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 or on certain products

(Text with EEA relevance)

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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 or on certain products

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,


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.

(6) The Authority concluded 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 substances. Neither the lifetime

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.
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) In the context of 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
assessment4. In that framework, it proposed new toxicological endpoints.

(8) The Commission submitted a request to the Authority under Article 43 of Regulation
(EC) No 396/2005 to assess the risks the current MRLs for acetamiprid may pose to
consumers in the light of the lower acute reference dose (ARfD), which was agreed by
the Standing Committee on Plants, Animals, Food and Feed on 13 December 20175.

(9) The Authority published a reasoned opinion6 where it identified 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) 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.

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

(12) 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.

(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

Annex II to Regulation (EC) No 396/2005 is amended in accordance with the Annex to this
Regulation.

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concerning the placing of plant protection products on the market and repealing Council

4 Conclusion on the peer review of the pesticide risk assessment of the active substance acetamiprid.

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.
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 table olives of code number 0161030, olives for oil production of code number 0402010, barley of code number 0500010 and oat of code number 0500050, it shall apply from its 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