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From:	European Commission
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To:	General Secretariat of the Council
No. Cion doc.:	D063880/09
Subject:	COMMISSION REGULATION (EU) .../... of XXX amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for cycloxydim, mepiquat, <i>Metschnikowia fructicola</i> strain NRRL Y-27328 and prohexadione in or on certain products

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Delegations will find attached document D063880/09.

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Encl.: D063880/09



Brussels, **XXX**  
SANTE/11195/2018 Rev. 7  
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[...] (2021) **XXX** draft

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

**of **XXX****

**amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for cycloxydim, mepiquat, *Metschnikowia fructicola* strain NRRL Y-27328 and prohexadione in or on certain products**

(Text with EEA relevance)

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

of **XXX**

**amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for cycloxydim, mepiquat, *Metschnikowia fructicola* strain NRRL Y-27328 and prohexadione 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<sup>1</sup>, and in particular Article 5(1) and Article 14(1)(a) thereof,

Whereas:

- (1) For prohexadione, maximum residue levels (MRLs) were set in Annex II to Regulation (EC) No 396/2005. For cycloxydim and mepiquat, MRLs were set in Part A of Annex III to that Regulation. For *Metschnikowia fructicola* strain NRRL Y-27328, no specific MRLs were set nor was that substance included in Annex IV to that Regulation, so the default value of 0.01 mg/kg laid down in Article 18(1)(b) thereof applies.
- (2) In the context of a procedure for the authorisation of the use of a plant protection product containing the active substance cycloxydim on strawberries, an application was submitted in accordance with Article 6(1) of Regulation (EC) No 396/2005 for modification of the existing MRL.
- (3) As regards mepiquat, such an application was submitted for cotton seeds. As regards prohexadione, such an application was submitted for linseeds, poppy seeds, sunflower seeds, rapeseeds, mustard seeds and gold of pleasure seeds.
- (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 reasoned opinions on the proposed MRLs<sup>2</sup>. It forwarded

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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 modification of the existing maximum residue level for cycloxydim in strawberries. EFSA Journal 2018;16(8):5404.  
Reasoned opinion on the modification of the existing maximum residue levels for mepiquat in cotton seeds and animal commodities. EFSA Journal 2018;16(10):5428.

those opinions to the applicants, the Commission and the Member States and made them available to the public.

- (6) As regards mepiquat, the Authority recommended increasing the MRLs for certain products of animal origin following the use of the substance on cotton seeds.
- (7) As regards all applications, the Authority concluded that all requirements with respect to data were met and that the modifications to the MRLs requested by the applicants 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 substances. Neither the lifetime 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.
- (8) In the context of the approval of the active substance *Metschnikowia fructicola* strain NRRL Y-27328, an MRL application was included in the summary dossier in accordance with Article 8(1)(g) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council<sup>3</sup>. That application was evaluated by the Member State concerned in accordance with Article 11(2) of that Regulation. The Authority assessed the application and delivered a conclusion on the peer review of the pesticide risk assessment<sup>4</sup>. In that framework, the Authority could not conclude on the dietary risk assessment for consumers as some information was not available and further consideration by risk managers was required. Such further consideration was reflected in the review report<sup>5</sup> which concluded that the organism is not pathogenic to humans and no toxins or toxic metabolites are expected to occur in food following the use of the active substance. In view of those conclusions, the Commission considers that the inclusion of *Metschnikowia fructicola* strain NRRL Y-27328 in Annex IV to Regulation (EC) No 396/2005 is appropriate.
- (9) For mepiquat in cotton seeds, a temporary MRL valid until 30 June 2021 was set in Regulation (EC) No 396/2005 by Commission Regulation (EU) 2018/832<sup>6</sup>. In the interest of legal certainty, it is appropriate for the MRLs provided for by this Regulation to apply from 1 July 2021.
- (10) Based on the reasoned opinions of the Authority and taking into account the factors relevant to the matter under consideration, the appropriate modifications to the MRLs fulfil the requirements of Article 14(2) of Regulation (EC) No 396/2005.
- (11) Regulation (EC) No 396/2005 should therefore be amended accordingly.

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Reasoned opinion on the modification of the existing maximum residue levels for prohexadione in various oilseeds. EFSA Journal 2018;16(8):5397.

<sup>3</sup> 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).

<sup>4</sup> Conclusion on the peer review of the pesticide risk assessment of the active substance *Metschnikowia fructicola* strain NRRL Y-27328. EFSA Journal 2017;15(12):5084.

<sup>5</sup> Review report for the active substance *Metschnikowia fructicola* strain NRRL Y-27328 (SANTE/10472/2018 Rev. 2).

<sup>6</sup> Commission Regulation (EU) 2018/832 of 5 June 2018 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for cyantraniliprole, cymoxanil, deltamethrin, difenoconazole, fenamidone, flubendiamide, fluopicolide, folpet, fosetyl, mandestrobin, mepiquat, metazachlor, propamocarb, propargite, pyrimethanil, sulfoxaflor and trifloxystrobin in or on certain products (OJ L 140, 6.6.2018, p. 38).

(12) 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*

Annexes II, III and IV to Regulation (EC) No 396/2005 are 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 however apply from 1 July 2021 as regards the MRLs for mepiquat.

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*