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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 dimethoate and omethoate in or on certain products

Delegations will find attached document D49632/02.

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

of XXX

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(Text with EEA relevance)

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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 dimethoate and omethoate 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/EEC¹, and in particular Article 14(1)(a) and Article 49(2) thereof,

Whereas:

- (1) For dimethoate (sum of dimethoate and omethoate expressed as dimethoate), maximum residue levels (MRLs) were set in Annex II and Part B of Annex III to Regulation (EC) No 396/2005.
- (2) On 22 April 2016 France informed the Commission of a national emergency measure taken in accordance with Article 54 of Regulation (EC) No 178/2002² suspending the imports and placing on the market in France of fresh cherries from other Member States of the European Union or from third countries, in which the use of plant protection products containing the active substance dimethoate is allowed for the treatment of cherry trees. In accordance with Article 54(2) of that Regulation, on 28 April 2016, during a meeting of the Standing Committee on Plants, Animals, Food and Feed, it was agreed that an MRL review should be prioritised, in order to establish new MRLs, based on a scientific review carried out by the European Food Safety Authority, hereinafter "the Authority". Therefore in accordance with Article 43 of Regulation (EC) No 396/2005, the Commission requested the Authority to carry out such a prioritised review of the existing MRLs for dimethoate and omethoate. The Authority submitted its reasoned opinion on 28 November 2016³.

OJ L 70, 16.3.2005, p. 1.

Regulation (EU) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

Reasoned opinion on the the prioritised review of the existing maximum residue levels for dimethoate and omethoate according to Article 43 of Regulation (EC) No 396/2005. EFSA Journal 2016;14(11):4647, 50 pp.

- (3) The Authority proposed to change the residue definition of 'sum of dimethoate and omethoate expressed as dimethoate' to the separate residue definitions 'dimethoate' and 'omethoate' and concluded that the MRLs for melons and sugar beet roots may raise concerns of consumer protection. The Authority therefore recommended lowering the existing MRLs for these commodities. It concluded that concerning the MRLs for witloof no information was available and that further consideration by risk managers was required. Therefore the MRLs for this product should be set at the specific limit of determination. The Authority concluded that concerning the MRLs for Chinese cabbages no information was available on good agricultural practices that are safe for consumers and that further consideration by risk managers was required. Therefore the MRLs for this product should be set at the specific limit of determination. It concluded that concerning the MRLs for grapefruits, oranges, lemons, limes, mandarins, cherries, table olives, beetroots, carrots, celeriacs, horeradishes, parsnips, parsley roots, radishes, salsifies, swedes, turnips, garlic, onions, shallots, spring onions, tomatoes, aubergines, pumpkins, watermelons, broccoli, cauliflowers, Brussels sprouts, head cabbages, lettuces, asparagus, peas, olives for oil production, barley grains, oat grains, rye grains, wheat grains, sugar beet roots and chicory roots some information was not available 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 existing level or the level identified by the Authority. These MRLs will be reviewed; the review will take into account the information available within two years from the publication of this Regulation.
- (4) The Commission consulted the European Union reference laboratories for residues of pesticides as regards the need to adapt certain limits of determination. Those laboratories concluded that for certain commodities technical development requires the setting of specific limits of determination.
- (5) Based on the reasoned opinion 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. Because a risk to consumers cannot be excluded at the current MRL, the values for dimethoate and omethoate of 0.01 mg/kg for melons should apply to all products from the date of application of this Regulation.
- (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 dimethoate in and on all products except melons, Regulation (EC) No 396/2005 as it stood before being amended by this Regulation shall continue to apply to products which were produced 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 Jean-Claude JUNCKER