COMMISSION REGULATION (EC) No 1837/97
of 24 September 1997
amending Annexes I, II and III 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
(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),
as last amended by Commission Regulation (EC) No
749/97 (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 informa-
tion 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-
ides 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-
ides (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 inter-
national 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 estab-
lished for eggs, milk or honey;

Whereas, febentel, fenbendazole, oxendazole and dexam-
ethasone should be inserted into Annex I to Regulation
(EEC) No 2377/90;

Whereas bromide, sodium salt should be inserted into
Annex II to Regulation (EEC) No 2377/90;

Whereas, in order to allow for the completion of scientific
studies, cefotiofur, danofloxacin and netobimin should be
inserted into Annex III 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 authorizations 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 THIS REGULATION:

Article 1

Annexes I, II and III to 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 60th 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.


For the Commission
Martin BANGEMANN
Member of the Commission
The Annexes to Regulation (EEC) No 2377/90 are hereby amended as follows:

A. Annex I is amended as follows:

2. Antiparasitic agents

2.1. Agents acting against endoparasites

2.1.3. Benzimidazoles and pro-benzimidazoles

<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>'2.1.3.1. Febantel'</td>
<td>Sum of extractable residues which may be oxidized to oxfendazole sulphone</td>
<td>Bovine, ovine, porcine, equidae</td>
<td>50 μg/kg, 50 μg/kg, 500 μg/kg, 50 μg/kg</td>
<td>Muscle, Fat, Liver, Kidney</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bovine, ovine</td>
<td>10 μg/kg</td>
<td>Milk</td>
<td></td>
</tr>
<tr>
<td>2.1.3.2. Fenbendazole</td>
<td>Sum of extractable residues which may be oxidized to oxfendazole sulphone</td>
<td>Bovine, ovine, porcine, equidae</td>
<td>50 μg/kg, 50 μg/kg, 500 μg/kg, 50 μg/kg</td>
<td>Muscle, Fat, Liver, Kidney</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bovine, ovine</td>
<td>10 μg/kg</td>
<td>Milk</td>
<td></td>
</tr>
<tr>
<td>2.1.3.3. Oxfendazole</td>
<td>Sum of extractable residues which may be oxidized to oxfendazole sulphone</td>
<td>Bovine, ovine, porcine, equidae</td>
<td>50 μg/kg, 50 μg/kg, 500 μg/kg, 50 μg/kg</td>
<td>Muscle, Fat, Liver, Kidney</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bovine, ovine</td>
<td>10 μg/kg</td>
<td>Milk</td>
<td></td>
</tr>
</tbody>
</table>
5. Corticoids

5.1. Glucocorticoids

<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>'5.1.1. Dexamethasone'</td>
<td>Dexamethasone</td>
<td>Bovine, porcine, equidae</td>
<td>0,75 µg/kg</td>
<td>Muscle</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2,0 µg/kg</td>
<td>Liver</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>0,75 µg/kg</td>
<td>Kidney</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bovine</td>
<td>0,3 µg/kg</td>
<td>Milk'</td>
<td></td>
</tr>
</tbody>
</table>

B. Annex II is amended as follows:

1. Inorganic compounds

<table>
<thead>
<tr>
<th>Pharmacologically active substance(s)</th>
<th>Animal species</th>
<th>Other provisions</th>
</tr>
</thead>
<tbody>
<tr>
<td>'1.29. Bromide, sodium salt'</td>
<td>All food producing mammals</td>
<td>For topical use only'</td>
</tr>
</tbody>
</table>

C. Annex III is amended as follows:

1. Anti-infectious agents

1.2. Antibiotics

1.2.4. Cephalexins

<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>'1.2.4.1. Cefoxitin'</td>
<td>Sum of all residues retaining the beta-lactam structure expressed as desfluoroylcetoxitin</td>
<td>Bovine</td>
<td>2 000 µg/kg</td>
<td>Liver, kidney</td>
<td>Provisional MRLs expire on 1.1.1999'</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>200 µg/kg</td>
<td>Muscle</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>600 µg/kg</td>
<td>Fat</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>100 µg/kg</td>
<td>Milk</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Porcine</td>
<td>4 000 µg/kg</td>
<td>Kidney</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>3 000 µg/kg</td>
<td>Liver</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>500 µg/kg</td>
<td>Muscle</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>600 µg/kg</td>
<td>Fat</td>
<td></td>
</tr>
</tbody>
</table>
### 1.2.6. Quinolones

<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>&quot;1.2.6.1. Danofloxacin&quot;</td>
<td>Danofloxacin</td>
<td>Bovine</td>
<td>900 µg/kg</td>
<td>Liver</td>
<td>Provisional MRLs expire on 1. 1. 1999'</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>500 µg/kg</td>
<td>Kidney</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>300 µg/kg</td>
<td>Muscle</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>200 µg/kg</td>
<td>Fat</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Chicken</td>
<td>1200 µg/kg</td>
<td>Liver, kidney</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>600 µg/kg</td>
<td>Skin + fat</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>300 µg/kg</td>
<td>Muscle</td>
<td></td>
</tr>
</tbody>
</table>

2. Antiparasitic agents

2.1. Agents acting against endo-parasites

2.1.1. Benzimidazoles and pro-benzimidazoles

<table>
<thead>
<tr>
<th>Pharmacologically active substance</th>
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<th>Target tissues</th>
<th>Other provisions</th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;2.1.1.9. Netobimin&quot;</td>
<td>Sum of netobimin and albendazole and metabolites of albendazole measured as 2-amino-benzimidazole sulphone</td>
<td>Bovine, ovine, caprine</td>
<td>100 µg/kg</td>
<td>Muscle, fat</td>
<td>Provisional MRLs expire on 31. 7. 1999'</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1000 µg/kg</td>
<td>Liver</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>500 µg/kg</td>
<td>Kidney</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>100 µg/kg</td>
<td>Milk</td>
<td></td>
</tr>
</tbody>
</table>