Council of the
European Union

Brussels, 23 November 2020
(OR. en)

13169/20

AGRILEG 147
PESTICIDE 37

COVER NOTE

From:	European Commission
date of receipt:	18 November 2020
To:	General Secretariat of the Council
No. Cion doc.:	D067439/05
Subject:	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 fluxapyroxad, hymexazol, metamitron, penflufen and spirotetramat in or on certain products

Delegations will find attached document D067439/05.

Encl.: D067439/05

EUROPEAN
COMMISSION

Brussels, XXX
SANTE/10032/2020
(POOL/E4/2020/10032/10032-EN.docx)
D067439/05
[…](2020) XXX draft

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 fluxapyroxad, hymexazol, metamitron, penflufen and spirotetramat 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 fluxapyroxad, hymexazol, metamitron, penflufen and spirotetramat 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 fluxapyroxad, hymexazol, metamitron and spirotetramat maximum residue levels (MRLs) were set in Part A of Annex III to Regulation (EC) No 396/2005. For penflufen no MRLs were set in Regulation (EC) No 396/2005, and as this active substance is not included in Annex IV to that Regulation, the default value of 0.01 mg/kg laid down in Article 18(1)(b) of Regulation (EC) No 396/2005 applies.

(2) For fluxapyroxad the European Food Safety Authority ('the Authority'), submitted a reasoned opinion on the review of the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005[2]. For some products, it recommended raising or keeping the existing MRLs. The MRLs for those products should be set in Annex II to Regulation (EC) No 396/2005 at the level identified by the Authority. The Authority concluded that concerning the MRLs for root and tuber vegetables, bulb vegetables, brassica vegetables, leaf vegetables, herbs and edible flowers, cardoons, celeries, Florence fennels, globe artichokes, leeks, rhubarbs, pulses, cereals, herbal infusions from leaves and herbs, herbal infusions from roots and sugar plants 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 level identified by the Authority. All of these MRLs will be reviewed; the review will take into account the information available within two years from the publication of this Regulation.

(3) For hymexazol the Authority submitted a reasoned opinion on the review of the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005[3]. It

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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 for fluxapyroxad according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2020;18(1):5984.

3 European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for hymexazol according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2019;17(11):5895.

recommended lowering the MRL for sugar beet roots. As there is no risk for consumers, this MRL should be set in Annex II to Regulation (EC) No 396/2005 at the level identified by the Authority.

(4) For metamitron the Authority submitted a reasoned opinion on the review of the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005[4]. It recommended lowering the existing MRLs for apples, pears, beetroots, carrots, horseradishes, parsnips, parsley roots/Hamburg roots parsley, turnips, onions and sugar beet roots. The MRLs for those products should be set in Annex II to Regulation (EC) No 396/2005 at the level identified by the Authority. The Authority concluded that concerning the MRLs for strawberries, Roman rocket/rucola, baby leaf crops (including brassica species), spinaches and similar leaves, herbal infusions from leaves and herbs, herbal infusions from roots, seed spices and fruit spices 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 also should be set in Annex II to Regulation (EC) No 396/2005 at the level identified by the Authority. All of 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 penflufen the Authority submitted a reasoned opinion on the review of the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005[5]. It recommended keeping the existing MRL for potatoes. This MRL should be set in Annex II to Regulation (EC) No 396/2005 at the level identified by the Authority.

(6) For spirotetramat the Authority submitted a reasoned opinion on the review of the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005[6]. It proposed to change the residue definition. It recommended lowering the existing MRLs for citrus fruits, pome fruits, strawberries, table olives, kiwi, avocados, bananas, granate apples/pomegranates, pineapples, other root and tuber vegetables except sugar beets, garlic, shallots, Solanaceae and Malvaceae, witloofs/Belgian endives, olives for oil production and chicory roots. For other products, it recommended raising or keeping the existing MRLs. The MRLs for those products should be set in Annex II to Regulation (EC) No 396/2005 at the level identified by the Authority. The Authority concluded that concerning the MRLs for Brussels sprouts and kohlrabies 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 also be set in Annex II to Regulation (EC) No 396/2005 at the level identified by the Authority. All of these MRLs will be reviewed; the review will take into account the information available within two years from the publication of this Regulation.

(7) Existing Codex maximum residue limits (CXLs) were taken into account in the reasoned opinions of the Authority. CXLs, which are safe for consumers in the Union were considered for MRL setting.

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4 European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for metamitron according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2020;18(1):5959.

5 European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for penflufen according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2019;17(10):5840.

6 European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for spirotetramat according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2020;18(1):5960.

(8) As regards products on which the use of the plant protection product concerned is not authorised, and for which no import tolerances or CXLs exist, MRLs should be set at the specific limit of determination (LOD) or the default MRL should apply, as provided for in Article 18(1)(b) of Regulation (EC) No 396/2005.

(9) The Commission consulted the European Union reference laboratories for residues of pesticides as regards the need to adapt certain LODs. As regards all substances concerned by this regulation, those laboratories concluded that for certain commodities technical development requires the setting of specific LODs.

(10) In the context of a procedure for the authorisation of the use of a plant protection product containing the active substance spirotetramat on "other small fruits and berries", an application was submitted in accordance with Article 6(1) of Regulation (EC) No 396/2005 for modification of the existing MRLs. In accordance with Article 8 of Regulation (EC) No 396/2005, this application was evaluated by Germany and the evaluation report was forwarded to the Authority and to the Commission. The Authority assessed the evaluation report and gave a reasoned opinion[7] on the proposed MRLs. It recommended raising the existing MRLs for those products. The MRLs for those products should be set in Annex II to Regulation (EC) No 396/2005 at the level identified by the Authority.

(11) In accordance with Article 6(2) and (4) of Regulation (EC) No 396/2005 applications for import tolerances were submitted for fluxapyroxad used in the United States on "other root and tuber vegetables except sugar beets" and Brazil on coffee beans. The applicants claim that the authorised uses of that substance on such crops in those countries lead to residues exceeding the MRL contained in Regulation (EC) No 396/2005 and that a higher MRL are necessary to avoid trade barriers for the importation of those crops. In accordance with Article 8 of Regulation (EC) No 396/2005, those applications were evaluated by the Member States concerned and the evaluation reports were forwarded to the Authority and to the Commission. The Authority assessed the applications and the evaluation reports, examining in particular the risks to the consumer and, where relevant, to animals and gave reasoned opinions on the proposed MRLs[8]. It forwarded those opinions to the applicants, the Commission and the Member States and made them available to the public.

(12) As regards all applications, the Authority concluded that all requirements with respect to data were met and that the modifications to the MRLs requested by the applicants were acceptable with regard to consumer safety on the basis of a consumer exposure assessment for 27 specific European consumer groups. It took into account the most recent information on the toxicological properties of the substances. Neither the lifetime exposure to these substances 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.

(13) 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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7 Reasoned opinion on the modification of the existing maximum residue levels for spirotetramat in small fruits and berries. EFSA Journal 2019;17(11):5904.

8 Reasoned opinion on the setting of import tolerances for fluxapyroxad in certain root crops and coffee beans. EFSA Journal 2020;18(1):5950.

(14) 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.

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

(16) 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.

(17) 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.

(18) 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 in the Union or imported into the Union before [*Office of Publication: please insert date 6 months after entry into force*].

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