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(Acts whose publication is obligatory)

COUNCIL REGULATION (EC) No 1308/1999

of 15 June 1999

amending Regulation (EC) No 2377/90 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 37 thereof,

Having regard to the proposal from the Commission [1],

Having regard to the opinion of the European Parliament [2],

Having regard to the opinion of the Economic and Social Committee [3],

Whereas:

(1) since the adoption of Council Regulation (EEC) No 2377/90 [4], the regulatory environment for veterinary medicinal products has altered radically, in particular as a result of the entry into force of Council Regulation (EC) No 2309/93 of 22 July laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products [5] and of the amendments made by Directive 93/40/EEC [6] to Council Directive 81/851/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products [7], and to Council Directive 81/852/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products [8];

(2) the Committee for Veterinary Medicinal Products is henceforth responsible to the European Agency for the Evaluation of Medicinal Products and it falls to that Agency, through that Committee, to issue an opinion on the maximum residue limits of veterinary medicinal products which are acceptable in foodstuffs of animal origin in accordance with Regulation (EEC) No 2377/90;

(3) Council Regulation (EC) No 297/95 of 10 February 1995 on fees payable to the European Agency for the Evaluation of Medicinal Products [9] establishes the fees payable to the Agency for examining applications for the establishment, amendment and extension of maximum residue limits;

(4) it is necessary, consequently, to amend Regulation (EEC) No 2377/90 by conferring on the Agency the task of dealing with applications for the establishment, amendment and extension of maximum residue limits and by aligning the decision-making process with respect to the authorisation and supervision of medicinal products for veterinary use with that introduced by Regulation (EEC) No 2309/93;

(5) the Agreement on the application of sanitary and phytosanitary measures which emerged from the multilateral negotiations of the Uruguay Round, approved on behalf of the Community by Council Decision 94/800/EC of 22 December 1994 concerning the conclusion on behalf of the European Community, as regards matters within its competence, of the agreements reached in the Uruguay Round multilateral negotiations (1986 to 1994) [10] creates transparency obligations as regards

[1] OJ C 131, 12.5.1999, p. 14.
[2] Opinion delivered on 4 May 1999 (not yet published in the Official Journal).
[3] Opinion deliverd on 28 April 1999. (not yet published in the Official Journal).
[4] OJ L 224, 18.8.1990, p. 1. Regulation as last amended by Commission Regulation (EC) No 2728/98 (OJ L 343, 18.12.1998, p. 8).
[5] OJ L 214, 24.8.1993, p. 1. Regulation as amended by Commission Regulation (EEC) No 649/98 (OJ L 88, 24.3.1998, p. 7).
[6] OJ L 214, 24.8.1993, p. 31.
[7] OJ L 317, 6.11.1981, p. 1.
[8] OJ L 317, 6.11.1981, p. 16.
[9] OJ L 35, 15.2.1995, p. 1. Regulation as amended by Regulation (EC) No 2743/98 (OJ L 345, 19.12.1998, p. 3).
[10] OJ L 336, 23.12.1994, p. 1.

health measures; Regulation (EEC) No 2377/90 must therefore be adapted in order to enable the Community to fulfil its obligations under that Agreement;

(6) it is also necessary to rectify certain material errors in Regulation (EEC) No 2377/90,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EEC) No 2377/90 is hereby amended as follows:

1. Articles 6 and 7 shall be replaced by the following:

'Article 6

1. In order to obtain the inclusion in Annexes I, II or III of a pharmacologically active substance which is intended for use in veterinary medicinal products for administration to food-producing animals, an application to establish a maximum residue limit shall be submitted to the European Agency for the Evaluation of Medicinal Products set up by Council Regulation (EEC) No 2309/93 (*), hereinafter referred to as "the Agency".

This application shall contain the information and particulars referred to in Annex V of this Regulation and shall conform with the principles laid down in Directive 81/852/EEC.

2. The application shall also be accompanied by the fee payable to the Agency.

Article 7

1. The Committee for Veterinary Medicinal Products referred to in Article 27 of Regulation (EC) No 2309/93 (hereinafter "the Committee") shall be responsible for formulating the Agency's opinion on the classification of substances referred to in Annexes I, II, III or IV to this Regulation.

2. Articles 52 and 53 of Regulation (EEC) No 2309/93 shall be applicable for the purposes of this Regulation.

3. The Agency shall ensure that the Committee's opinion is delivered within a period of 120 days following the reception of a valid application.

If the information submitted by the applicant is not sufficient to enable such an opinion to be prepared, the Committee may ask the applicant to supply additional information within a specific time limit. The deadline for the opinion shall then be deferred until the additional information has been received.

4. The Agency shall forward the opinion to the applicant. Within 15 days of receipt of the opinion, the applicant may provide written notice to the Agency that he wishes to appeal. In that case he shall forward the detailed grounds for his appeal to the Agency within 60 days of receipt of the opinion. Within 60 days of the receipt of the grounds for appeal, the Committee shall consider whether its opinion should be revised and the reasons for the conclusion reached on the appeal shall be annexed to the report referred to in paragraph 5.

5. The Agency shall forward the definitive opinion of the Committee within 30 days of its adoption both to the Commission and to the applicant. The opinion shall be accompanied by a report describing the safety evaluation of the substance by the Committee, which shall give the grounds for its conclusions.

6. The Commission shall prepare draft measures taking account of Community legislation and shall start the procedure provided for in Article 8. The Committee referred to in Article 8 shall adapt its rules of procedure in order to take account of the tasks conferred on it by this Regulation.

(*) OJ L 214, 24.8.1993, p. 1'.

2. Article 8(1) shall be replaced by the following:

'1. Where the procedure laid down in this Article is to be followed, the Chairman shall, without delay, refer the matter to the Standing Committee on Veterinary Medicinal Products, hereinafter referred to as "the Standing Committee", either on his own initiative or at the request of a Member State.'

3. In Article 8(2) and (3), the word 'Committee' shall be replaced by 'Standing Committee'.

4. In Article 9(2), the first sentence shall be replaced by the following:

'The Commission shall as soon as possible examine the grounds given by the Member State concerned and, after consulting the Committee for Veterinary Medicinal Products, it shall then deliver its opinion forthwith and take appropriate measures; the person responsible for marketing may be requested to provide the Committee with oral or written explanations'.

5. In Article 10, the words 'Committee for Adaptation to Technical Progress of the Directives on Veterinary Medicinal Products' and the term 'Committee' shall be replaced by 'Standing Committee'.

6. Article 12 shall be replaced by the following:

'Article 12

As soon as possible after the amendment of Annexes I, II, III or IV, the Commission shall publish a summary of the assessment of the safety of the substances concerned that have been examined by the Committee for Veterinary Medicinal Products. The confidential nature of any proprietary data shall be respected. The

Agency shall provide the competent authorities and the Commission with appropriate methods for identifying pharmacologically active substances for which the MRL's have been determined in Annexes I and II'.

7. In Article 14, second paragraph, the first indent shall be replaced by the following:

'— until 1 January 1998 in the case of pyrazolinones (including pyrazolidinediones and phenylbutazones), nitroimidazoles and arsalinic acid, and'.

Article 2

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

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

Done at Luxembourg, 15 June 1999.

For the Council

The President

K.-H. FUNKE