COMMISSION IMPLEMENTING REGULATION (EU) No 1186/2012
of 11 December 2012
amending the Annex to Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin, as regards the substance phoxim

(Text with EEA relevance)

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) Phoxim is currently included in Table 1 of the Annex to Regulation (EU) No 37/2010 as an allowed substance, for ovine species, applicable to muscle, fat and kidney, for porcine species, applicable to muscle, skin and fat, liver and kidney and for chicken, applicable to muscle, skin and fat, liver, kidney and eggs, excluding animals producing milk for human consumption.

(4) An application for the extension of the existing entry for phoxim to include bovine species has been submitted to the European Medicines Agency.

(5) According to Article 5 of Regulation (EC) No 470/2009 the European Medicines Agency is to consider using MRLs established for a pharmacologically active substance in a particular foodstuff for another foodstuff derived from the same species, or MRLs established for a pharmacologically active substance in one or more species for other species. The Committee for Medicinal Products for Veterinary Use recommended establishing a MRL for phoxim for bovine species applicable to muscle, fat, liver and kidney, excluding animals producing milk for human consumption, and the extrapolation of the MRLs for phoxim from ovine, bovine and porcine species, and chicken to all food-producing species except fin fish, applicable to muscle, fat, liver, kidney and eggs, excluding animals producing milk for human consumption.

(6) The entry for phoxim in Table 1 of the Annex to Regulation (EU) No 37/2010 should therefore be amended to include all food-producing species except fin fish.

(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 third day following that of its publication in the Official Journal of the European Union.

It shall apply from 13 February 2013.

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

Done at Brussels, 11 December 2012.

For the Commission
The President
José Manuel BARROSO
The entry corresponding to phoxim 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>Phoxim</td>
<td>Phoxim</td>
<td>All food-producing species except fin fish.</td>
<td>25 μg/kg, 550 μg/kg, 50 μg/kg, 30 μg/kg, 60 μg/kg</td>
<td>Muscle, Fat, Liver, Kidney, Eggs</td>
<td>For porcine and poultry species the fat MRL relates to “skin and fat in natural proportions”. Not for use in animals from which milk is produced for human consumption.</td>
<td>Antiparasitic agents/Agents against ectoparasites.</td>
</tr>
</tbody>
</table>