COMMISSION IMPLEMENTING REGULATION (EU) No 1191/2012
of 12 December 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 sodium salicylate
(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) Sodium salicylate is currently included in Table 1 of the Annex to Regulation (EU) No 37/2010 as an allowed substance for bovine and porcine species, excluding animals producing milk for human consumption, for all food-producing species except fin fish species, for topical use only, and for turkey, applicable to muscle, skin and fat, liver and kidney, excluding animals producing eggs for human consumption. The provisional MRL for that substance set out for turkey expires on 1 July 2015.

(4) Additional data were provided and assessed leading the Committee for Medicinal Products for Veterinary Use to recommend that the provisional MRLs for sodium salicylate for turkey should be set as definitive.

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

(6) 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 that of its publication in the Official Journal of the European Union.

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

Done at Brussels, 12 December 2012.

For the Commission
The President
José Manuel BARROSO

The entry corresponding to sodium salicylate 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>Sodium salicylate</td>
<td>NOT APPLICABLE</td>
<td>Bovine, porcine</td>
<td>No MRL required</td>
<td>NOT APPLICABLE</td>
<td>For oral use. Not for use in animals from which milk is produced for human consumption.</td>
<td>NO ENTRY</td>
</tr>
<tr>
<td></td>
<td></td>
<td>All food-producing species except fish</td>
<td>No MRL required</td>
<td>NOT APPLICABLE</td>
<td>For topical use only.</td>
<td></td>
</tr>
<tr>
<td>Salicylic acid</td>
<td>Turkey</td>
<td>400 µg/kg</td>
<td>2 500 µg/kg</td>
<td>200 µg/kg</td>
<td>150 µg/kg</td>
<td>Muscle Skin and fat in natural proportions Liver Kidney</td>
</tr>
</tbody>
</table>