



Council of the
European Union

Brussels, 30 October 2018
(OR. en)

13688/18

AGRILEG 179

COVER NOTE

From:	European Commission
date of receipt:	24 October 2018
To:	General Secretariat of the Council
No. Cion doc.:	D058389/03
Subject:	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 acetamiprid in certain products

Delegations will find attached document D058389/03.

Encl.: D058389/03



EUROPEAN
COMMISSION

Brussels, **XXX**
SANTE/10617/2018
(POOL/E4/2018/10617/10617-EN.doc)
D058389/03
[...](2018) **XXX** draft

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 acetamiprid in certain products

(Text with EEA relevance)

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 acetamiprid in 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 14(1)(a) thereof,

Whereas:

- (1) For acetamiprid, maximum residue levels (MRLs) were set in Annex II to Regulation (EC) No 396/2005.
- (2) In the context of a procedure for the authorisation of the use of a plant protection product containing the active substance acetamiprid on table olives and olives for oil production, an application was submitted in accordance with Article 6(1) of Regulation (EC) No 396/2005 for modification of the existing MRLs.
- (3) Such an application was also submitted for the use of acetamiprid on barley and oat.
- (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 a reasoned opinion on the proposed MRLs². The Authority forwarded that opinion to the applicant, the Commission and the Member States and made it available to the public.

¹ OJ L 70, 16.3.2005, p. 1.

² EFSA scientific reports available online: <http://www.efsa.europa.eu>: Reasoned opinion on the focussed assessment of certain existing MRLs of concern for acetamiprid and modification of the existing MRLs for table olives, olives for oil production, barley and oats. EFSA Journal 2018;16(5):5262.

- (6) The Authority concluded in its reasoned opinion that all requirements with respect to data were met and that the modifications to the MRLs requested by the applicant 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 substance. Neither the lifetime exposure to this substance via consumption of all food products that may contain it, 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) In the context of the procedure for the renewal of the approval of the active substance acetamiprid in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council³, the Authority submitted a conclusion on the peer review of the pesticide risk assessment concerning that active substance⁴, where new toxicological endpoints were proposed. These endpoints were agreed by the Standing Committee on Plants, Animals, Food and Feed on 13 December 2017⁵.
- (8) In accordance with Article 43 of Regulation (EC) No 396/2005, the Commission requested the Authority to assess the risks the current MRLs for acetamiprid may pose to consumers in the light of the resulting lower acute reference dose (ARfD).
- (9) The Authority identified in its reasoned opinion⁶ consumer intake concerns for apples, pears, peaches, head cabbages, Chinese cabbages, kales, lettuces, escaroles, spinaches, purslanes, chards and celeries. Member States were consulted to report potential fall-back Good Agricultural Practices (GAPs) that would not lead to an unacceptable risk for consumers. Member States identified fall-back GAPs for all concerned products except for Chinese cabbages, kales and celeries, for which the MRLs should be set at the relevant limit of determination.
- (10) As regards escaroles, the Authority concluded that some information was not available and that further consideration by risk managers was required. As there is no risk for consumers in relation to the fall-back GAP, the MRL for that product should be set in Annex II to Regulation (EC) No 396/2005 at the level identified by the Authority. This MRL will be reviewed; the review will take into account the information available within two years from the publication of this Regulation.
- (11) 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.
- (12) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (13) 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

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 acetamiprid. EFSA Journal 2016;14(11):4610.

⁵ Review report for the active substance acetamiprid (SANTE/10502/2017 Rev. 4).

⁶ Reasoned opinion on the focussed assessment of certain existing MRLs of concern for acetamiprid and modification of the existing MRLs for table olives, olives for oil production, barley and oats. EFSA Journal 2018;16(5):5262.

operators to prepare themselves to meet the new requirements which will result from the modification of the MRLs.

- (14) 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

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*].

However, for acetamiprid in olives for oil production, table olives, barley and oat, it shall apply from [*Office of Publication: please insert date of 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
Jean-Claude JUNCKER