THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,


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

Whereas:

(1) The maximum residue limit (MRL) for pharmacologically active substances intended for use in the Union in veterinary medicinal products for food-producing animals or in biocidal products used in animal husbandry should be established in accordance with Regulation (EC) No 470/2009.


(3) Clorsulon is currently included in Table 1 of the Annex to Regulation (EU) No 37/2010 as an allowed substance, for bovine species, applicable to muscle, liver and kidney, excluding animals producing milk for human consumption.

(4) Ireland has submitted to the European Medicines Agency a request for an opinion for the extrapolation of the existing entry for clorsulon applicable to bovine milk.

(5) The Committee for Medicinal Products for Veterinary Use (CVMP) has recommended the establishment of a provisional MRL for clorsulon for bovine milk and the removal of the provision banning the use of that substance in animals from which milk is produced for human consumption.

(6) The entry for clorsulon in Table 1 of the Annex to Regulation (EU) No 37/2010 should therefore be amended to include the recommended provisional MRL for bovine milk and to remove the existing ban.

(7) The provisional MRL for clorsulon set out in that Table should expire on 1 January 2014. The CVMP recommended a two-year period to allow for the completion of scientific studies required to respond to the list of questions addressed by the CVMP to Ireland.

(8) It is appropriate to provide for a reasonable period of time for the stakeholders concerned to take measures that may be required to comply with the newly set MRL.

(9) 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

The Annex to Regulation (EU) No 37/2010 is amended as set out in 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 1 August 2012.

THE ANNEX TO COMMISSION REGULATION (EU) No 37/2010

<table>
<thead>
<tr>
<th>Substance</th>
<th>MRL (μg/kg)</th>
<th>Use</th>
<th>Article</th>
<th>Table 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clorsulon</td>
<td>2000</td>
<td>Bovine muscle, liver and kidney</td>
<td>14</td>
<td>3</td>
</tr>
</tbody>
</table>

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

Done at Brussels, 1 June 2012.

For the Commission
The President
José Manuel BARROSO
The entry corresponding to clorsulon in Table 1 of the Annex to Regulation (EU) No 37/2010 is replaced by the following:

<table>
<thead>
<tr>
<th>Pharmacologically active substance</th>
<th>Marker residue</th>
<th>Animal species</th>
<th>MRL</th>
<th>Target tissues</th>
<th>Other provisions (according to Article 14(7) of Regulation (EC) No 470/2009)</th>
<th>Therapeutic classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clorsulon</td>
<td>Clorsulon</td>
<td>Bovine</td>
<td>35 μg/kg</td>
<td>Muscle</td>
<td>Provisional MRL shall expire on 1 January 2014</td>
<td>Antiparasitic agents/Agents against endoparasites</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>100 μg/kg</td>
<td>Liver</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>200 μg/kg</td>
<td>Kidney</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>16 μg/kg</td>
<td>Milk</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>