COMMISSION IMPLEMENTING REGULATION (EU) No 221/2012
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 closantel
(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) Closantel is currently included in Table 1 of the Annex to Regulation (EU) No 37/2010 as an allowed substance, for bovine and ovine species, 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 closantel applicable to bovine and ovine milk.

(5) The Committee for Medicinal Products for Veterinary Use has recommended the establishment of provisional MRL for closantel for bovine and ovine milk and the removal of the provision 'Not for use in animals from which milk is produced for human consumption'.

(6) The entry for closantel in Table 1 of the Annex to Regulation (EU) No 37/2010 should therefore be amended to include the recommended provisional MRL for bovine and ovine milk and to remove the existing provision 'Not for use in animals from which milk is produced for human consumption'. The provisional MRL set out in that Table for closantel 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 closantel 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>Closantel</td>
<td>Closantel</td>
<td>Bovine</td>
<td>1 000 µg/kg, 3 000 µg/kg</td>
<td>Muscle, Fat, Liver, Kidney</td>
<td>Antiparasitic agents/Antiendoparasites</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ovine</td>
<td>1 500 µg/kg, 2 000 µg/kg, 1 500 µg/kg, 5 000 µg/kg</td>
<td>Muscle, Fat, Liver, Kidney</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bovine, Ovine</td>
<td>45 µg/kg</td>
<td>Milk</td>
<td>Provisional MRL shall expire on 1 January 2014</td>
<td></td>
</tr>
</tbody>
</table>