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Subject:	COMMISSION REGULATION (EU) .../... of XXX 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
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Delegations will find attached document D48330/02.

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Brussels, **XXX**
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[...](2016) **XXX** draft

COMMISSION REGULATION (EU) .../...

of **XXX**

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)

COMMISSION REGULATION (EU) .../...

of **XXX**

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/EEC¹, 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) thereof². Commission Implementing Regulation (EU) No 767/2013³ 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 1278/2011⁴ 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 All existing authorisations for plant protection products containing bitertanol have been withdrawn and no uses authorised in third countries have been notified.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

¹ OJ L 70, 16.3.2005, p. 1.

² 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.

³ 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).

⁴ 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).

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.

- (3) For chlormequat, the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005⁵. 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 95th 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 MRLs⁶. As there is no risk to consumers, the MRL for cultivated fungi should be set at the level corresponding to the 99th 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) thereof⁷. 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.

⁵ 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.

⁶ 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.

⁷ 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.

- (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,

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 [*Office of Publications please insert date 6 months after entry into force of this Regulation*].

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 [*Office of Publications please insert date 6 months after entry into force of this Regulation*].

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 [*Office of Publication: please insert date 6 months after entry into force*].

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

Done at Brussels,

For the Commission
The President
Jean-Claude JUNCKER