COMMISSION IMPLEMENTING REGULATION (EU) No 123/2012
of 13 February 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 monepantel
(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) Monepantel is currently included in Table 1 of the Annex to Regulation (EU) No 37/2010 as an allowed substance, for ovine and caprine species, applicable to muscle, fat, liver, and kidney, excluding animals producing milk for human consumption. The provisional maximum residue limits for that substance set out for caprine species expired on 1 January 2012.

(4) Additional data were provided and assessed leading the Committee for Medicinal Products for Veterinary Use to recommend that the provisional MRLs for monepantel for caprine species should be set as definitive.

(5) The entry for monepantel in Table 1 of the Annex to Regulation (EU) No 37/2010 should therefore be amended accordingly.

(6) 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 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, 13 February 2012.

For the Commission

The President

José Manuel BARROSO

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The entry monepantel 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>Monepantel</td>
<td>Monepantel-sulfone</td>
<td>Ovine, caprine</td>
<td>700 μg/kg</td>
<td>Muscle</td>
<td>Not for use in animals producing milk for human consumption.</td>
<td>Antiparasitic agents/Agents acting against endoparasites'</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>7 000 μg/kg</td>
<td>Fat</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>5 000 μg/kg</td>
<td>Liver</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2 000 μg/kg</td>
<td>Kidney</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>