



**COUNCIL OF
THE EUROPEAN UNION**

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Subject: COMMISSION REGULATION (EU) No .../.. 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 diphenylamine in or on certain products (Text with EEA relevance)

Delegations will find attached Commission document D024729/05.

Encl.: D024729/05



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COMMISSION REGULATION (EU) No .../..

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 diphenylamine in
or on certain products**

(Text with EEA relevance)

COMMISSION REGULATION (EU) No .../..

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 diphenylamine 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) and Article 18(1)(b) thereof,

Whereas:

- (1) For diphenylamine maximum residue levels (MRLs) were set in Annex II and Part B of Annex III to Regulation (EC) No 396/2005. Diphenylamine was the subject of Commission Decision 2009/859/EC of 30 November 2009 concerning the non-inclusion of diphenylamine in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance² and it is the subject of 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 market³.
- (2) The European Food Safety Authority ('the Authority') gave a reasoned opinion on the existing MRLs for diphenylamine pursuant to Article 12(1) of Regulation (EC) No 396/2005 on 22 August 2011⁴, examining in particular the risks to the consumer. That opinion has been forwarded to the Commission and the Member States and was made available to the public.
- (3) In that opinion the Authority recommends neither the inclusion of diphenylamine in Annex IV to Regulation (EC) No 396/2005 nor the inclusion of the CXLs in Annex II to that Regulation.
- (4) All existing authorisations for plant protection products containing diphenylamine have been revoked. The MRLs set out for this active substance in Annexes II and III should therefore be deleted, except for apples and pears.

¹ OJ L 70, 16.3.2005, p. 1.

² OJ L 314, 1.12.2009, p. 79.

³ OJ L 171, 30.6.2012, p. 2.

⁴ European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for diphenylamine according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2011; 9(8):2336 [20 pp.]. doi:10.2903/j.efsa.2011.2336.

- (5) As regards diphenylamine in apples and pears, Member States, third Countries and food business operators informed the Commission of an unavoidable cross-contamination that affects untreated apples and pears and which is due to the presence of residues of diphenylamine in storage facilities, in particular machinery, surfaces and containers with particular regard to bins, and that is technically not feasible to completely remove at this stage.
- (6) Based on the monitoring data received on the cross-contamination, it is appropriate to set a temporary MRL as low as possible, given the consumer concerns raised by diphenylamine, and that would still allow the normal marketing and trade of untreated apples and pears.
- (7) Although no final consumer risk assessment can be performed at this stage due to several data gaps identified by the Authority on the diphenylamine dossier⁴, it can be reasonably expected that a temporary MRL of 0,1 mg/kg, which is fifty times lower than the current MRL of 5 mg/kg, should not pose any unacceptable risk to consumers.
- (8) Pursuant to Article 16(2) of Regulation (EC) No 396/2005, the Commission will review the situation within two years from the date of entry into force of the present Regulation based on any new monitoring data and other new elements that would become available.
- (9) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (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 the Food Chain and Animal Health and neither the European Parliament nor the Council has opposed them,

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

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, however, 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
José Manuel BARROSO*

ANNEX

Annexes II, III and V to Regulation (EC) No 396/2005 are amended as follows:

- (1) In Annex II, the column for diphenylamine is deleted.
- (2) In Part B of Annex III, the column for diphenylamine deleted.
- (3) In Part A of Annex III, the following column is added:
[For Official Journal: insert table Annex IIIA existing].
- (4) in Annex V, the following column is added:
[For Official Journal: insert table Annex V existing].