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Delegations will find attached document D041473/02.

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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 diethofencarb, mesotrione, metosulam and pirimiphos-methyl 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 diethofencarb, mesotrione, metosulam and pirimiphos-methyl 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 18(1)(b) and Article 49(2) thereof,

Whereas:

- (1) For diethofencarb and metosulam, maximum residue levels (MRLs) were set in Part A of Annex III to Regulation (EC) No 396/2005. For mesotrione and pirimiphos-methyl, MRLs were set in Annex II and Part B of Annex III to that Regulation.
- (2) For diethofencarb, the European Food Safety Authority, hereinafter "the Authority", submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005². It concluded that concerning the MRLs for pears, wine grapes, tomatoes and aubergines 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. The Authority concluded that concerning the MRLs for cucumbers, courgettes, bovine muscle, fat, liver and kidney, sheep muscle, fat, liver and kidney, goat muscle, fat, liver and kidney, bovine, sheep and goat milk no information was available and that further consideration by risk managers was required. The MRLs for these products should be set at the specific limit of determination. As not data were available for setting MRLs

¹ OJ L 70, 16.3.2005, p. 1.

² European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for diethofencarb according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2015;13(2):4030.

in commodities of animal origin, also the MRL for apple, which is used as animal feed, should be set at the specific limit of determination.

- (3) For mesotrione, 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) thereof³. It proposed to change the residue definition and recommended lowering the MRLs for sweet corn, linseed, poppy seed, rape seed and maize. It concluded that concerning the MRL for sugar cane 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. This MRL 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 MRL for sea weeds no information was available, and that further consideration by risk managers was required. The MRL for this product should be set at the specific limit of determination.
- (4) For metosulam, the Authority, submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005⁴. It recommended lowering the MRLs for barley, maize, oats, rye and wheat grain. It concluded that concerning the MRLs for pome fruit, stone fruit, table grapes, wine grapes, strawberries, cane fruit, other small fruit and berries, potatoes and sweet corn some information was not available and that further consideration by risk managers was required. As there is no risk for consumers, the MRLs for these 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) For pirimiphos-methyl, 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) thereof⁵. It identified a long-term risk for consumers for all MRLs. It is therefore appropriate to lower the MRLs for buckwheat, maize, rice and rye. It concluded that concerning the MRLs for barley, millet, oats, sorghum, wheat, swine muscle, fat, liver and kidney, bovine muscle, fat, liver and kidney, sheep muscle, fat, liver and kidney, goat muscle, fat, liver and kidney, poultry muscle, fat and liver, bovine, sheep and goat milk and bird 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 these 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. The Authority concluded that concerning the MRLs for almonds, hazelnuts, pistachios, walnuts, pulses (dry) and palm nuts no information was

³ European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for mesotrione according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2015;13(1):3976.

⁴ European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for metosulam according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2015;13(1):3983.

⁵ European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for pirimiphos-methyl according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2015;13(1):3974.

available, and that further consideration by risk managers was required. The MRLs for these products should be set at the specific limit of determination. The Authority concluded that concerning the MRLs for linseed, peanuts, poppy seed, sesame seed, sunflower seed, rape seed, soya bean, mustard seed, cotton seed, pumpkin seeds, safflower, borage, gold of pleasure, hempseed and castor bean no information was available, and that further consideration by risk managers was required. As there is a risk for cross-contamination, the MRLs for these products as well as for buckwheat, maize, rice and rye should be set at the level identified by the Authority.

- (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.
- (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 produced before [*Office of Publications please insert the 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