COMMISSION REGULATION (EC) No 281/96
of 14 February 1996
amending Annexes I 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
2804/95 (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 information
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 level 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 residues
(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 esta-
blished for eggs, milk or honey;

Whereas tetracycline, oxytetracycline, chlorotetracycline
and all substances belonging to the sulphonamide group
should be inserted into Annex I to Regulation (EEC) No
2377/90;

Whereas, in order to allow for the completion of scientific
studies in progress, the duration of the validity of the
provisional maximum residue limits previously defined in
Annex III to Regulation (EEC) No 2377/90 should be
extended for trimethoprim;

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 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 and III 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 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, 14 February 1996.

For the Commission
Martin BANGEMANN
Member of the Commission
### ANNEX

A. Annex I is amended as follows:

1. Anti-infectious agents
2. Chemotherapeutics
3. Sulfonamides

<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>'All substances belonging to the sulfonamide group</td>
<td>Parent drug</td>
<td>Bovine, Ovine, Caprine</td>
<td>100 µg/kg</td>
<td>Milk</td>
<td>The combined residues of all substances in the sulfonamide group should not exceed 100 µg/kg</td>
</tr>
</tbody>
</table>

1.2. Antibiotics
1.2.6. Tetracyclines

<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>'1.2.6.1. Tetracycline</td>
<td>Sum of parent drug and its 4-epimer</td>
<td>All food producing species</td>
<td>600 µg/kg</td>
<td>Kidney</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>300 µg/kg</td>
<td>Liver</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>100 µg/kg</td>
<td>Muscle</td>
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</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></td>
<td>200 µg/kg</td>
<td>Eggs</td>
<td></td>
</tr>
<tr>
<td>1.2.6.2. Oxytetracycline</td>
<td>Sum of parent drug and its 4-epimer</td>
<td>All food producing species</td>
<td>600 µg/kg</td>
<td>Kidney</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>300 µg/kg</td>
<td>Liver</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>100 µg/kg</td>
<td>Muscle</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>100 µg/kg</td>
<td>Milk</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>200 µg/kg</td>
<td>Eggs</td>
<td></td>
</tr>
<tr>
<td>1.2.6.3. Chlortetracycline</td>
<td>Sum of parent drug and its 4-epimer</td>
<td>All food producing species</td>
<td>600 µg/kg</td>
<td>Kidney</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>300 µg/kg</td>
<td>Liver</td>
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<td></td>
<td></td>
<td></td>
<td>100 µg/kg</td>
<td>Muscle</td>
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<td></td>
<td></td>
<td></td>
<td>100 µg/kg</td>
<td>Milk</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>200 µg/kg</td>
<td>Eggs</td>
<td></td>
</tr>
</tbody>
</table>

B. Annex III is amended as follows:

1. Anti-infectious agents
1.1. Chemotherapeutics
1.1.2. Diamino pyrimidine derivatives

<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>'1.1.2.1. Trimethoprim</td>
<td>Trimethoprim</td>
<td>All food producing species</td>
<td>50 µg/kg</td>
<td>Muscle, liver, kidney, fat, milk</td>
<td>Provisional MRLs expire on 1 January 1998</td>
</tr>
</tbody>
</table>