Commission Regulation (EC) No 1518/2005 of 19 September 2005 amending Annexes I and III to Council Regulation (EEC) No 2377/90 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin, as regards acetylisovaleryltylosin and fluazuron (Text with EEA relevance)

COMMISSION REGULATION (EC) No 1518/2005

of 19 September 2005

amending Annexes I and III to Council Regulation (EEC) No 2377/90 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin, as regards acetylisovaleryltylosin and fluazuron

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin[(1)], and in particular Article 2 and the third paragraph of Article 4 thereof,

Having regard to the opinions of the European Medicines Agency formulated by the Committee for Medicinal Products for Veterinary Use,

Whereas:

(1) All pharmacologically active substances which are used within the Community in veterinary medicinal products intended for administration to food-producing animals should be evaluated in accordance with Regulation (EEC) No 2377/90.

(2) Acetylisovaleryltylosin has been included in Annex I to Regulation (EEC) No 2377/90 for porcine species for muscle, skin and fat, liver and kidney. That substance has also been included in Annex III to that Regulation for skin and fat and for liver, for poultry species excluding animals from which eggs are produced for human consumption, awaiting completion of scientific studies. These studies have now been completed and acetylisovaleryltylosin should therefore be inserted in Annex I to that Regulation for poultry species.

(3) An application for establishing of maximum residue limits for ‘fluazuron’ has been submitted. In order to allow for the completion of scientific studies for bovine species, fluazuron should be included in Annex III to that Regulation.

(4) Regulation (EEC) No 2377/90 should be amended accordingly.

(5) An adequate period should be allowed before the applicability of this Regulation in order to enable Member States to make any adjustment which may be necessary in

the light of this Regulation to the marketing authorisations granted in accordance with Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products[(2)].

(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

Annexes I and III to Regulation (EEC) No 2377/90 are amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the third day following its publication in the *Official Journal of the European Union*.

It shall apply from 19 November 2005.

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

Done at Brussels, 19 September 2005.

For the Commission

Günter VERHEUGEN

Vice-President