Commission Regulation (EU) 2019/90 of 18 January 2019 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 bromuconazole, carboxin, fenbutatin oxide, fenpyrazamine and pyridaben in or on certain products (Text with EEA relevance)

COMMISSION REGULATION (EU) 2019/90

of 18 January 2019

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 bromuconazole, carboxin, fenbutatin oxide, fenpyrazamine and pyridaben 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 bromuconazole, carboxin, fenpyrazamine and pyridaben maximum residue levels (MRLs) were set in Part A of Annex III to Regulation (EC) No 396/2005. For fenbutatin oxide MRLs were set in Annex II and in Part B of Annex III to that Regulation.

(2) For bromuconazole, the European Food Safety Authority ('the Authority') submitted a reasoned opinion on the review of the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005[(2)]. It concluded that concerning the MRLs for rye, wheat, bovine (muscle, fat, liver, kidney), sheep (muscle, fat, liver, kidney), goat (muscle, fat, liver, kidney), equine (muscle, fat, liver, kidney), poultry (muscle, fat, liver), milk (cattle, sheep, goat, horse) and birds eggs, some information was not available and that further consideration by risk managers was required. As there is no risk for consumers, the MRLs for those products should be set in Annex II to Regulation (EC) No 396/2005 at the existing level or the level identified by the Authority. These MRLs will be reviewed; the review will take into account the information available within two years from the publication of this Regulation.

(3) For carboxin, the Authority submitted a reasoned opinion on the review of the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005[(3)]. It proposed to change the residue definition and concluded that concerning the MRLs for all commodities some information was not available and that further consideration by risk managers was required. As a risk for consumers cannot be excluded, the Authority recommended reducing the MRLs for plant and animal commodities to the relevant

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limit of determination (LOD). These MRLs will be reviewed; the review will take into account the information available within two years from the publication of this Regulation.

(4) For fenbutatin oxide, the Authority submitted a reasoned opinion on the review of the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005[(4)]. Commission Implementing Regulation (EU) No 486/2014[(5)] provides for withdrawing the approval of fenbutatin oxide, as the further confirmatory information for this active substance required by Commission Directive 2011/30/EU[(6)] has not been submitted. All existing authorisations for plant protection products containing fenbutatin oxide have been revoked. In accordance with Article 17 of Regulation (EC) No 396/2005 in conjunction with Article 14(1)(a) thereof, the MRLs set out for fenbutatin oxide in Annex II and Part B of Annex III to Regulation (EC) No 396/2005 should therefore be deleted. The Authority did not recommend maintaining existing Codex maximum residue limits (CXLs) since toxicological data for the active substance and its metabolite, di-hydroxy fenbutatin oxide, were not provided and the risk to consumers could not be assessed. The Authority recommended reducing the MRLs for plant and animal commodities to the relevant LODs. These default values should be set in Annex V to Regulation (EC) No 396/2005 in accordance with Article 18(1)(b) of that Regulation.

(5) For fenpyrazamine, the Authority submitted a reasoned opinion on the review of the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005[(7)]. For apricots, cherries, plums, table grapes, wine grapes, strawberries, blackberries, dewberries, raspberries (red and yellow), blueberries, tomatoes, sweet peppers/bell peppers, aubergines/eggplants, cucumbers, gherkins and courgettes, the Authority recommended keeping the existing MRLs and it recommended increasing the MRL for peaches. The Authority concluded that concerning the MRL for almonds, some information was not available and that further consideration by risk managers was required. This MRL will be reviewed; the review will take into account the information available within two years from the publication of this Regulation.

(6) For pyridaben, the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005[(8)]. It recommended lowering the MRLs for grapefruits, oranges, lemons, limes and mandarins and strawberries and keeping the existing MRLs for cucumbers, gherkins and courgettes. The Authority concluded that concerning the MRLs for apples, pears, quinces, medlars, loquats/Japanese medlars, apricots, peaches, tomatoes, aubergines/eggplants, beans with pods, bovine (muscle, fat, liver, kidney), sheep (muscle, fat, liver, kidney), goat (muscle, fat, liver, kidney), equine (muscle, fat, liver, kidney) and milk (cattle, sheep, goat, horse), some information was not available and that further consideration by risk managers was required. As there is no risk for consumers, the MRLs for those products should be set in Annex II to Regulation (EC) No 396/2005 at the level identified by the Authority. These MRLs will be reviewed; the review will take into account the information available within two years from the publication of this Regulation. The Authority concluded that concerning the MRLs for plums, table grapes, wine grapes, currants (black, red and white), gooseberries (green, red and yellow) and

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sweet peppers/bell peppers, no information was available and that further consideration by risk managers was required. The MRLs for these products should be set at the specific LOD.

(7) As regards products on which the use of the plant protection product concerned is not authorised, and for which no import tolerances or CXLs exist, MRLs should be set at the specific LOD or the default MRL should apply, as provided for in Article 18(1)(b) of Regulation (EC) No 396/2005.

(8) The Commission consulted the European Union reference laboratories for residues of pesticides as regards the need to adapt certain limits of determination. As regards several substances, those laboratories concluded that for certain commodities technical development requires the setting of specific limits of determination.

(9) 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.

(10) 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.

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

(12) 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.

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

(14) 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

Regulation (EC) No 396/2005 as it stood before being amended by this Regulation shall continue to apply to products which were produced in the Union or imported into the Union before 13 August 2019.

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 13 August 2019.

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

Done at Brussels, 18 January 2019.

For the Commission

The President

Jean-Claude JUNCKER

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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 following columns for bromuconazole, carboxin, fenpyrazamine, pyridaben are added:

PESTICIDE RESIDUES AND
MAXIMUM RESIDUE LEVELS (MG/KG)

Code number	**Groups and examples of individual products to which the MRLs apply[b]**	**Bromuconazole (sum of diastereoisomers) (F)**	**Carboxin (carboxin plus its metabolites carboxin sulfoxide and oxycarboxin (carboxin sulfone), expressed as carboxin)**	**Fenpyrazamine (F)**	**Pyridaben (F)**
(1)	(2)	(3)	(4)	(5)	(6)
0100000	**FRUITS, FRESH or FROZEN; TREE NUTS**	**0,01[a]**			
0110000	**Citrus fruits**		**0,03[a]**	0,01[a]	**0,3**
0110010	Grapefruits				
0110020	Oranges				
0110030	Lemons				
0110040	Limes				
0110050	Mandarins				
0110990	Others (2)				
0120000	**Tree nuts**		0,05[a]	0,01[a]	**0,01[a]**
0120010	Almonds			(+)	
0120020	Brazil nuts				
0120030	Cashew nuts				
0120040	Chestnuts				