EUROPEAN
COMMISSION

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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 thiacloprid in or on certain products

(Text with EEA relevance)

COMMISSION REGULATION (EU) …/…

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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 thiacloprid 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 thiacloprid, 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 thiacloprid on rapeseed, an application was submitted in accordance with Article 6(1) of Regulation (EC) No 396/2005 for modification of the existing MRL in honey and other apiculture products.

(3) In accordance with Article 8 of Regulation (EC) No 396/2005, that application was evaluated by the Member State concerned and the evaluation report was forwarded to the Commission.

(4) The European Food Safety Authority, hereinafter 'the Authority', assessed the application and the evaluation report, examining in particular the risks to the consumer and, where relevant, to animals and gave a reasoned opinion on the proposed MRL[2]. It forwarded that opinion to the Commission and the Member States and made it available to the public.

(5) The Authority concluded that all requirements with respect to data were met and that the modification to the MRL requested by the applicant was 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 this substance via consumption of all food products that may contain it nor the short-term exposure due to high consumption of the relevant product showed that there is a risk that the acceptable daily intake or the acute reference dose is exceeded.

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1 OJ L 70, 16.3.2005, p. 1.

2 EFSA scientific reports available online: http://www.efsa.europa.eu:
Reasoned opinion on the modification of the existing maximum residue level for thiacloprid in honey. EFSA Journal 2016;14(2):4418 [21 pp.].

(6) The Authority proposed MRLs, which were based on the residue trials submitted by the applicant and on EU wide monitoring data, to be considered by the risk managers. As there is no risk to consumers, the MRL for thiacloprid in honey should be set at the level of 0.2 mg/kg on the basis of the available residue trials. The monitoring data are in a similar range and confirm such level.

(7) Based on the reasoned opinion of the Authority and taking into account the factors relevant to the matter under consideration, the appropriate modification to the MRL fulfils the requirements of Article 14(2) of Regulation (EC) No 396/2005.

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

(9) 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*.

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