Commission Regulation (EU) 2016/67 of 19 January 2016 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for ametoctradin, chlorothalonil, diphenylamine, flonicamid, fluazinam, fluoxastrobin, halauxifen-methyl, propamocarb, prothioconazole, thiacloprid and trifloxystrobin in or on certain products (Text with EEA relevance)

COMMISSION REGULATION (EU) 2016/67

of 19 January 2016

amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for ametoctradin, chlorothalonil, diphenylamine, flonicamid, fluazinam, fluoxastrobin, halauxifen-methyl, propamocarb, prothioconazole, thiacloprid and trifloxystrobin 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 chlorothalonil, propamocarb, thiacloprid and trifloxystrobin, maximum residue levels (MRLs) were set in Annex II to Regulation (EC) No 396/2005. For ametoctradin, flonicamid, fluazinam, fluoxastrobin and prothioconazole MRLs were set in Part A of Annex III to that Regulation. For diphenylamine MRLs were set in Annex V and Part A of Annex III to that Regulation. For halauxifen-methyl, no specific MRLs were set nor was that 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 ametoctradin on sage and basil, 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 flonicamid, such an application was submitted for peppers, Brussels sprouts, peas (without pods), cotton seeds, barley, oat and rye. As regards fluazinam, such an application was submitted for tomatoes. As regards fluoxastrobin and prothioconazole, such applications were submitted for shallots. As regards propamocarb, such an application was submitted for leeks. As regards thiacloprid, such an application was submitted for Jerusalem artichokes.

Changes to legislation: *There are outstanding changes not yet made to Commission Regulation (EU) 2016/67. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(4) In accordance with Article 6(2) and (4) of Regulation (EC) No 396/2005 an application was submitted for chlorothalonil used on cranberries. The applicant claims that the authorised uses of that substance on such crop in the United States of America 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, those 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 those opinions to the Commission and the Member States and made them available to the public.

(7) As regards propamocarb, the Authority recommends setting a new MRL on leeks at the level of 30 mg/kg, which was derived by rounding up the value of 20 mg/kg calculated with the Organisation for Economic Cooperation and Development (OECD) MRL calculator. By applying the cooking factor of 0,88 derived for leafy crops to leeks, such proposed MRL will not result in an exceedence of the acute reference dose, thus being safe for the consumer. However, given the concerns raised by some Member States, it is more appropriate to set the MRL at the unrounded level of 20 mg/kg. Such value adequately covers the intended uses on leeks.

(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. It took into account the most recent information on the toxicological properties of the substances. The Authority also concluded that 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 or the acute reference dose is exceeded.

(9) As regards diphenylamine, Commission Regulation (EU) No 772/2013[(3)] set temporary MRLs for apples and pears. Monitoring data show that an unavoidable cross-contamination affecting untreated apples and pears still occurs. In order to provide the necessary time for business operators to completely remove the residues of diphenylamine in storage facilities, it is appropriate to maintain those temporary MRLs, which will be reviewed. The review will take into account the information available within 2 years from the publication of this Regulation.

(10) On 5 July 2013 the Codex Alimentarius Commission (CAC)[(4)] adopted a Codex maximum residue limit (CXL) for trifloxystrobin in olives for oil production. The CXL is safe for consumers in the Union[(5)] and should therefore be included in Regulation (EC) No 396/2005 as MRL.

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(11) As regards thiacloprid and trifloxystrobin, several MRLs were modified by Commission Regulation (EU) 2015/1200[(6)]. That Regulation lowered the MRLs for thiacloprid in Jerusalem artichokes and for trifloxystrobin in olives for oil production to the relevant limits of determination as of 12 February 2016. In the interest of legal certainty, it is appropriate for the MRLs provided for by this Regulation, to apply from the same date.

(12) For halauxifen-methyl, the Authority submitted a conclusion on the peer review of the pesticide risk assessment of that active substance[(7)]. In that framework, it recommended to set MRLs covering the representative uses according to good agricultural practices in the Union. The Commission consulted the European Union reference laboratories on the appropriate limits of determination.

(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, III and V 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*.

It shall however apply from 12 February 2016 as regards the MRL for thiacloprid in Jerusalem artichokes and the MRL for trifloxystrobin in olives for oil production.

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

Done at Brussels, 19 January 2016.

For the Commission

The President

Jean-Claude JUNCKER

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ANNEX

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

(1) Annex II is amended as follows:

(a) the columns for chlorothalonil, propamocarb, thiacloprid and trifloxystrobin 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]**	**Chlorothalonil (R)**	**Propamocarb (Sum of propamocarb and its salts, expressed as propamocarb) (R)**	**Thiacloprid (A) (F) (R)**	**Trifloxystrobin**
(1)	(2)	(3)	(4)	(5)	(6)
0100000	**FRUITS, FRESH or FROZEN; TREE NUTS**		0,01[a]		
0110000	**Citrus fruits**	0,01[a]		0,01[a]	0,5
0110010	Grapefruits				
0110020	Oranges				
0110030	Lemons				
0110040	Limes				
0110050	Mandarins				
0110990	Others				
0120000	**Tree nuts**	0,01[a]		0,02[a]	0,02
0120010	Almonds				
0120020	Brazil nuts				
0120030	Cashew nuts				
0120040	Chestnuts				
0120050	Coconuts				

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0120060	Hazelnuts/ cobnuts				
0120070	Macadamias				
0120080	Pecans				
0120090	Pine nut kernels				
0120100	Pistachios				
0120110	Walnuts				
0120990	Others				
0130000	**Pome fruits**	2 (+)			0,7
0130010	Apples			0,3	
0130020	Pears			0,3	
0130030	Quinces			0,7	
0130040	Medlars			0,7	
0130050	Loquats/ Japanese medlars			0,7	
0130990	Others			0,01[a]	
0140000	**Stone fruits**			0,5	3
0140010	Apricots	1 (+)			
0140020	Cherries (sweet)	0,01[a]			
0140030	Peaches	1 (+)			
0140040	Plums	0,01[a]			
0140990	Others	0,01[a]			
0150000	**Berries and small fruits**				
0151000	(a) *grapes*	3 (+)		0,01[a]	3
0151010	Table grapes				
0151020	Wine grapes				
0152000	(b) *strawberries*	4 (+)		1	1