Commission Regulation (EU) No 812/2011 of 10 August 2011 amending Annex III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for dimethomorph, fluopicolide, mandipropamid, metrafenone, nicotine and spirotetramat in or on certain products (Text with EEA relevance)

COMMISSION REGULATION (EU) No 812/2011

of 10 August 2011

amending Annex III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for dimethomorph, fluopicolide, mandipropamid, metrafenone, nicotine and spirotetramat 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 dimethomorph, fluopicolide, mandipropamid, metrafenone, nicotine and spirotetramat maximum residue levels (MRLs) were set in Part A of Annex III to Regulation (EC) No 396/2005.

(2) In the context of a procedure, in accordance with Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market[(2)], for the authorisation of the use of a plant protection product containing the active substance mandipropamid on hops an application was made under Article 6(1) of Regulation (EC) No 396/2005 for modification of the existing MRL.

(3) As regards dimethomorph, such an application was made for use on strawberries and lamb's lettuce. As regards fluopicolide, such an application was made for use on onions, tomatoes, cucurbits (edible peel), flowering brassica, head brassica, kohlrabi, lettuce and leek.

(4) In accordance with Article 6(2) and (4) of Regulation (EC) No. 396/2005 an application was made for metrafenone for use on wine grapes and table grapes. The authorised use of metrafenone on wine grapes and table grapes in the United States leads to higher residues than the MRL in Annex III to Regulation (EC) No 396/2005. To avoid trade barriers for the importation of wine and table grapes, a higher MRL is necessary. Avoiding trade barriers is also in conformity with the objectives of the Agreement

Changes to legislation: *There are outstanding changes not yet made to Commission Regulation (EU) No 812/2011. 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*

between the European Community and the United States of America on trade in wine[3], as stated in Article 1 of that Agreement.

(5) 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.

(6) As regards nicotine, the Commission received information from food business operators showing the presence of nicotine in tea, herbal infusions, spices, rose hips and fresh herbs leading to higher residues than the default MRL of 0,01 mg/kg laid down in that Regulation.

(7) The European Food Safety Authority, hereinafter "the Authority", assessed for dimethomorph, fluopicolide, mandipropamid and metrafenone 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[4]. For nicotine the Authority assessed the available monitoring data and gave a reasoned opinion on the setting of temporary MRLs for nicotine in the products concerned[5]. It forwarded these opinions to the Commission and the Member States and made them available to the public.

(8) The Authority concluded in its reasoned opinions 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 these substances, nor the short term exposure due to extreme consumption of the relevant crops showed that there is a risk that the acceptable daily intake (ADI) or the acute reference dose (ARfD) is exceeded.

(9) As regards fluopicolide on onions, tomatoes, cucurbits (edible peel), flowering brassica, head cabbage and Brussels sprouts the Authority concluded that the MRLs were already fixed at the levels covering the current authorised uses.

(10) Based on the reasoned opinions of the Authority and taking into account the factors relevant to the matter under consideration, the proposed modifications to the MRLs fulfil the requirements of Article 14(2) of Regulation (EC) No 396/2005.

(11) As regards spirotetramat, the Codex Alimentarius Commission has adopted CXLs.[6] These CXLs should be included in Regulation (EC) No 396/2005 as MRLs, with the exception of those CXLs which are not safe for a European consumer group and for which the Union presented a reservation to the CAC.

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

(13) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health and neither the European Parliament nor the Council has opposed them,

HAS ADOPTED THIS REGULATION:

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Article 1

Annex III to Regulation (EC) No 396/2005 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the 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 August 2011.

For the Commission

The President

José Manuel BARROSO

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ANNEX

In Part A of Annex III to Regulation (EC) No 396/2005, the columns for dimethomorph, fluopicolide, mandipropamid, metrafenone, nicotine and spirotetramat 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]	**Dimethomorph**	**Fluopicolide**	**Mandipropamid**	**Metrafenone**	**Nicotine**	**Spirotetramat and its 4 metabolites BYI08330-enol, BYI08330-ketohydroxy, BYI08330-monohydroxy, and BYI08330 enol-glucoside, expressed as spirotetramat (R)**
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
0100000	1. **FRUIT FRESH OR FROZEN; NUTS**						
0110000	(i) **Citrus fruit**	0,05[a]	0,01[a]	0,01[a]	0,05[a]		1
0110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo (except mineola), ugli and other hybrids)						
0110020	Oranges (Bergamot, bitter orange, chinotto						

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	and other hybrids)						
0110030	Lemons (Citron, lemon)						
0110040	Limes						
0110050	Mandarins (Clementine, tangerine, mineola and other hybrids)						
0110990	Others						
0120000	(ii) **Tree nuts (shelled or unshelled)**	0,05[a]	0,01[a]	0,01[a]	0,05[a]		**0,5**
0120010	Almonds						
0120020	Brazil nuts						
0120030	Cashew nuts						
0120040	Chestnuts						
0120050	Coconuts						
0120060	Hazelnuts (Filbert)						
0120070	Macadamia						
0120080	Pecans						
0120090	Pine nuts						
0120100	Pistachios						
0120110	Walnuts						
0120990	Others						
0130000	(iii) **Pome fruit**	0,05[a]	0,01[a]	0,01[a]	0,05[a]		1
0130010	Apples (Crab apple)						