Commission Regulation (EU) No 765/2010 of 25 August 2010 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 chlorothalonil clothianidin, difenoconazole, fenhexamid, flubendiamide, nicotine, spirotetramat, thiacloprid and thiamethoxam in or on certain products (Text with EEA relevance)

COMMISSION REGULATION (EU) No 765/2010

of 25 August 2010

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(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, fenhexamid and thiacloprid maximum residue levels (MRLs) were set in Annex II and Part B of Annex III to Regulation (EC) No 396/2005. For clothianidin, difenoconazole, flubendiamide, spirotetramat and thiamethoxam, MRLs were set in Part A of Annex III to Regulation (EC) No 396/2005. Up to now, for nicotine no specific MRLs were set nor was that substance included in Annex IV 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 difenoconazole on swedes and turnips an application was made under Article 6(1) of Regulation (EC) No 396/2005 for modification of the existing MRLs.

(3) As regards chlorothalonil, such an application was made for the use on barley. In view of that application, it is necessary to set MRLs for meat, fat, liver, kidney and milk from bovines, sheep and goats, since cereals are used as feed and residues may end up on forage for these animals. As regards fenhexamid, such an application was made for the use on lettuce. As regards flubendiamide, such an application was made for the use on aubergine, cucurbits and beans with pods. As regards spirotetramat, such an application was made for the use on onions. As regards thiacloprid, such an application was made for the use on strawberries, while also a Codex MRL exists for that combination. As

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regards thiamethoxam, such an application was made for carrots. In view of residues of clothianidin caused by the use of thiamethoxam, it is also necessary to modify the MRL for clothianidin on carrots.

(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.

(5) As regards nicotine in wild fungi, the Commission received information from Member States and business operators showing the presence of nicotine in wild fungi leading to higher residues than the default MRL of 0,01 mg/kg laid down in that Regulation.

(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[(3)]. In the case of nicotine, the Commission asked the Authority to give an opinion on public health risks of nicotine residues in mushrooms. Given the urgency the Authority issued a 'statement', referring to several remaining uncertainties, rather than a reasoned opinion[(4)]. It forwarded these opinions and that statement to the Commission and the Member States and made them available to the public.

(7) 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.

(8) As regards nicotine on wild fungi, the Authority points out that its statement is affected by a number of uncertainties and limitations. In addition to that statement, monitoring data were collected in 2009 to investigate the presence of this substance in wild mushrooms. Those data were generated by Member States, food business operators and by the Chinese government and showed that nicotine is present in wild mushrooms at levels that vary depending on the source and variety, but that exceed, in almost the totality of the samples, the default MRL of 0,01 mg/kg. These findings provide evidence of the unavoidable presence of nicotine in wild fungi, in particular ceps (*Boletus edulis*). Therefore, it is appropriate to set temporary MRLs for nicotine in wild fungi, based on the available monitoring data and on the opinion of the Authority. Those temporary MRLs should be reviewed within two years, to evaluate new data and information that will become available, including any scientific evidence on the natural occurrence or formation of nicotine in wild fungi.

(9) Based on the reasoned opinions and statement 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)(a) of Regulation (EC) No 396/2005.

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

(11) 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:

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*.

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

Done at Brussels, 25 August 2010.

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 chlorothalonil, fenhexamid and thiacloprid 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]	**Chlorothalonil (R)**	**Fenhexamid**	**Thiacloprid (F)**
(1)	(2)	(3)	(4)	(5)
0100000	1. **FRUIT FRESH OR FROZEN; NUTS**			
0110000	(i) **Citrus fruit**	0,01[b]	0,05[b]	0,02[b]
0110010	Grapefruit			
0110020	Oranges			
0110030	Lemons			
0110040	Limes			
0110050	Mandarins			
0110990	Others			
0120000	(ii) **Tree nuts (shelled or unshelled)**	0,01[b]	0,05[b]	0,02[b]
0120010	Almonds			
0120020	Brazil nuts			

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
(R) = The residue definition differs for the following combinations pesticide-code number:
Chlorothalonil — code code 1012000: SDS-3701
Chlorothalonil — code 1013000: SDS-3701
Chlorothalonil — code 1014000: SDS-3701.

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0120030	Cashew nuts			
0120040	Chestnuts			
0120050	Coconuts			
0120060	Hazelnuts			
0120070	Macadamia			
0120080	Pecans			
0120090	Pine nuts			
0120100	Pistachios			
0120110	Walnuts			
0120990	Others			
0130000	(iii) **Pome fruit**	1	0,05[b]	0,3
0130010	Apples			
0130020	Pears			
0130030	Quinces			
0130040	Medlar	[c]	[c]	[c]
0130050	Loquat	[c]	[c]	[c]
0130990	Others			
0140000	(iv) **Stone fruit**			
0140010	Apricots	1	5	0,3
0140020	Cherries	0,01[b]	5	0,3
0140030	Peaches	1	5	0,3
0140040	Plums	0,01[b]	1	0,1
0140990	Others	0,01[b]	0,05[b]	0,02[b]
0150000	(v) **Berries & small fruit**			

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

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(F) = Fat soluble
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Chlorothalonil — code code 1012000: SDS-3701
Chlorothalonil — code 1013000: SDS-3701
Chlorothalonil — code 1014000: SDS-3701.