

Commission Regulation (EU) 2020/1566 of 27 October 2020 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 bupirimate, carfentrazone-ethyl, ethirimol, and pyriofenone in or on certain products (Text with EEA relevance)

COMMISSION REGULATION (EU) 2020/1566

of 27 October 2020

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 bupirimate, carfentrazone-ethyl, ethirimol, and pyriofenone 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) and Article 49(2) thereof,

Whereas:

- (1) For carfentrazone-ethyl maximum residue levels (MRLs) were set in Annex II to Regulation (EC) No 396/2005. For bupirimate, ethirimol and pyriofenone MRLs were set in Part A of Annex III to that Regulation.
- (2) For bupirimate the European Food Safety Authority ('the Authority') submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005⁽²⁾. It proposed two separate residue definitions, 'bupirimate' and 'ethirimol', in order to cover the presence of the metabolite ethirimol from the use of bupirimate in commodities of plant origin. It proposed to change the residue definitions for commodities of animal origin into 'desethyl ethirimol'. The Authority recommended lowering the MRLs of bupirimate for strawberries, blackberries, dewberries, currants (black, red and white), gooseberries (green, red and yellow), tomatoes, sweet peppers/bell peppers, and courgettes. For other products, it recommended raising or keeping the existing MRLs. 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. The Authority further concluded that concerning the MRLs for table and wine grapes, aubergines/eggplants and products of animal origin 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.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) 2020/1566. (See end of Document for details)

- (3) As regards ethirimol, which is the major degradation product of bupirimate, the Authority recommended lowering the MRLs of ethirimol for apples, pears, apricots, peaches, blackberries, dewberries, tomatoes, sweet peppers/bell peppers, cucumbers, gherkins and courgettes. For other products, it recommended raising or keeping the existing MRLs. 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. The Authority further concluded that concerning the MRLs for table and wine grapes, aubergines/eggplants and products of animal origin 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.
- (4) For carfentrazone-ethyl the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005⁽³⁾. The Authority proposed to change the residue definition. The Authority confirmed the proposal to change the residue definition in its peer review⁽⁴⁾. It recommended raising or keeping the existing MRLs. 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.
- (5) For pyriofenone the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005⁽⁵⁾. It recommended raising or keeping the existing MRLs. 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. The Authority further concluded that concerning the MRLs for swine (muscle, fat tissue, liver, kidney), bovine (muscle, fat tissue, liver, kidney), sheep (muscle, fat tissue, liver, kidney), goat (muscle, fat tissue, liver, kidney), equine (muscle, fat tissue, 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 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.
- (6) Existing Codex maximum residue limits (CXLs) were taken into account in the reasoned opinions of the Authority. CXLs which are safe for consumers in the Union, were considered for MRL setting.
- (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 limit of determination (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 LODs. As regards several substances,

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those laboratories concluded that for certain commodities technical development requires the setting of specific LODs.

- (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 and III 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 17 May 2021.

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 17 May 2021.

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

Changes to legislation: There are currently no known outstanding effects for
the Commission Regulation (EU) 2020/1566. (See end of Document for details)

Done at Brussels, 27 October 2020.

For the Commission

The President

Ursula VON DER LEYEN

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) 2020/1566. (See end of Document for details)

ANNEX

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

(1) Annex II is amended as follows:

(a) the following columns for bupirimate, ethirimol and pyriofenone are added:

[ANNEX II -1]

Pesticide residues and maximum residue levels (mg/kg) Limit of analytical determination 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 Bupirimate (A) (F) (R) (A) The EU reference labs identified the reference standard for the desethyl ethirimol as commercially not available. When re-viewing the MRL, the Commission will take into account the commercial availability of the reference standard referred to in the first sentence by 28 October 2021, or, if that reference standard is not commercially available by that date, the unavailability of it. (R) The residue definition differs for the following combinations pesticide-code number: Bupirimate - code 1000000: Desethyl ethirimol (+) The European Food Safety Authority identified some information on residue trials as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 28 October 2022, or, if that information is not submitted by that date, the lack of it. 0151000 grapes 0151010 Table grapes 0151020 Wine grapes 0231030 Aubergines/eggplants (+) The European Food Safety Authority identified some information on analytical methods as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 28 October 2022, or, if that information is not submitted by that date, the lack of it. 1011000 swine 1011010 Muscle 1011020 Fat 1011030 Liver 1011040 Kidney 1011050 Edible offals (other than liver and kidney) 1011990 Others (2) 1012000 bovine 1012010 Muscle 1012020 Fat 1012030 Liver 1012040 Kidney 1012050 Edible offals (other than liver and kidney) 1012990 Others (2) 1013000 sheep 1013010 Muscle 1013020 Fat 1013030 Liver 1013040 Kidne 1013050 Edible offals (other than liver and kidney) 1013990 Others (2) 1014000 goat 1014010 Muscle 1014020 Fat 1014030 Liver 1014040 Kidney 1014050 Edible offals (other than liver and kidney) 1014990 Others (2) 1015000 equine 1015010 Muscle 1015020 Fat 1015030 Liver 1015040 Kidney 1015050 Edible offals (other than liver and kidney) 1015990 Others (2) 1016000 poultry 1016010 Muscle 1016020 Fat 1016030 Liver 1016040 Kidney 1016050 Edible offals (other than liver and kidney) 1016990 Others (2) 1020000 Milk 1020010 Cattle 1020020 Sheep 1020030 Goat 1020040 Horse 1020990 Others (2) 1030000 Birds eggs 1030010 Chicken 1030020 Duck 1030030 Geese 1030040 Quail 1030990 Others (2) Ethirimol (A) (F) (R) (A) The EU reference labs identified the reference standard for the desethyl ethirimol as commercially not available. When re-viewing the MRL, the Commission will take into account the commercial availability of the reference standard referred to in the first sentence by 28 October 2021, or, if that reference standard is not commercially available by that date, the unavailability of it. (R) The residue definition differs for the following combinations pesticide-code number: Ethirimol - code 1000000: Desethyl ethirimol (+) The European Food Safety Authority identified some information on residue trials as unavailable. When re-viewing the MRL, the Commission will take