



Council of the
European Union

Brussels, 6 April 2016
(OR. en)

7599/16

AGRILEG 35

COVER NOTE

From:	European Commission
date of receipt:	6 April 2016
To:	General Secretariat of the Council

No. Cion doc.:	D044023/02
----------------	------------

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

Delegations will find attached document D044023/02.

Encl.: D044023/02



EUROPEAN
COMMISSION

Brussels, **XXX**
SANTE/10376/2015 Rev. 1
(POOL/E4/2015/10376/10376R1-
EN.doc) D044023/02
[...](2016) **XXX** draft

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

of **XXX**

amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for AMTT, diquat, dodine, glufosinate and tritosulfuron in or on certain products

(Text with EEA relevance)

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

of **XXX**

amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for AMTT, diquat, dodine, glufosinate and tritosulfuron 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 diquat maximum residue levels (MRLs) were set in Annex II and Part B of Annex III to Regulation (EC) No 396/2005. For dodine, glufosinate and tritosulfuron maximum residue levels (MRLs) were set in Part A of Annex III to Regulation (EC) No 396/2005.
- (2) For diquat, the European Food Safety Authority, hereinafter "the Authority", submitted a reasoned opinion on the existing MRLs in accordance with Article 12(2) of Regulation (EC) No 396/2005 in conjunction with Article 12(1) thereof². It identified concerning the MRLs for barley, maize and wheat a risk for consumers. It is therefore appropriate to lower these MRLs. It concluded that concerning the MRLs for all other products 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.

¹ OJ L 070, 16.3.2005, p. 1.

² European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for diquat according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2015;13(1):3972.

- (3) For dodine, the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005³. It concluded that concerning the MRLs for products of animal origin 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. The Authority concluded that concerning the MRLs for blueberries, cranberries, currants, gooseberries and celeries no information was available and that further consideration by risk managers was required. The MRLs for these products should be set at the specific limit of determination.
- (4) For glufosinate, the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(2) of Regulation (EC) No 396/2005 in conjunction with Article 12(1) thereof⁴. It concluded that concerning the MRLs for blueberries, gooseberries, cress, land cress, rocket, red mustard and baby leaf crops 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. The Authority concluded that concerning the MRLs for sweet corn, Brussels sprouts, head cabbage, Chinese cabbage, kale, kohlrabi, cardoons, celeries, fennel, leek and rhubarb no information was available and that further consideration by risk managers was required. The MRLs for these products should be set at the specific limit of determination. Taking into account additional information on the appropriate variability factor provided by Hungary after publication of the reasoned opinion and as there is no risk for consumers, the MRL for potatoes should be set in Annex II to Regulation (EC) No 396/2005 at the existing level.
- (5) For tritosulfuron, the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005⁵. It proposed to set two distinct residue definitions, one for tritosulfuron and the other for its metabolite AMTT, in view of their different toxicological properties. It recommended keeping the existing MRLs for tritosulfuron. As regards the metabolite AMTT, the Authority recommended setting all MRLs at the relevant limit of determination (LOD). Analytical methods to achieve the lowest possible LOD need to be developed for AMTT. Once those methods are available, the levels set by this Regulation may be reviewed at any stage.

³ European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for dodine according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2015;13(1):3946.

⁴ European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for glufosinate according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2015;13(1):3950.

⁵ European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for tritosulfuron according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2015;13(1):3964.

- (6) As regards products on which the use of the plant protection product concerned is not authorised, and for which no import tolerances or Codex maximum residue limits (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.
- (7) 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.
- (8) 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.
- (9) 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.
- (10) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (11) 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 MRLs, the values for diquat of 0.02 mg/kg for barley, maize and wheat should apply to all products from the date of application of this Regulation.
- (12) 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.
- (13) 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 V to Regulation (EC) No 396/2005 are amended in accordance with the Annex to this Regulation.

Article 2

As regards the active substances dodine, glufosinate and tritosulfuron and the metabolite AMTT in and on all products, 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*].

As regards the active substance diquat in and on all products except barley, maize and wheat, 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*].

1. 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