Council of the
European Union

Brussels, 2 April 2019
(OR. en)

8139/19

AGRILEG 72
PESTICIDE 12

COVER NOTE

From:	European Commission
date of receipt:	1 April 2019
To:	General Secretariat of the Council
No. Cion doc.:	D060905/02
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 aminopyralid, captan, cyazofamid, flutianil, kresoxim-methyl, lambda-cyhalothrin, mandipropamid, pyraclostrobin, spiromesifen, spirotetramat, teflubenzuron and tetraconazole in or on certain products

Delegations will find attached document D060905/02.

Encl.: D060905/02

EUROPEAN
COMMISSION

Brussels, XXX
SANTE/11315/2018
(POOL/E4/2018/11315/11315-EN.doc)
D060905/02
[…](2019) 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 aminopyralid, captan, cyazofamid, flutianil, kresoxim-methyl, lambda-cyhalothrin, mandipropamid, pyraclostrobin, spiromesifen, spirotetramat, teflubenzuron and tetraconazole 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 aminopyralid, captan, cyazofamid, flutianil, kresoxim-methyl, lambda-cyhalothrin, mandipropamid, pyraclostrobin, spiromesifen, spirotetramat, teflubenzuron and tetraconazole 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) thereof,

Whereas:

(1) For captan, cyazofamid, kresoxim-methyl, lambda-cyhalothrin, pyraclostrobin and teflubenzuron, maximum residue levels (MRLs) were set in Annex II to Regulation (EC) No 396/2005. For aminopyralid, mandipropamid, spiromesifen, spirotetramat and tetraconazole, MRLs were set in Part A of Annex III to that Regulation. For flutianil, no specific MRLs were set nor was the substance included in Annex IV to that Regulation, so the default value of 0.01 mg/kg laid down in Article 18(1)(b) thereof applies.

(2) In the context of a procedure for the authorisation of the use of a plant protection product containing the active substance aminopyralid on barley, millet, oat, rye and sorghum, an application was submitted in accordance with Article 6(1) of Regulation (EC) No 396/2005 for modification of the existing MRLs.

(3) As regards captan, such an application was submitted for cranberries and hops. As regards cyazofamid, such an application was submitted for potatoes, tomatoes and cucurbits. As regards kresoxim-methyl, such an application was submitted for products of animal origin following the use of the active substance on feed. As regards lambda-cyhalothrin, such an application was submitted for celeries, Florence fennels, soyabeans, sunflower seeds and rice. As regards mandipropamid, such an application was submitted for beetroots, radishes, cauliflowers, Brussels sprouts, witloofs, peas (without pods) and globe artichokes. As regards pyraclostrobin, such an application was submitted for citrus fruits, table grapes, flowering brassica, head cabbages, “lettuces and salad plants”, “spinaches and similar leaves”, globe artichokes, leeks and soyabeans. As regards spirotetramat, such an application was submitted for “other small fruits and berries”, kiwi fruits, garlic, Florence fennels and rhubarbs. As regards tetraconazole, such an application was submitted for kaki, linseeds and poppy seeds.

[1] OJ L 70, 16.3.2005, p. 1.

(4) In accordance with Article 6(2) and (4) of Regulation (EC) No 396/2005 applications for import tolerances were submitted for mandipropamid used in Nigeria and Cameroon on cocoa beans, pyraclostrobin used in Indonesia on rice, in Brazil on coffee beans, passionfruits and pineapples and in the United States on American persimmons and sugar canes, spiromesifen used in Brazil on coffee beans and teflubenzuron used in Brazil on grapefruits and mandarins. The applicants claim that the authorised uses of those substances on such crops in those countries 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.

(5) 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 Commission.

(6) The European Food Safety Authority ('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[2]. It forwarded those opinions to the applicants, the Commission and the Member States and made them available to the public.

---

[2] EFSA scientific reports available online: http://www.efsa.europa.eu:

Reasoned opinion on the modification of the existing maximum residue levels for aminopyralid in certain cereals. EFSA Journal 2019;17(1):5534.

Reasoned opinion on the modification of the existing maximum residue level for captan in cranberries. EFSA Journal 2018;16(12):5499

Reasoned opinion on the modification of the existing maximum residue level for captan in hops. EFSA Journal 2018;16(12):5498.

Reasoned opinion on the evaluation of confirmatory data following the Article 12 MRL review for cyazofamid. EFSA Journal 2018;16(11):5487.

Reasoned opinion on the evaluation of confirmatory data following the Article 12 MRL review for kresoxim-methyl. EFSA Journal 2018;16(11):5471.

Reasoned opinion on the modification of the existing maximum residue levels for lambda-cyhalothrin in celeries, fennel and rice. EFSA Journal 2019;17(1):5546.

Reasoned opinion on the modification of the existing maximum residue levels for mandipropamid in various crops. EFSA Journal 2019;17(2):5599.

Reasoned opinion on the setting of an import tolerance for mandipropamid in cocoa beans. EFSA Journal 2018;16(11):5491.

Reasoned opinion on the modification of the existing maximum residue levels for pyraclostrobin in soyabean. EFSA Journal 2018;16(11):5466.

Reasoned opinion on the modification of the existing maximum residue levels and setting of import tolerances for pyraclostrobin in various crops. EFSA Journal 2018;16(11):5488.

Reasoned opinion on the setting of an import tolerance for pyraclostrobin in rice. EFSA Journal 2018;16(11):5483.

Reasoned opinion on the evaluation of confirmatory data following the Article 12 MRL review for pyraclostrobin. EFSA Journal 2018;16(11):5472.

Reasoned opinion on the setting of an import tolerance for spiromesifen in coffee beans. EFSA Journal 2019;17(1):5558.

Reasoned opinion on the modification of the existing maximum residue levels for spirotetramat in various crops. EFSA Journal 2019;17(1):5589.

Reasoned opinion on the setting of import tolerances for teflubenzuron in grapefruits, mandarins and broccoli. EFSA Journal 2018;16(11):5474.

Reasoned opinion on the modification of the existing maximum residue levels for tetraconazole in kaki/Japanese persimmon, linseeds and poppy seeds. EFSA Journal 2019;17(1):5577.

(7) As regards captan, the applicant submitted information previously unavailable during the review conducted in accordance with Article 12 of Regulation (EC) No 396/2005: a validated analytical method for high water and acid matrices and made the reference standards for 3-OH THPI and 5-OH THPI commercially available.

(8) As regards cyazofamid, the applicant submitted such previously missing information on freezer storage conditions.

(9) As regards kresoxim-methyl, the applicant submitted a new storage stability study for products of animal origin to demonstrate the validity of the feeding study in ruminants.

(10) As regards pyraclostrobin, the applicant submitted the missing residue trials on table grapes and the validated analytical method for coffee beans. As regards the uses of pyraclostrobin on American persimmons, "spinaches and similar leaves" and sugar canes, the submitted data was insufficient to set new MRLs. As regards the uses of that active substance on escaroles, the Authority did not recommend increasing the existing MRL as a risk to consumers could not be excluded.

(11) As regards lambda-cyhalothrin, the Authority concluded that the information provided was not sufficient to support the EU uses on soyabeans and sunflower seeds. It recommeded setting the MRLs for soyabeans and sunflower seeds at 0.05 mg/kg and 0.2 mg/kg, respectively, which correspond to the existing Codex residue limits (CXLs). These CXLs are safe for consumers in the Union[3].

(12) As regards tetraconazole, the Authority recommended increasing the MRLs for poultry fat and birds eggs following the use of that active substance on feed.

(13) As regards all other 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.

(14) In the context of the approval of the active substance flutianil, an MRL application was included in the summary dossier in accordance with Article 8(1)(g) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council[4]. That application was evaluated by the Member State concerned in accordance with Article 11(2) of that Regulation. The Authority assessed the application and delivered a conclusion on the peer review of the pesticide risk assessment of the active substance, where it recommended setting MRLs covering the representative uses on grapes according to Good Agricultural Practices (GAPs) in the Union[5].

(15) Based on the reasoned opinions and the conclusion of the Authority and taking into account the factors relevant to the matter under consideration, the appropriate

---

3 Revision of the review of the existing maximum residue levels for the active substance lambda-cyhalothrin. EFSA Journal 2015;13(12):4324.

4 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 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).

5 Conclusion on the peer review of the pesticide risk assessment of the active substance flutianil. EFSA Journal 2014;12(8):3805.

modifications to the MRLs fulfil the requirements of Article 14(2) of Regulation (EC) No 396/2005.

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

(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 and III to Regulation (EC) No 396/2005 are amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Jean-Claude JUNCKER