Commission Regulation (EC) No 1451/2006 of 29 September 2006 amending Annexes I and II 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 fluazuron, sodium nitrite and peforelin (Text with EEA relevance)

COMMISSION REGULATION (EC) No 1451/2006

of 29 September 2006

amending Annexes I and II 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 fluazuron, sodium nitrite and peforelin

(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 Articles 2 and 3 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 used in the Community in veterinary medicinal products intended for food-producing animals should be evaluated in accordance with Regulation (EEC) No 2377/90.

(2) The substance fluazuron is included in Annex III to Regulation (EEC) No 2377/90 for bovine for muscle, fat, liver and kidney, excluding animals from which milk is produced for human consumption. Additional data were provided and assessed leading to the recommendation that fluazuron should be included in Annex I to Regulation (EEC) No 2377/90 for bovine for muscle, fat, liver and kidney, excluding animals from which milk is produced for human consumption.

(3) Following examination of an application for the establishment of maximum residue limits for sodium nitrite in dairy cattle, it is considered appropriate to include this substance in Annex II to Regulation (EEC) No 2377/90 for the bovine species for topical use only.

(4) Following examination of an application for the establishment of maximum residue limits for peforelin in porcine species, it is considered appropriate to include this substance in Annex II to Regulation (EEC) No 2377/90 for the porcine species.

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

(6) 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 authorisations to place the veterinary medicinal products concerned on the market which have been 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)] to take account of the provisions of this Regulation.

(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

Annexes I and II 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 29 November 2006.

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

Done at Brussels, 29 September 2006.

For the Commission

Günter VERHEUGEN

Vice-President

ANNEX

A.

The following substance is inserted in Annex I to Regulation (EEC) No 2377/90:

2. Anti-parasitic agents

2.2. Agents acting against ecto-parasites

2.2.4. Acyl urea derivatives

Pharmacologically active substance(s)	**Marker residue**	**Animal species**	**MRLs**	**Target tissues**
‘**Fluazuron**	Fluazuron	Bovine[a]	200 µg/kg	Muscle
			7 000 µg/kg	Fat
			500 µg/kg	Liver
			500 µg/kg	Kidney

a Not for use in animals from which milk is produced for human consumption.’

B. The following substances are inserted in Annex II to Regulation (EEC) No 2377/90:

1. Inorganic chemicals

Pharmacologically active substance(s)	**Animal species**
‘**Sodium nitrite**	Bovine[a]

a For topical use only.’

2. Organic compounds

Pharmacologically active substance(s)	**Animal species**
‘**Peforelin**	Porcine’

(**1**) OJ L 224, 18.8.1990, p. 1. Regulation as last amended by Commission Regulation (EC) No 1231/2006 (OJ L 225, 17.8.2006, p. 3).

(**2**) OJ L 311, 28.11.2001, p. 1. Directive as last amended by Directive 2004/28/EC (OJ L 136, 30.4.2004, p. 58).

Changes to legislation:
There are currently no known outstanding effects for the Commission Regulation (EC) No 1451/2006.