Council of the
European Union

Brussels, 22 March 2021
(OR. en)

7216/21

AGRILEG 53
PESTICIDE 5

COVER NOTE

From:	European Commission
date of receipt:	19 March 2021
To:	General Secretariat of the Council
No. Cion doc.:	D063854/04
Subject:	COMMISSION REGULATION (EU) …/… of XXX amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acequinocyl, acibenzolar-S-methyl, *Bacillus subtilis* strain IAB/BS03, emamectin, flonicamid, flutolanil, fosetyl, imazamox and oxathiapiprolin in or on certain products

Delegations will find attached document D063854/04.

Encl.: D063854/04

EUROPEAN
COMMISSION

XXX
SANTE/11822/2019 Rev. 1
(POOL/E4/2019/11822/11822R1-EN.docx) D063854/04
[…](2021) XXX draft

COMMISSION REGULATION (EU) …/…

of XXX

amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acequinocyl, acibenzolar-S-methyl, *Bacillus subtilis* strain IAB/BS03, emamectin, flonicamid, flutolanil, fosetyl, imazamox and oxathiapiprolin in or on certain products

(Text with EEA relevance)

COMMISSION REGULATION (EU) …/…

of XXX

amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acequinocyl, acibenzolar-S-methyl, *Bacillus subtilis* strain IAB/BS03, emamectin, flonicamid, flutolanil, fosetyl, imazamox and oxathiapiprolin 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 5(1) and Article 14(1)(a) thereof,

Whereas:

(1) For acibenzolar-S-methyl, flonicamid, flutolanil, imazamox and oxathiapiprolin, maximum residue levels ('MRLs') were set in Annex II to Regulation (EC) No 396/2005. For acequinocyl, emamectin and fosetyl, MRLs were set in Part A of Annex III to that Regulation. For *Bacillus subtilis* strain IAB/BS03, no specific MRLs were set nor was that 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 acequinocyl on citrus fruits, 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 acibenzolar-S-methyl, such an application was submitted for hazelnuts/cobnuts. As regards emamectin, such an application was submitted for kiwi fruits and peaches. As regards flonicamid, such an application was submitted for strawberries, blackberries, raspberries, "other small fruits and berries", "other root and tuber vegetables", "lettuces and salad plants" and pulses. As regards flutolanil, such an application was submitted for beans (with pods) and globe artichokes. As regards fosetyl, such an application was submitted for potatoes, wheat and products of animal origin following the use of the active substance on feed. As regards imazamox, such an application was submitted for peas (with pods), soyabeans, maize/corn and rice. As regards oxathiapiprolin, such an application was submitted for hops.

(4) In accordance with Article 6(2) and (4) of Regulation (EC) No 396/2005 an application for import tolerance was submitted for oxathiapiprolin used in China on grapes and in Canada and the United States on bulb vegetables, “Solanaceae and Malvaceae”, cucurbits, flowering brassica, Brussels sprouts, head cabbages, “lettuces and salad plants”, “spinaches and similar leaves”, peas, leeks and ginseng. The

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

applicant claims 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 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.

(7) As regards flutolanil, the applicant submitted information previously unavailable during the review conducted in accordance with Article 12 of Regulation (EC) No 396/2005. That information concerns residue trials, analytical methods, storage stability and metabolism in ruminants.

(8) As regards imazamox, the applicant submitted such an information on residue trials, analytical methods and plant metabolism.

(9) As regards oxathiapiprolin, the Authority concluded that for Brussels sprouts and peas (without pods), the submitted data was insufficient to set new MRLs. 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

---

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

Reasoned opinion on the modification of the existing maximum residue levels for acequinocyl in citrus fruits. EFSA Journal 2019;17(8):5746.

Reasoned opinion on the modification of the existing maximum residue level for acibenzolar- S-methyl in hazelnuts. EFSA Journal 2019;17(6):5705.

Reasoned opinion on the modification of the existing maximum residue levels for emamectin in kiwi and peaches. EFSA Journal 2019;17(5):5710.

Reasoned opinion on the modification of the existing maximum residue levels for flonicamid in strawberries and other berries. EFSA Journal 2019;17(7):5745.

Reasoned opinion on the modification of the existing maximum residue levels for flonicamid in various crops. EFSA Journal 2018;16(9):5410.
Reasoned opinion on the modification of the existing maximum residue levels for flonicamid in various root crops. EFSA Journal 2018;16(9):5414.

Reasoned opinion on the evaluation of confirmatory data following the Article 12 MRL review for flutolanil. EFSA Journal 2018;17(2):5593.

Reasoned opinion on the modification of the existing maximum residue level for fosetyl/phosphonic acid for potatoes and wheat. EFSA Journal 2019;17(5):5703.

Reasoned opinion on the evaluation of confirmatory data following the Article 12 MRL review for imazamox. EFSA Journal 2019;17(2):5584.

Reasoned opinion on the modification of the existing maximum residue levels and setting of import tolerances for oxathiapiprolin in various commodities. EFSA Journal 2019;17(7):5759.

products showed that there is a risk that the acceptable daily intake or the acute reference dose is exceeded.

(10) In the context of the approval of the active substance *Bacillus subtilis* strain IAB/BS03, 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[3]. 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[4]. In that conclusion, the Authority could not conclude on the dietary risk assessment for consumers as some information was not available and further consideration by risk managers was required. Such further consideration was reflected in the review report[5] which concluded that the organism is not pathogenic to humans and no toxins or toxic metabolites are expected to occur in food following the use of the active substance. In view of those conclusions, the Commission considers that *Bacillus subtilis* strain IAB/BS03 should be included in Annex IV to Regulation (EC) No 396/2005.

(11) Based on the reasoned opinions and the conclusion of the Authority and taking into account the factors relevant to the matter under consideration, the respective modifications to the MRLs fulfil the requirements of Article 14(2) of Regulation (EC) No 396/2005.

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

(13) 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, III and IV 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

---

3 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).

4 Conclusion on the peer review of the pesticide risk assessment of the active substance *Bacillus subtilis* strain IAB/BS03. EFSA Journal 2018;16(6):5261

5 Review report for the active substance *Bacillus subtilis* strain IAB/BS03 (SANTE/10318/2019).

The President
Ursula VON DER LEYEN