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for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin (repealed)

Article 1

1 For the purposes of this Regulation, the following definitions shall apply:

a 'residues of veterinary medicinal products': means all pharmacologically active substances, whether active principles, excipients or degradation products, and their metabolites which remain in foodstuffs obtained from animals to which the veterinary medicinal product in question has been administered;

b 'maximum residue limit': means the maximum concentration of residue resulting from the use of a veterinary medicinal product (expressed in mg/kg or µg/kg on a fresh weight basis) which may be accepted by the Community to be legally permitted or recognized as acceptable in or on a food.

It is based on the type and amount of residue considered to be without any toxicological hazard for human health as expressed by the acceptable daily intake (ADI), or on the basis of a temporary ADI that utilizes an additional safety factor. It also takes into account other relevant public health risks as well as food technology aspects.

When establishing a maximum residue limit (MRL), consideration is also given to residues that occur in food of plant origin and/or come from the environment. Furthermore, the MRL may be reduced to be consistent with good practices in the use of veterinary drugs and to the extent that practical analytical methods are available.

2 This Regulation shall not apply to active principles of biological origin intended to produce active or passive immunity or to diagnose a state of immunity used in immunological veterinary medicinal products.

Article 2

The list of pharmacologically active substances used in veterinary medicinal products in respect of which maximum residue limits have been established shall be contained in Annex I, which shall be adopted in accordance with the procedure laid down in Article 8. Except as provided for in Article 9, any amendments to Annex I shall be adopted in accordance with the same procedure.

Article 3

Where, following an evaluation of a pharmacologically active substance used in veterinary medicinal products, it appears that it is not necessary for the protection of public health to establish a maximum residue limit, that substance shall be included in a list in Annex II, which shall be adopted in accordance with the procedure laid down in Article 8. Except as provided for in Article 9, any amendments to Annex II shall be adopted in accordance with the same procedure.

Article 4

A provisional maximum residue limit may be established for a pharmacologically active substance used in veterinary medicinal products on the date of entry into force of this Regulation, provided that there are no grounds for supposing that residues of the substance concerned at the level proposed present a hazard for the health of the consumer. A provisional maximum residue limit shall apply for a defined period of time, which shall not exceed five years. That period may be extended once only in exceptional

cases for a period not in excess of two years if that proves expedient for the completion of scientific studies in progress.

In exceptional circumstances, a provisional maximum residue limit may also be established for a pharmacologically active substance not previously used in veterinary medicinal products on the date of entry into force of this Regulation provided that there are no grounds for supposing that residues of the substance concerned at the limit proposed present a hazard for the health of the consumer.

The list of pharmacologically active substances used in veterinary medicinal products in respect of which provisional maximum residue limits have been established shall be contained in Annex III, which shall be adopted in accordance with the procedure laid down in Article 8. Except as provided for in Article 9, any amendments to Annex III shall be adopted in accordance with the same procedure.

Article 5

Where it appears that a maximum residue limit cannot be established in respect of a pharmacologically active substance used in veterinary medicinal products because residues of the substances concerned, at whatever limit, in foodstuffs of animal origin constitute a hazard to the health of the consumer, that substance shall be included in a list in Annex IV, which shall be adopted in accordance with the procedure laid down in Article 8. Except as provided for in Article 9, any amendments to Annex IV shall be adopted in accordance with the same procedure.

The administration of the substances listed in Annex IV to food-producing animals shall be prohibited throughout the Community.

[F1 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[(1)], 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.

Textual Amendments

F1 Substituted by 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.

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.**]**

Textual Amendments

F1 Substituted by 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.

[F2 Article 8

1 The Commission shall be assisted by the Standing Committee on Veterinary Medicinal Products.

2 Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC[(2)] shall apply.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3 The Standing Committee shall adopt its Rules of Procedure.**]**

Textual Amendments

F2 Substituted by Council Regulation (EC) No 806/2003 of 14 April 2003 adapting to Decision 1999/468/EC the provisions relating to committees which assist the Commission in the exercise of its implementing powers laid down in Council instruments adopted in accordance with the consultation procedure (qualified majority).

Article 9

1 Where a Member State, as a result of new information or a reassessment of existing information, considers that the urgent amendment of a provision contained in Annexes I to IV is necessary in order to protect human or animal health, and therefore requires swift action to be taken, that Member State may temporarily suspend the operation of the provision concerned in its own territory. In that case, it shall immediately notify the other Member States and the Commission of the measures, attaching a statement of the reasons therefor.

2 **[**F1The 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**]**. The Commission shall immediately notify the Council and the Member States of any measures taken. Any Member State may refer the Commission's measures to the Council within 15 days of such notification. The Council, acting by a qualified majority, may take a different decision within 30 days of the date on which the matter was referred to it.

3 If the Commission considers that it is necessary to amend the provision of Annex I to IV concerned in order to resolve the difficulties referred to in paragraph 1 and to ensure the protection of human health, it shall initiate the procedure laid down in Article 10 with a view to adopting those amendments; the Member State which has taken measures under paragraph 1 may maintain them until the Council or the Commission has taken a decision in accordance with the abovementioned procedure.

Textual Amendments

F1 Substituted by 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.

*[*F2*Article 10*

1 The Commission shall be assisted by the Standing Committee on Veterinary Medicinal Products.

2 Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC shall apply.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at 15 days.**]**

Textual Amendments

F2 Substituted by Council Regulation (EC) No 806/2003 of 14 April 2003 adapting to Decision 1999/468/EC the provisions relating to committees which assist the Commission in the exercise of its implementing powers laid down in Council instruments adopted in accordance with the consultation procedure (qualified majority).

Article 11

Any changes which are necessary to adapt Annex V to take account of scientific and technical progress shall be adopted in accordance with the procedure laid down in Article 2c of Directive 81/852/EEC.

[F1 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 **[**X1Annexes I and III.**]]**

Editorial Information

X1 Substituted by Corrigendum to Council Regulation (EC) No 1308/1999 of 15 June 1999 amending 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 (Official Journal of the European Communities L 156 of 23 June 1999).

Textual Amendments

F1 Substituted by 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.

Article 13

Member States may not prohibit or impede the putting into circulation within their territories of foodstuffs of animal origin originating in other Member States on the grounds that they contain residues of veterinary medicinal products if the quantity of residue does not exceed the maximum residue limit provided for in Annex I or III, or if the substance concerned is listed in Annex II.

Article 14

With effect from 1 January 1997, the administration to food-producing animals of veterinary medicinal products containing pharmacologically active substances which are not mentioned in Annexes I, II or III shall be prohibited within the Community, except in the case of clinical trials accepted by the competent authorities following notification or authorization in accordance with the legislation in force and which do not cause foodstuffs obtained from livestock participating in such trials to contain residues which constitute a hazard to human health.

[F3However, the date referred to in the previous subparagraph shall be deferred for substances the use of which was authorized on the date of entry into force of this Regulation and in respect of which documented applications for the establishment of maximum residue limits have been lodged with the Commission or with the European Agency for the Evaluation of Medicinal Products before 1 January 1996:

— **[**F1until 1 January 1998 in the case of pyrazolinones (including pyrazolidinediones and phenylbutazones), nitroimidazoles and arsalinic acid, and**]**

— until 1 January 2000 in the case of other substances.

The Agency shall publish a list of these substances before 7 June 1997.**]**

Textual Amendments

F1 Substituted by 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.

F3 Inserted by Council Regulation (EC) No 434/97 of 3 March 1997 amending 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.

Article 15

This Regulation shall in no way prejudice the application of Community legislation prohibiting the use in livestock farming of certain substances having a hormonal action.

Nothing in this Regulation shall prejudice the measures taken by Member States to prevent the unauthorized use of veterinary medicinal products.

Article 16

This Regulation shall enter into force on 1 January 1992.

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

(1) **[**[F1]OJ L 214, 24.8.1993, p. 1**]**

(2) **[**[F2]OJ L 184, 17.7.1999, p. 23.**]**

Textual Amendments

F1 Substituted by 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.

F2 Substituted by Council Regulation (EC) No 806/2003 of 14 April 2003 adapting to Decision 1999/468/EC the provisions relating to committees which assist the Commission in the exercise of its implementing powers laid down in Council instruments adopted in accordance with the consultation procedure (qualified majority).

Status:
Point in time view as at 22/02/2005.

Changes to legislation:
There are currently no known outstanding effects for the Council Regulation (EEC) No 2377/90 (repealed).