COMMISSION IMPLEMENTING REGULATION (EU) No 1277/2014
of 1 December 2014
amending Regulation (EU) No 37/2010, as regards the substance ‘lasalocid’

(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 is to be established in accordance with Regulation (EC) No 470/2009.

(2) Pharmacologically active substances and their classification regarding MRLs in foodstuffs of animal origin are set out in the Annex to Commission Regulation (EU) No 37/2010 (2).

(3) Lasalocid is currently included in Table 1 of the Annex to Regulation (EU) No 37/2010 as an allowed substance, for poultry species, applicable to muscle, skin and fat, liver, kidney and eggs, and for bovine species, applicable to muscle, fat, liver and kidney, excluding animals producing milk for human consumption.

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

(5) Additional data on lasalocid was provided and assessed by the Committee for Medicinal Products for Veterinary Use. As a result that Committee recommended the amendment of the current acceptable daily intake for lasalocid, as well as the amendment of the existing MRL for lasalocid in poultry.

(6) In accordance with 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 concluded that the extrapolation to other food producing species cannot be supported for this substance.

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

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.

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 20 February 2015.

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

Done at Brussels, 1 December 2014.

For the Commission

The President

Jean-Claude JUNCKER
In Table 1 of the Annex to Regulation (EU) No 37/2010, the entry for the substance 'lasalocid' 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>'Lasalocid'</td>
<td>Lasalocid A</td>
<td>Poultry</td>
<td>60 μg/kg</td>
<td>Muscle</td>
<td>NO ENTRY</td>
<td>Anti-infectious agents/Anti-biotics</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>300 μg/kg</td>
<td>Liver</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>150 μg/kg</td>
<td>Kidney</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>300 μg/kg</td>
<td>Skin and fat in natural proportions</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>150 μg/kg</td>
<td>Eggs</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bovine</td>
<td>10 μg/kg</td>
<td>Muscle</td>
<td>Not for use in animals from which milk is produced for human consumption</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>20 μg/kg</td>
<td>Fat</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>100 μg/kg</td>
<td>Liver</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>20 μg/kg</td>
<td>Kidney</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>