of 5 January 2006
amending Annexes I and II to Council Regulation (EEC) No 2377/90 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin, as regards dihydrostreptomycin, tosylchloramide sodium and Piceae turiones recentes extractum
(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin (1), and in particular Articles 2 and 3 thereof,

Having regard to the opinions of the European Medicines Agency formulated by the Committee for Medicinal Products for Veterinary Use,

Whereas:

(1) All pharmacologically active substances which are used within the Community in veterinary medicinal products intended for administration to food-producing animals should be evaluated in accordance with Regulation (EEC) No 2377/90.

(2) Dihydrostreptomycin has been included in Annex I to Regulation (EEC) No 2377/90 for bovine and ovine species, for muscle, fat, liver, kidney and milk, and for porcine species for muscle, liver, kidney and skin and fat in natural proportions. That entry should be extended from bovine and ovine species to all ruminants.

(3) Tosylchloramide has been included in Annex II to Regulation (EEC) No 2377/90 for fin fish for water borne only and for bovine for topical use only. That entry should be extended to Equidae for topical use only.

(4) An application for establishing of maximum residue limits for Piceae turiones recentes extractum has been submitted. This substance should be included in Annex II to that Regulation for all food producing species for oral use only.

(5) Regulation (EEC) No 2377/90 should be amended accordingly.

(6) An adequate period should be allowed before the applicability of this Regulation in order to enable Member States to make any adjustment which may be necessary in the light of this Regulation to the marketing authorisations granted in accordance with Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (2).

(7) 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

Annexes I and II to Regulation (EEC) No 2377/90 are amended in accordance with 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.

It shall apply from 7 March 2006.

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

Done at Brussels, 5 January 2006.

For the Commission
Günter VERHEUGEN
Vice-President
A. The following substance is inserted in Annex I to Regulation (EEC) No 2377/90:

1. Anti-infectious agents
2. Antibiotics

<table>
<thead>
<tr>
<th>Pharmacologically active substance(s)</th>
<th>Marker residue</th>
<th>Animal species</th>
<th>MRLs</th>
<th>Target tissues</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dihydrostreptomycin</td>
<td>Dihydrostreptomycin</td>
<td>all ruminants</td>
<td>500 µg/kg</td>
<td>Muscle</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>500 µg/kg</td>
<td>Fat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>500 µg/kg</td>
<td>Liver</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1 000 µg/kg</td>
<td>Kidney</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>200 µg/kg</td>
<td>Milk</td>
</tr>
</tbody>
</table>

B. The following substances are inserted in Annex II to Regulation (EEC) No 2377/90:

2. Organic compounds

<table>
<thead>
<tr>
<th>Pharmacologically active substance(s)</th>
<th>Animal species</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tosylchloramide sodium</td>
<td>Equidae (1)</td>
</tr>
</tbody>
</table>

(1) For topical use only.

6. Substances of vegetable origin

<table>
<thead>
<tr>
<th>Pharmacologically active substance(s)</th>
<th>Animal species</th>
</tr>
</thead>
<tbody>
<tr>
<td>Piceae turiones recentes extractum</td>
<td>All food producing species (1)</td>
</tr>
</tbody>
</table>

(1) For oral use only.