



Council of the
European Union

Brussels, 30 April 2019
(OR. en)

8934/19

AGRILEG 91
PESTICIDE 16

COVER NOTE

| | |
|------------------|------------------------------------|
| From: | European Commission |
| date of receipt: | 23 April 2019 |
| To: | General Secretariat of the Council |

| | |
|----------------|--|
| No. Cion doc.: | D059759/04 |
| 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 2,5 dichlorobenzoic acid methylester, mandipropamid and profoxydim in or on certain products |

Delegations will find attached document D059759/04.

Encl.: D059759/04



Brussels, **XXX**
/SANTE/10935/2018
(POOL/E4/2018/10935/10935-EN.doc)
D059759/04
[...](2019) **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 2,5-dichlorobenzoic acid methylester, mandipropamid and profoxydim 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 2,5-dichlorobenzoic acid methylester, mandipropamid and profoxydim 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 mandipropamid and profoxydim maximum residue levels (MRLs) were set in Part A of Annex III to Regulation (EC) No 396/2005. For 2,5-dichlorobenzoic acid methylester no MRLs are set in Regulation (EC) No 396/2005, and as this active substance is not included in Annex IV to that Regulation, the default value of 0,01 mg/kg laid down in Article 18(1)(b) of that Regulation applies.
- (2) For 2,5-dichlorobenzoic acid methylester, 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 396/2005². The Authority concluded that residues of 2,5-dichlorobenzoic acid methylester are not expected to occur in any plant or animal commodities since its unique and restricted use as a pesticide in wine grapes after grafting is not expected to result in significant residues in wine grapes. It is therefore appropriate to set the MRLs at the specific limit of determination. These default values should be set in Annex V to Regulation (EC) No 396/2005.
- (3) For mandipropamid, the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005³. The Authority proposed to change the residue definition to mandipropamid (any ratio of constituent isomers). It recommended raising or keeping the existing MRLs. It concluded that concerning the MRLs for potatoes, onions, spring onions/green onions and Welsh onions, tomatoes and courgettes, 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

¹ OJ L 70, 16.3.2005, p. 1.

² European Food Safety Authority; Review of the existing maximum residue levels for 2,5-dichlorobenzoic acid methylester according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2018;16(6):5331.

³ European Food Safety Authority; Review of the existing maximum residue levels for mandipropamid according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2018;16(5):5284.

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) For profoxydim, the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005⁴. It recommended keeping the existing MRLs.
- (5) 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.
- (6) 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.
- (7) 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.
- (8) 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.
- (9) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (10) 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.
- (11) 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.
- (12) 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

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 of application of this Regulation*].

⁴ European Food Safety Authority; Review of the existing maximum residue levels for profoxydim according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2018;16(5):5282.

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