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#### COVER NOTE

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To:	General Secretariat of the Council
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Subject:	COMMISSION REGULATION (EU) .../... of XXX 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 2-phenylphenol, bensulfuron-methyl, dimethachlor and lufenuron in or on certain products

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Delegations will find attached document D052946/02.

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Encl.: D052946/02



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

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

**of **XXX****

**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 2-phenylphenol, bensulfuron-methyl, dimethachlor and lufenuron in or on certain products**

(Text with EEA relevance)

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

of **XXX**

**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 2-phenylphenol, bensulfuron-methyl, dimethachlor and lufenuron 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) and Article 49(2) thereof,

Whereas:

- (1) For 2-phenylphenol maximum residue levels (MRLs) were set in Annex II to Regulation (EC) No 396/2005. For dimethachlor and lufenuron MRLs were set in Part A of Annex III to that Regulation. For bensulfuron-methyl MRLs were not yet set before.
- (2) For 2-phenylphenol the European Food Safety Authority, hereinafter "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<sup>2</sup>. It proposed to change the residue definition for plant products and recommended lowering the MRLs for muscle, fat, liver and kidney from swine, bovine and equine, and for milk from cattle and horse. It concluded that concerning the MRL for citrus, some information was not available and that further consideration by risk managers was required. As there is no risk for consumers, the MRL for this product should be set in Annex II to Regulation (EC) No 396/2005 at the existing level or the level identified by the Authority. As regards the MRL for pears the Codex maximum residue limit is safe for consumers. It is therefore appropriate to set the MRL for pears at the same level.

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<sup>1</sup> OJ L 070, 16.3.2005, p. 1.

<sup>2</sup> European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for 2-phenylphenol according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2017;15(1):4696.

- (3) For bensulfuron-methyl the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005<sup>3</sup>. It recommended raising or keeping the existing MRLs.
- (4) For dimethachlor the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005<sup>4</sup>. It recommended raising or keeping the existing MRLs.
- (5) For lufenuron the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005<sup>5</sup>. It proposed to change the residue definition for all products and recommended lowering the MRLs for citrus fruits, pome fruits, cherries sweet, plums, table grapes, wine grapes, figs, kaki/Japanese persimmons, kiwi fruits, potatoes, tomatoes, sweet peppers/bell peppers, cucumbers, courgettes and soya bean. For other products it recommended raising or keeping the existing MRLs. It concluded that concerning the MRLs for apricot, peaches, strawberries, gherkins, lamb's lettuces/corn salads, lettuces, escaroles/broad leaved endives, cresses and other sprouts and shoots, land cresses, roman rocket/rucola, red mustards, baby leaf crops (including *Brassica* species), liver and kidney from swine, bovine, sheep, goat, equine and poultry liver, 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) 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.
- (7) 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.
- (8) 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.
- (9) 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.

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<sup>3</sup> European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for bensulfuron-methyl according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2016;14(10):4596.

<sup>4</sup> European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for dimethachlor according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2016;14(11):4632.

<sup>5</sup> European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for lufenuron according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2017;15(1):4652.

- (10) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (11) 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.
- (12) 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.
- (13) 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 lawfully produced before [*Office of Publications please insert date of application 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*