COMMISSION REGULATION (EC) No 1873/2003

of 24 October 2003

amending Annex 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

(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], as last amended by Commission Regulation (EC) No 1490/2003 [2], and in particular Articles 7 and 8 thereof,

Whereas:

(1) In accordance with Regulation (EEC) No 2377/90, maximum residue limits should be established for all pharmacologically active substances that are used within the Community in veterinary medicinal products intended for administration to food-producing animals.

(2) Maximum residue limits should be established after examination, within the Committee for Veterinary Medicinal Products (CVMP), of all the relevant information provided by applicants in accordance with the provisions of Regulation (EEC) No 2377/90 and taking into account all publicly available relevant scientific information concerning the safety of residues of the substance concerned for the consumer of foodstuffs of animal origin and in particular opinions of the Scientific Committee on Veterinary Measures related to Public Health (SCVPH) and the evaluations of the Joint FAO/WHO Expert Committee on Food Additives.

(3) In establishing maximum residue limits for residues of veterinary medicinal products in foodstuffs of animal origin, it is necessary to specify relevant food obtained from the treated animal ('target tissue') as well as the nature of the residue that is relevant for the monitoring of residues ('marker residue'). In the case of veterinary medicinal products intended for use in lactating animals maximum residue limits must be established for milk.

(4) Regulation (EEC) No 2377/90 provides that the establishment of maximum residue limits shall in no way prejudice the application of other relevant Community legislation.

(5) Progesterone is a progestagen hormone. It is subject to restrictions of use and control measures provided for hormones established in Council Directive 96/22/EC of 29 April 1996 [3], as amended by Directive 2003/74/EC of the European Parliament and of the Council [4], which rules that hormones may be only administered to farm animals for therapeutic or zootechnical purposes under specified conditions.

(6) The SCVPH repeatedly confirmed that the use of hormones for growth promotion purposes in meat production poses a potential health risk to consumers due to their intrinsic pharmacological and toxicological properties and epidemiological findings. However, at present the data available on progesterone are insufficient to make any quantitative estimate of the risk arising form the exposure to residues in meat and meat products originating from treated animals. No threshold levels can be defined for progesterone in this regard.

(7) The CVMP considered in its initial and subsequent evaluations, that it was not necessary, for the protection of public health, to establish maximum residues limits for progesterone when used in veterinary medicinal products authorised in accordance with Community legislation. It has therefore proposed to include progesterone in the list in Annex II of Regulation (EEC) No 2377/90. According to Article 13 of Regulation (EEC) No 2377/90, Member States may not prohibit or impede the putting into circulation of foodstuffs of animal origin from other Member States on the grounds that they contain residues of veterinary medicinal products if the substances concerned are listed in Annex II thereof.

(8) Animals also naturally produce progesterone. The level of endogenous secretion of progesterone in the animals is variable, depending notably on gender, age, breed and sexual cycle. Validated methods are available to detect progesterone in animal tissues. However, these methods cannot distinguish between naturally occurring hormones and residues of progesterone as a means of controlling that the restrictions of use established in Directive 96/22/EC are observed.

[1] OJ L 224, 18.8.1990, p. 1.
[2] OJ L 214, 26.8.2003, p. 3.
[3] OJ L 125, 23.5.1996, p. 3.
[4] OJ L 262, 14.10.2003, p. 17.

(9) According to Regulation (EC) No 178/2002 of the European Parliament and of the Council [1], as amended by Regulation (EC) No 1642/2003 [2], risk management shall take into account the results of risk assessment and other factors legitimate to the matter under consideration, such as detection methods and feasibility of controls for the purpose of avoiding risks from misuse of such substances.

(10) The Commission considers that safeguards as to the possibility of misuse of veterinary medicinal products containing progesterone are necessary. Restricting the terms of the use of progesterone to administration only via the intravaginal route in female animals of bovine, ovine, caprine and equine species provides this additional safeguard needed to avoid misuse as the relevant veterinary medicinal products cannot, due to their specific presentation, be realistically used for prohibited purposes. It is therefore considered appropriate to include progesterone in Annex II to Regulation (EEC) No 2377/90 in accordance with the Annex to the present proposal for a Commission Regulation, which limits the use of progesterone to this specific purpose and product formulation.

(11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products,

HAS ADOPTED THE FOLLOWING REGULATION:

Article 1

Annex II to Regulation (EEC) No 2377/90 is hereby amended as set out in the Annex hereto.

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 the 60th day following its publication.

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

Done at Brussels, 24 October 2003.

For the Commission
Erkki LIIKANEN
Member of the Commission

[1] OJ L 31, 1.2.2002, p. 1.
[2] OJ L 245, 29.9.2003, p. 4.

ANNEX

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

2. **Organic substances**

Pharmacologically active substance(s)	Animal species
'Progesterone (*)	Bovine, ovine, caprine, *Equidae* (female)
(*) Only for intravaginal therapeutic or zootechnical use and in accordance with the provisions of Directive 96/22/EC.'	