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 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.


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

<table>
<thead>
<tr>
<th>Pharmacologically active Substance</th>
<th>Marker residue</th>
<th>Animal Species</th>
<th>MRL</th>
<th>Target Tissues</th>
<th>Other Provisions (according to Article 14(7) of Regulation (EC) No 470/2009)</th>
<th>Therapeutic Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fenbendazole</td>
<td>Sum of extractable residues which may be oxidised to oxfendazole sulone</td>
<td>All food-producing species except fin fish</td>
<td>50 μg/kg</td>
<td>Muscle&lt;br&gt;50 μg/kg&lt;br&gt;500 μg/kg&lt;br&gt;50 μg/kg&lt;br&gt;10 μg/kg&lt;br&gt;1 300 μg/kg</td>
<td>For porcine and poultry species the fat MRL relates to &quot;skin and fat in natural proportions&quot;</td>
<td>Antiparasitic agents/Antiendoparasites</td>
</tr>
</tbody>
</table>