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)

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 Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council[(1)], and in particular Article 14 in conjunction with Article 17 thereof,

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 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin[(2)].

(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.

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 489/2013. (See end of Document for details)*

(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