EUROPEAN
COMMISSION

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COMMISSION REGULATION (EU) …/…

of XXX

amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for abamectin in or on certain products

(Text with EEA relevance)

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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) and Article 49(2) thereof,

Whereas:

(1) For abamectin, maximum residue levels (MRLs) were set in Annex II to Regulation (EC) No 396/2005.

(2) During the review of those MRLs in accordance with Article 12 of Regulation (EC) No 396/2005, the European Food Safety Authority ("the Authority"), identified in its reasoned opinion[2] some information as unavailable for certain products. The available information was sufficient for the Authority to propose MRLs that are safe for consumers and the data gaps were indicated in Annex II of that Regulation specifying the date by which the missing information was to be submitted to the Authority in support of the proposed MRLs.

(3) The applicant submitted the missing data together with a request based on Article 6 of Regulation (EC) 396/2005 to modify the existing MRLs for abamectin in certain products.

(4) In accordance with Article 8 of Regulation (EC) No 396/2005, the application was evaluated by the Member State concerned and the evaluation report was forwarded to the Commission.

(5) The Authority assessed the application and the evaluation report, examining in particular risks to consumers and, where relevant, to animals.

(6) On 23 January 2020, the Authority published a reasoned opinion on the evaluation of the confirmatory data submitted following the MRL review under Article 12 of

[1] OJ L 070, 16.3.2005, p. 1.

[2] European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels (MRLs) for abamectin according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2014;12(9):3823.

Regulation (EC) No 396/2005 and on the request to modify the existing maximum residue levels for abamectin in various commodities[3].

(7) For almonds, hazelnuts/cobnuts, walnuts, currants (black, red and white), gooseberries (green, red and yellow), papayas and witloofs/Belgian endives information concerning residue trials was not submitted by the applicant. The Authority concluded that the data gap was thus not sufficiently addressed and that risk managers may consider setting or keeping those MRLs at the limit of determination (LOD). Therefore, for these products, it is appropriate to set the MRLs in Annex II to Regulation (EC) No 396/2005 at the LOD. It is therefore appropriate to amend the Annex II and to delete the reference concerning additional information from that Annex.

(8) For quinces, medlars, loquats/Japanese medlars, the applicant proposed to derive an MRL based on an alternative Good Agricultural Practices (GAP). This use and the residue trials were already assessed in a previous reasoned opinion[4]. The Authority concluded that the residue data were sufficient to support lower MRL proposals for those products. Therefore, for those products, MRLs in Annex II to Regulation (EC) No 396/2005 should be set at the level identified by the Authority.

(9) For celery leaves, beans with pods and peas with pods, Authority concluded that residue data were sufficient to support the MRL for those products. Therefore, for these products, MRLs should be set in Annex II to Regulation (EC) No 396/2005 at the level requested by the applicant.

(10) In accordance with Article 6(2) and (4) of Regulation (EC) No 396/2005 applications for import tolerances were submitted for abamectin used in the United States on certain products.

(11) The applicant states that the authorised uses of abamectin on such crops in that country lead to residues exceeding the MRLs contained in Regulation (EC) No 396/2005 and that higher MRLs are necessary to avoid trade barriers for the importation of those crops.

(12) In accordance with Article 8 of Regulation (EC) No 396/2005, those applications were evaluated by the Member State concerned and the evaluation report was forwarded to the Commission.

(13) The Authority assessed the applications and the evaluation report, examining in particular risks to consumers and, where relevant, to animals.

(14) On 10 July 2020, the Authority published a reasoned opinion on setting of import tolerances for abamectin in various crops[5].

(15) As regards modifications to MRLs requested by the applicant for avocados, cresses and other sprouts and shoot, land cresses, Roman rocket/rucola, baby leaf crops (including brassica species), other lettuces and salad plants, purslanes, Florence fennels and cotton seeds, the Authority concluded, that all requirements with respect to completeness of data submission were met and that the modifications to the MRLs requested by the applicant were acceptable with regard to consumer safety on the basis

[3] European Food Safety Authority; Reasoned opinion on evaluation of confirmatory data following the Article 12 MRL review and modification of the existing maximum residue levels for abamectin in various commodities. EFSA Journal 2020;18(1):5989.

[4] European Food Safety Authority; Reasoned opinion on the modification of the existing MRLs forabamectin in various crops. EFSA Journal 2015;13(7):4189.

[5] European Food Safety Authority; Reasoned opinion on setting of import tolerances for abamectin in various crops. EFSA Journal 2020;18(7):6173.

of a consumer exposure assessment for 27 specific European consumer groups. The Authority took into account the most recent information on the toxicological properties of the substance. Neither the lifetime exposure to the substance via consumption of all food products that may contain them, nor the short-term exposure due to high consumption of the relevant products showed that there is a risk that the acceptable daily intake or the acute reference dose is exceeded. Therefore, for these products, MRLs should be set in Annex II to Regulation (EC) No 396/2005 at the level requested by the applicant.

(16) In the context of the procedure for the renewal of the approval of the active substance abamectin in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council[6], the Authority published a conclusion on the peer review of the risk assessment[7] of that active substance. The Authority proposed, based on the developmental neurotoxicity studies, that a lower acceptable daily intake (ADI) and acute reference dose (ARfD) should be established.

(17) On 3 February 2021 and in accordance with Article 43 of Regulation (EC) No 396/2005, the Commission requested the Authority to provide a reasoned opinion assessing the risks on certain existing MRLs for abamectin that may pose to consumers in light of the lower ADI and ARfD.

(18) On 6 October 2021, the Authority published a reasoned opinion on the focussed assessment of certain existing maximum residues levels of concern for abamectin[8].

(19) For apples, pears and escaroles/broad-leaved endives, the Authority identified unacceptable risks concerning the current MRLs. Member States were consulted and requested to report potential fall-back GAPs which would lead to safe MRLs for consumers. For apples and pears, a fall-back GAP could not proposed by the Member States. Supporting data was not available for the GAP reported for escaroles/broad-leaved endives. Therefore, no MRL could be derived for apples, pears and escaroles/broad-leaved endives. Therefore, for these products, it is appropriate to set the MRLs in Annex II to Regulation (EC) No 396/2005 at the LOD.

(20) For strawberries, tomatoes, cucumbers, courgettes, lamb's lettuces/corn salads, lettuces, chervil and parsley, the Authority identified unacceptable risks concerning the current MRLs. Member States were consulted and requested to report potential fall-back GAPs which would lead to safe MRLs for consumers. Member States identified such GAPs for strawberries, tomatoes, cucumbers, courgettes, lamb's lettuces/corn salads, lettuces, chervil and parsley. The Authority therefore recommended lowering the MRLs for those products. Therefore, for these products, MRLs should be set in Annex II to Regulation (EC) No 396/2005 at the level identified by the Authority.

(21) For sweet peppers/bell peppers, the Authority identified unacceptable risks for consumers with the current MRLs. Member States were consulted and requested to report potential fall-back GAPs which would lead to safe MRLs for consumers. The Authority concluded that although Member States identified a fall-back GAP for sweet

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6 Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309 24.11.2009, p. 1).

7 European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance abamectin. EFSA Journal 2020;18(8):6227.

8 European Food Safety Authority; Focused assessment of certain existing MRLs of concern for abamectin. EFSA Journal 2021;19(10):6842.

peppers/bell peppers, some information was not available and that further consideration by risk managers was required. As there is no risk for consumers, the MRLs for sweet peppers/bell peppers should be set in Annex II to Regulation (EC) No 396/2005 at 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.

(22) The Commission consulted the European Union reference laboratories for residues of pesticides on the need to adapt certain LODs. For abamectin, those laboratories proposed product specific LODs that are analytically feasible.

(23) 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.

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

(25) In order to allow for the normal marketing, processing and consumption of products, this Regulation should not apply to products which have been produced in the Union or imported into the Union before the modified MRLs start applying and for which information shows that a high level of consumer protection is maintained. This is the case for all products except for apples, pears, strawberries, tomatoes, sweet peppers/bell peppers, cucumbers, courgettes, lamb's lettuces/corn salads, lettuces, escaroles/broad-leaved endives, chervil and parsley.

(26) 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 adapt themselves to meet the new requirements which will result from the modification of the MRLs.

(27) 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

Annex II to Regulation (EC) No 396/2005 is amended in accordance with the Annex to this Regulation.

Article 2

As regards active substance abamectin in and on all products except apples, pears, strawberries, tomatoes, sweet peppers/bell peppers, cucumbers, courgettes, lamb's lettuces/corn salads, lettuces, escaroles/broad-leaved endives, chervil and parsley, 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*].

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