COMMISSION IMPLEMENTING REGULATION (EU) No 222/2012
of 14 March 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 triclabendazole
(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) Triclabendazole 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 and kidney, excluding animals producing milk for human consumption.

(4) Ireland has submitted to the European Medicines Agency a request for an opinion for the extrapolation of the existing entry for triclabendazole applicable to all ruminants’ milk.

(5) The Committee for Medicinal Products for Veterinary Use has recommended the establishment of provisional MRLs for triclabendazole for all ruminants’ milk and the removal of the provision ‘Not for use in animals producing milk for human consumption’.

(6) The entry for triclabendazole in Table 1 of the Annex to Regulation (EU) No 37/2010 should therefore be amended to include the recommended provisional MRL for all ruminants’ milk and to remove the existing provision ‘Not for use in animals producing milk for human consumption’. The provisional MRL set out in that table for triclabendazole should expire on 1 January 2014. The CVMP recommended a two-year period to allow for the completion of scientific studies required to respond to the list of questions addressed by the CVMP to Ireland.

(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 its publication in the Official Journal of the European Union.

It shall apply from 14 May 2012.

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

Done at Brussels, 14 March 2012.

For the Commission

The President

José Manuel BARROSO

---

ANNEX

The entry corresponding to triclabendazole 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>Triclabendazole</td>
<td>Sum of the extractable residues that may be oxidised to ketotriclabendazole</td>
<td>All ruminants</td>
<td>225 μg/kg, 100 μg/kg, 250 μg/kg, 150 μg/kg</td>
<td>Muscle, Fat, Liver, Kidney</td>
<td></td>
<td>Antiparasitic agents/agents against endoparasites’</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>10 μg/kg</td>
<td>Milk</td>
<td>Provisional MRL shall expire on 1 January 2014</td>
<td></td>
</tr>
</tbody>
</table>