COMMISSION IMPLEMENTING REGULATION (EU) No 394/2013
of 29 April 2013
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 monepantel
(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) Monepantel is currently included in Table 1 of the Annex to Regulation (EU) No 37/2010 as an allowed substance, for ovine and caprine species, applicable to muscle, fat, liver and kidney, excluding animals producing milk for human consumption.
(4) An application for the extension of the existing entry for monepantel applicable to ovine milk 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 the establishment of a MRL for monepantel for ovine milk, and the extrapolation of the MRLs for monepantel from ovine species, applicable to milk, to caprine species, applicable to milk.
(6) The entry for monepantel in Table 1 of the Annex to Regulation (EU) No 37/2010 should therefore be amended to include the MRLs for ovine and caprine species, applicable to milk.
(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 29 June 2013.

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

Done at Brussels, 29 April 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 monepantel 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>'Monepantel'</td>
<td>Monepantel-sulfone</td>
<td>Ovine, caprine</td>
<td>700 μg/kg</td>
<td>Muscle, Fat, Liver, Kidney, Milk</td>
<td>Antiparasitic agents/Agents acting against endoparasites'</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>7 000 μg/kg</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>5 000 μg/kg</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>2 000 μg/kg</td>
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<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>170 μg/kg</td>
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</table>