

Brussels, XXX SANTE/11706/2016 Rev. 1 [...](2016) XXX draft

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

of XXX

amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for fenpropidin and pymetrozin in or on certain products

(Text with EEA relevance)

EN EN

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

#### of XXX

amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for fenpropidin and pymetrozin 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) and Article 49(2) thereof,

#### Whereas:

- (1) For fenpropidin and pymetrozin maximum residue levels (MRLs) were set in Annex II to Regulation (EC) No 396/2005.
- For fenpropidin, the Authority, submitted a reasoned opinion on the existing MRLs in (2) accordance with Article 12(1) of Regulation (EC) No 396/2005 and proposed to change the residue definition.<sup>2</sup> By Regulation (EU) No 61/2014<sup>3</sup> the recommendations of the Authority on the review of the existing MRLs were implemented. As the EU reference labs identified that the reference standard for 2-methyl-2-[4-(2-methyl-3piperidin-1-yl-propyl)-phenyl|propionic acid was not commercially available, the Commission added by means of Reg. (EU) No 61/2014 a footnote to fenpropidin in annex II to Reg. (EC) No 396/2002, stating that it will take into account the commercial availability of the reference standard referred to in the previous sentence by 25 January 2015, or, if this reference standard is not commercially available by that date, the unavailability of it. In the meanwhile this deadline has expired and the requested standard is still not commercially available. As this hampers the enforcement of the MRLs for commodities of animal origin that are established in annex II to reg. (EC) No 396/2005, those MRLs should be lowered to the limit of determination (LOD). In order to avoid residues exceeding the MRLs for commodities of animal origin, also the MRLs for plant commodities that can be used as feed should be lowered. Therefore the MRLs for barley, oat, rye, wheat and sugar beet root should be lowered to the LOD. In order to allow the enforcement of the MRLs at the LOD for

-

OJ L 70, 16.3.2005, p. 1.

<sup>&</sup>lt;sup>2</sup> European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for fenpropidin according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2011;9(8):2333. [42 pp.]

<sup>&</sup>lt;sup>3</sup> Commission Regulation (EU) No 61/2014 of 24 January 2014 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 cyromazine, fenpropidin, formetanate, oxamyl and tebuconazole in or on certain products; OJ L22, 25.1.2014, p. 1.

- commodities of animal origin, the residue definition for those commodities should be changed to 'fenpropidin'.
- (3) For pymetrozine, 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) thereof and proposed to change the residue definition.<sup>4</sup> By Regulation (EU) No 398/2014<sup>3</sup> the recommendations of the Authority on the review of the existing MRLs were implemented. As the EU reference labs identified that the reference standards for 6-hydroxymethylpymetrozine and its phosphate conjugate were not commercially available, the Commission added by means of Reg. (EU) No 398/2014 a footnote to pymetrozine in annex II to Reg. (EC) No 396/2002, stating that it will take into account the commercial availability of the reference standards referred to in the previous sentence by 25 April 2015, or, if these reference standards are not commercially available by that date, the unavailability of them. In the meanwhile this deadline has expired and the requested standards are still not commercially available. As this hampers the enforcement of the MRLs for commodities of animal origin that are established in annex II to reg. (EC) No 396/2005, those MRLs should be lowered to the limit of determination (LOD). In order to avoid residues exceeding the MRLs for commodities of animal origin, also the MRLs for plant commodities that can be used as feed should be lowered. Therefore the MRLs for citrus fruits, head cabbage, kale and cotton seed should be lowered to the LOD. In order to allow the enforcement of the MRLs at the LOD for commodities of animal origin, the residue definition for those commodities should be changed to "pymetrozine'.
- (4) 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.
- (5) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (6) In order to allow normal marketing, processing and consumption of products, this Regulation should provide for a transitional arrangement for products which have been lawfully produced before the modification of the MRLs and for which information shows that a high level of consumer protection is maintained.
- (7) A reasonable period should be allowed to elapse before the modified MRLs become applicable in order to permit Member States and interested parties to prepare themselves to meet the new requirements which will result from the modification of the MRLs.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

## HAS ADOPTED THIS REGULATION:

#### Article 1

Annexes II Regulation (EC) No 396/2005 are amended in accordance with the Annex to this Regulation.

<sup>&</sup>lt;sup>4</sup> European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for pymetrozine according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2012; 10(10):2919. [67 pp.], revised version of 10 January 2013.

## Article 2

As regards the active substances fenpropidin and pymetrozin 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 before [Office of Publications please insert date 6 months after entry into force 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