Commission Regulation (EU) No 1004/2013 of 15 October 2013 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 8-hydroxyquinoline, cyproconazole, cyprodinil, fluopyram, nicotine, pendimethalin, penthiopyrad and trifloxystrobin in or on certain products (Text with EEA relevance)

COMMISSION REGULATION (EU) No 1004/2013

of 15 October 2013

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 8-hydroxyquinoline, cyproconazole, cyprodinil, fluopyram, nicotine, pendimethalin, penthiopyrad 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 pendimethalin and trifloxystrobin maximum residue levels (MRLs) were set in Annex II and Part B of Annex III to Regulation (EC) No 396/2005. For cyproconazole, cyprodinil, fluopyram, nicotine and penthiopyrad MRLs were set in Part A of Annex III to Regulation (EC) No 396/2005. For 8-hydroxyquinoline, no specific MRLs were set in Annex II and III nor was the substance included in Annex IV to Regulation (EC) No 396/2005, so the default value of 0.01 mg/kg applies.

(2) In the context of a procedure for the authorisation of the use of a plant protection product containing the active substance 8-hydroxyquinoline on tomatoes, an application was made in accordance with Article 6(1) of Regulation (EC) No 396/2005 for modification of the existing MRL.

(3) As regards cyproconazole, such an application was made for mustard seed and gold of pleasure. As regards cyprodinil, such an application was made for radishes and cucurbits (inedible peel). As regards pendimethalin, such an application was made for salsify, celeriac, swedes, turnips, celery and herbal infusions (roots). As regards trifloxystrobin, such an application was made for beans (with pods).

(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) No 1004/2013. 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 cyproconazole on mustard seed and gold of pleasure, the submitted data are sufficient to set new MRLs for the northern EU use only. As regards the use of pendimethalin on celeriac, swedes, turnips and celery, the Authority concluded that the submitted data are not sufficient to set new MRLs.

(7) 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 these substances, 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.

(8) As regards penthiopyrad the applicant submitted further data confirming that the metabolism of penthiopyrad in genetically modified crop is comparable to the one occuring in its conventional counterpart. To avoid trade barriers for the importation of sunflower seed, rape seed, soya bean and cotton seed higher MRLs are necessary. The new MRLs for those products should therefore be set in Part A of Annex III to Regulation (EC) No 396/2005.

(9) As regards fluopyram, by Regulation (EU) No 270/2012[(3)] provisional MRLs were set for several products until 31 December 2013, pending the submission of further residue data. Such data were submitted to Germany, the evaluating Member State for that substance, on 17 December 2012. In order to provide the necessary time for the evaluating Member State to evaluate those data and prepare an evaluation report, for the Authority to evaluate that report and for the Commission to take its decision, it is appropriate to extend the validity of these MRLs until two years from the publication of this Regulation.

(10) As regards nicotine, by Regulation (EU) No 812/2011[(4)] provisional MRLs were set for tea, herbal infusions, spices, rose hips and fresh herbs until 14 August 2013, pending the submission and evaluation of new data and information on the natural occurrence or formation of nicotine in the concerned products. The Commission was informed of a research project which is being carried out to investigate on the sources of nicotine resulting in those crops. In view of the expected duration of the study and in order to provide the necessary time for the Commission to take its decision, it is appropriate to extend the validity of these MRLs until three years from the publication of this Regulation.

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(11) 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 relevant requirements of Article 14(2) of Regulation (EC) No 396/2005.

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

(13) In the interest of legal certainty, the provisions concerning nicotine should apply from 15 August 2013.

(14) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

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 day following that of its publication in the *Official Journal of the European Union*.

It shall, however, apply from 15 August 2013 for nicotine in rose hips of code number 0154050, fresh herbs of code number 0256000, tea of code number 0610000, herbal infusions of code number 0630000 and spices of code number 0800000.

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

Done at Brussels, 15 October 2013.

For the Commission

The President

José Manuel BARROSO

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ANNEX

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

(1) In Annex II, the columns for pendimethalin 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**[a]	**Pendimethalin (F)**	**Trifloxystrobin (F) (R)**
(1)	(2)	(3)	(4)
0100000	1. **FRUIT FRESH OR FROZEN NUTS**	0,05[b]	
0110000	(i) **Citrus fruit**		0,3
0110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo (except mineola), ugli and other hybrids)		
0110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)		
0110030	Lemons (Citron, lemon, Buddha's hand (*Citrus medica* var. *sarcodactylis*))		

a For the complete list of products of plant and animal origin to which MRLs apply, reference should be made to Annex I.

b Indicates lower limit of analytical determination

c Pesticide-code combination for which the MRL as set in Annex III Part B applies.

(F) = Fat soluble

Trifloxystrobin (F) (R)

(R) = The residue definition differs for the following combinations pesticide-code number:
Trifloxystrobin- code 1000000: the sum of trifloxystrobin and its metabolite (E, E)-methoxyimino- {2-[1-(3-trifluoromethyl-phenyl)-ethylideneamino-oxymethyl]-phenyl}-acetic acid (CGA 321113)

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0110040	Limes		
0110050	Mandarins (Clementine, tangerine, mineola and other hybrids tangor (*Citrus reticulata* x *sinensis*))		
0110990	Others		
0120000	(ii) **Tree nuts**		0,02[b]
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**		0,5
0130010	Apples (Crab apple)		
0130020	Pears (Oriental pear)		

a For the complete list of products of plant and animal origin to which MRLs apply, reference should be made to Annex I.

b Indicates lower limit of analytical determination

c Pesticide-code combination for which the MRL as set in Annex III Part B applies.

(F) = Fat soluble

Trifloxystrobin (F) (R)

(R) = The residue definition differs for the following combinations pesticide-code number:
Trifloxystrobin- code 1000000: the sum of trifloxystrobin and its metabolite (E, E)-methoxyimino- {2-[1-(3-trifluoromethyl-phenyl)-ethylideneamino-oxymethyl]-phenyl}-acetic acid (CGA 321113)