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.

(2) Pharmacologically active substances and their classification regarding MRLs in foodstuffs of animal origin are set out in the Annex to Commission Regulation (EU) No 37/2010 (2).

(3) Prednisolone 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, fat, liver, kidney and milk.

(4) An application for the extension of the existing entry for prednisolone applicable to equidae has been submitted to the European Medicines Agency.

(5) The Committee for Medicinal Products for Veterinary Use recommended the establishment of a MRL for prednisolone for equidae species, applicable to muscle, fat, liver and kidney.

(6) The entry for prednisolone in Table 1 of the Annex to Regulation (EU) No 37/2010 should therefore be amended to include the MRL for equidae.

(7) 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.

(8) 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 twentieth day following that of its publication in the Official Journal of the European Union.

It shall apply from 3 July 2013.

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

Done at Brussels, 2 May 2013.

For the Commission

The President

José Manuel BARROSO

In Table 1 of the Annex to Regulation (EU) No 37/2010, the entry corresponding to prednisolone 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>Prednisolone</td>
<td>Prednisolone</td>
<td>Bovine</td>
<td>4 μg/kg</td>
<td>Muscle</td>
<td>NO ENTRY</td>
<td>Corticoids/ Glucocorticoids’</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>4 μg/kg</td>
<td>Fat</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>10 μg/kg</td>
<td>Liver</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>10 μg/kg</td>
<td>Kidney</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>6 μg/kg</td>
<td>Milk</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Equidae</td>
<td></td>
<td>4 μg/kg</td>
<td>Muscle</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>8 μg/kg</td>
<td>Fat</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>6 μg/kg</td>
<td>Liver</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>15 μg/kg</td>
<td>Kidney</td>
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</tbody>
</table>