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)

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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), point (a) and Article 49(2) thereof,

Whereas:

(1) For napropamide[2], pyridaben[3] and tebufenpyrad[4], 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 citrus fruits, strawberries and cane fruits, the applicant submitted the missing information concerning its storage stability. The Authority concluded that the data gap indicated in Annex II to Regulation (EC) No 396/2005 was sufficiently addressed[5]. Therefore, for those products, it is appropriate to maintain

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

2 Commission Regulation (EU) 2020/770 of 8 June 2020 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 myclobutanil, napropamide and sintofen in or on certain products (OJ L 184, 12.6.2020, p. 1), ELI: http://data.europa.eu/eli/reg/2020/770/oj.

3 Commission Regulation (EU) 2019/90 of 18 January 2019 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 bromuconazole, carboxin, fenbutatin oxide, fenpyrazamine and pyridaben in or on certain products (OJ L 22, 24.1.2019, p. 52), ELI: http://data.europa.eu/eli/reg/2019/90/oj.

4 Commission Regulation (EU) 2017/693 of 7 April 2017 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 bitertanol, chlormequat and tebufenpyrad in or on certain products (OJ L 101, 13.4.2017, p. 1), ELI: http://data.europa.eu/eli/reg/2017/693/oj.

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

the existing MRLs and delete the respective footnotes requiring the submission of additional information from 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, has not 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 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 delete the respective footnotes requiring the submission of additional information from Annex II to Regulation (EC) No 396/2005.

(5) For napropamide in or on 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 delete the respective footnotes requiring the submission of additional information from Annex II to Regulation (EC) No 396/2005.

(6) For nanopramide in or on 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 products should be maintained as they are already at the LOD. Therefore, for those products, it is appropriate to maintain the MRLs for napropamide at the LOD and delete the respective footnotes requiring the submission of additional information from 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 on pears and apples were submitted in support of alternative Good Agricultural Practices for a group of pome fruits. The Authority concluded that the provided residue trials are sufficient[6] to derive a lower MRL for the whole group of pome fruits. Therefore, for pome fruits, it is appropriate to set the MRLs at the level proposed by the Authority and delete the respective footnotes requiring the submission of additional information from 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 those products, it is appropriate to set the MRLs for pyridaben at the product-specific LOD and delete respective footnotes requiring the submission of additional information from 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

[6] 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.

(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. Therefore, for milk (cattle, sheep, goat, horse) it is appropriate to maintain the MRLs which are already at the LOD and since a lower LOD of 0.01 mg/kg for bovine (muscle, fat, liver, kidney), sheep (muscle, fat, liver, kidney), goat (muscle, fat, liver, kidney), equine (muscle, fat, liver, kidney) is now achievable using the analytical method provided by the applicant, it is appropriate to lower the current LOD of 0.05 mg/kg for those products to the LOD of 0.01 mg/kg, set that LOD and delete the respective footnotes requiring the submission of additional information from Annex II to Regulation (EC) No 396/2005.

(10) For tebufenpyrad in or on apricots, peaches, blackberries and dewberries, the applicant submitted the missing information concerning residue trials and the Authority concluded that the data gap indicated in Annex II to Regulation (EC) No 396/2005 was sufficiently addressed[7]. Based on the residue trials provided, the Authority proposed lowering the existing MRLs for apricots and peaches and maintaining MRLs for blackberries and dewberries. Therefore, for apricots and peaches it is appropriate to set the MRLs at the level proposed by the Authority and maintain the MRLs for blackberries and dewberries and delete the respective footnotes requiring the submission of additional information from 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 delete respective footnotes requiring the submission of additional information from 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 delete the respective 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 respective footnotes requiring the submission of additional information from Annex II to Regulation (EC) No 396/2005.

(14) For tebufenpyrad in or on table grapes, the Authority found that it could not be excluded that the acute reference dose would be exceeded with the current MRL. Risk managers therefore proposed to set a lower MRL for table grapes, based on the less

[7] European Food Safety Authority; "Evaluation of confirmatory data for tebufenpyrad to address data gaps identified in the MRL review", EFSA Journal 2023;21(2):7774.

critical and safe fall-back Good Agricultural Practices[8]. It is therefore appropriate to lower the existing MRL for tebufenpyrad in Annex II to Regulation (EC) No 396/2005.

(15) The Commission consulted the European Union reference laboratories as regards the need to adapt certain LODs. 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 the Union before the new MRLs become applicable and for which a high level of consumer protection is maintained.

(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*].

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*].

[8] European Food Safety Authority; "Review of the existing maximum residue levels for tebufenpyrad according to Article 12 of Regulation (EC) No 396/2005", EFSA Journal 2016;14(4):4469.

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