Commission Regulation (EU) No 35/2013 of 18 January 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 dimethomorph, indoxacarb, pyraclostrobin and trifloxystrobin in or on certain products (Text with EEA relevance)

COMMISSION REGULATION (EU) No 35/2013

of 18 January 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 dimethomorph, indoxacarb, pyraclostrobin 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 indoxacarb, pyraclostrobin and trifloxystrobin maximum residue levels (MRLs) were set in Annex II and Part B of Annex III to Regulation (EC) No 396/2005. For dimethomorph MRLs were set in Part A of Annex III to Regulation (EC) No 396/2005.

(2) In the context of a procedure for the authorisation of the use of a plant protection product containing the active substance dimethomorph on leafy brassica, scarole, cress and land cress, an application was made under Article 6(1) of Regulation (EC) No 396/2005 for modification of the existing MRLs.

(3) As regards indoxacarb, such an application was made for strawberries, raspberries, Chinese cabbage, lamb's lettuce, scarole, witloof, beans with pods, cardoons, fennel, rhubarb and soya beans. As regards pyraclostrobin, such an application was made for leafy brassica, sweet corn, maize, millet and sorghum. As regards trifloxystrobin, such an application was made for spring onions and globe artichokes.

(4) In accordance with Article 6(2) and (4) of Regulation (EC) No 396/2005 an application was made for dimethomorph on flowering brassica, head cabbage, lettuce, celery, garlic, onions and shallots. The applicant claims that the authorised use of dimethomorph 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 those crops.

Changes to legislation: *There are outstanding changes not yet made to Commission Regulation (EU) No 35/2013. 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) 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.

(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[(2)]. 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, as regards the use of dimethomorph on flowering brassica, the submitted data are sufficient to set a new MRL for broccoli only. As regards indoxacarb on scarole and soya bean, the submitted data do not show a need to modify the existing MRLs. For witloof, the submitted data are not sufficient to set a new MRL. As regards the use of pyraclostrobin on sweet corn, the submitted data are not sufficient to set a new MRL.

(8) As regards use of dimethomorph on cress and land cress no modification of the MRLs is necessary, since the MRLs set out in Part A of Annex III to Regulation (EC) No 396/2005 are identical with those requested. As regards use of pyraclostrobin on maize, millet and sorghum, 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.

(9) 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.

(10) 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.

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

(12) 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.

***Changes to legislation:** There are outstanding changes not yet made to Commission Regulation (EU) No 35/2013. 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*

Article 2

This Regulation shall enter into force on the twentieth 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, 18 January 2013.

For the Commission

The President

José Manuel BARROSO

Changes to legislation: *There are outstanding changes not yet made to Commission Regulation (EU) No 35/2013. 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*

ANNEX

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

(1) In Annex II, the columns for indoxacarb, pyraclostrobin 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]	**Indoxacarb as sum of the isomers S and R (F)**	**Pyraclostrobin (F)**	**Trifloxystrobin (F)**
(1)	(2)	(3)	(4)	(5)
0100000	1. **FRUIT FRESH OR FROZEN; NUTS**			
0110000	(i) **Citrus fruit**	0,02[b]		0,3
0110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo (except mineola), ugli and other hybrids)		1	
0110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)		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

Trifloxystrobin (F)

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)

***Changes to legislation:** There are outstanding changes not yet made to Commission Regulation (EU) No 35/2013. 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*

0110030	Lemons (Citron, lemon)		1	
0110040	Limes		1	
0110050	Mandarins (Clementine, tangerine, mineola and other hybrids)		1	
0110990	Others		1	
0120000	(ii) **Tree nuts (shelled or unshelled)**	0,05[b]		0,02[b]
0120010	Almonds		0,02[b]	
0120020	Brazil nuts		0,02[b]	
0120030	Cashew nuts		0,02[b]	
0120040	Chestnuts		0,02[b]	
0120050	Coconuts		0,02[b]	
0120060	Hazelnuts (Filbert)		0,02[b]	
0120070	Macadamia		0,02[b]	
0120080	Pecans		0,02[b]	
0120090	Pine nuts		0,02[b]	
0120100	Pistachios		1	
0120110	Walnuts		0,02[b]	
0120990	Others		0,02[b]	
0130000	(iii) **Pome fruit**		0,3	0,5

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)

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)