



Brussels, **XXX**  
SANTE/10909/2018 Rev. 1  
[...](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 amitrole, fipronil, flufenoxuron, flupyr-sulfuron-methyl, imazosulfuron, isoproturon, orthosulfamuron and triasulfuron 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 amitrole, fipronil, flufenoxuron, flupyrsulfuron-methyl, imazosulfuron, isoproturon, orthosulfamuron and triasulfuron 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/EEC<sup>1</sup>, and in particular Article 14(1)(a), Article 18(1)(b) and Article 49(2) thereof,

Whereas:

- (1) For amitrole, fipronil, flupyrsulfuron-methyl, imazosulfuron, isoproturon and triasulfuron, maximum residue levels (MRLs) were set in Annex II to Regulation (EC) No 396/2005. For flufenoxuron and orthosulfamuron, MRLs were set in Part A of Annex III to that Regulation.
- (2) The approval of the active substance amitrole was not renewed by Commission Implementing Regulation (EU) 2016/871<sup>2</sup>. The approval of the active substance fipronil expired on 30 September 2017<sup>3</sup>. The active substance flufenoxuron was not approved by Commission Implementing Regulation (EU) No 942/2011<sup>4</sup>. The approval of the active substance flupyrsulfuron-methyl was not renewed by Commission Implementing Regulation (EU) 2017/1496<sup>5</sup>. The approval of the active substance

---

<sup>1</sup> OJ L 70, 16.3.2005, p. 1.

<sup>2</sup> Commission Implementing Regulation (EU) 2016/871 of 1 June 2016 concerning the non-renewal of approval of the active substance amitrole, 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 Commission Implementing Regulation (EU) No 540/2011 (OJ L 145, 2.6.2016, p. 4).

<sup>3</sup> Commission Implementing Regulation (EU) 2016/2035 of 21 November 2016 amending Implementing Regulation (EU) No 540/2011 as regards the approval periods of the active substances fipronil and maneb (OJ L 314, 22.11.2016, p. 7).

<sup>4</sup> Commission Implementing Regulation (EU) No 942/2011 of 22 September 2011 concerning the non-approval of the active substance flufenoxuron, 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 Commission Decision 2008/934/EC (OJ L 246, 23.9.2011, p. 13).

<sup>5</sup> Commission Implementing Regulation (EU) 2017/1496 of 23 August 2017 concerning the non-renewal of approval of the active substance DPX KE 459 (flupyrsulfuron-methyl), 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 Commission Implementing Regulation (EU) No 540/2011 (OJ L 218, 24.8.2017, p. 7).

imazosulfuron expired on 31 July 2017<sup>6</sup>. The approval of the active substance isoproturon was not renewed by Commission Implementing Regulation (EU) 2016/872<sup>7</sup>. The active substance orthosulfamuron was not approved by Commission Implementing Regulation (EU) 2017/840<sup>8</sup>. The approval of the active substance triasulfuron was not renewed by Commission Implementing Regulation (EU) 2016/864<sup>9</sup>.

- (3) All existing authorisations for plant protection products containing those active substances have been revoked. It is therefore appropriate to delete the 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, except for the MRL for flufenoxuron in tea, which is safe to consumers<sup>10</sup> and corresponds to an import tolerance request from Japan.
- (4) In view of the non-renewal of approval of the active substances amitrole, flupyrsulfuron-methyl, isoproturon and triasulfuron, the expiry of the approval of the active substances fipronil and imazosulfuron, and the non-approval of the active substances flufenoxuron and orthosulfamuron, 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, except for the MRL for flufenoxuron in tea.
- (5) The Commission consulted the European Union reference laboratories as regards the need to adapt certain LODs. Those laboratories concluded that for certain products 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.

---

<sup>6</sup> Commission Implementing Regulation (EU) No 1197/2012 of 13 December 2012 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances acetamiprid, alpha-cypermethrin, *Ampelomyces quisqualis* Strain: AQ 10, benalaxyl, bifenazate, bromoxynil, chlorpropham, desmedipham, etoxazole, *Gliocladium catenulatum* Strain: J1446, imazosulfuron, laminarin, mepanipyrim, methoxyfenozide, milbemectin, phenmedipham, *Pseudomonas chlororaphis* Strain: MA 342, quinoxifen, S-metolachlor, tepraloxym, thiacloprid, thiram and ziram (OJ L 342, 14.12.2012, p. 27).

<sup>7</sup> Commission Implementing Regulation (EU) 2016/872 of 1 June 2016 concerning the non-renewal of approval of the active substance isoproturon, 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 Commission Implementing Regulation (EU) No 540/2011 (OJ L 145, 2.6.2016, p. 7).

<sup>8</sup> Commission Implementing Regulation (EU) 2017/840 of 17 May 2017 concerning the non-approval of the active substance orthosulfamuron, 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 125, 18.5.2017, p. 10).

<sup>9</sup> Commission Implementing Regulation (EU) 2016/864 of 31 May 2016 concerning the non-renewal of approval of the active substance triasulfuron, 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 Commission Implementing Regulation (EU) No 540/2011 (OJ L 144, 1.6.2016, p. 32).

<sup>10</sup> Reasoned opinion on the modification of the existing MRL for flufenoxuron in tea (dried leaves and stalks, fermented of *Camellia sinensis*). EFSA Scientific Report (2009); 267.

- (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:

*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 Publication: please insert date 6 months after entry into force*].

*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*