COMMISSION IMPLEMENTING REGULATION (EU) No 202/2012
of 8 March 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 pegylated bovine granulocyte colony stimulating factor

(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) An application for the establishment of maximum residue limits for pegylated bovine granulocyte colony stimulating factor in bovine species has been submitted to the European Medicines Agency.

(4) The Committee for Medicinal Products for Veterinary Use has recommended that there is no need to establish an MRL for pegylated bovine granulocyte colony stimulating factor in bovine species.

(5) Table 1 of the Annex to Regulation (EU) No 37/2010 should therefore be amended to include the substance pegylated bovine granulocyte colony stimulating factor in bovine species.

(6) 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.

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

Done at Brussels, 8 March 2012.

For the Commission

The President

José Manuel BARROSO

In Table 1 of the Annex to Regulation (EU) No 37/2010, the following substance is inserted in alphabetical order:

<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>&quot;Pegylated bovine granulocyte colony stimulating factor&quot;</td>
<td>Not applicable</td>
<td>Bovine</td>
<td>No MRL required</td>
<td>Not applicable</td>
<td>NO ENTRY</td>
<td>Biological/Immunomodulator*</td>
</tr>
</tbody>
</table>