



Council of the
European Union

Brussels, 26 July 2018
(OR. en)

11453/18

AGRILEG 117

COVER NOTE

From:	European Commission
date of receipt:	25 July 2018
To:	General Secretariat of the Council
No. Cion doc.:	D057183/02
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 diphenylamine and oxadixyl in or on certain products

Delegations will find attached document D057183/02.

Encl.: D057183/02



Brussels, **XXX**
SANTE/10070/2018
(POOL/E4/2018/10070/10070-EN.doc)
D057183/02
[...](2018) **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 diphenylamine and oxadixyl 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 diphenylamine and oxadixyl 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 diphenylamine and oxadixyl, maximum residue levels (MRLs) were set in Part A of Annex III to Regulation (EC) No 396/2005.
- (2) The active substance diphenylamine was not approved by Commission Implementing Regulation (EU) No 578/2012². The active substance oxadixyl was not included in Annex I to Directive 91/414/EEC by Commission Regulation (EC) No 2076/2002³. All existing authorisations for plant protection products containing these active substances have been revoked.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 Annex III in accordance with Article 17 of Regulation (EC) No 396/2005 in conjunction with Article 14(1)(a) thereof.

¹ OJ L 70, 16.3.2005, p. 1.

² Commission Implementing Regulation (EU) No 578/2012 of 29 June 2012 concerning the non approval of the active substance diphenylamine, 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 (OJ L 171, 30.6.2012, p. 2).

³ Commission Regulation (EC) No 2076/2002 of 20 November 2002 extending the time period referred to in Article 8(2) of Council Directive 91/414/EEC and concerning the non-inclusion of certain active substances in Annex I to that Directive and the withdrawal of authorisations for plant protection products containing these substances (OJ L 319, 23.11.2002, p. 3).

- (3) For diphenylamine temporary MRLs were set by Regulation (EU) No 772/2013⁴ for apples and pears until 2 September 2015, to address an unavoidable cross-contamination that affected untreated apples and pears and which was due to the presence of residues of diphenylamine in storage facilities. Commission Regulation (EU) 2016/67⁵ extended the validity of those MRLs until 22 January 2018 to provide the necessary time for business operators to completely remove the residues of diphenylamine in storage facilities. The European Food Safety Authority ('the Authority') and food business operators submitted recent monitoring data showing that residues of diphenylamine no longer occur at levels above the relevant limit of determination (LOD).
- (4) For oxadixyl temporary MRLs were set by Regulation (EU) No 592/2012⁶ for parsley, celeries and the group of lettuces and salad plants until 31 December 2014, to address an unavoidable cross-contamination that affected untreated crops and which was due to the presence of residues of oxadixyl in soil. Commission Regulation (EU) 2016/46⁷ extended the validity of those MRLs until 19 January 2018 in view of the persistence of that active substance in soil. The Authority and food business operators submitted recent monitoring data showing that residues of oxadixyl no longer occur at levels above the relevant LOD.
- (5) In view of the non-approval of the active substance diphenylamine and the non-inclusion of the active substance oxadixyl in Annex I to Directive 91/414/EEC, the MRLs for these substances should be set at the LOD in accordance with Article 18 of Regulation (EC) No 396/2005. 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 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.
- (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

⁴ Commission Regulation (EU) No 772/2013 of 8 August 2013 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 diphenylamine in or on certain products (OJ L 217, 13.8.2013, p. 1).

⁵ Commission Regulation (EU) 2016/67 of 19 January 2016 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 ametoctradin, chlorothalonil, diphenylamine, flonicamid, fluazinam, fluoxastrobin, halauxifen-methyl, propamocarb, prothioconazole, thiacloprid and trifloxystrobin in or on certain products (OJ L 15, 22.1.2016, p. 2).

⁶ Commission Regulation (EU) No 592/2012 of 4 July 2012 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 bifenazate, captan, cyprodinil, fluopicolide, hexythiazox, isoprothiolane, metaldehyde, oxadixyl and phosmet in or on certain products (OJ L 176, 6.7.2012, p. 1).

⁷ Commission Regulation (EU) 2016/46 of 18 January 2016 amending Annex III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for oxadixyl and spinetoram in or on certain products (OJ L 12, 19.1.2016, p. 28).

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 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]*.

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