COMMISSION IMPLEMENTING REGULATION (EU) No 115/2013
of 8 February 2013
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 diclazuril

(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 (hereinafter '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) Diclazuril is currently included in Table 1 of the Annex to Regulation (EU) No 37/2010 as an allowed substance, for all ruminants and porcine species, for oral use only.

(4) An application for the extension of the existing entry for diclazuril applicable to poultry 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 recommended the establishment of a MRL for diclazuril for chicken and pheasant, applicable to muscle, skin and fat, liver and kidney, excluding animals from which eggs are produced for human consumption, and the extrapolation of MRLs for diclazuril from chicken and pheasant to poultry, applicable to muscle, skin and fat, liver and kidney, excluding animals from which eggs are produced for human consumption.

(6) The entry for diclazuril in Table 1 of the Annex to Regulation (EU) No 37/2010 should therefore be amended to include the MRL for poultry.

(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 twentieth day following that of its publication in the Official Journal of the European Union.

It shall apply from 10 April 2013.

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

Done at Brussels, 8 February 2013.

For the Commission  
The President  
José Manuel BARROSO
ANNEX

The entry corresponding to diclazuril 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>Diclazuril</td>
<td>NOT APPLICABLE</td>
<td>All ruminants, porcine</td>
<td>No MRL required</td>
<td>NOT APPLICABLE</td>
<td>For oral use only</td>
<td>NO ENTRY</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Poultry</td>
<td>500 µg/kg</td>
<td>Muscle</td>
<td>Not for use in animals from which eggs are produced for human consumption</td>
<td>Antiparasitic agents/Agents acting against protozoa'</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>500 µg/kg</td>
<td>Skin and fat in natural proportions</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1 500 µg/kg</td>
<td>Liver</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1 000 µg/kg</td>
<td>Kidney</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>