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COVER NOTE

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| From: | European Commission |
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| To: | General Secretariat of the Council |

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| 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 the maximum residue levels for cyprodinil in blueberries, cranberries, currants and gooseberries |
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Delegations will find attached document D073959/03.

Encl.: D073959/03



Brussels, **XXX**
SANTE/10532/2021
(POOL/E4/2021/10532/10532-EN.docx)
D073959/03
[...](2021) **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 the maximum residue levels for cyprodinil in blueberries, cranberries, currants and gooseberries

(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 the maximum residue levels for cyprodinil in blueberries, cranberries, currants and gooseberries

(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 cyprodinil, 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 cyprodinil on blueberries, cranberries, currants and gooseberries, an application was submitted in accordance with Article 6(1) of Regulation (EC) No 396/2005 for modification of the existing MRLs.
- (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 MRLs². 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 modification to the MRLs 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. The Authority 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 establishment of an acute reference dose is not necessary on the basis of the low acute toxicity profile of the active substance.

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 levels for cyprodinil in blueberries, cranberries, currants and gooseberries. EFSA Journal 2021;19(3):6499.

- (6) Based on the reasoned opinion of the Authority, and taking into account the factors relevant to the matter under consideration, the proposed modification to the MRLs fulfils 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 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
Ursula VON DER LEYEN