COMMISSION IMPLEMENTING REGULATION (EU) No 489/2013
of 27 May 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 double stranded ribonucleic acid homologous to viral ribonucleic acid coding for part of the coat protein and part of the intergenic region of the Israel Acute Paralysis Virus

(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 MRLs for double stranded ribonucleic acid homologous to viral ribonucleic acid coding for part of the coat protein and part of the intergenic region of the Israel Acute Paralysis Virus for bees has been submitted to the European Medicines Agency.

(4) The Committee for Medicinal Products for Veterinary Use has recommended that for this pharmacologically active substance a standard pharmacological and toxicological approach, including the setting of a level of acceptable daily intake, is not appropriate and that there is no need to establish an MRL, applicable to honey, for double stranded ribonucleic acid homologous to viral ribonucleic acid coding for part of the coat protein and part of the intergenic region of the Israel Acute Paralysis Virus for bees.

(5) According to Article 5 of Regulation (EC) No 470/2009 the European Medicines Agency is to always consider the use of 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 has concluded that the extrapolation to other food producing species cannot be supported for this substance.

(6) Table 1 of the Annex to Regulation (EU) No 37/2010 should therefore be amended to include the substance double stranded ribonucleic acid homologous to viral ribonucleic acid coding for part of the coat protein and part of the intergenic region of the Israel Acute Paralysis Virus for bees while establishing the absence of the need to establish a MRL, applicable to honey.

(7) 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.

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

Done at Brussels, 27 May 2013.

For the Commission
The President
José Manuel BARROSO

ANNEX

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>Double stranded ribonucleic acid homologous to viral ribonucleic acid coding for part of the coat protein and part of the intergenic region of the Israel Acute Paralysis Virus</td>
<td>NOT APPLICABLE</td>
<td>Bees</td>
<td>No MRL required</td>
<td>Honey</td>
<td>NO ENTRY</td>
<td>NO ENTRY</td>
</tr>
</tbody>
</table>