COMMISSION IMPLEMENTING REGULATION (EU) No 85/2012
of 1 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 altrenogest
(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 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) Altrenogest is currently included in Table 1 of the Annex to Regulation (EU) No 37/2010 as an allowed substance, for porcine species, applicable to skin, fat and liver and to equidae species, applicable to fat and liver.

(4) An application for the modification of the existing entry for altrenogest has been submitted to the European Medicines Agency.

(5) Additional data were provided and assessed leading the Committee for Medicinal Products for Veterinary Use to recommend the modification of the current MRLs for altrenogest.

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

(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 2 April 2012.

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

Done at Brussels, 1 February 2012.

For the Commission

The President

José Manuel BARROSO

In Table 1 of the Annex to Regulation (EU) No 37/2010, the entry for the substance altrenogest 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>'Altrenogest'</td>
<td>Altrenogest</td>
<td>Porcine</td>
<td>4 μg/kg 2 μg/kg</td>
<td>Skin and fat Liver</td>
<td>Only for zootechnical use and in accordance with the provisions of Directive 96/22/EC</td>
<td>Agents acting on the reproductive system</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Equidae</td>
<td>4 μg/kg 4 μg/kg</td>
<td>Fat</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>