



Council of the
European Union

Brussels, 26 July 2018
(OR. en)

11436/18

AGRILEG 116

COVER NOTE

| | |
|------------------|---|
| From: | European Commission |
| date of receipt: | 25 July 2018 |
| To: | General Secretariat of the Council |
| No. Cion doc.: | D057182/02 |
| 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 abamectin, acibenzolar-S-methyl, clopyralid, emamectin, fenhexamid, fenpyrazamine, fluazifop-P, isofetamid, <i>Pasteuria nishizawae</i> Pn1, talc E533B and tebuconazole in or on certain products |

Delegations will find attached document D057182/02.

Encl.: D057182/02



Brussels, **XXX**
SANTE/10478/2018
(POOL/E4/2018/10478/10478-EN.doc)
D057182/02
[...](2018) **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 abamectin, acibenzolar-S-methyl, clopyralid, emamectin, fenhexamid, fenpyrazamine, fluazifop-P, isofetamid, *Pasteuria nishizawae* Pn1, talc E533B and tebuconazole 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 abamectin, acibenzolar-S-methyl, clopyralid, emamectin, fenhexamid, fenpyrazamine, fluazifop-P, isofetamid, *Pasteuria nishizawae* Pn1, talc E533B and tebuconazole 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/EEC¹, and in particular Article 5(1) and Article 14(1)(a) thereof,

Whereas:

- (1) For abamectin, acibenzolar-S-methyl, fenhexamid, fluazifop-P, isofetamid and tebuconazole, maximum residue levels (MRLs) were set in Annex II to Regulation (EC) No 396/2005. For clopyralid, emamectin and fenpyrazamine, MRLs were set in Part A of Annex III to that Regulation. For *Pasteuria nishizawae* Pn1 and talc E533B, no specific MRLs were set nor were those 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 abamectin 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 aubergines and cucurbits. As regards clopyralid, such an application was submitted for spring onions and leeks. As regards emamectin, such an application was submitted for leafy brassica, beans (with pods) and peas (with pods). As regards fenhexamid, such an application was submitted for plums, blueberries, cranberries, currants, gooseberries and beans (with pods). As regards fenpyrazamine, such an application was submitted for lettuces, salad plants, spinaches and similar leaves. As regards fluazifop-P, such an application was submitted for tomatoes. As regards isofetamid, such an application

¹ OJ L 70, 16.3.2005, p. 1.

was submitted for tomatoes, peppers, aubergines, okra and cucurbits (with edible peel). As regards tebuconazole, such an application was submitted for olives, rice, 'herbs and edible flowers' and herbal infusions from flowers, leaves and herbs.

- (4) 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.
- (5) 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 MRLs². The Authority forwarded those opinions to the applicants, the Commission and the Member States and made them available to the public.
- (6) 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. The Authority 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.
- (7) As regards abamectin, the applicant also submitted validated analytical methods for crop matrices with high acid and water content. As regards tebuconazole, the applicant also submitted validated analytical methods for all crop matrices. The relevant footnotes should therefore be deleted from Annex II to Regulation (EC) No 396/2005.
- (8) In the context of the approval of the active substance *Pasteuria nishizawae* Pn1, 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

² EFSA scientific reports available online: <http://www.efsa.europa.eu>:
Reasoned opinion on the modification of the existing maximum residue level for abamectin in citrus fruits. EFSA Journal 2018;16(4):5254.
Reasoned opinion on the modification of the existing maximum residue levels for acibenzolar-S-methyl in aubergines and cucurbits with edible and inedible peel. EFSA Journal 2018;16(4):5256.
Reasoned opinion on the modification of the existing maximum residue levels for clopyralid in spring/green/Welsh onions and leeks. EFSA Journal 2018;16(1):5149.
Reasoned opinion on the modification of the existing maximum residue levels for emamectin in leafy brassica and beans and peas with pods. EFSA Journal 2018;16(4):5255.
Reasoned opinion on the modification of the existing maximum residue levels for fenhexamid in various crops. EFSA Journal 2018;16(1):5158.
Reasoned opinion on the modification of the existing maximum residue levels for fenpyrazamine in lettuces, salad plants, spinaches and similar leaves. EFSA Journal 2018;16(3):5231.
Reasoned opinion on the modification of the existing maximum residue level for fluazifop-P in tomato. EFSA Journal 2018;16(4):5253.
Reasoned opinion on the modification of the existing maximum residue levels for isofetamid in tomatoes, peppers, aubergines, okra and cucurbits with edible peel. EFSA Journal 2018;16(5):5264.
Reasoned opinion on the Modification of the existing maximum residue levels for tebuconazole in olives, rice, herbs and herbal infusions (dried). EFSA Journal 2018;16(5):5257.

Council³. Such 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 the inclusion of *Pasteuria nishizawae* Pn1 in Annex IV to Regulation (EC) No 396/2005.⁴

- (9) Talc E533B is approved as basic substance by Commission Implementing Regulation (EU) 2018/691⁵. The conditions of use of that substance are not expected to lead to the presence of residues in food or feed commodities that may pose a risk to the consumer. It is therefore appropriate to include that substance in Annex IV to Regulation (EC) No 396/2005.
- (10) Based on the reasoned opinions and the conclusions 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.
- (11) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (12) 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 *Pasteuria nishizawae* Pn1. EFSA Journal 2018;16(2):5159.

⁵ Commission Implementing Regulation (EU) 2018/691 of 7 May 2018 approving the basic substance talc E533B in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 117, 8.5.2018, p. 6).

The President
Jean-Claude JUNCKER