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 napropamide, pyridaben and tebufenpyrad in or on certain products

(Text with EEA relevance)

COMMISSION REGULATION (EU) …/…

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amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for napropamide, pyridaben 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/EEC[1], and in particular Article 14(1)(a) and Article 49(2) thereof,

Whereas:

(1) For napropamide, pyridaben and tebufenpyrad, maximum residue levels ('MRLs') were set in Annex II to Regulation (EC) No 396/2005.

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

(3) For napropamide in or on the food groups of citrus fruits, cane fruits and strawberries, the applicant submitted the missing information concerning storage stability. The Authority concluded that the data gap indicated in Annex II to Regulation (EC) No 396/2005 was sufficiently addressed[2]. Therefore, for those products, it is appropriate to maintain existing MRLs and to delete the respective footnotes requiring the submission of additional information in Annex II to Regulation (EC) No 396/2005.

(4) For napropamide in or on blueberries, cranberries, currants (black, red and white), gooseberries (green, red and yellow), rose hips and elderberries, the applicant submitted the missing information concerning storage stability. The applicant, however, hasn't submitted the missing information on crop metabolism for those products. The Authority concluded that the data gap previously identified on crop metabolism has not been addressed and recommended that risk managers consider lowering the MRLs for that substance in or on those products to the limit of determination ('LOD'). Therefore, for those products, it is appropriate to set the MRLs for napropamide at the product-specific LOD and to delete respective footnotes

[1] OJ L 70, 16.3.2005, p. 1, ELI: http://data.europa.eu/eli/reg/2005/396/oj.

[2] European Food Safety Authority; "Evaluation of confirmatory data following the Article 12 MRL review for napropamide", EFSA Journal, 2023;21(7):8125.

requiring the submission of additional information in Annex II to Regulation (EC) No 396/2005.

(5) For napropamide in or on the food group of herbs and edible flowers, the applicant did not submit the missing information concerning residue trials. The Authority concluded that the data gap previously identified has not been addressed and recommended that risk managers consider lowering the MRLs in or on those products to the LOD. Therefore, for these products, it is appropriate to set the MRLs for napropamide at the product-specific LOD and to delete the respective footnotes requiring the submission of additional information in Annex II to Regulation (EC) No 396/2005.

(6) For napropamide in or on the food groups of herbal infusions from flowers, leaves and herbs, roots, herbal infusions from any other part of the plant, and fruit spices, the applicant did not submit the missing information concerning analytical method for matrices difficult to analyse. The Authority concluded that although that data gap was not addressed, the MRLs for those food groups should be maintained as they are already at the LOD. Therefore, for those food groups, it is appropriate to maintain the MRLs for napropamide at the LOD and to delete footnotes requiring the submission of additional information in Annex II to Regulation (EC) No 396/2005.

(7) For pyridaben in or on apples, pears, quinces, medlars, loquats/Japanese medlars, and other pome fruits, the applicant did not submit the missing information concerning residue trials. However, the new residue data were submitted in support of alternative Good Agricultural Practices for apples. The Authority concluded that the provided residue trials are considered sufficient[3] to derive a lower MRL for apples which can be extrapolated to the whole group of pome fruits. Therefore, for pome fruits, it is appropriate to set the MRLs for pyridaben at the level proposed by the Authority and to delete the respective footnotes requiring the submission of additional information in Annex II to Regulation (EC) No 396/2005.

(8) For pyridaben in or on apricots, peaches and beans (with pods), the applicant did not submit the missing information concerning residue trials. The Authority concluded that the data gap previously identified was not addressed and recommended that risk managers consider lowering the MRLs for those products to the LOD. Therefore, for these products, it is appropriate to set the MRLs for pyridaben at the product-specific LOD and to delete the respective footnotes requiring the submission of additional information in Annex II to Regulation (EC) No 396/2005.

(9) For pyridaben in or on bovine (muscle, fat, liver, kidney), sheep (muscle, fat, liver, kidney), goat (muscle, fat, liver, kidney), equine (muscle, fat, liver, kidney), and milk (cattle, sheep, goat, horse), the applicant submitted the missing information concerning storage stability, feeding studies and analytical methods. The Authority concluded that the data gap indicated in Annex II to Regulation (EC) No 396/2005 was sufficiently addressed. Since a lower LOD of 0.01 mg/kg in the products of animal origin (except honey and other apiculture products) is now achievable using the analytical method provided by the applicant, it is appropriate to lower the current LOD of 0.05 mg/kg to the LOD of 0.01 mg/kg and set MRLs at that LOD and to delete respective footnotes requiring the submission of additional information in Annex II to Regulation (EC) No 396/2005.

[3] European Food Safety Authority; "Evaluation of confirmatory data following Article 12 MRL review and modification of the existing MRLs in pome fruits for pyridaben", EFSA Journal, 2023;21(4):7970.

(10) For tebufenpyrad in or on apricots, peaches, blackberries and dewberries, the applicant submitted the missing information concerning residue trials for and the Authority concluded that the data gap indicated in Annex II to Regulation (EC) No 396/2005 was sufficiently addressed[4]. Based on the information provided the existing MRLs can be lowered for apricots and peaches but can be maintained for blackberries and dewberries, Therefore, it is appropriate to set MRLs for tebufenpyrad at a lower level for apricots and peaches and maintain for blackberries and dewberries and to delete the respective footnotes requiring the submission of additional information in Annex II to Regulation (EC) No 396/2005.

(11) For tebufenpyrad in or on beans (with pods) and hops, the applicant did not submit the missing information on residue trials for beans (with pods) and on analytical methods for hops. The Authority concluded that the data gap previously identified was not addressed and recommended that risk managers consider lowering the MRLs for those products to the LOD. Therefore, for those products, it is appropriate to set the MRLs for tebufenpyrad at the product-specific LOD and to delete footnotes requiring the submission of additional information in Annex II to Regulation (EC) No 396/2005.

(12) For tebufenpyrad in or on products of animal origin, except honey and other apiculture products, the applicant submitted the missing information. The Authority concluded that the data gap indicated in Annex II to Regulation (EC) No 396/2005 was sufficiently addressed. Therefore, for those products, it is appropriate to maintain the existing MRLs for tebufenpyrad, and to delete the footnotes requiring the submission of additional information in Annex II to Regulation (EC) No 396/2005.

(13) For tebufenpyrad in or on honey and other apiculture products, the applicant did not submit the missing information on specific analytical methods for honey. The Authority concluded that the data gap previously identified was not addressed and recommended to maintain the current MRL which is at the LOD. Therefore, for those products, it is appropriate to maintain the MRL for tebufenpyrad at the LOD and delete footnotes requiring the submission of additional information in Annex II to Regulation (EC) No 396/2005.

(14) For tebufenpyrad, the Authority found that it could not be excluded that the acute reference dose would be exceeded for table grapes. It is therefore appropriate to lower the MRL to the LOD for tebufenpyrad in Annex II to Regulation (EC) No 396/2005 in accordance with Article 17 of Regulation (EC) No 396/2005 in conjunction with Article 4(1), point (a), thereof.

(15) The Commission consulted the European Union reference laboratories as regards the need to adapt certain LODs for napropamide, pyridaben and tebufenpyrad. Those laboratories concluded that for certain products technical developments permit the setting of lower LODs.

(16) 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.

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

(18) In order to allow for the normal marketing, processing and consumption of products, this Regulation should not apply to products which have been placed on the market in

[4] European Food Safety Authority; "Evaluation of confirmatory data following the Article 12 MRL review for tebufenpyrad" EFSA Journal 2023;21(2):7774.

the Union before the new MRLs become applicable and for which a high level of consumer protection is maintained except for tebufenpyrad in or on table grapes.

(19) 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 the requirements which result from the modification of the MRLs.

(20) 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

Regulation (EC) No 396/2005 as it stood before being amended by this Regulation shall continue to apply to all products which have been placed on the market in the Union before [*Office of Publications: please insert date 6 months after date of entry into force of this regulation*] except for tebufenpyrad in or on table grapes.

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 Publications: please insert date 6 months after date of entry into force of this regulation*].

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