0140990	Others	0,01[a]	
0150000	**Berries and small fruits**		
0151000	(a) *grapes*	0,01[a] (+)	
0151010	Table grapes		
0151020	Wine grapes		
0152000	(b) *strawberries*	0,15 (+)	
0153000	(c) *cane fruits*		
0153010	Blackberries	0,08 (+)	
0153020	Dewberries	0,01[a]	
0153030	Raspberries (red and yellow)	0,08 (+)	
0153990	Others	0,01[a]	
0154000	(d) *other small fruits and berries*	0,01[a]	
0154010	Blueberries		
0154020	Cranberries		