Commission Regulation (EU) No 524/2011 of 26 May 2011 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 biphenyl, deltamethrin, ethofumesate, isopyrazam, propiconazole, pymetrozine, pyrimethanil and tebuconazole in or on certain products (Text with EEA relevance)

COMMISSION REGULATION (EU) No 524/2011

of 26 May 2011

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 biphenyl, deltamethrin, ethofumesate, isopyrazam, propiconazole, pymetrozine, pyrimethanil and tebuconazole 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 deltamethrin, ethofumesate, propiconazole, pymetrozine and pyrimethanil maximum residue levels (MRLs) were set in Annex II and Part B of Annex III to Regulation (EC) No 396/2005. For tebuconazole, MRLs were set in Part A of Annex III to Regulation (EC) No 396/2005. For isopyrazam no MRLs were set before in any of the Annexes to Regulation (EC) No 396/2005, so the default value of 0.01 mg/kg applied. Up to now, for biphenyl no specific MRLs were set nor was the substance included in Annex IV to Regulation (EC) No 396/2005. Biphenyl was formerly used as a plant protection product. In accordance with Article 18(1)(b) Regulation (EC) No 396/2005 the default MRL of 0.01 mg/kg is to apply to all products listed in Annex I thereto.

(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 pymetrozine on spinach, purslane and beet leaves an application was made under Article 6(1) of Regulation (EC) No 396/2005 for modification of the existing MRLs.

(3) As regards deltamethrin, such an application was made for the use on potatoes. As regards ethofumesate, such an application was made for the use in herbal infusions for leaves and flowers and thyme. As regards isopyrazam, such an application was made for the use on several cereals. As regards propiconazole, such an application was made for the use on table and wine grapes, and apples As regards pyrimethanil, such an

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application was made for the use on peas with pods. As regards tebuconazole, such an application was made for the use on various citrus fruit.

(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 biphenyl, the Commission received information from Germany and business operators showing the presence of biphenyl on fresh herbs and herbal infusions containing pesticide residues higher than the default MRL. Germany submitted an evaluation report and informed that due to the ubiquitous presence of this substance from various sources it is impossible to produce herbs,tea rose hips, spices and herbal infusions containing residues of biphenyl complying with the MRL. Referring to the procedure described in Article 16(1) (a) of Regulation (EC) No 396/2005 Germany made an application for temporary MRLs to enable the placing on the market of the affected products.

(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)]. It forwarded these opinions 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) For biphenyl the Authority recommended only to raise the MRLs for which data demonstrated that this was necessary. It also advised that because of analytical problems in some cases it might not be possible to enforce the existing MRL and suggested that the lowest limit of analytical determination (LOD) for these crops might be raised. This was confirmed by information obtained from the EU reference laboratory.

(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) of Regulation (EC) No 396/2005.

(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:

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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 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.

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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 deltamethrin, ethofumesate, propiconazole, pymetrozine and pyrimethanil 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]	**Deltamethrin (cis-deltamethrin) (F)**	**Ethofumesate (sum of ethofumesate and the metabolite 2,3-dihydro-3,3-dimethyl-2-oxo-benzofuran-5-yl methane sulphonate expressed as ethofumesate)**	**Propiconazole**	**Pymetrozine**	**Pyrimethanil**
(1)	(2)	(3)	(4)	(5)	(6)	(7)
0100000	1. **FRUIT FRESH OR FROZEN; NUTS**		0,05[b]			
0110000	(i) **Citrus fruit**	0,05[b]		0,05[b]	0,3	10
0110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo (except mineola), ugli and other hybrids)					

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

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0110020	Oranges (Bergamot, bitter orange, chinotto 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[b]		0,05[b]	0,02[b]	
0120010	Almonds					0,2
0120020	Brazil nuts					0,05[b]
0120030	Cashew nuts					0,05[b]
0120040	Chestnuts					0,05[b]
0120050	Coconuts					0,05[b]
0120060	Hazelnuts (Filbert)					0,05[b]
0120070	Macadamia					0,05[b]
0120080	Pecans					0,05[b]
0120090	Pine nuts					0,05[b]
0120100	Pistachios					0,2

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