



Brussels, **XXX**  
SANTE/11242/2019 Rev. 1  
**[...]**(2019) **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 maximum residue levels for dimethoate and omethoate in or on cherries**

(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 maximum residue levels for dimethoate and omethoate in or on cherries**

(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 dimethoate and omethoate, maximum residue levels (MRLs) were set in Annex II to Regulation (EC) No 396/2005.
- (2) The approval of the active substance dimethoate was not renewed by Commission Implementing Regulation (EU) 2019/1090<sup>2</sup>.
- (3) All existing authorisations for plant protection products containing dimethoate have been revoked in relation to uses on cherries. It is therefore appropriate to delete the MRLs for cherries set out for dimethoate and omethoate in Annex II of Regulation (EC) No 396/2005 in accordance with Article 17 of Regulation (EC) No 396/2005 in conjunction with Article 14(1)(a) thereof.
- (4) In the context of the non-renewal of the approval of dimethoate, the European Food Safety Authority ('the Authority') delivered a conclusion on the peer review of the pesticide risk assessment of that active substance<sup>3</sup>. In that framework, the Authority could not exclude a risk to consumers due to the exposure to residues of dimethoate, for which the genotoxic potential could not be excluded, and to its main metabolite omethoate which was concluded to be an in vivo mutagenic agent.
- (5) 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.
- (6) Regulation (EC) No 396/2005 should therefore be amended accordingly.

---

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

<sup>2</sup> Commission Implementing Regulation (EU) 2019/1090 of 26 June 2019 concerning the non-renewal of approval of the active substance dimethoate, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 173, 27.6.2019, p. 39).

<sup>3</sup> EFSA (European Food Safety Authority), 2018. Conclusion on the peer review of the pesticide risk assessment of the active substance dimethoate, EFSA Journal 2018;16(10):5454. <https://www.efsa.europa.eu/en/efsajournal/pub/5454>.

- (7) 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.
- (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*.

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*  
*Jean-Claude JUNCKER*