# Commission Implementing Regulation (EU) No 1161/2012 of 7 December 2012 amending the Annex to Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin, as regards the substance fenbendazole (Text with EEA relevance)

## COMMISSION IMPLEMENTING REGULATION (EU) No 1161/2012

## of 7 December 2012

## amending the Annex to Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin, as regards the substance fenbendazole

## (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 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council[(1)], and in particular Article 14 in conjunction with Article 17 thereof,

Having regard to the opinion of the European Medicines Agency formulated by the Committee for Medicinal Products for Veterinary Use,

Whereas:

(1) The maximum residue limit ('MRL') for pharmacologically active substances intended for use in the Union in veterinary medicinal products for food-producing animals or in biocidal products used in animal husbandry should be established in accordance with Regulation (EC) No 470/2009.

(2) Pharmacologically active substances and their classification regarding MRLs in foodstuffs of animal origin are set out in the Annex to Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin[(2)].

(3) Fenbendazole is currently included in Table 1 of the Annex to Regulation (EU) No 37/2010 as an allowed substance, for all ruminants, applicable to muscle, fat, liver, kidney and milk, and for porcine and equidae species applicable to muscle, fat, liver and kidney.

(4) An application for the extension of the existing entry for fenbendazole to include chicken has been submitted to the European Medicines Agency.

(5) According to Article 5 of Regulation (EC) No 470/2009 the European Medicines Agency is to consider using MRLs established for a pharmacologically active substance in a particular foodstuff for another foodstuff derived from the same species, or MRLs established for a pharmacologically active substance in one or more species for other species. The Committee for Medicinal Products for Veterinary Use CVMP recommended the extrapolation of the MRLs for fenbendazole from all ruminants, porcine and equidae species to all food-producing species except fin fish, applicable to muscle, fat, liver, kidney, milk and eggs.

(6) The entry for fenbendazole in Table 1 of the Annex to Regulation (EU) No 37/2010 should therefore be amended to include all food-producing species except fin fish, and the target tissue eggs.

(7) It is appropriate to provide for a reasonable period of time for the stakeholders concerned to take measures that may be required to comply with the newly set MRL.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products,

HAS ADOPTED THIS REGULATION:

*Article 1*

The Annex to Regulation (EU) No 37/2010 is amended as set out in the Annex to this Regulation.

*Article 2*

This Regulation shall enter into force on the third day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 6 February 2013.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 7 December 2012.

*For the Commission*

*The President*

José Manuel BARROSO

ANNEX

The entry corresponding to fenbendazole in Table 1 of the Annex to Regulation (EU) No 37/2010 is replaced by the following:

| **Pharmacologically active Substance** | **Marker residue** | **Animal Species** | **MRL** | **Target Tissues** | **Other Provisions (according to Article 14(7) of Regulation (EC) No 470/2009)** | **Therapeutic Classification** |
|---|---|---|---|---|---|---|
| 'Fenbendazole' | Sum of extractable residues which may be oxidised to oxfendazole sulfone | All food-producing species except fin fish | 50 µg/kg | Muscle | For porcine and poultry species the fat MRL relates to "skin and fat in natural proportions" | Antiparasitic agents/ Agents against endoparasites' |
| | | | 50 µg/kg | Fat | | |
| | | | 500 µg/kg | Liver | | |
| | | | 50 µg/kg | Kidney | | |
| | | | 10 µg/kg | Milk | | |
| | | | 1 300 µg/ kg | Eggs | | |

(**1**) OJ L 152, 16.6.2009, p. 11.

(**2**) OJ L 15, 20.1.2010, p. 1.

**Status:**
Point in time view as at 07/12/2012.

**Changes to legislation:**
There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 1161/2012.