Commission Regulation (EU) 2015/1101 of 8 July 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 difenoconazole, fluopicolide, fluopyram, isopyrazam and pendimethalin in or on certain products (Text with EEA relevance)

COMMISSION REGULATION (EU) 2015/1101

of 8 July 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 difenoconazole, fluopicolide, fluopyram, isopyrazam and pendimethalin 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 pendimethalin maximum residue levels (MRLs) were set in Annex II to Regulation (EC) No 396/2005. For difenoconazole, fluopicolide, fluopyram and isopyrazam MRLs were set in Part A of Annex III to Regulation (EC) No 396/2005.

(2) In the context of a procedure for the authorisation of the use of a plant protection product containing the active substance difenoconazole on lettuces, lamb's lettuce, scarole, rocket 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 fluopicolide, such an application was submitted for garlic and shallots. As regards fluopyram, such an application was submitted for apricots, peaches, plums, cane fruit, other small fruits and berries of code number 0154000, other root and tuber vegetables of code number 0213000, aubergines, scarole, spinaches, witloof, beans (without pods), peas (with pods), linseed, poppy seed, mustard seed, gold of pleasure, herbal infusions (dried roots), hops, spices (roots or rhizome), chicory roots. As regards isopyrazam, such an application was submitted for tomatoes, aubergines and cucurbits. As regards pendimethalin, such an application was submitted for carrots, celeriac, horseradish, parsnips, parsley root, salsify, swedes, turnips, root and rhizome spices, chicory roots.

(4) 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.

Changes to legislation: *There are outstanding changes not yet made to Commission Regulation (EU) 2015/1101. 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*

(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 these opinions to the Commission and the Member States and made them available to the public.

(6) The Authority concluded in its reasoned opinions that, as regards the use of fluopyram on apricots and chicory roots, the submitted data were not sufficient to set new MRLs. Based on the relevant reasoned opinion, the use of difenoconazole on lettuce and rocket does not require a modification of the existing MRLs. As regards the use of pendimethalin on root and rhizome spices, the evaluating Member State confirmed that there are no authorised uses on those crops. The existing MRLs should therefore remain unchanged.

(7) As regards fluopicolide, the Authority assessed an application with a view of setting an MRL for onions resulting from EU uses and gave a reasoned opinion on the proposed MRL[(3)]. Although it recommended to keep the Codex maximum residue limit (CXL) that had been set for that crop at the level of 1 mg/kg by Commission Regulation (EU) No 520/2011[(4)], it confirmed that for onions, an MRL at a level of 0,3 mg/kg would have been appropriate if based solely on the Good Agricultural Practices (GAPs) in the Union. In accordance with the existing EU guidelines on extrapolation of MRLs, it is appropriate to set that MRL value of 0,3 mg/kg for garlic and shallots.

(8) As regards fluopyram, the applicant clarified that the GAP on peaches refers to both Northern and Southern EU. Moreover, it provided further information outlining the experimental designs and the GAP on cane fruit. In view of such, it is appropriate to set MRLs at the level of 1,5 mg/kg for peaches and 3 mg/kg for cane fruit.

(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 crops and products showed that there is a risk that the acceptable daily intake (ADI) or the acute reference dose (ARfD) is exceeded.

(10) 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.

(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:

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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, 8 July 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 column for pendimethalin is 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]	**Pendimethalin (F)**
(1)	(2)	(3)
0100000	**FRUITS, FRESH or FROZEN; TREE NUTS**	0,05[a]
0110000	**Citrus fruits**	
0110010	Grapefruits	
0110020	Oranges	
0110030	Lemons	
0110040	Limes	
0110050	Mandarins	
0110990	Others	
0120000	**Tree nuts**	
0120010	Almonds	
0120020	Brazil nuts	
0120030	Cashew nuts	
0120040	Chestnuts	
0120050	Coconuts	
0120060	Hazelnuts/cobnuts	
0120070	Macadamias	
0120080	Pecans	
0120090	Pine nut kernels	
0120100	Pistachios	
0120110	Walnuts	
0120990	Others	
0130000	**Pome fruits**	
0130010	Apples	
0130020	Pears	
0130030	Quinces	

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0130040	Medlars	
0130050	Loquats/Japanese medlars	
0130990	Others	
0140000	**Stone fruits**	
0140010	Apricots	
0140020	Cherries (sweet)	
0140030	Peaches	
0140040	Plums	
0140990	Others	
0150000	**Berries and small fruits**	
0151000	(a) *grapes*	
0151010	Table grapes	
0151020	Wine grapes	
0152000	(b) *strawberries*	(+)
0153000	(c) *cane fruits*	
0153010	Blackberries	
0153020	Dewberries	
0153030	Raspberries (red and yellow)	
0153990	Others	
0154000	(d) *other small fruits and berries*	
0154010	Blueberries	
0154020	Cranberries	
0154030	Currants (black, red and white)	
0154040	Gooseberries (green, red and yellow)	
0154050	Rose hips	
0154060	Mulberries (black and white)	
0154070	Azaroles/Mediterranean medlars	
0154080	Elderberries	