Commission Regulation (EU) 2017/978 of 9 June 2017 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for fluopyram; hexachlorocyclohexane (HCH), alpha-isomer; hexachlorocyclohexane (HCH), beta-isomer; hexachlorocyclohexane (HCH), sum of isomers, except the gamma isomer; lindane (hexachlorocyclohexane (HCH), gamma-isomer); nicotine and profenofos in or on certain products (Text with EEA relevance)

COMMISSION REGULATION (EU) 2017/978

of 9 June 2017

amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for fluopyram; hexachlorocyclohexane (HCH), alpha-isomer; hexachlorocyclohexane (HCH), beta-isomer; hexachlorocyclohexane (HCH), sum of isomers, except the gamma isomer; lindane (hexachlorocyclohexane (HCH), gamma-isomer); nicotine and profenofos 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), Article 18(1)(b) and Article 49(2) thereof,

Whereas:

(1) For fluopyram and nicotine maximum residue levels (MRLs) were set in Part A of Annex III to Regulation (EC) No 396/2005. For profenofos, hexachlorocyclohexane (HCH) alpha-isomer; hexachlorocyclohexane (HCH) beta-isomer; hexachlorocyclohexane (HCH), sum of isomers, except the gamma isomer and lindane (hexachlorocyclohexane (HCH), gamma-isomer) MRLs were set in Annex II and Part B of Annex III to that Regulation.

(2) For fluopyram by Commission Regulation (EU) No 270/2012[(2)] provisional MRLs were set for several products until 31 December 2013, pending the submission of further residue data. Commission Regulation (EU) No 1004/2013[(3)] extended the validity of these MRLs until 19 October 2015, pending the evaluation of these data. Based on the reasoned opinion[(4)] of the European Food Safety Authority, hereinafter 'the Authority', it is appropriate to reduce to the relevant limit of determination (LOD) the provisional MRLs for solanacea, other fruiting vegetables, cardoons, celeries, Florence fennels, other stem vegetables, cotton seeds, other oilseeds, common millet/prosomillet, other cereals, herbal infusions from any other parts of the plant, seed spices, caraway and

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other sugar plants for all of which no data was submitted, and sweet corn for which residue trials in primary and rotational crops show that residues are below the LOD.

(3) For hexachlorocyclohexane (HCH), alpha-isomer; hexachlorocyclohexane (HCH), beta-isomer; hexachlorocyclohexane (HCH), sum of isomers, except the gamma isomer and lindane (hexachlorocyclohexane (HCH), gamma-isomer), the Authority submitted monitoring data to the Commission showing that residues no longer occur at levels above the relevant MRL or LOD and that lower LODs were achievable by newly available analytical methods also allowing to distinguish the different isomers of hexachlorocyclohexane (HCH). It is therefore appropriate to modify some of the existing MRLs and LODs for hexachlorocyclohexane (HCH), alpha-isomer; hexachlorocyclohexane (HCH), beta-isomer and lindane (hexachlorocyclohexane (HCH), gamma-isomer) and delete the MRLs for hexachlorocyclohexane (HCH), sum of isomers, except the gamma isomer.

(4) For nicotine by Commission Regulation (EU) No 401/2015[(5)] provisional MRLs were set for rose hips, herbs and edible flowers, wild fungi, teas, herbal infusions and spices until 19 October 2016, pending the submission and evaluation of new data and information on the natural occurrence or formation of nicotine in the concerned products. Scientific evidence is not conclusive to demonstrate that nicotine occurs naturally in the concerned products and to elucidate the mechanism of formation. The Authority and food business operators submitted recent monitoring data showing that residues of this substance still occur in those products. It is therefore appropriate to continue to monitor the levels of nicotine in these products and to extend the validity of these MRLs until five years from the publication of this Regulation.

(5) For profenofos by Commission Regulation (EU) No 1096/2014[(6)] provisional MRLs were set for fresh herbs and herbal infusions, pending the submission of monitoring data on the occurrence of this substance in the concerned products. The Authority and food business operators submitted recent monitoring data showing that residues of this substance still occur in those products. It is therefore appropriate to continue to monitor the levels of profenofos in these products and to extend the validity of these MRLs until five years from the publication of this Regulation.

(6) 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.

(7) Through the World Trade Organisation, the trading partners of the Union were consulted on the new MRLs and their comments have been taken into account.

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

(9) In order to allow for the normal marketing, processing and consumption of products, this Regulation should provide for a transitional arrangement for products which have been produced before the modification of the MRLs and for which information shows that a high level of consumer protection is maintained.

(10) A reasonable period should be allowed to elapse before the modified MRLs become applicable in order to permit Member States, third countries and food business operators

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to prepare themselves to meet the new requirements which will result from the modification of the MRLs.

(11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

As regards the active substances fluopyram; hexachlorocyclohexane (HCH), alpha-isomer; hexachlorocyclohexane (HCH), beta-isomer; hexachlorocyclohexane (HCH), sum of isomers, except the gamma isomer; lindane (hexachlorocyclohexane (HCH), gamma-isomer); nicotine and profenofos in and on all products, Regulation (EC) No 396/2005 as it stood before being amended by this Regulation shall continue to apply to products which were produced before 4 January 2018.

Article 3

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

It shall apply from 4 January 2018.

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

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ANNEX

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

(1) Annex II is amended as follows:

(a) the column for profenofos 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**[c]	**Profenofos (F)**
(1)	(2)	(3)
0100000	**FRUITS, FRESH or FROZEN; TREE NUTS**	
0110000	**Citrus fruits**	0,01[a]
0110010	Grapefruits	
0110020	Oranges	
0110030	Lemons	
0110040	Limes	
0110050	Mandarins	
0110990	Others	
0120000	**Tree nuts**	0,02[a]
0120010	Almonds	

a Indicates lower limit of analytical determination

b Pesticide-code combination for which the MRL as set in Annex III Part B applies.

c For the complete list of products of plant and animal origin to which MRLs apply, reference should be made to Annex I.

(F) = Fat soluble

Profenofos (F)

(+) The following MRL applies to chilli peppers: 3 mg/kg.

0231020 Sweet peppers/bell peppers

(+) Monitoring data carried out between 2012 and 2015, show that residues of profenofos occur in herbs. Further monitoring data is necessary to compare the evolution of the occurrence of profenofos in herbs. When re-viewing the MRL, the Commission will take into account the information, if it is submitted by 18 October 2021, or, if that information is not submitted by that date, the lack of it.

0256000 herbs and edible flowers
0256010 Chervil
0256020 Chives
0256030 Celery leaves
0256040 Parsley
0256990 Others

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0120020	Brazil nuts	
0120030	Cashew nuts	
0120040	Chestnuts	
0120050	Coconuts	
0120060	Hazelnuts/cobnuts	
0120070	Macadamias	
0120080	Pecans	
0120090	Pine nut kernels	
0120100	Pistachios	
0120110	Walnuts	
0120990	Others	
0130000	**Pome fruits**	0,01[a]
0130010	Apples	
0130020	Pears	
0130030	Quinces	
0130040	Medlars	[b]
0130050	Loquats/Japanese medlars	[b]
0130990	Others	
0140000	**Stone fruits**	0,01[a]
0140010	Apricots	
0140020	Cherries (sweet)	

a Indicates lower limit of analytical determination

b Pesticide-code combination for which the MRL as set in Annex III Part B applies.

c For the complete list of products of plant and animal origin to which MRLs apply, reference should be made to Annex I.

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Profenofos (F)

(+) The following MRL applies to chilli peppers: 3 mg/kg.

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