



EUROPEAN  
COMMISSION

Brussels, **XXX**  
SANTE/11195/2018 Rev. 1  
(POOL/E4/2018/11195/11195R1-  
EN.doc) D059754/03  
[...](2019) **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, epoxiconazole, flonicamid, haloxyfop, mandestrobin, 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, epoxiconazole, flonicamid, haloxyfop, mandestrobin, 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 flonicamid, haloxyfop, mandestrobin, mepiquat and prohexadione, maximum residue levels (MRLs) were set in Annex II to Regulation (EC) No 396/2005. For cycloxydim and epoxiconazole, 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 epoxiconazole, such an application was submitted for beetroots. As regards flonicamid, such an application was submitted for strawberries, blackberries, raspberries, "other small fruits and berries", "other root and tuber vegetables", "lettuces and salad plants" and pulses. 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 6(2) and (4) of Regulation (EC) No 396/2005 applications for import tolerances were submitted for haloxyfop-P used in Australia on linseeds and mandestrobin used in Canada on strawberries and grapes. The applicants claim that the authorised uses of those substances on such crops in those countries lead to residues exceeding the MRLs contained in Regulation (EC) No 396/2005 and that higher MRLs are necessary to avoid trade barriers for the importation of those crops.

---

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

- (5) 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.
- (6) 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 those opinions to the applicants, the Commission and the Member States and made them available to the public.
- (7) As regards mepiquat, the Authority recommended increasing the MRLs for certain products of animal origin following the use of the substance on cotton seeds.
- (8) 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.
- (9) For *Metschnikowia fructicola* strain NRRL Y-27328, the Authority submitted a conclusion on the peer review of the pesticide risk assessment<sup>3</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>4</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.

---

<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 level for epoxiconazole in beetroots. EFSA Journal 2018;16(9):5419.  
Reasoned opinion on the modification of the existing maximum residue levels for flonicamid in various crops. EFSA Journal 2018;16(9):5410.  
Reasoned opinion on the modification of the existing maximum residue levels for flonicamid in various root crops. EFSA Journal 2018;16(9):5414.  
Reasoned opinion on the setting of import tolerances for haloxyfop-P in linseed and rapeseed. EFSA Journal 2018;16(11):5470.  
Reasoned opinion on the setting of import tolerances for mandestrobin in strawberries and table and wine grapes. EFSA Journal 2018;16(8):5395.  
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.  
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> 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>4</sup> Review report for the active substance *Metschnikowia fructicola* strain NRRL Y-27328 (SANTE/10472/2018 Rev. 2).

- (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.
- (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*.

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*