COMMISSION REGULATION (EC) No 270/97
of 14 February 1997
down a Community procedure for the establishment of maximum residue limits
of veterinary medicinal products in foodstuffs of animal origin

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),
as last amended by Commission Regulation (EC) No
211/97 (2), and in particular Articles 6, 7 and 8 thereof,

Whereas, in accordance with Regulation (EEC) No
2377/90, maximum residue limits must be established
progressively for all pharmacologically active substances
which are used within the Community in veterinary
medicinal products intended for administration to food-
producing animals;

Whereas maximum residue limits should be established
only after the examination within the Committee for
Veterinary Medicinal Products of all the relevant infor-
mation concerning the safety of residues of the substance
concerned for the consumer of foodstuffs of animal origin
and the impact of residues on the industrial processing of
foodstuffs;

Whereas, in establishing maximum residue limits for res-
dues of veterinary medicinal products in foodstuffs of
animal origin, it is necessary to specify the animal species
in which residues may be present, the levels which may
be present in each of the relevant meat tissues obtained
from the treated animal (target tissue) and the nature of
the residue which is relevant for the monitoring of res-
dues (marker residue);

Whereas, for the control of residues, as provided for in
appropriate Community legislation, maximum residue
limits should usually be established for the target tissues
of liver or kidney; whereas, however, the liver and kidney
are frequently removed from carcasses moving in interna-
tional trade, and maximum residue limits should there-
fore also always be established for muscle or fat tissues;

Whereas, in the case of veterinary medicinal products
intended for use in laying birds, lactating animals or
honey bees, maximum residue limits must also be est-
ablished for eggs, milk or honey;

Whereas, doramectin and cefazolin (for milk) should be
inserted into Annex I to Regulation (EEC) No 2377/90;

Whereas alfaprostol, cefazolin, medroxyprogesterone
acetate and propylene glycol should be inserted into
Annex II to Regulation (EEC) No 2377/90;

Whereas, in order to allow for the completion of scientific
studies, cephapirin should be inserted into Annex III to
Regulation (EEC) No 2377/90;

Whereas it appears that maximum residue limits cannot
be established for chloroform because residues, at
whatever limit, in foodstuffs of animal origin constitute a
hazard to the health of the consumer; whereas chloroform
should therefore be inserted into Annex IV to Regulation
(EEC) No 2377/90;

Whereas a period of 60 days should be allowed before the
entry into force of this Regulation in order to allow
Member States to make any adjustment which may be
necessary to the authorisations to place the veterinary
medicinal products concerned on the market which have
been granted in accordance with Council Directive
81/851/EEC (3), as last amended by Directive
93/40/EEC (4), to take account of the provisions of this
Regulation;

Whereas the measures provided for in this Regulation are
in accordance with the opinion of the Standing
Committee on Veterinary Medicinal Products,

HAS ADOPTED THE FOLLOWING REGULATION:

Article 1

Annex I, II, III and IV of Regulation (EEC) No 2377/90
are hereby amended as set out in the Annex hereto.

Article 2

This Regulation shall enter into force on the sixtieth day
following its publication in the Official Journal of the
European Communities.

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

Done at Brussels, 14 February 1997.

For the Commission
Martin BANGEMANN
Member of the Commission
ANNEX

A. Annex I to Regulation (EEC) No 2377/90 is amended as follows:

1. Anti-infectious agents

1.2. Antibiotics

1.2.2. Cephalosporins

<table>
<thead>
<tr>
<th>Pharmacologically active substance</th>
<th>Marker residue</th>
<th>Animal species</th>
<th>MRLs</th>
<th>Target tissues</th>
<th>Other provisions</th>
</tr>
</thead>
<tbody>
<tr>
<td>'1.2.2.2. Cefazolin</td>
<td>Cefazolin</td>
<td>Bovine</td>
<td>50 µg/kg</td>
<td>Milk*</td>
<td></td>
</tr>
</tbody>
</table>

2. Anti-parasitic agents

2.3. Agents acting against endo- and ectoparasites

2.3.1. Avermectins

<table>
<thead>
<tr>
<th>Pharmacologically active substance</th>
<th>Marker residue</th>
<th>Animal species</th>
<th>MRLs</th>
<th>Target tissues</th>
<th>Other provisions</th>
</tr>
</thead>
<tbody>
<tr>
<td>'2.3.1.3. Doramectin</td>
<td>Doramectin</td>
<td>Bovine</td>
<td>150 µg/kg</td>
<td>Fat</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>100 µg/kg</td>
<td>Liver</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>30 µg/kg</td>
<td>Kidney</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>10 µg/kg</td>
<td>Muscle*</td>
<td></td>
</tr>
</tbody>
</table>

B. Annex II is amended as follows:

2. Organic compounds

<table>
<thead>
<tr>
<th>Pharmacologically active substance(s)</th>
<th>Animal species</th>
<th>Other provisions</th>
</tr>
</thead>
<tbody>
<tr>
<td>'2.75. Alfaprostol</td>
<td>Bovine, porcine, equidae</td>
<td>For intramammary use only (except if the udder maybe used as food for human consumption).</td>
</tr>
<tr>
<td>2.76. Cefazolin</td>
<td>Bovine</td>
<td></td>
</tr>
<tr>
<td>2.77. Medroxyprogesterone acetate</td>
<td>Ovine</td>
<td>For intravaginal use for zootechnical purposes only</td>
</tr>
<tr>
<td>2.78. Propylene glycol</td>
<td>All food producing species’</td>
<td></td>
</tr>
</tbody>
</table>
C. Annex III is amended as follows:

1. Anti-infectious agents

1.2. Antibiotics

1.2.4. Cephalosporins

<table>
<thead>
<tr>
<th>Pharmacologically active substance</th>
<th>Marker residue</th>
<th>Animal species</th>
<th>MRLs</th>
<th>Target tissues</th>
<th>Other provisions</th>
</tr>
</thead>
<tbody>
<tr>
<td>'1.2.4.2. Cepahpin'</td>
<td>Sum of cepahpin and desacetylcephapin</td>
<td>Bovine</td>
<td>100 µg/kg</td>
<td>Kidney</td>
<td>Provisional MRLs expire on 1.1.1999</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>50 µg/kg</td>
<td>Muscle, liver, fat</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>10 µg/kg</td>
<td>Milk</td>
<td></td>
</tr>
</tbody>
</table>

D. Annex IV is amended as follows:

List of pharmacologically active substances for which no maximum levels can be fixed:

9. Chloroform'