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 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 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 maximum residue limits 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 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

[1] OJ L 152, 16.6.2009, p. 11.

[2] OJ L 15, 20.1.2010, p. 1.

ANNEX

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

Pharmacologically active Substance	Marker residue	Animal Species	MRL	Target Tissues	Other Provisions (according to Article 14(7) of Regulation (EC) No 470/2009)	Therapeutic Classification
"Pegylated bovine granulocyte colony stimulating factor	Not applicable	Bovine	No MRL required	Not applicable	NO ENTRY	Biological/Immunomodulator"