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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 methoxyfenozide, propoxur, spinosad and thiram in or on certain products

(Text with EEA relevance)

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COMMISSION REGULATION (EU) …/…

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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 methoxyfenozide, propoxur, spinosad and thiram 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), Article 18(1)(b) and Article 49(2) thereof,

Whereas:

(1) For methoxyfenozide and spinosad, MRLs were set in Annex II to Regulation (EC) 396/2005. For propoxur and thiram, MRLs were set in Annex II and Part B of Annex III to Regulation (EC) No 396/2005.

(2) For methoxyfenozide, in the frame of the renewal of the approval under Regulation (EC) No 1107/2009, the Authority published a conclusion on the peer review of the substance confirming the existing acceptable daily intake (ADI) and establishing a lower acute reference dose (ARfD)[2].

(3) In accordance with Article 43 of Regulation (EC) No 396/2005, the Commission requested the Authority to assess the risks that the current MRLs for methoxyfenozide may pose to consumers in the light of the resulting lower ARfD.

(4) The Authority identified in its reasoned opinion[3] consumer intake concerns for oranges, grapefruits, mandarins, pears, peaches, apples, tomatoes and broccoli. Member States were consulted to report potential fall-back Good Agricultural Practices (GAPs) that would not lead to an unacceptable risk for consumers. Member States identified fall-back GAPs only for tomatoes. For citrus fruits, the Authority confirmed that existing MRLs are safe with the use of a peeling factor established during the peer review. For all other concerned products, the MRLs should be set at the relevant limit of determination (LOD).

(5) For propoxur, in accordance with Article 43 of Regulation (EC) No 396/2005, the Commission requested the Authority to assess its toxicological properties, to derive toxicological reference values and to evaluate the existing MRLs. In its reasoned

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1 OJ L 070, 16.3.2005, p. 1.

2 Conclusion on the peer review of the pesticide risk assessment of the active substance methoxyfenozide. EFSA Journal 2017;15(9):4978

3 European Food Safety Authority; Focused assessment of certain existing MRLs of concern for methoxyfenozide. EFSA Journal 2020;18(12):6330.

opinion[4], the Authority could not derive EU toxicological reference values for propoxur and could not conclude on consumer safety. From a risk management perspective, in the absence of such data, for all products, a risk for consumers cannot be excluded. As the substance is no longer approved in the EU and no uses are authorised, MRLs should be set in Annex V to Regulation (EC) No 396/2005 at the LOD.

(6) For spinosad, in the frame of the renewal of the approval under Regulation (EC) No 1107/2009, the Authority published a conclusion on the peer review of the substance establishing for the first time an ARfD[5].

(7) In accordance with Article 43 of Regulation (EC) No 396/2005, the Commission requested the Authority to assess the risks that the current MRLs for spinosad may pose to consumers in the light of the new ARfD.

(8) The Authority identified in its reasoned opinion[6] consumer intake concerns for sweet peppers/bell peppers, lettuces, escaroles/broad-leaved endives, spinaches, chards/beet leaves and witloofs/Belgian endives. A chronic intake concern was also identified. Member States were consulted to report potential fall-back GAPs that would not lead to an unacceptable risk for consumers. Member States identified fall-back GAPs for all concerned products. For those products MRLs should be set at the level identified by the Authority.

(9) For thiram, the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005[7]. Thiram is no longer approved in the EU and all authorisations for this substance have been revoked. The Authority assessed the existing import tolerances for thiram but in the absence of toxicological data for its metabolite M1, could not finalise the consumer risk assessment and concluded that further consideration by risk managers was required. From a risk management perspective, in the absence of such data, for all products, a risk for consumers cannot be excluded and MRLs should be set in Annex V to Regulation (EC) No 396/2005 at the LOD.

(10) 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 LOD or the default MRL should apply, as provided for in Article 18(1)(b) of Regulation (EC) No 396/2005.

(11) 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.

(12) 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.

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4 European Food Safety Authority; Reasoned opinion on the toxicological properties and maximum residue levels for propoxur. EFSA Journal 2021;19(1):6374.

5 European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance spinosad. EFSA Journal 2018;16(5):5252.

6 European Food Safety Authority; Focused assessment of certain existing MRLs of concern for spinosad. EFSA Journal 2021;19(2):6404.

7 European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for thiram according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2021;19(1):6391.

(13) 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.

(14) Regulation (EC) No 396/2005 should therefore be amended accordingly.

(15) 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.

(16) 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.

(17) 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

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 [*Office of Publications: please insert date 6 months after entry into force of this Regulation*], except for methoxyfenozide in pears, peaches, apples and broccoli, for propoxur on all commodities and for thiram on all commodities.

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
Ursula VON DER LEYEN