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Subject:	COMMISSION REGULATION (EU) .../... of XXX amending Annexes II and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bifenazate, daminozide and tolyfluanid in or on certain products
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Delegations will find attached document D48340/02.

Encl.: D48340/02



Brussels, **XXX**
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[...](2016) **XXX** draft

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

of **XXX**

amending Annexes II and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bifenazate, daminozide and tolylfluanid in or on certain products

(Text with EEA relevance)

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

of **XXX**

amending Annexes II and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bifenazate, daminozide and tolylfluanid 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 bifenazate maximum residue levels (MRLs) were set in Annex II to Regulation (EC) No 396/2005. For daminozide and tolylfluanid MRLs were set in Annex V to that Regulation.
- (2) For bifenazate, 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 By Regulation (EU) No 79/2014³ the recommendations of the Authority on the review of the existing MRLs were implemented.
- (3) For daminozide, the Authority, submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005⁴ By Regulation (EU)

¹ OJ L 70, 16.3.2005, p. 1.

² European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for bifenazate according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2011;9(12):2484. [48 pp.]

³ Commission Regulation (EU) No 79/2014 of 29 January 2014 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 bifenazate, chlorpropham, esfenvalerate, fludioxonil and thiobencarb in or on certain products; OJ L27, 30.1.2014, p. 9.

⁴ European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for daminozide according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2012;10(4):2650. [16 pp.]

No 87/2014⁵ the recommendations of the Authority on the review of the existing MRLs were implemented.

- (4) For tolylfluanid, the Authority, submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005⁶ By Regulation (EU) 2015/552⁷ the recommendations of the Authority on the review of the existing MRLs were implemented.
- (5) As regards products for which neither relevant authorisations nor import tolerances were reported at Union level nor Codex MRLs were available, the Authority concluded that further consideration by risk managers was required. Taking into account the current scientific and technical knowledge, MRLs for bifenazate were set under Regulation (EU) No 79/2014 at the specific limit of determination and MRLs for daminozide and tolylfluanid were set under Regulation (EU) No 87/2014 and Regulation (EU) 2015/552, at the default MRL in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005.
- (6) The Commission consulted the European Union reference laboratories as regards the need to adapt certain of these LODs. In case of complex residue definitions consisting of several components, each of the components must be analysed with an LOD that is technically feasible and as low as possible. If an MRL is established at the LOD, this LOD is the sum of the LODs for all components of the residue definition. As for bifenazate, daminozide and tolylfluanid, the residue definition is composed out of multiple components, those laboratories concluded that, taking into account the need to analyse all components of a residue definitions at a level that is technically feasible, the MRLs set at the LOD (sum of LODs of the components) should be increased.
- (7) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (8) 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 and V to Regulation (EC) No 396/2005 are amended in accordance with the Annex to this Regulation.

⁵ Commission Regulation (EU) No 87/2014 of 31 January 2014 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 acetamiprid, butralin, chlorotoluron, daminozide, isoproturon, picoxystrobin, pyrimethanil and trinexapac in or on certain products; OJ L35, 5.2.2014, p. 1.

⁶ European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for tolylfluanid according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2013;11(7):3300. [37 pp.]

⁷ Commission Regulation (EU) 2015/552 of 7 April 2015 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 1,3-dichloropropene, bifenox, dimethenamid-P, prohexadione, tolylfluanid and trifluralin; OJ L92, 8.4.2015, p. 20.

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*.

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