



Council of the  
European Union

Brussels, 13 August 2021  
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**AGRILEG 174**  
**PESTICIDE 32**

**COVER NOTE**

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| From:            | Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director |
| date of receipt: | 12 August 2021  |
| To:              | Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union |

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| No. Cion doc.: | D074197/03  |
| Subject:       | COMMISSION REGULATION (EU) .../... of XXX amending Annex III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for chlorantraniliprole in pulses |

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Delegations will find attached document D074197/03.

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Encl.: D074197/03



Brussels, **XXX**  
SANTE/10626/2021 Rev. 1  
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[...](2021) **XXX** draft

**COMMISSION REGULATION (EU) .../...**

**of **XXX****

**amending Annex III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for chlorantraniliprole in pulses**

(Text with EEA relevance)

# COMMISSION REGULATION (EU) .../...

of **XXX**

## **amending Annex III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for chlorantraniliprole in pulses**

(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<sup>1</sup>, and in particular Article 14(1)(a) thereof,

Whereas:

- (1) For chlorantraniliprole, maximum residue levels ('MRLs') were set in Part A of Annex III to Regulation (EC) No 396/2005.
- (2) In accordance with Article 6(2) and (4) of Regulation (EC) No 396/2005 an application for import tolerance was submitted for chlorantraniliprole used in the United States on pulses. The applicant states that the authorised uses of that substance on pulses in the United States lead to residues exceeding the MRL contained in Regulation (EC) No 396/2005 and that a higher MRL is necessary to avoid trade barriers for the importation of those crops.
- (3) In accordance with Article 8 of Regulation (EC) No 396/2005, the application was evaluated by the Member State concerned and the evaluation report was forwarded to the Commission.
- (4) The European Food Safety Authority ('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<sup>2</sup>. It forwarded that opinion to the applicant, 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 modifications to the MRL 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. It took into account the most recent information on the toxicological properties of the substance. The lifetime exposure to the substance via consumption of all food products that may contain it showed that there is no risk that the acceptable daily intake is exceeded. Moreover, the Authority concluded that the

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<sup>1</sup> OJ L 70, 16.3.2005, p. 1.

<sup>2</sup> EFSA scientific reports available online: <http://www.efsa.europa.eu>:

Reasoned opinion on the setting of import tolerances for chlorantraniliprole in strawberries and pulses. EFSA Journal 2020;18(11):6300.

establishment of an acute reference dose is not necessary due to the low acute toxicity profile of the substance.

- (6) Based on the reasoned opinion of the Authority and taking into account the factors relevant to the matter under consideration, the proposed modifications to the MRL fulfil the requirements of Article 14(2) of Regulation (EC) No 396/2005.
- (7) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (8) 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 III 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*  
*Ursula VON DER LEYEN*