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

Delegations will find attached document D035769/04.

Encl.: D035769/04



Brussels, **XXX**
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[...](2015) **XXX** draft

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

of **XXX**

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

(Text with EEA relevance)

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

of **XXX**

amending Annexes III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for guazatine 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), Article 18(1)(b) and Article 49(2) thereof,

Whereas:

- (1) For guazatine, maximum residue levels (MRLs) were set in Part A of Annex III to Regulation (EC) No 396/2005.
- (2) The European Food Safety Authority, hereinafter "the Authority", submitted a reasoned opinion on the existing MRLs for guazatine in accordance with Article 12(1) of Regulation (EC) No 396/2005². All existing authorisations for plant protection products containing the active substance guazatine have been revoked. Neither were import tolerances reported at Union level nor were Codex MRLs available. In the absence of information on specific good agricultural practices that could be used in a consumer risk assessment, the Authority concluded that a value of 0.05 mg/kg provides a satisfactory level of protection for the European consumers. It is therefore appropriate to set the MRLs at the specific limit of determination. It is also appropriate to change the residue definition.
- (3) Moreover, Belgium indicated that the existing MRLs for guazatine in grapefruit and oranges may raise concerns of consumer protection. In particular, an acute consumer risk could not be excluded even by a refined risk assessment, taking into account a processing factor for citrus fruit. The European Commission and the Member States represented in the Standing Committee on Plants, Animals, Food and Feed considered

¹ OJ L 70, 16.3.2005, p. 1.

² European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels (MRLs) for guazatine according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2013;11(5):3239. [20 pp.].

it an appropriate risk management decision to lower the MRLs to a level that has been demonstrated to be safe for European consumers.

- (4) In accordance with Article 6(2) and (4) of Regulation (EC) No 396/2005 an application was submitted for guazatine used on citrus fruits. In accordance with Article 8 of Regulation (EC) No 396/2005 this application was evaluated by the Member State concerned and the evaluation report was forwarded to the Commission. The Authority assessed the application and the evaluation report, examining in particular the risks to the consumer and, where relevant, to animals and gave a reasoned opinion on the proposed MRLs³. It forwarded this opinion to the Commission and the Member States and made it available to the public. It concluded in the opinion that it does not recommend setting the proposed MRLs since the available data were not sufficient to exclude a risk for European consumers.
- (5) The applicant requested an administrative review of the Authority's reasoned opinion according to Article 13 of Regulation (EC) No 396/2005. This review led to the conclusion that no substantial flaws and errors of assessment on the part of the Authority were identified.
- (6) 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.
- (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 lawfully produced before the modification of the MRLs and for which information shows that a high level of consumer protection is maintained.
- (9) The transitional arrangement provided for by this Regulation should take the concerns of consumer protection with the existing MRLs for guazatine in grapefruit and oranges into account.
- (10) 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.
- (11) 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.
- (12) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

³ European Food Safety Authority; Reasoned opinion on the modification of the existing MRL for guazatine in citrus fruits. EFSA Journal 2014;12(8):3818. [29 pp.].

HAS ADOPTED THIS REGULATION:

Article 1

Annexes III and V to Regulation (EC) No 396/2005 are amended in accordance with the Annex to this Regulation.

Article 2

As regards guazatine, Regulation (EC) No 396/2005 as it stood before being amended by this Regulation shall continue to apply to all products which were lawfully produced before [Office of Publications please insert date 6 months after entry into force], except grapefruit and oranges.

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*.

However, 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