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<sup>(1)</sup> Text with EEA relevance.

# EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

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## II

(Non-legislative acts)

## REGULATIONS

## COMMISSION REGULATION (EU) 2017/693

of 7 April 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 bitertanol, chlormequat and tebufenpyrad 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 <sup>(1)</sup>, and in particular Article 14(1)(a), Article 16(1)(a), Article 17, Article 18(1)(b) and Article 49(2) thereof,

Whereas:

- (1) For bitertanol and chlormequat maximum residue levels (MRLs) were set in Annex II and Part B of Annex III to Regulation (EC) No 396/2005. For tebufenpyrad MRLs were set in Part A of Annex III to that Regulation.
- (2) For bitertanol, the European Food Safety Authority, hereinafter 'the Authority', submitted a reasoned opinion on the existing MRLs in accordance with Article 12(2) of Regulation (EC) No 396/2005 in conjunction with Article 12(1) thereof <sup>(2)</sup>. Commission Implementing Regulation (EU) No 767/2013 <sup>(3)</sup> provides for withdrawing the approval of bitertanol, as the required further confirmatory information for this active substance in accordance with Commission Implementing Regulation (EU) No 1278/2011 <sup>(4)</sup> has not been submitted. All existing authorisations for plant protection products containing bitertanol have been withdrawn and no uses authorised in third countries have been notified. In accordance with Article 17 of Regulation (EC) No 396/2005 in conjunction with Article 14(1)(a) thereof, the MRLs set out for bitertanol in Annex II and Part B of Annex III to that Regulation should be deleted. The Authority proposed to change the residue definition to the sum of bitertanol isomers and recommended to reduce the MRLs for plant and animal commodities to the relevant limit of determination (LOD). These different default values should be set in Annex V to Regulation (EC) No 396/2005 in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005.

<sup>(1)</sup> OJ L 70, 16.3.2005, p. 1.

<sup>(2)</sup> European Food Safety Authority: Review of the existing maximum residue levels for bitertanol according to Article 12 of Regulation (EC) No 396/2005. *EFSA Journal* 2016;14(2):4386.

<sup>(3)</sup> Commission Implementing Regulation (EU) No 767/2013 of 8 August 2013 withdrawing the approval of the active substance bitertanol, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011 (OJ L 215, 9.8.2013, p. 5).

<sup>(4)</sup> Commission Implementing Regulation (EU) No 1278/2011 of 8 December 2011 approving the active substance bitertanol, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 and Commission Decision 2008/934/EC (OJ L 327, 9.12.2011, p. 49).

- (3) For chlormequat, the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005 <sup>(1)</sup>. It proposed to change the residue definition to the sum of chlormequat and its salts expressed as chlormequat chloride. Recent monitoring data shows that residues occur on untreated cultivated fungi and untreated pears at a level higher than the limit of determination. Such residues may result from a cross-contamination of cultivated fungi with straw lawfully treated with chlormequat, respectively from unintentional carry-over from former uses of chlormequat in pears. The Authority proposed to base the MRL for pears on the 95<sup>th</sup> percentile of the results from targeted monitoring data and proposed five different MRLs for cultivated fungi to be considered by the risk managers, which were based on the approaches recommended by the Food and Agriculture Organization of the United Nations respectively for the setting of MRLs in spices and of extraneous MRLs <sup>(2)</sup>. As there is no risk to consumers, the MRL for cultivated fungi should be set at the level corresponding to the 99<sup>th</sup> percentile of all the sample results. These MRLs will be reviewed; the review will take into account the information available within four years from the publication of this Regulation.
- (4) For tebufenpyrad, the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(2) of Regulation (EC) No 396/2005 in conjunction with Article 12(1) thereof <sup>(3)</sup>. It identified a risk for consumers concerning the MRLs for sweet peppers/bell peppers. It is therefore appropriate to lower these MRLs. The Authority concluded that concerning the MRLs for apricots, peaches, blackberries, dewberries, beans (fresh, with pods), cotton seed and commodities 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.
- (5) As regards products on which the use of the plant protection product concerned is not authorised, and for which no import tolerances or Codex maximum residue limits (CXLs) exist, MRLs should be set at the specific limit of determination or the default MRL should apply, as provided for in Article 18(1)(b) of Regulation (EC) No 396/2005.
- (6) The Commission consulted the European Union reference laboratories for residues of pesticides as regards the need to adapt certain LODs. As regards several substances, those laboratories concluded that for certain commodities technical development requires the setting of specific limits of determination.
- (7) 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.
- (8) 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.
- (9) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (10) 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. Because a risk to consumers cannot be excluded at the current MRL, the value for tebufenpyrad of '0,01\* mg/kg' for sweet peppers/bell peppers should apply from the date of application of this Regulation.
- (11) 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.
- (12) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

<sup>(1)</sup> European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for chlormequat according to Article 12 of Regulation (EC) No 396/2005. *EFSA Journal* 2016;14(3):4422.

<sup>(2)</sup> FAO, 2009. Submission and evaluation of pesticide residues data for the estimation of Maximum Residue Levels in food and feed. Pesticide Residues. 2nd Ed. FAO Plant Production and Protection Paper 197, 264 pp.

<sup>(3)</sup> European Food Safety Authority; Review of the existing maximum residue levels for tebufenpyrad according to Article 12 of Regulation (EC) No 396/2005. *EFSA Journal* 2016;14(4):4469.

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 bitertanol and chlormequat 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 3 November 2017.

As regards the active substance tebufenpyrad in and on all products except sweet peppers/bell peppers, Regulation (EC) No 396/2005 as it stood before being amended by this Regulation shall continue to apply to products which were produced before 3 November 2017.

*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 3 November 2017.

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

Done at Brussels, 7 April 2017.

*For the Commission*  
*The President*  
Jean-Claude JUNCKER

## 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 bitertanol is deleted.

(b) The column for chlormequat 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 (*)	Chlormequat (sum of chlormequat and its salts, expressed as chlormequat-chloride)
(1)	(2)	(3)
0100000	<b>FRUITS, FRESH or FROZEN; TREE NUTS</b>	
0110000	<b>Citrus fruits</b>	<b>0,01 (*)</b>
0110010	Grapefruits	
0110020	Oranges	
0110030	Lemons	
0110040	Limes	
0110050	Mandarins	
0110990	Others	
0120000	<b>Tree nuts</b>	<b>0,01 (*)</b>
0120010	Almonds	
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	<b>Pome fruits</b>	
0130010	Apples	<b>0,01 (*)</b>
0130020	Pears	<b>0,07 (+)</b>
0130030	Quinces	<b>0,01 (*)</b>
0130040	Medlars	<b>0,01 (*)</b>
0130050	Loquats/Japanese medlars	<b>0,01 (*)</b>
0130990	Others	<b>0,01 (*)</b>

(1)	(2)	(3)
1040000	Honey and other apiculture products	0,05 (*)
1050000	Amphibians and Reptiles	0,01 (*)
1060000	Terrestrial invertebrate animals	0,01 (*)
1070000	Wild terrestrial vertebrate animals	0,01 (*)

(\*) Indicates lower 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.

#### Chlormequat (sum of chlormequat and its salts, expressed as chlormequat-chloride)

(+) Recent monitoring data show that chlormequat levels in pears are declining but still occur at levels above the limit of determination due to former uses. It is therefore appropriate to set a temporary MRL at a value of 0.07 mg/kg pending the submission of further monitoring data. When reviewing the MRL, the Commission will take into account the information, if it is submitted by 13 April 2021, or, if that information is not submitted by that date, the lack of it.

##### 0130020 Pears

(+) Temporary MRL valid until 31 July 2019 pending the submission of supporting data. After this date the MRL will be 0,01\* mg/kg unless modified by a Regulation in light of new information.

##### 0151010 Table grapes

(+) Monitoring show that cross-contamination of untreated cultivated fungi may occur with straw lawfully treated with chlormequat. This cross-contamination may not be fully avoidable in all cases. When reviewing the MRL, the Commission will take into account the information, if it is submitted by 13 April 2021, or, if that information is not submitted by that date, the lack of it.

##### 0280010 Cultivated fungi

(+) The European Food Safety Authority identified some information on crop metabolism 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 13 April 2019, or, if that information is not submitted by that date, the lack of it.

##### 0401060 Rapeseeds/canola seeds

##### 0401090 Cotton seeds

(+) The applicable maximum residue level for horseradish (*Armoracia rusticana*) in the spice group (code 0840040) is the one set for horseradish (*Armoracia rusticana*) in the Vegetables category, root and tuber vegetables group (code 0213040) taking into account changes in the levels by processing (drying) according to Art. 20 (1) of Regulation (EC) No 396/2005.

##### 0840040 Horseradish'

(c) The following column for tebufenpyrad is added:

#### 'Pesticide residues and maximum residue levels (mg/kg)

Code number	Groups and examples of individual products to which the MRLs apply (†)	Tebufenpyrad (F)
(1)	(2)	(3)
0100000	FRUITS, FRESH or FROZEN; TREE NUTS	
0110000	Citrus fruits	0,6
0110010	Grapefruits	
0110020	Oranges	

(1)	(2)	(3)
0110030	Lemons	
0110040	Limes	
0110050	Mandarins	
0110990	Others	
0120000	<b>Tree nuts</b>	<b>0,01 (*)</b>
0120010	Almonds	
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	<b>Pome fruits</b>	
0130010	Apples	0,3
0130020	Pears	0,3
0130030	Quinces	0,8
0130040	Medlars	0,8
0130050	Loquats/Japanese medlars	0,8
0130990	Others	0,01 (*)
0140000	<b>Stone fruits</b>	
0140010	Apricots	0,4 (+)
0140020	Cherries (sweet)	0,01 (*)
0140030	Peaches	0,4 (+)
0140040	Plums	0,2
0140990	Others	0,01 (*)
0150000	<b>Berries and small fruits</b>	
0151000	(a) <i>grapes</i>	0,6
0151010	Table grapes	
0151020	Wine grapes	
0152000	(b) <i>strawberries</i>	1
0153000	(c) <i>cane fruits</i>	
0153010	Blackberries	0,05 (+)
0153020	Dewberries	0,05 (+)
0153030	Raspberries (red and yellow)	0,15
0153990	Others	0,01 (*)
0154000	(d) <i>other small fruits and berries</i>	1,5
0154010	Blueberries	
0154020	Cranberries	