COMMISSION REGULATION (EC) No 1798/96
of 17 September 1996
amending Annex 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

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
1742/96 (2) and in particular Articles 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 resi-
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 resi-
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
established for eggs, milk or honey;

Whereas, scientific data to address outstanding questions
on safety and residues have been provided, these were
considered insufficient to conclude the assessment on
albendazole, thiamphenicol, oxibendazole, flubendazole
and azaperone, so that they can be inserted into Annex I
to Council Regulation (EC) No 2377/90;

Whereas additional information has now been provided
in respect of albendazole, thiamphenicol, oxibendazole,
flubendazole and azaperone; the duration of validity of the
provisional maximum residue limits previously defined in
Annex III to Regulation (EC) No 2377/90 for the above-
mentioned substances shall be extended in order that
completion of the scientific evaluation in progress may be
achieved;

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 Regula-
tion;

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

Annex III to Regulation (EEC) No 2377/90 is 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.

Done at Brussels, 17 September 1996.

For the Commission
Martin BANGEMANN
Member of the Commission
ANNEX

Annex III to Regulation (EEC) No 2377/90 is modified as follows:

1. Anti-infectious agents

1.2. Antibiotics

1.2.3. Thiamphenicol and related compounds

<table>
<thead>
<tr>
<th>Pharmacologically active substance(s)</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>'1.2.3.1. Thiamphenicol'</td>
<td>Thiamphenicol</td>
<td>Bovine, poultry</td>
<td>40 µg/kg</td>
<td>Muscle, liver, kidney, fat</td>
<td>Provisional MRLs expire on 1. 1. 1988'</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>
<th>Marker residue</th>
<th>Animal species</th>
<th>MRLs</th>
<th>Target tissues</th>
<th>Other provisions</th>
</tr>
</thead>
<tbody>
<tr>
<td>'2.1.1.4. Albendazole'</td>
<td>Sum of albendazole and metabolites which are measured as 2-amino-benzimidazole sulphone</td>
<td>Bovine, ovine</td>
<td>100 µg/kg</td>
<td>Muscle, fat, milk</td>
<td>Provisional MRLs expire on 1. 1. 1998.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>500 µg/kg</td>
<td>Kidney</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>1 000 µg/kg</td>
<td>Liver</td>
<td></td>
</tr>
<tr>
<td>'2.1.1.7. Flubendazole'</td>
<td>Flubendazole</td>
<td>Poultry and game birds</td>
<td>500 µg/kg</td>
<td>Liver</td>
<td>Provisional MRLs expire on 1. 1. 1998</td>
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<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>400 µg/kg</td>
<td>Eggs</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Porcine</td>
<td>10 µg/kg</td>
<td>Muscle, liver, kidney, fat</td>
<td></td>
</tr>
<tr>
<td>Pharmacologically active substance</td>
<td>Marker residue</td>
<td>Animal species</td>
<td>MRLs</td>
<td>Target tissues</td>
<td>Other provisions</td>
</tr>
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<tr>
<td>2.1.1.8. Oxibendazole</td>
<td>Oxibendazole</td>
<td>Bovine, ovine, porcine, equidae</td>
<td>100 µg/kg</td>
<td>Muscle, liver, kidney, fat</td>
<td>Provisional MRLs expire on 1.1.1998.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bovins, ovine</td>
<td>50 µg/kg</td>
<td>Milk</td>
<td></td>
</tr>
</tbody>
</table>

3. Agents acting on the nervous system

3.1. Agents acting on the central nervous system

3.1.1. Butyrofenone tranquilizers

<table>
<thead>
<tr>
<th>Pharmacologically active substance(s)</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>3.1.1.1. Azaperone</td>
<td>Azaperol</td>
<td>All food producing species</td>
<td>100 µg/kg</td>
<td>Kidney</td>
<td>Provisional MRLs expire on 1.1.1998.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>50 µg/kg</td>
<td>Liver, muscle, fat</td>
<td></td>
</tr>
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