

Brussels, 30 October 2018 (OR. en)

13679/18

AGRILEG 177

COVER NOTE

From:	European Commission
date of receipt:	24 October 2018
To:	General Secretariat of the Council
No. Cion doc.:	D057191/03
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 buprofezin, diflubenzuron, ethoxysulfuron, ioxynil, molinate, picoxystrobin and tepraloxydim in or on certain products

Delegations will find attached document D057191/03.

Encl.: D057191/03

13679/18 GSC/lt



Brussels, XXX SANTE/10151/2018 (POOL/E4/2018/10151/10151-EN.doc) D057191/03 [...](2018) 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 buprofezin, diflubenzuron, ethoxysulfuron, ioxynil, molinate, picoxystrobin and tepraloxydim in or on certain products

(Text with EEA relevance)

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

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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 buprofezin, diflubenzuron, ethoxysulfuron, ioxynil, molinate, picoxystrobin and tepraloxydim 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 buprofezin and diflubenzuron, maximum residue levels (MRLs) were set in in Part A of Annex III to Regulation (EC) No 396/2005. For ethoxysulfuron, MRLs were set in Annex II and Part B of Annex III to Regulation (EC) No 396/2005. For ioxynil, molinate, picoxystrobin and tepraloxydim, MRLs were set in Annex II to Regulation (EC) No 396/2005.
- (2) The approval of the active substance buprofezin was restricted to uses on non-edible crops by Commission Implementing Regulation (EU) 2017/360². The approval of the active substance diflubenzuron was restricted to uses on non-edible crops by Commission Implementing Regulation (EU) 2017/855³. All existing authorisations for plant protection products containing these active substances for uses on edible crops have been revoked. It is therefore appropriate to delete the existing MRLs set out for these substances in Annex III 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.

OJ L 70, 16.3.2005, p. 1.

Commission Implementing Regulation (EU) 2017/360 of 28 February 2017 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance buprofezin (OJ L 54, 1.3.2017, p. 11).

Commission Implementing Regulation (EU) 2017/855 of 18 May 2017 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance diflubenzuron (OJ L 128, 19.5.2017, p. 10).

- (3) The approval of the active substance ethoxysulfuron expired on 31 March 2014. The approval of the active substance ioxynil expired on 28 February 2015. The approval of the active substance molinate expired on 31 July 2014. The approval of the active substance picoxystrobin was not renewed by Commission Implementing Regulation (EU) 2017/1455⁴. The approval of the active substance tepraloxydim expired on 31 May 2015. All existing authorisations for plant protection products containing these active substances have been revoked. It is therefore appropriate to delete the existing MRLs set out for these substances in Annexes II and III 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 view of the restriction of the approval of the active substances buprofezin and diflubenzuron, the expiry of the approval of the active substances ethoxysulfuron, ioxynil, molinate and tepraloxydim, and the non-renewal of approval of the active substance picoxystrobin, the MRLs for these substances should be set at the relevant limit of determination (LOD) in accordance with Article 18 of Regulation (EC) No 396/2005. For ioxynil, it is also appropriate to change the residue definition, as a less complex residue definition facilitates enforcement by official control laboratories.
- (5) The Commission consulted the European Union reference laboratories as regards the need to adapt certain LODs. Those laboratories concluded that for certain commodities technical development permits the setting of lower LODs. For the active substances for which all MRLs should be reduced to the relevant LOD, default values should be listed in Annex V in accordance with Article 18(1)(b) 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 measure 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.
- (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:

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Commission Implementing Regulation (EU) 2017/1455 of 10 August 2017 concerning the non-renewal of approval of the active substance picoxystrobin, 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 208, 11.8.2017, p. 28).

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 ethoxysulfuron, ioxynil, molinate and tepraloxydim 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 in the Union or imported into the Union before [Office of Publications please insert date of application 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