Commission Regulation (EU) No 34/2013 of 16 January 2013 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 2-phenylphenol, ametoctradin, Aureobasidium pullulans strains DSM 14940 and DSM 14941, cyproconazole, difenoconazole, dithiocarbamates, folpet, propamocarb, spinosad, spirodiclofen, tebufenpyrad and tetraconazole in or on certain products (Text with EEA relevance)

COMMISSION REGULATION (EU) No 34/2013

of 16 January 2013

amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 2-phenylphenol, ametoctradin, *Aureobasidium pullulans* strains DSM 14940 and DSM 14941, cyproconazole, difenoconazole, dithiocarbamates, folpet, propamocarb, spinosad, spirodiclofen, tebufenpyrad and tetraconazole 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 2-phenylphenol, diquat, dithiocarbamates and folpet maximum residue levels (MRLs) were set in Annex II to Regulation (EC) No 396/2005. For ametoctradin, bixafen, cyproconazole, difenoconazole, epoxiconazole, propamocarb, spinosad, spirodiclofen, tebufenpyrad and tetraconazole MRLs were set in Part A of Annex III to Regulation (EC) No 396/2005. For *Aureobasidium pullulans* strains DSM 14940 and DSM 14941, 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 ametoctradin on leek an application was made under Article 6(1) of Regulation (EC) No 396/2005 for modification of the existing MRLs.

(3) As regards bixafen, such an application was made for oilseed rape, linseed, poppy seed and mustard seed. As regards cyproconazole, such an application was made for poppy seed. As regards difenoconazole, such an application was made for raspberries, blackberries and cucurbits (edible peel). As regards diquat, such an application was made for borage. As regards dithiocarbamates, such an application was made for garlic, onions, shallots, cucurbits and asparagus. As regards epoxiconazole, such an application

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was made for products of animal origin considering residue levels in feed items resulting from the use of epoxiconazole on maize. As regards folpet, such an application was made for wine grapes. As regards propamocarb, such an application was made for kale. As regards spinosad, such an application was made for celery, fennel, raspberries and blackberries. As regards spirodiclofen, such an application was made for strawberries and bananas. As regards tebufenpyrad, such an application was made for cucumbers and courgettes. As regards tetraconazole, such an application was made for rape seed.

(4) In the context of a procedure for the authorisation of the use of a plant protection product containing the active substance *Aureobasidium pullulans* strains DSM 14940 and DSM 14941, an application was made under Article 6(1) of Regulation (EC) No 396/2005 for the inclusion of that active substance in Annex IV to Regulation (EC) No 396/2005.

(5) In accordance with Article 6(2) and (4) of Regulation (EC) No 396/2005 an application was made for ametoctradin on potatoes, tropical root and tuber vegetables, onions, garlic, shallots, spring onions, tomatoes, peppers, aubergines, okra, other solanaceae, cucumbers, gherkins, courgettes, other cucurbits (edible peel), cucurbits (inedible peel), broccoli, head cabbage, Chinese cabbage, lettuce, scarole, cress, land cress, rucola/ rocket, red mustard, leaves and sprouts of Brassica spp., spinach, beet leaves, purslane, celery, fennel and hops. The applicant claims that the authorised use of ametoctradin on such crops in the United States and Canada leads to residues exceeding the MRLs in Regulation (EC) No 396/2005 and that higher MRLs are necessary to avoid trade barriers for the importation of these crops.

(6) As regards spirodiclofen, such an application was made to raise the current MRLs for papaya, avocado and mango because the authorised use of that substance on such crops in the United States leads to residues exceeding the MRLs in Regulation (EC) No 396/2005. To avoid trade barriers for the importation of these crops higher MRLs are necessary.

(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 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.

(9) The Authority concluded in its reasoned opinions that, as regards the use of ametoctradin on spring onions, the submitted data are not sufficient to set a new MRL. For tomatoes and peppers the submitted data do not show a need to modify the existing MRLs. As regards the use of bixafen on oilseed rape, linseed, poppy seed and mustard seed, the submitted data are not sufficient to set a new MRL. As regards diquat, the Authority concluded that the intended use is not sufficiently supported by residue data and that no new uses can be currently authorised before a comprehensive review of the existing MRLs has been performed. As regards residues of epoxiconazole in animal products, the submitted data do not show a need to modify the existing MRLs. As

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regards the use of spirodiclofen on strawberries, the submitted data are not sufficient to set a new MRL.

(10) As regards dithiocarbamates deriving from the use of metiram on asparagus, onions shallots and cucurbits (edible peel), no modification of the MRLs is necessary, since the MRLs set out in Annex II to Regulation (EC) No 396/2005 are identical with those requested.

(11) As regards *Aureobasidium pullulans* strains DSM 14940 and DSM 14941, the Authority concluded that its inclusion in Annex IV to Regulation (EC) No 396/2005 is appropriate.

(12) 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 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.

(13) As regards 2-phenylphenol in citrus fruit, in Regulation (EC) No 304/2010[(3)] MRLs were set until 30 September 2012, pending the submission and evaluation of two additional residue trials on citrus fruit and valid storage stability studies. Those trials and data were submitted to Spain, rapporteur Member State for that substance, in March 2012. Spain evaluated those data and prepared an evaluation report, which was submitted to the Commission on 18 July 2012. In order to to provide the necessary time 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 30 September 2014.

(14) 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.

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

(16) In the interest of legal certainty, the amendment concerning 2-phenylphenol should apply from 1 October 2012.

(17) 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, III and IV to Regulation (EC) No 396/2005 are amended in accordance with the Annex to this Regulation.

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Article 2

This Regulation shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

Point (1)(a) of the Annex shall apply from 1 October 2012.

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

Done at Brussels, 16 January 2013.

For the Commission

The President

José Manuel BARROSO

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ANNEX

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

(1) Annex II is amended as follows:

(a) The column for 2-phenylphenol is 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]	**2-phenylphenol**
(1)	(2)	(3)
0100000	1. **FRUIT FRESH OR FROZEN; NUTS**	
0110000	(i) **Citrus fruit**	**5 (+)**
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.

2-phenylphenol
(+) MRL valid until 30 September 2014 pending the submission and evaluation of two additional residue trials on citrus fruit and valid storage stability studies.

0110000	(i) **Citrus fruit**
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)
0110040	Limes
0110050	Mandarins (Clementine, tangerine, mineola and other hybrids)
0110990	Others