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Subject:	COMMISSION REGULATION (EU) .../... of XXX amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for prochloraz in or on certain products

Delegations will find attached document D063862/03.

Encl.: D063862/03



EUROPEAN  
COMMISSION

Brussels, **XXX**  
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**COMMISSION REGULATION (EU) .../...**

**of **XXX****

**amending Annexes II and III to Regulation (EC) No 396/2005 of the European  
Parliament and of the Council as regards maximum residue levels for prochloraz in or  
on certain products**

(Text with EEA relevance)

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

of **XXX**

## **amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for prochloraz 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 14(1)(a) and Article 49(2) thereof,

Whereas:

- (1) For prochloraz, maximum residue limits (MRLs) were set in Annex II and Part B of Annex III to Regulation (EC) No 396/2005.
- (2) For that active substance, the European Food Safety Authority ("the Authority") submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005<sup>2</sup>. The Authority proposed to change the residue definition to the sum of prochloraz, BTS 44595 (M201-04) and BTS 44596 (M201-03), expressed as prochloraz. The Authority identified a risk for consumers concerning the MRLs for citrus fruits, kiwi, bananas, mangoes, pineapples and bovine liver. It is therefore appropriate to lower these MRLs to the Limit of Determination (LOD) or the level identified by the Authority. The Authority recommended lowering the MRLs for garlic, shallots, lettuces and salad plants, purslanes, herbs and edible flowers, peas, linseeds, sunflower seeds, rapeseeds/canola seeds, barley, oat, rice, rye, wheat, coffee beans, herbal infusions from flowers, leaves and herbs and roots, spices, sugar beet roots, bovine (fat, kidney), equine fat and poultry liver. As there is no risk for consumers, the MRLs for those products should be set in Annex II to Regulation (EC) No 396/2005 at the level identified by the Authority. The Authority concluded that concerning the Codex maximum residue levels (CXLs) for kumquats, litchis/lychees, passionfruits/maracujas, prickly pears/cactus fruits, star apples/cainitos, American persimmons/Virginia kaki, avocados, papayas, Granate apples/pomegranates, cherimoyas, guavas, breadfruits, durians and soursops/guanabanas, some information was not available in relation to the new residue definition and that further consideration by risk managers was required. As there is no risk for consumers, the MRLs for those products should be set in Annex II to Regulation (EC) No 396/2005 at the level of the existing CXLs. These MRLs will be reviewed; the review will take

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

<sup>2</sup> European Food Safety Authority; Review of the existing maximum residue levels for prochloraz according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2018; 16(8):5401.

into account the information available within two years from the publication of this Regulation.

- (3) As regards products on which the use of the plant protection products concerned is not authorised, and for which no import tolerances or CXLs exist, MRLs should be set at the specific limit of determination or the default MRL should apply, as provided for in Article 18(1)(b) of Regulation (EC) No 396/2005.
- (4) The Commission consulted the European Union reference laboratories for residues of pesticides as regards the need to adapt certain limits of determination. As regards several substances, those laboratories concluded that for certain commodities technical development requires the setting of specific limits of determination.
- (5) 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.
- (6) Through the World Trade Organisation, the trading partners of the Union were consulted on the new MRLs and their comments have been taken into account.
- (7) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (8) In order to allow for the normal marketing, processing and consumption of products, this Regulation should provide for a transitional arrangement for products which have been produced before the modification of the MRLs and for which information shows that a high level of consumer protection is maintained.
- (9) A reasonable period should be allowed to elapse before the modified MRLs become applicable in order to permit Member States, third countries and food business operators to prepare themselves to meet the new requirements which will result from the modification of the MRLs.
- (10) 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 and III to Regulation (EC) No 396/2005 are amended in accordance with the Annex to this Regulation.

#### *Article 2*

As regards the active substance prochloraz in and on all products except citrus fruits, kiwi, bananas, mangoes, pineapples and bovine liver, Regulation (EC) No 396/2005 as it stood before being amended by this Regulation shall continue to apply to products which were produced in the Union or imported into the Union before *[Office of Publications: please insert date 6 months after entry into force of this Regulation]*.

#### *Article 3*

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 apply from *[Office of Publication: please insert date 6 months after entry into force]*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

*For the Commission*  
*The President*