Commission Regulation (EC) No 542/2008 of 16 June 2008 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 cyfluthrin and lectin extracted from red kidney beans (Phaseolus vulgaris) (Text with EEA relevance)

COMMISSION REGULATION (EC) No 542/2008

of 16 June 2008

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 cyfluthrin and lectin extracted from red kidney beans (*Phaseolus vulgaris*)

(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 opinion 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 cyfluthrin is currently included in Annex I to Regulation (EEC) No 2377/90 for bovine species for muscle, fat, liver and kidney and for bovine species for milk provided that, for milk, the further provisions in Council Directive 94/29/EC of 23 June 1994 amending the Annexes to Directives 86/362/EEC and 86/363/EEC on the fixing of maximum levels for pesticide residues in and on cereals and foodstuffs of animal origin respectively[(2)] are observed. Following a request to extend the existing entry for cyfluthrin for bovine species in Annex I to all ruminants, the Committee for Medicinal Products for Veterinary Use (hereinafter CVMP), having reviewed the maximum residue limits (hereinafter MRLs) already established for the substance cyfluthrin, concluded that the existing MRLs for bovine species could not be extrapolated to all ruminants, as residue data from ovine species was not available. The CVMP concluded that the extrapolation was possible for caprine species only. As a consequence, it is considered appropriate to extend the current entry in Annex I of Regulation (EEC) No 2377/90 for cyfluthrin to include caprine species, with the same

MRLs values as for bovine species, for muscle, fat, liver, kidney and milk, provided that, for milk, the further provisions in Directive 94/29/EC are observed.

(3) Lectin extracted from red kidney beans (*Phaseolus vulgaris*) is currently not included in the Annexes to Regulation (EEC) No 2377/90. Following an examination of an application for the establishment of MRLs for lectin extracted from red kidney beans (*Phaseolus vulgaris*) in porcine species, the CVMP concluded that there is no need to establish MRLs for lectin extracted from red kidney beans (*Phaseolus vulgaris*) and recommended the inclusion of that substance in Annex II for porcine species, for oral use only. As a consequence, it is found appropriate to insert this substance in Annex II to Regulation (EEC) No 2377/90 for porcine species, for oral use only.

(4) Regulation (EEC) No 2377/90 should therefore 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 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[3] to take account of the provisions of this Regulation.

(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 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 16 August 2008.

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

Done at Brussels, 16 June 2008.

For the Commission

Günter VERHEUGEN

Vice-President

ANNEX

A.In point 2.2.3 of Annex I (List of pharmacologically active substances for which maximum residue limits have been fixed), the entry for 'Cyfluthrin' is replaced by the following:

2.2.3.

PYRETHROIDS

Pharmacologically active substance(s)	**Marker residue**	**Animal species**	**MRLs**	**Target tissues**	**Other provisions**
'Cyfluthrin	Cyfluthrin (sum of isomers)	Bovine, caprine	10 µg/kg	Muscle	
			50 µg/kg	Fat	
			10 µg/kg	Liver	
			10 µg/kg	Kidney	
			20 µg/kg	Milk	Further provisions in Directive 94/29/EC are to be observed'

B. In point 6 of Annex II (List of substances not subject to maximum residue limits), the following substance is inserted:

6.

SUBSTANCES OF VEGETABLE ORIGIN

Pharmacologically active substance(s)	**Animal species**	**Other provisions**
'Lectin extracted from red kidney beans *(Phaseolus vulgaris)*	Porcine	For oral use only'

(**1**) OJ L 224, 18.8.1990, p. 1. Regulation as last amended by Commission Regulation (EC) No 203/2008 (OJ L 60, 5.3.2008, p. 18).

(**2**) OJ L 189, 23.7.1994, p. 67.

(**3**) 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 542/2008.