Commission Regulation (EU) No 978/2011 of 3 October 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 acetamiprid, biphenyl, captan, chlorantraniliprole, cyflufenamid, cymoxanil, dichlorprop-P, difenoconazole, dimethomorph, dithiocarbamates, epoxiconazole, ethephon, flutriafol, fluxapyroxad, isopyrazam, propamocarb, pyraclostrobin, pyrimethanil and spirotetramat in or on certain products (Text with EEA relevance)

COMMISSION REGULATION (EU) No 978/2011

of 3 October 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 acetamiprid, biphenyl, captan, chlorantraniliprole, cyflufenamid, cymoxanil, dichlorprop-P, difenoconazole, dimethomorph, dithiocarbamates, epoxiconazole, ethephon, flutriafol, fluxapyroxad, isopyrazam, propamocarb, pyraclostrobin, pyrimethanil 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 acetamiprid, captan, dithiocarbamates, ethephon, pyraclostrobin and pyrimethanil maximum residue levels (MRLs) were set in Annex II and Part B of Annex III to Regulation (EC) No 396/2005. For biphenyl, chlorantraniliprole, cyflufenamid, cymoxanil, dichlorprop-P, difenoconazole, dimethomorph, epoxiconazole, flutriafol, isopyrazam, propamocarb and spirotetramat, MRLs were set in Part A of Annex III to Regulation (EC) No 396/2005. For fluxapyroxad, 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.

(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 acetamiprid on plums, melons, figs, cauliflower, other flowering brassica (except broccoli), lettuce, scarole, rucola, leaves and sprouts of brassica, beans and peas (with pods), peas (without pods), globe artchokes, dry beans and peas, rape seed and wheat an application was made under Article 6(1) of Regulation (EC) No 396/2005 for modification of the existing MRLs.

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(3) As regards captan, such an application was made for apricots, peaches and plums. As regards cymoxanil, such an application was made for spinach. As regards chlorantraniliprole, such an application was made for cauliflower and other flowering brassica and beans with pods. As regards dichlorprop-P, such an application was made for oranges and for kidney and liver, taking into account existing uses on cereals and grass fed to ruminants. As regards cyflufenamid, such an application was made for apples, pears, table and wine grapes, cucumbers, courgettes and melon. As regards difenoconazole, such an application was made for beet leaves, globe artichokes, broccoli, cardoons and strawberries. As regards dimethomorph, such an application was made for oranges, scarole, cress, land cress, red mustard, leaves and sprouts of brassica. As regards dithiocarbamates, such an application was made for radishes. As regards epoxiconazole, such an application was made for certain cereals and for kidney and milk, taking into account uses on cereals fed to ruminants. As regards spirotetramat, such an application was made for herbs. As regards propamocarb, such an application was made for leek, spinach, witloof and lamb's lettuce. As regards pyraclostrobin, such an application was made for citrus fruit, peanuts, cotton seed, linseed, poppy seed, sesame seed, rape seed, mustard seed, safflower, borage, gold of pleasure, castor bean, sunflower seed and soya bean. As regards pyrimethanil, such an application was made for lettuce and scarole.

(4) In accordance with Article 6(2) and (4) of Regulation (EC) No 396/2005 an application was made for acetamiprid for pome fruit, table and wine grapes, strawberries, blueberries, onions, tomatoes, aubergines, broccoli, head cabbage, spinach, celery and cotton seed. The authorised use of acetamiprid on these crops in the United States leads to higher residues than the MRLs in Regulation (EC) No 396/2005. To avoid trade barriers for the importation of these crops, higher MRLs are necessary.

(5) As regards chlorantraniliprole, such an application was made to raise the current MRLs for oranges from Brazil and South Africa, table and wine grapes and radishes from the United States and cane fruit, blueberries and cranberries from Canada and the United States. Concerning the same active substance, such an application was made to raise the current MRLs for rice and ruminants meat, liver, kidney, milk and eggs from the United States, taking into account existing uses on products fed to the animals concerned. As regards flutriafol, such an application was made to raise the current MRL for soybeans from the United States. As regards isopyrazam, such an application was made to raise the current MRL for bananas from Central America. As regards fluxapyroxad, such an application was made to raise the current MRLs for pome fruit, stone fruit (cherry, peach, plum, apricot and nectarine), potato, other root vegetables, bulb vegetables, sweet corn, brassica vegetables, leafy vegetables and fresh herbs, peas and beans with and without pods, pulses (dry), oilseeds, cereals (wheat, triticale, rye, barley, oat, maize and sorghum) and sugar beet and for fat, liver, eggs and milk from the United States, Canada and Brazil, taking into account uses on cereals fed to food procucing animals. In all these cases higher MRLs are necessary in order to avoid trade barriers for the importation of the products concerned.

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(6) As regards ethephon, recently submitted data that require further evaluation, justify the extension of the expiry date for the MRLs on table olives and cotton seed.

(7) 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.

(8) The Commission received information from Germany and the European Spice Association about residues of biphenyl on nutmeg and mace which exceed the current MRLs. Germany stated that due to the ubiquitous presence of biphenyl from unknown sources it was impossible to produce nutmeg and mace complying with the MRLs for biphenyl. Germany submitted an application in accordance with Article 6(3) of Regulation (EC) No 396/2005 for modifications to those MRLs and an evaluation report.

(9) 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.

(10) The Authority concluded in its reasoned opinions that, as regards use of acetamiprid on melons and peas with and without pods, the data were not adequate to support the MRLs requested. As regards acetamiprid on scarole, based on the proposal in the evaluation report, the Authority recommended to lower the MRL in order to prevent exceedence of the ARfD. As regards chlorantraniliprole the Authority concluded that, as regards use on oranges and rice the data were not adequate to support the MRLs requested. For table and wine grapes the Authority concluded that the MRLs were already fixed at the levels corresponding to the intended authorised use. As regards dimethomorph on scarole, the Authority identified an short term intake concern for the requested MRL and recommended to keep the MRL at the current value. As regards propamocarb the Authority concluded that, as regards use on lamb's lettuce the data were not adequate to support the MRL requested. For spinach and leek, the Authority identified a short term intake concern for the requested MRL and recommended to keep the MRL at the current value. As regards pyraclostrobin the Authority concluded that, as regards use on grapefruit, lemon, limes and mandarin the data were not adequate to support the MRLs requested. For sunflower seed and soya the Authority concluded that the MRLs were already fixed at the levels corresponding to the intended authorised use. As regards fluxapyroxad the Authority concluded that, as regards use on cherries and cotton the data were not adequate to support the MRLs requested. For potatoes the Authority concluded that the MRL was already fixed at the level corresponding to the intended authorised use.

(11) 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

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

(12) 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.

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

(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 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, 3 October 2011.

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) (a) In Annex II, the columns for acetamiprid, captan, dithiocarbamates and pyraclostrobin 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]**	**Acetamiprid (R)**	**Captan**	**Dithiocarbamates (dithiocarbamates expressed as CS2, including maneb, mancozeb, metiram, propineb, thiram and ziram)**	**Pyraclostrobin (F)**	**Pyrimethanil**
(1)	(2)	(3)	(4)	(5)	(6)	(7)
0100000	1. **FRUIT FRESH OR FROZEN; NUTS**					
0110000	(i) **Citrus fruit**	1	0,02[b]	5		10
0110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo (except mineola), ugli and other hybrids)				1	
0110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)				**2**	