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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

(OJ L 224, 18.8.1990, p. 1)

Amended by:

		Official Journal		
		No	page	date
►M1	Commission Regulation (EEC) No 675/92 of 18 March 1992	L 73	8	19.3.1992
►M2	Commission Regulation (EEC) No 762/92 of 27 March 1992	L 83	14	28.3.1992
►M3	Commission Regulation (EEC) No 3093/92 of 27 October 1992	L 311	18	28.10.1992
►M4	Commission Regulation (EEC) No 895/93 of 16 April 1993	L 93	10	17.4.1993
►M5	Council Regulation (EEC) No 2901/93 of 18 October 1993	L 264	1	23.10.1993
►M6	Commission Regulation (EC) No 3425/93 of 14 December 1993	L 312	12	15.12.1993
►M7	Commission Regulation (EC) No 3426/93 of 14 December 1993	L 312	15	15.12.1993
►M8	Commission Regulation (EC) No 955/94 of 28 April 1994	L 108	8	29.4.1994
►M9	Commission Regulation (EC) No 1430/94 of 22 June 1994	L 156	6	23.6.1994
►M10	Commission Regulation (EC) No 2701/94 of 7 November 1994	L 287	7	8.11.1994
►M11	Commission Regulation (EC) No 2703/94 of 7 November 1994	L 287	19	8.11.1994
►M12	Commission Regulation (EC) No 3059/94 of 15 December 1994	L 323	15	16.12.1994
►M13	Commission Regulation (EC) No 1102/95 of 16 May 1995	L 110	9	17.5.1995
►M14	Commission Regulation (EC) No 1441/95 of 26 June 1995	L 143	22	27.6.1995
►M15	Commission Regulation (EC) No 1442/95 of 26 June 1995	L 143	26	27.6.1995
►M16	Commission Regulation (EC) No 1798/95 of 25 July 1995	L 174	20	26.7.1995
►M17	Commission Regulation (EC) No 2796/95 of 4 December 1995	L 290	1	5.12.1995
►M18	Commission Regulation (EC) No 2804/95 of 5 December 1995	L 291	8	6.12.1995
►M19	Commission Regulation (EC) No 281/96 of 14 February 1996	L 37	9	15.2.1996
►M20	Commission Regulation (EC) No 282/96 of 14 February 1996	L 37	12	15.2.1996
►M21	Commission Regulation (EC) No 1140/96 of 25 June 1996	L 151	6	26.6.1996
►M22	Commission Regulation (EC) No 1147/96 of 25 June 1996	L 151	26	26.6.1996
►M23	Commission Regulation (EC) No 1311/96 of 8 July 1996	L 170	4	9.7.1996
►M24	Commission Regulation (EC) No 1312/96 of 8 July 1996	L 170	8	9.7.1996
►M25	Commission Regulation (EC) No 1433/96 of 23 July 1996	L 184	21	24.7.1996
►M26	Commission Regulation (EC) No 1742/96 of 6 September 1996	L 226	5	7.9.1996
►M27	Commission Regulation (EC) No 1798/96 of 17 September 1996	L 236	23	18.9.1996
►M28	Commission Regulation (EC) No 2010/96 of 21 October 1996	L 269	5	22.10.1996
►M29	Commission Regulation (EC) No 2017/96 of 22 October 1996	L 270	2	23.10.1996
►M30	Commission Regulation (EC) No 2034/96 of 24 October 1996	L 272	2	25.10.1996

►**M31** Commission Regulation (EC) No 17/97 of 8 January 1997	L 5	12	9.1.1997
►**M32** Commission Regulation (EC) No 211/97 of 4 February 1997	L 35	1	5.2.1997
►**M33** Commission Regulation (EC) No 270/97 of 14 February 1997	L 45	8	15.2.1997
►**M34** Council Regulation (EC) No 434/97 of 3 March 1997	L 67	1	7.3.1997
►**M35** Commission Regulation (EC) No 716/97 of 23 April 1997	L 106	10	24.4.1997
►**M36** Commission Regulation (EC) No 748/97 of 25 April 1997	L 110	21	26.4.1997
►**M37** Commission Regulation (EC) No 749/97 of 25 April 1997	L 110	24	26.4.1997
►**M38** Commission Regulation (EC) No 1836/97 of 24 September 1997	L 263	6	25.9.1997
►**M39** Commission Regulation (EC) No 1837/97 of 24 September 1997	L 263	9	25.9.1997
►**M40** Commission Regulation (EC) No 1838/97 of 24 September 1997	L 263	14	25.9.1997
►**M41** Commission Regulation (EC) No 1850/97 of 25 September 1997	L 264	12	26.9.1997
►**M42** Commission Regulation (EC) No 121/98 of 16 January 1998	L 11	11	17.1.1998
►**M43** Commission Regulation (EC) No 426/98 of 23 February 1998	L 53	3	24.2.1998
►**M44** Commission Regulation (EC) No 613/98 of 18 March 1998	L 82	14	19.3.1998
►**M45** Commission Regulation (EC) No 1000/98 of 13 May 1998	L 142	18	14.5.1998
►**M46** Commission Regulation (EC) No 1076/98 of 27 May 1998	L 154	14	28.5.1998
►**M47** Commission Regulation (EC) No 1191/98 of 9 June 1998	L 165	6	10.6.1998
►**M48** Commission Regulation (EC) No 1568/98 of 17 July 1998	L 205	1	22.7.1998
►**M49** Commission Regulation (EC) No 1569/98 of 17 July 1998	L 205	7	22.7.1998
►**M50** Commission Regulation (EC) No 1570/98 of 17 July 1998	L 205	10	22.7.1998
►**M51** Commission Regulation (EC) No 1916/98 of 9 September 1998	L 250	8	10.9.1998
►**M52** Commission Regulation (EC) No 1917/98 of 9 September 1998	L 250	13	10.9.1998
►**M53** Commission Regulation (EC) No 1958/98 of 15 September 1998	L 254	7	16.9.1998
►**M54** Commission Regulation (EC) No 2560/98 of 27 November 1998	L 320	28	28.11.1998
►**M55** Commission Regulation (EC) No 2686/98 of 11 December 1998	L 337	20	12.12.1998
►**M56** Commission Regulation (EC) No 2692/98 of 14 December 1998	L 338	5	15.12.1998
►**M57** Commission Regulation (EC) No 2728/98 of 17 December 1998	L 343	8	18.12.1998
►**M58** Commission Regulation (EC) No 508/1999 of 4 March 1999	L 60	16	9.3.1999

Corrected by:

►**C1** Corrigendum, OJ L 222, 20.9.1995, p. 17 (1442/95)

►**C2** Corrigendum, OJ L 316, 5.12.1996, p. 37 (1442/95)

►**C3** Corrigendum, OJ L 76, 18.3.1997, p. 34 (1442/95)

►**C4** Corrigendum, OJ L 271, 8.10.1998, p. 42 (1568/98)

▼B

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

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 43 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 the use of veterinary medicinal products in food-producing animals may result in the presence of residues of foodstuffs obtained from treated animals;

Whereas as a result of scientific and technical progress it is possible to detect the presence of residues of veterinary medicines in foodstuffs at ever lower levels; whereas it is therefore necessary to establish maximum residue limits for pharmacologically active substances which are used in veterinary medicinal products in respect of all the various foodstuffs of animal origin, including meat, fish, milk, eggs and honey;

Whereas in order to protect public health, maximum residue limits must be established in accordance with generally recognized principles of safety assessment, taking into account any other scientific assessment of the safety of the substances concerned which may have been undertaken by international organizations, in particular the Codex Alimentarius or, where such substances are used for other purposes, by other scientific committees established within the Community;

Whereas the use of veterinary medicinal products plays an important part in agricultural production; whereas the establishment of maximum residue levels will facilitate the marketing of foodstuffs of animal origin;

Whereas the establishment of different maximum residue levels by Member States may hinder the free movement of foodstuffs and of veterinary medicinal products themselves;

Whereas it is therefore necessary to lay down a procedure for the establishment of maximum residue levels of veterinary medicinal products by the Community, following a single scientific assessment of the highest possible quality;

Whereas the need for the establishment of maximum residue levels throughout the Community is recognized in the Community rules relating to trade in foodstuffs of animal origin;

Whereas provisions must be adopted with a view to the systematic establishment of maximum residue levels for new substances capable of pharmacological action intended for administration to food-producing animals;

Whereas arrangements must also be made for the establishment of maximum residue levels for substances which are currently used in veterinary medicines administered to food-producing animals; whereas, however, in view of the complexity of this matter and the large number of substances involved, long transitional arrangements are required;

Whereas, after scientific assessment by the Committee for Veterinary Medicinal Products, maximum residue levels must be adopted by a

([1]) OJ No C 61, 10. 3. 1989. p. 5.
([2]) OJ No C 96, 17. 4. 1990, p. 273.
([3]) OJ No C 201, 17. 8. 1989, p. 1.

▼B

rapid procedure which ensures close cooperation between the Commission and the Member States through the Committee set up under 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 [1], as last amended by Directive 87/20/EEC [2]; whereas an urgent procedure is also required to ensure the swift review of any tolerance which might prove insufficient to protect public health;

Whereas medicinally induced immunological responses are usually indistinguishable from those which arise naturally, and do not affect consumers of food of animal origin;

Whereas the information necessary to assess the safety of residues should be presented in accordance with the principles laid down by Directive 81/852/EEC,

HAS ADOPTED THIS REGULATION:

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.

[1] OJ No L 317, 6. 11. 1981, p. 16.
[2] OJ No L 15, 17. 1. 1987, p. 34.

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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.

Article 6

1. In order to obtain the inclusion in Annex I, II, or III of a new pharmacologically active substance which is:

— intended for use in veterinary medicinal products for administration to food-producing animals, and

— intended to be placed on the market of one or more Member States which have not previously authorized the use of the substance concerned in food-producing animals,

the person responsible for marketing shall submit an application to the Commission. The application shall contain the information and particulars referred to in Annex V and shall comply with the principles laid down in Directive 81/852/EEC.

2. After verifying within a period of 30 days that the application is submitted in correct form, the Commission shall forthwith submit the application for examination by the Committee for Veterinary Medicinal

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Products set up under Article 16 of Directive 81/851/EEC. The Committee shall appoint one of its members to act as rapporteur and to undertake an initial evaluation of the application.

3. Within 120 days of referral of the application to the Committee for Veterinary Medicinal Products, and having regard to the observations formulated by the members of the Committee, the Commission shall prepare a draft of the measures to be taken. If the information submitted by the person responsible for marketing is insufficient to enable such a draft to be prepared, that person will be requested to provide the Committee with additional information for examination. The rapporteur shall update the evaluation report to take account of the additional information received.

4. Within 90 days of receipt of the additional information referred to in paragraph 3, the Commission shall prepare a draft of the measures to be taken, which shall forthwith be communicated to the Member States and the person responsible for marketing. Within a further 60 days, the person responsible for marketing may, at his request, provide oral or written explanations for consideration by the Committee for Veterinary Medicinal Products. The Commission may, at the request of the applicant, extend this time limit.

5. Within a further 60 days the Commission shall submit the draft measures to the Committee for the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Veterinary Medicinal Products Sector, set up under Article 2b of Directive 81/852/EEC, for the application of the procedure laid down in Article 8.

Article 7

1. Paragraphs 2 to 6 shall apply in respect of pharmacologically active substances which are authorized for use in veterinary medicinal products on the date of entry into force of this Regulation.

2. After consulting the Committee on Veterinary Medicinal Products, the Commission shall publish a timetable for the consideration of these substances, including time limits for submission of the information referred to in Annex V.

The persons responsible for marketing the veterinary medicinal products concerned shall ensure that all relevant information is submitted to the Commission in accordance with the requirements of Annex V and in conformity with the principles laid down in Directive 81/852/EEC before expiry of the relevant time limits. The competent authorities of the Member States shall bring any other relevant information to the attention of the Commission.

3. After verifying within 30 days that the information is submitted in correct form, the Commission shall forthwith submit the information for examination to the Committee for Veterinary Medicinal Products, which shall deliver its opinion within a renewable period of 120 days. That Committee shall appoint one of its members to act as rapporteur and to undertake an evaluation of the information.

4. Having regard to the observations formulated by the members of the Committee for Veterinary Medicinal Products, the Commission shall prepare, within a maximum period of 30 days, a draft of the measures to be taken. If the information submitted by the person responsible for marketing is insufficient to enable such a draft to be prepared, that person will be requested to provide additional information, within a specified period, for examination by the Committee. The rapporteur shall update the evaluation report to take account of the additional information received.

5. The draft of the measures to be taken shall be communicated forthwith by the Commission to the Member States and those persons responsible for marketing who have submitted information to the Commission before expiry of the time limit established in accordance with paragraph 2. These persons may, at their request, provide oral or

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written explanations to the Committee for Veterinary Medicinal Products.

6. The Commission shall forthwith submit the draft measures to the Committee for Adaptation to Technical Progress of the Directives on Veterinary Medicinal Products for the application of the procedure laid down in Article 8.

Article 8

1. Where the procedure laid down in this Article is to be followed, the chairman shall, without delay, refer the matter to the Committee for Adaptation to Technical Progress of the Directives on Veterinary Medicinal Products either on his own initiative or at the request of a representative of a Member State.

2. The representative of the Commission shall submit a draft of the measures to be adopted to the Committee for Adaptation to Technical Progress. The Committee shall deliver its opinion on the draft within a time limit set by the chairman, having regard to the urgency of the matter. It shall act by a qualified majority, the votes of the Member States being weighted as provided for in Article 148 (2) of the Treaty. The chairman shall not vote.

3. (a) The Commission shall adopt the measures envisaged where they are in accordance with the opinion of the Committee.

(b) Where the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is adopted, the Commission shall without delay propose to the Council the measures to be adopted. The Council shall act by a qualified majority.

(c) If, after a period of three months of the proposal being referred to it, the Council has not acted, the proposed measures shall be adopted by the Commission, unless the Council has voted against them by a simple 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. The Commission shall as soon as possible examine the grounds given by the Member State concerned and, after consulting the Member States within 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 above-mentioned procedure.

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Article 10

1. Where the procedure laid down in this Article is to be followed, the chairman shall, without delay, refer the matter to the Committee for Adaptation to Technical Progress of the Directives on Veterinary Medicinal Products either on his own initiative or at the request of a representative of a Member State.

2. The representative of the Commission shall submit to the Committee a draft of the measures to be adopted. The Committee shall deliver its opinion on the draft within a time limit set by the chairman, having regard to the urgency of the matter. It shall act by a qualified majority, the votes of the Member States being weighted as provided for in Article 148 (2) of the Treaty. The chairman shall not vote.

3. (a) The Commission shall adopt the measures envisaged, where they are in accordance with the opinion of the Committee.

(b) Where the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is adopted, the Commission shall without delay propose to the Council the measures to be adopted. The Council shall act by a qualified majority.

(c) If within 15 days of the proposals being submitted to it, the Council has not acted, the proposed measures shall be adopted by the Commission.

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.

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 by the Committee for Veterinary Medicinal Products. The confidential nature of any proprietary data shall be respected.

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.

▼M34

However, 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:

— until 1 January 1998 in the case of products derived from pyrasolidon, nitroimidazoles, arsanilic acid and phenylbutazone, and

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

▼M34

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

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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.

▼M58

ANNEX I

LIST OF PHARMACOLOGICALLY ACTIVE SUBSTANCES FOR WHICH MAXIMUM RESIDUE LIMITS HAVE BEEN FIXED

1. Anti-infectious agents

1.1. Chemotheurapeutics

1.1.1. Sulfonamides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
All substances belonging to the sulfonamide group	Parent drug	All food-producing species	100 µg/kg	Muscle	The combined total residues of all substances within the sulfonamide group should not exceed 100 µg/kg
			100 µg/kg	Fat	
			100 µg/kg	Liver	
			100 µg/kg	Kidney	
		Bovine, ovine, caprine	100 µg/kg	Milk	

1.1.2. Diamino pyrimidine derivatives

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Baquiloprim	Baquiloprim	Bovine	10 µg/kg	Fat	
			300 µg/kg	Liver	
			150 µg/kg	Kidney	
			30 µg/kg	Milk	
		Porcine	40 µg/kg	Skin and fat	
			50 µg/kg	Liver	
			50 µg/kg	Kidney	
Trimethoprim	Trimethoprim	Bovine	50 µg/kg	Muscle	
			50 µg/kg	Fat	
			50 µg/kg	Liver	

▼M58

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
			50 µg/kg	Kidney	
			50 µg/kg	Milk	
		Porcine	50 µg/kg	Muscle	
			50 µg/kg	Skin and fat	
			50 µg/kg	Liver	
			50 µg/kg	Kidney	
		Equidae	100 µg/kg	Muscle	
			100 µg/kg	Fat	
			100 µg/kg	Liver	
			100 µg/kg	Kidney	
		Poultry	50 µg/kg	Muscle	
		Not for use in animals from which eggs are produced for human consumption	50 µg/kg	Skin and fat	
			50 µg/kg	Liver	
			50 µg/kg	Kidney	
		Fin fish	50 µg/kg	Muscle and skin in natural proportions	

1.2. Antibiotics

1.2.1. Penicillins

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Amoxicyllin	Amoxicyllin	All food-producing species	50 µg/kg	Muscle	
			50 µg/kg	Fat	
			50 µg/kg	Liver	
			50 µg/kg	Kidney	
			4 µg/kg	Milk	

▼M58

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Ampicillin	Ampicillin	All food-producing species	50 µg/kg	Muscle	
			50 µg/kg	Fat	
			50 µg/kg	Liver	
			50 µg/kg	Kidney	
			4 µg/kg	Milk	
Benzylpenicillin	Benzylpenicillin	All food-producing species	50 µg/kg	Muscle	
			50 µg/kg	Fat	
			50 µg/kg	Liver	
			50 µg/kg	Kidney	
			4 µg/kg	Milk	
Cloxacillin	Cloxacillin	All food-producing species	300 µg/kg	Muscle	
			300 µg/kg	Fat	
			300 µg/kg	Liver	
			300 µg/kg	Kidney	
			30 µg/kg	Milk	
Dicloxacillin	Dicloxacillin	All food-producing species	300 µg/kg	Muscle	
			300 µg/kg	Fat	
			300 µg/kg	Liver	
			300 µg/kg	Kidney	
			30 µg/kg	Milk	
Oxacillin	Oxacillin	All food-producing species	300 µg/kg	Muscle	
			300 µg/kg	Fat	
			300 µg/kg	Liver	
			300 µg/kg	Kidney	

▼M58

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
			30 µg/kg	Milk	
Penethamate	Benzylpenicillin	Bovine	50 µg/kg	Muscle	
			50 µg/kg	Fat	
			50 µg/kg	Liver	
			50 µg/kg	Kidney	
			4 µg/kg	Milk	

1.2.2. Cephalosporins

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Cefazolin	Cefazolin	Bovine, ovine, caprine	50 µg/kg	Milk	
Cefquinome	Cefquinome	Bovine	50 µg/kg	Muscle	
			50 µg/kg	Fat	
			100 µg/kg	Liver	
			200 µg/kg	Kidney	
			20 µg/kg	Milk	

1.2.3. Quinolones

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Danofloxacin	Danofloxacin	Bovine	200 µg/kg	Muscle	
		Not for use in animals from which milk is produced for human consumption	100 µg/kg	Fat	
			400 µg/kg	Liver	
			400 µg/kg	Kidney	
		Chicken	200 µg/kg	Muscle	

▼M58

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
		Not for use in animals from which eggs are produced for human consumption	100 µg/kg	Skin and fat	
			400 µg/kg	Liver	
			400 µg/kg	Kidney	
Difloxacin	Difloxacin	Chicken, turkey	300 µg/kg	Muscle	
			400 µg/kg	Skin and fat	
			1 900 µg/kg	Liver	
			600 µg/kg	Kidney	
Enrofloxacin	Sum of enrofloxacin and ciprofloxacin	Bovine	100 µg/kg	Muscle	
			100 µg/kg	Fat	
			300 µg/kg	Liver	
			200 µg/kg	Kidney	
			100 µg/kg	Milk	
		Rabbits	100 µg/kg	Muscle	
			100 µg/kg	Fat	
			200 µg/kg	Liver	
			300 µg/kg	Kidney	
		Porcine	100 µg/kg	Muscle	
			100 µg/kg	Skin and fat	
			200 µg/kg	Liver	
			300 µg/kg	Kidney	
		Poultry	100 µg/kg	Muscle	
		Not for use in animals from which eggs are produced for human consumption	100 µg/kg	Skin and fat	
			200 µg/kg	Liver	

▼M58

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
			300 µg/kg	Kidney	
Sarafloxacin	Sarafloxacin	Chicken	10 µg/kg	Skin and fat	
			100 µg/kg	Liver	
		Salmonidae	30 µg/kg	Muscle and skin in natural proportions	

1.2.4. Macrolides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Spiramycin	Sum of spiramycin and neospiramycin	Bovine	200 µg/kg	Muscle	
			300 µg/kg	Fat	
			300 µg/kg	Liver	
			300 µg/kg	Kidney	
			200 µg/kg	Milk	
		Chicken	200 µg/kg	Muscle	
			300 µg/kg	Skin and fat	
			400 µg/kg	Liver	
Tilmicosin	Tilmicosin	Bovine, ovine, porcine	50 µg/kg	Muscle	
			50 µg/kg	Fat	
			1 000 µg/kg	Liver	
			1 000 µg/kg	Kidney	
		Ovine	50 µg/kg	Milk	
		Chicken	75 µg/kg	Muscle	Not for use in animals from which eggs are produced for human consumption
			75 µg/kg	Skin and fat	
			1 000 µg/kg	Liver	
			250 µg/kg	Kidney	

▼M58

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Tylosin	Tylosin A	Bovine	100 µg/kg	Muscle	
			100 µg/kg	Fat	
			100 µg/kg	Liver	
			100 µg/kg	Kidney	
			50 µg/kg	Milk	
		Porcine	100 µg/kg	Muscle	
			100 µg/kg	Skin and fat	
			100 µg/kg	Liver	
			100 µg/kg	Kidney	
		Poultry	100 µg/kg	Muscle	
		Not for use in hens producing eggs for human consumption	100 µg/kg	Skin and fat	
			100 µg/kg	Liver	
			100 µg/kg	Kidney	

1.2.5. Florfenicol and related compounds

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Florfenicol	Sum of florfenicol and its metabolites measured as florfenicol-amine	Bovine	200 µg/kg	Muscle	
			3 000 µg/kg	Liver	
			300 µg/kg	Kidney	
Thiamphenicol	Thiamphenicol	Bovine	50 µg/kg	Muscle	
			50 µg/kg	Fat	
			50 µg/kg	Liver	
			50 µg/kg	Kidney	
			50 µg/kg	Milk	

▼M58

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
		Chicken	50 µg/kg	Muscle	
		Not for use in animals from which eggs are produced for human consumption	50 µg/kg	Skin and fat	
			50 µg/kg	Liver	
			50 µg/kg	Kidney	

1.2.6. Tetracyclines

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Chlortetracycline	Sum of parent drug and its 4- epimer	All food-producing species	100 µg/kg	Muscle	
			300 µg/kg	Liver	
			600 µg/kg	Kidney	
			100 µg/kg	Milk	
			200 µg/kg	Eggs	
Doxycycline	Doxycycline	Bovine	100 µg/kg	Muscle	
		Not for use in animals from which milk is produced for human consumption	300 µg/kg	Liver	
			600 µg/kg	Kidney	
		Porcine	100 µg/kg	Muscle	
			300 µg/kg	Skin and fat	
			300 µg/kg	Liver	
			600 µg/kg	Kidney	
		Poultry	100 µg/kg	Muscle	

▼M58

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
		Not for use in animals from which eggs are produced for human consumption	300 µg/kg	Skin and fat	
			300 µg/kg	Liver	
			600 µg/kg	Kidney	
Oxytetracycline	Sum of parent drug and its 4-epimer	All food-producing species	100 µg/kg	Muscle	
			300 µg/kg	Liver	
			600 µg/kg	Kidney	
			100 µg/kg	Milk	
			200 µg/kg	Eggs	
Tetracycline	Sum of parent drug and its 4-epimer	All food-producing species	100 µg/kg	Muscle	
			300 µg/kg	Liver	
			600 µg/kg	Kidney	
			100 µg/kg	Milk	
			200 µg/kg	Eggs	

1.2.7. Naphtalene-ringed ansamycin

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Rifaximin	Rifaximin	Bovine	60 µg/kg	Milk	

1.2.8. Pleuromutilines

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Valnemulin	Valnemulin	Porcine	50 µg/kg	Muscle	
			500 µg/kg	Liver	

▼M58

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
			100 µg/kg	Kidney	

2. Antiparasitic agents

2.1. Agents acting against endoparasites

2.1.1. Salicylanilides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Closantel	Closantel	Bovine	1 000 µg/kg	Muscle	
			3 000 µg/kg	Fat	
			1 000 µg/kg	Liver	
			3 000 µg/kg	Kidney	
		Ovine	1 500 µg/kg	Muscle	
			2 000 µg/kg	Fat	
			1 500 µg/kg	Liver	
			5 000 µg/kg	Kidney	

2.1.2. Tatra-hydro-imidazoles (imidazolthiazoles)

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Levamisole	Levamisole	Bovine, ovine, porcine, poultry	10 µg/kg	Muscle	
			10 µg/kg	Fat	
			100 µg/kg	Liver	
			10 µg/kg	Kidney	

▼M58

2.1.3. Benzimidazoles and pro-benzimidazoles

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Albendazole	Sum of albendazole sulphoxide, albendazole sulphone, and albendazole 2-amino sulphone, expressed as albendazole	Bovine, ovine	100 µg/kg	Muscle	
			100 µg/kg	Fat	
			1 000 µg/kg	Liver	
			500 µg/kg	Kidney	
			100 µg/kg	Milk	
Febantel	Sum of extractable residues which may be oxidised to oxfendazole	Bovine, ovine	10 µg/kg	Milk	
		Bovine, ovine, porcine, equidae	50 µg/kg	Muscle	
			50 µg/kg	Fat	
			500 µg/kg	Liver	
			50 µg/kg	Kidney	
Fenbendazole	Sum of extractable residues which may be oxidised to oxfendazole sulphone	Bovine, ovine	10 µg/kg	Milk	
		Bovine, ovine, porcine, equide	50 µg/kg	Muscle	
			50 µg/kg	Fat	
			500 µg/kg	Liver	
			50 µg/kg	Kidney	
Flubendazole	Sum of flubendazole and (2-amino 1H-benzimidazol-5-yl) (4fluorophenyl) methanone	Porcine, chicken, game birds	50 µg/kg	Muscle	
			50 µg/kg	Skin and fat	

▼M58

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
			400 µg/kg	Liver	
			300 µg/kg	Kidney	
	Flubendazole	Chicken	400 µg/kg	Eggs	
Oxfendazole	Sum of extractable residues which may be oxidised to oxfendazole sulphone	Bovine, ovine	10 µg/kg	Milk	
		Bovine, ovine, porcine, equidae	50 µg/kg	Muscle	
			50 µg/kg	Fat	
			500 µg/kg	Liver	
			50 µg/kg	Kidney	
Oxibendazole	Oxibendazole	Porcine	100 µg/kg	Muscle	
			500 µg/kg	Skin and fat	
			200 µg/kg	Liver	
			100 µg/kg	Kidney	
Thiabendazole	Sum of thiabendazole and 5-hydroxythiabendazole	Bovine	100 µg/kg	Muscle	
			100 µg/kg	Fat	
			100 µg/kg	Liver	
			100 µg/kg	Kidney	
			100 µg/kg	Milk	
Triclabendazole	Sum of extractable residues that may be oxidised to ketotriclabendazole	Bovine, ovine	100 µg/kg	Muscle	Not for use in animals from which milk is produced for human consumption
			100 µg/kg	Liver	
			100 µg/kg	Kidney	

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2.2. Agents acting against ectoparasites

2.2.1. Organophosphates

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Diazinon	Diazinon	Bovine, ovine, caprine	20 µg/kg	Milk	
		Bovine, porcine, ovine, caprine	20 µg/kg	Muscle	
			700 µg/kg	Fat	
			20 µg/kg	Liver	
			20 µg/kg	Kidney	

2.2.2. Formamidines

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Amitraz	Sum of amitraz and all metabolites containing the 2,4-DMA moiety, expressed as amitraz	Bovine	200 µg/kg	Fat	
			200 µg/kg	Liver	
			200 µg/kg	Kidney	
			10 µg/kg	Milk	
		Ovine	400 µg/kg	Fat	
			100 µg/kg	Liver	
			200 µg/kg	Kidney	
			10 µg/kg	Milk	
		Porcine	400 µg/kg	Skin and fat	
			200 µg/kg	Liver	
			200 µg/kg	Kidney	

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2.2.3. Pyrethroids

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Flumethrin	Flumethrin (sum of trans-Z isomers)	Bovine	10 µg/kg	Muscle	
			150 µg/kg	Fat	
			20 µg/kg	Liver	
			10 µg/kg	Kidney	
			30 µg/kg	Milk	

2.3. Agents acting against endo- and ectoparasites

2.3.1. Avermectins

Phramacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Abamectin	Avermectin B1a	Bovine	10 µg/kg	Fat	
			20 µg/kg	Liver	
Doramectin	Doramectin	Bovine	10 µg/kg	Muscle	Not for use in bovine from which milk is produced for human consumption
			150 µg/kg	Fat	
			100 µg/kg	Liver	
			30 µg/kg	Kidney	
		Porcine, ovine	20 µg/kg	Muscle	Not for use in ovine from which milk is produced for human consumption
			100 µg/kg	Fat	
			50 µg/kg	Liver	
			30 µg/kg	Kidney	
Eprinomectin	Eprinomectin B1a	Bovine	30 µg/kg	Muscle	
			30 µg/kg	Fat	
			600 µg/kg	Liver	
			100 µg/kg	Kidney	

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Phramacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
			30 µg/kg	Milk	
Ivermectin	22, 23-Dihydro-avermectin B1a	Bovine	40 µg/kg	Fat	
			100 µg/kg	Liver	
		Porcine, ovine, equidae	20 µg/kg	Fat	
			15 µg/kg	Liver	
		Deer, including reindeer	20 µg/kg	Muscle	
			100 µg/kg	Fat	
			50 µg/kg	Liver	
			20 µg/kg	Kidney	
Moxidectin	Moxidectin	Bovine, ovine	50 µg/kg	Muscle	
			500 µg/kg	Fat	
			100 µg/kg	Liver	
			50 µg/kg	Kidney	

2.4. Agents acting against protozoa

2.4.1. Triazinetrione derivative

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Toltrazuril	Toltrazuril sulfone	Chicken	100 µg/kg	Muscle	Not for use in animals from which eggs are produced for human consumption
			200 µg/kg	Skin and fat	
			600 µg/kg	Liver	
			400 µg/kg	Kidney	
		Turkey	100 µg/kg	Muscle	
			200 µg/kg	Skin and fat	
			600 µg/kg	Liver	
			400 µg/kg	Kidney	

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3. Agents acting on the nervous system

3.1. Agents acting on the central nervous system

3.1.1. Butyrophenone tranquillisers

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Azaperone	Sum of azaperone and azaperol	Porcine	100 µg/kg	Muscle	
			100 µg/kg	Skin and fat	
			100 µg/kg	Liver	
			100 µg/kg	Kidney	

3.2. Agents acting on the autonomic nervous system

3.2.1. Anti-adrenergics

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Carazolol	Carazolol	Porcine	5 µg/kg	Muscle	
			5 µg/kg	Skin and fat	
			25 µg/kg	Liver	
			25 µg/kg	Kidney	

4. Anti-inflammatory agents

4.1. Nonsteroidal anti-inflammatory agents

4.1.1. Arylpropionic acid derivative

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Vedaprofen	Vedaprofen	Equidae	50 µg/kg	Muscle	
			20 µg/kg	Fat	
			100 µg/kg	Liver	

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Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
			1 000 µg/kg	Kidney	

4.1.2. Fenamate group derivatives

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Tolfenamic acid	Tolfenamic acid	Bovine	50 µg/kg	Muscle	
			400 µg/kg	Liver	
			100 µg/kg	Kidney	
			50 µg/kg	Milk	
		Porcine	50 µg/kg	Muscle	
			400 µg/kg	Liver	
			100 µg/kg	Kidney	

5. Corticoides

5.1. Glucocorticoides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Dexamethasone	Dexamethasone	Bovine	0,3 µg/kg	Milk	
		Bovine, porcine, equidae	0,75 µg/kg	Muscle	
			2 µg/kg	Liver	
			0,75 µg/kg	Kidney	

ANNEX II

LIST OF SUBSTANCES NOT SUBJECT TO MAXIMUM RESIDUE LIMITS

1. Inorganic chemicals

Pharmacologically active substance(s)	Animal species	Other provisions
Aluminium distearate	All food-producing species	
Aluminium hydroxide acetate	All food-producing species	
Aluminium phosphate	All food-producing species	
Aluminium tristearate	All food-producing species	
Ammonium chloride	All food-producing species	
Bismuth subcarbonate	All food-producing species	For oral use only
Bismuth subgallate	All food-producing species	For oral use only
Bismuth subnitrate	All food-producing species	For oral use only
Bismuth subsalicylate	All food-producing species	For oral use only
Boric acid and borates	All food-producing species	
Bromide, sodium salt	All mammalian food-producing species	For topical use only

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Pharmacologically active substance(s)	Animal species	Other provisions
Calcium acetate Calcium benzoate Calcium carbonate Calcium chloride Calcium gluconate Calcium hydroxide Calcium hypophosphite Calcium malate Calcium oxide Calcium phosphate Calcium polyphosphates Calcium propionate Calcium silicate Calcium stearate Calcium sulphate	All food-producing species	
Calcium glucoheptonate	All food-producing species	
Calcium glucono glucoheptonate	All food-producing species	
Calcium gluconolactate	All food-producing species	
Calcium glutamate	All food-producing species	
Cobalt carbonate	All food-producing species	
Cobalt dichloride	All food-producing species	
Cobalt gluconate	All food-producing species	
Cobalt oxide	All food-producing species	
Cobalt sulphate	All food-producing species	
Cobalt trioxide	All food-producing species	
Copper chloride	All food-producing species	
Copper gluconate	All food-producing species	
Copper heptanoate	All food-producing species	

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Pharmacologically active substance(s)	Animal species	Other provisions
Copper methionate	All food-producing species	
Copper oxide	All food-producing species	
Copper sulphate	All food-producing species	
Dicopper oxide	All food-producing species	
Hydrochloric acid	All food-producing species	For use as excipient
Hydrogen peroxide	All food-producing species	
Iodine and iodine inorganic compounds including: — Sodium and potassium-iodide — Sodium and potassium-iodate — Iodophors including polyvinylpyrrolidone-iodine	All food-producing species	
Iron dichloride	All food-producing species	
Iron sulphate	All food-producing species	
Magnesium Magnesium sulphate Magnesium hydroxide Magnesium stearate Magnesium glutamate Magnesium orotate Magnesium aluminium silicate Magnesium oxide Magnesium carbonate Magnesium phosphate Magnesium glycerophosphate Magnesium aspartate Magnesium citrate Magnesium acetate Magnesium trisilicate	All food-producing species	
Nickel gluconate	All food-producing species	
Nickel sulphate	All food-producing species	

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Pharmacologically active substance(s)	Animal species	Other provisions
Potassium DL-aspartate	All food-producing species	
Potassium glucuronate	All food-producing species	
Potassium glycerophosphate	All food-producing species	
Potassium nitrate	All food-producing species	
Potassium selenate	All food-producing species	
Sodium chlorite	Bovine	For topical use only
Sodium dichloroisocyanurate	Bovine, ovine, caprine	For topical use only
Sodium hypophosphite	All food-producing species	
Sodium selenate	All food-producing species	
Sodium selenite	All food-producing species	
Sulphur	Bovine, porcine, ovine, caprine, equidae	
Zinc acetate Zinc chloride Zinc gluconate Zinc oleate Zinc stearate	All food-producing species	

2. Organic compounds

Pharmacologically active substance(s)	Animal species	Other provisions
17β-Oestradiol	All mammalian food-producing species	For therapeutic and zootechnical uses only
2-Aminoethanol	All food-producing species	
2-Aminoethyl dihydrogenphosphate	All food-producing species	

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Pharmacologically active substance(s)	Animal species	Other provisions
2-Pyrrolidone	All food-producing species	At parenteral doses up to 40 mg/kg bw
8-Hydroxyquinoline	All mammalian food-producing species	For topical use in newborn animals only
Acetyl cysteine	All food-producing species	
Alfacalcidol	Bovine	For parturient cows only
Alfaprostol	Rabbits Bovine, porcine, equidae	
Bacitracin	Bovine	For intramammary use in lactating cows only and for all tissues except milk
Benzalkonium chloride	All food-producing species	For use as an excipient at concentrations up to 0,05 % only
Benzocaine	All food-producing species	For use as local anaesthetic only
Benzylalcohol	All food-producing species	For use as excipient
Betaine	All food-producing species	
Bronopol	Salmonidae	For use only on farmed fertilised eggs
Brotizolam	Bovine	For therapeutic uses only
Buserelin	All food-producing species	
Butorphanol tartrate	Equidae	For intravenous administration only
Butyl 4-hydroxybenzoate	All food-producing species	
Butylscopolaminium bromide	All food-producing species	
Caffeine	All food-producing species	
Carbetocin	All mammalian food-producing species	

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Pharmacologically active substance(s)	Animal species	Other provisions
Cefazolin	Bovine Ovine, caprine	For intramammary use, except if the udder may be used as food for human consumption
Cetostearyl alcohol	All food-producing species	
Cetrimide	All food-producing species	
Chlorhexidine	All food-producing species	For topical use only
Chlorocresol	All food-producing species	
Clazuril	Pigeon	
Cloprostenol	Bovine, porcine, equidae	
Coco alkyl dimethyl betaines	All food-producing species	For use as excipient
Corticotropin	All food-producing species	
D-Phe 6 -luteinising-hormone releasing hormone	All food-producing species	
Dembrexine	Equidae	
Denaverine hydrochloride	Bovine	
Detomidine	Bovine, equidae	For therapeutic uses only
Diclazuril	Ovine	For oral use in lambs only
Diethyl phtalate	All food-producing species	
Diethylene glycol monoethyl ether	Bovine, porcine	
Dimanganese trioxide	All food-producing species	For oral use only
Dimethyl phtalate	All food-producing species	
Dinoprost	All mammalian food-producing species	

▼M58

Pharmacologically active substance(s)	Animal species	Other provisions
Dinoprost tromethamine	All mammalian food-producing species	
Diprophylline	All food-producing species	
Etamiphylline camsylate	All food-producing species	
Ethanol	All food-producing species	For use as excipient
Ethyl lactate	All food-producing species	
Etiproston tromethamine	Bovine, porcine	
Fertirelin acetate	Bovine	
Flumethrin	Bees (honey)	
Folic acid	All food-producing species	
Glycerol formal	All food-producing species	
Gonadotrophin releasing hormone	All food-producing species	
Heptaminol	All food-producing species	
Hesperidin	Equidae	
Hesperidin methyl chalcone	Equidae	
Hexetidine	Equidae	For topical use only
Human chorion gonadotrophin	All food-producing species	
Human menopausal urinary gonadotrophin	Bovine	
Hydrocortisone	All food-producing species	For topical use only
Iodine organic compounds — Iodoform	All food-producing species	

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Pharmacologically active substance(s)	Animal species	Other provisions
Isobutane	All food-producing species	
Isoflurane	Equidae	For use as anaesthetic only
Isoxsuprine	Bovine, equidae	For therapeutic use only in accordance with Council Directive 96/22/EEC (OJ L 125, 23.5.1996, p. 3)
Ketamine	All food-producing species	
Ketanserin tartrate	Equidae	
Ketoprofen	Bovine, porcine, equidae	
L-tartaric acid and its mono- and di-basic salt of sodium, potassium and calcium	All food-producing species	For use as excipient
Lactic acid	All food-producing species	
Lecirelin	Bovine, equidae, rabbits	
Lobeline	All food-producing species	
Luprostiol	All mammalian species	
Malic acid	All food-producing species	For use as excipient
Manganese carbonate	All food-producing species	For oral use only
Manganese chloride	All food-producing species	For oral use only
Manganese gluconate	All food-producing species	For oral use only
Manganese glycerophosphate	All food-producing species	For oral use only
Manganese oxide	All food-producing species	For oral use only
Manganese pidolate	All food-producing species	For oral use only
Manganese ribonucleate	All food-producing species	For oral use only

▼M58

Pharmacologically active substance(s)	Animal species	Other provisions
Manganese sulphate	All food-producing species	For oral use only
Mecillinam	Bovine	For intrauterine use only
Medroxyprogesterone acetate	Ovine	For intravaginal use for zootechnical purposes only
Melatonin	Ovine, caprine	
Menadione	All food-producing species	
Menbutone	Bovine, ovine, caprine, porcine, equidae	
Menthol	All food-producing species	
Methyl nicotinate	Bovine, equidae	For topical use only
Mineral hydrocarbons, low to high viscosity including microcristalline waxes, approximately C10-C60; aliphatic, branched aliphatic and alicyclic compounds	All food-producing species	Excludes aromatic and unsaturated compounds
N-butane	All food-producing species	
N-butanol	All food-producing species	For use as excipient
Natamycin	Bovine, equidae	For topical use only
Neostigmine	All food-producing species	
Nicoboxil	Equidae	For topical use only
Nonivamide	Equidae	For topical use only
Oleyloleate	All food-producing species	For topical use only
Oxytocin	All mammalian food-producing species	
Pancreatin	All mammalian food-producing species	For topical use only
Papain	All food-producing species	

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Pharmacologically active substance(s)	Animal species	Other provisions
Papaverine	Bovine	Newborn calves only
Peracetic acid	All food-producing species	
Phenol	All food-producing species	
Phloroglucinol	All food-producing species	
Phytomenadione	All food-producing species	
Policresulen	All food-producing species	For topical use only
Polyethylene glycol 15 hydroxystearate	All food-producing species	For use as excipient
Polyethylene glycol 7 glyceryl cocoate	All food-producing species	For topical use only
Polyethylene glycol stearates with 8-40 oxyethylene units	All food-producing species	For use as excipient
Polysulphated glycosaminoglycan	Equidae	
Praziquantel	Ovine Equidae	For use in non-lactating sheep only
Pregnant mare serum gonadotrophin	All food-producing species	
Prethcamide (crotethamide and cropropamide)	All mammalian food-producing species	
Procaine	All food-producing species	
Propane	All food-producing species	
Propylene glycol	All food-producing species	
Quatresin	All food-producing species	For use as preservative only at concentrations of up to 0,5 %
R-Cloprostenol	Bovine, porcine, equidae	

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Pharmacologically active substance(s)	Animal species	Other provisions
Rifaximin	All mammalian food-producing species Bovine	For topical use only For intramammary use, except if the udder may be used as food for human consumption
Romifidine	Equidae	For therapeutic uses only
Sodium 2-methyl-2-phenoxy-propanoate	Bovine, porcine, caprine, equidae	
Sodium benzyl 4-hydroxybenzoate	All food-producing species	
Sodium butyl 4-hydroxybenzoate	All food-producing species	
Sodium cetostearyl sulphate	All food-producing species	For topical use only
Somatosalm	Salmon	
Tanninum	All food-producing species	
Tau fluvalinate		
Terpin hydrate	Bovine, porcine, ovine, caprine	
Tetracaine	All food-producing species	For use as anaesthetic only
Theobromine	All food-producing species	
Theophylline	All food-producing species	
Thiomersal	All food-producing species	For use only as preservatives in multidose vaccines at a concentration not exceeding 0,02 %
Thymol	All food-producing species	
Timerfonate	All food-producing species	For use only as preservatives in multidose vaccines at a concentration not exceeding 0,02 %
Trimethylphloroglucinol	All food-producing species	
Vitamin D	All food-producing species	

▼M58

Pharmacologically active substance(s)	Animal species	Other provisions
Wool alcohols	All food-producing species	For topical use only

3. Substances generally recognised as safe

Pharmacologically active substance(s)	Animal species	Other provisions
Absinthium extract	All food-producing species	
Acetylmethionine	All food-producing species	
Aluminium hydroxide	All food-producing species	
Aluminium monostearate	All food-producing species	
Ammonium sulfate	All food-producing species	
Benzoyl benzoate	All food-producing species	
Benzyl p-hydroxybenzoate	All food-producing species	
Calcium borogluconate	All food-producing species	
Calcium citrate	All food-producing species	
Camphor	All food-producing species	External use only
Cardamon extract	All food-producing species	
Diethyl sebacate	All food-producing species	
Dimethicone	All food-producing species	
Dimethyl acetamide	All food-producing species	
Dimethyl sulphoxide	All food-producing species	
Epinephrine	All food-producing species	

▼M58

Pharmacologically active substance(s)	Animal species	Other provisions
Ethyl oleate	All food-producing species	
Ethylenediaminetetraacetic acid and salts	All food-producing species	
Eucalyptol	All food-producing species	
Follicle stimulating hormone (natural FSH from all species and their synthetic analogues)	All food-producing species	
Formaldehyde	All food-producing species	
Formic acid	All food-producing species	
Glutaraldehyde	All food-producing species	
Guaiacol	All food-producing species	
Heparin and its salts	All food-producing species	
Human chorionic gonadotropin (natural HCG and its synthetic analogues)	All food-producing species	
Iron ammonium citrate	All food-producing species	
Iron dextran	All food-producing species	
Iron glucoheptonate	All food-producing species	
Isopropanol	All food-producing species	
Lanolin	All food-producing species	
Luteinising hormone (natural LH from all species and their synthetic analogues)	All food-producing species	
Magnesium chloride	All food-producing species	
Magnesium gluconate	All food-producing species	

▼M58

Pharmacologically active substance(s)	Animal species	Other provisions
Magnesium hypophosphite	All food-producing species	
Mannitol	All food-producing species	
Methylbenzoate	All food-producing species	
Monothioglycerol	All food-producing species	
Montanide	All food-producing species	
Myglyol	All food-producing species	
Orgotein	All food-producing species	
Poloxalene	All food-producing species	
Poloxamer	All food-producing species	
Polyethylene glycols (molecular weight ranging from 200 to 10 000)	All food-producing species	
Polysorbate 80	All food-producing species	
Serotonin	All food-producing species	
Sodium chloride	All food-producing species	
Sodium cromoglycate	All food-producing species	
Sodium dioctylsulphosuccinate	All food-producing species	
Sodium formaldehydesulphoxylate	All food-producing species	
Sodium lauryl sulphate	All food-producing species	
Sodium pyrosulphite	All food-producing species	
Sodium stearate	All food-producing species	
Sodium thiosulphate	All food-producing species	

▼M58

Pharmacologically active substance(s)	Animal species	Other provisions
Tragacanth	All food-producing species	
Urea	All food-producing species	
Zinc oxide	All food-producing species	
Zinc sulphate	All food-producing species	

4. Substances used in homeopathic veterinary medicinal products

Pharmacologically active substance(s)	Animal species	Other provisions
All substances used in homeopathic veterinary medicinal products provided that their concentration in the product does not exceed one part per ten thousand	All food-producing species	

5. Substances used as food additives in foodstuffs for human consumption

Pharmacologically active substance(s)	Animal species	Other provisions
Substances with an E number	All food-producing species	Only substances approved as additives in foodstuffs for human consumption, with the exception of preservatives listed in part C of Annex III to European Parliament and Council Directive 95/2/EC (OJ L 61, 18.3.1995, p. 1).

6. Substances of vegetable origin

Pharmacologically active substance(s)	Animal species	Other provisions
Angelicae radix aetheroleum	All food-producing species	
Anisi aetheroleum	All food-producing species	
Balsamum peruvianum	All food-producing species	For topical use only

▼M58

Pharmacologically active substance(s)	Animal species	Other provisions
Carvi aetheroleum	All food-producing species	
Caryophylli aetheroleum	All food-producing species	
Chrysanthemi cinerariifolii flos	All food-producing species	For topical use only
Cinnamomi cassiae aetheroleum	All food-producing species	
Cinnamomi ceylanici aetheroleum	All food-producing species	
Citri aetheroleum	All food-producing species	
Citronellae aetheroleum	All food-producing species	
Coriandri aetheroleum	All food-producing species	
Echinacea purpurea	All food-producing species	For topical use only
Eucalypti aetheroleum	All food-producing species	
Foeniculi aetheroleum	All food-producing species	
Hamamelis virginiana	All food-producing species	For topical use only
Hyperici oleum	All food-producing species	For topical use only
Lespedeza capitata	All food-producing species	
Lini oleum	All food-producing species	
Majoranae herba	All food-producing species	
Matricariae flos	All food-producing species	
Medicago sativa extractum	All food-producing species	For topical use only
Melissae folium	All food-producing species	
Menthae piperitae aetheroleum	All food-producing species	

▼M58

Pharmacologically active substance(s)	Animal species	Other provisions
Millefolii herba	All food-producing species	
Myristicae aetheroleum	All food-producing species	For use in newborn animals only
Oxidation products of *Terebinthinae oleum*	Bovine, porcine, ovine, caprine	
Pyrethrum extract	All food-producing species	For topical use only
Quercus cortex	All food-producing species	
Quillaia saponins	All food-producing species	
Ricini oleum	All food-producing species	For use as excipient
Rosmarini aetheroleum	All food-producing species	
Rosmarini folium	All food-producing species	
Salviae folium	All food-producing species	
Sambuci flos	All food-producing species	
Sinapis nigrae semen	All food-producing species	
Terebinthinae aetheroleum rectificatum	All food-producing species	For topical use only
Terebinthinae laricina	All food-producing species	For topical use only
Thymi aetheroleum	All food-producing species	
Tiliae flos	All food-producing species	
Urticae herba	All food-producing species	

▼M58

ANNEX III

LIST OF PHARMACOLOGICALLY ACTIVE SUBSTANCES USED IN VETERINARY MEDICINAL PRODUCTS FOR WHICH PROVISIONAL MAXIMUM RESIDUE LIMITS HAVE BEEN FIXED

1. Anti-infectious agents

1.1. Chemotheurapeutics

1.1.2. Benzenesulphonamides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Clorsulon	Clorsulon	Bovine	50 µg/kg 150 µg/kg 400 µg/kg	Muscle Liver Kidney	Provisional MRLs expire on 1 January 2000

1.2. Antibiotics

1.2.1. Beta-lactamase inhibitors

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Clavulanic acid	Clavulanic acid	Bovine, ovine Bovine, ovine, porcine	200 µg/kg 200 µg/kg 200 µg/kg 200 µg/kg 200 µg/kg	Milk Muscle Fat Liver Kidney	Provisional MRLs expire on 1 July 1999

1.2.2. Macrolides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Erythromycin	MRLs apply to all microbiological active residues expressed as erythromycin equivalent	Bovine, ovine	40 µg/kg	Milk	Provisional MRLs expire on 1 June 2000

▼M58

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
		Bovine, ovine, porcine, poultry	400 µg/kg	Muscle	
			400 µg/kg	Fat	
			400 µg/kg	Liver	
			400 µg/kg	Kidney	
		Poultry	200 µg/kg	Eggs	
Josamycin	Josamycin	Chicken	200 µg/kg	Muscle	Provisional MRLs expire on 1 July 2000
			200 µg/kg	Fat	
			200 µg/kg	Liver	
			400 µg/kg	Kidney	
			200 µg/kg	Eggs	

1.2.5. Aminoglycosides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Aminosidine	Aminosidine	Bovine, porcine, rabbits, chicken	500 µg/kg	Muscle	Provisional MRLs expire on 1 July 2000
			1 500 µg/kg	Liver	
			1 500 µg/kg	Kidney	
Apramycin	Apramycin	Bovine	1 000 µg/kg	Muscle	Provisional MRLs expire on 1 July 1999
		For use in non-lactating cattle only	1 000 µg/kg	Fat	
			10 000 µg/kg	Liver	
			20 000 µg/kg	Kidney	
		Porcine	1 000 µg/kg	Muscle	
			1 000 µg/kg	Skin and fat	
			1 000 µg/kg	Liver	
			5 000 µg/kg	Kidney	

▼M58

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Dihydrostreptomycin	Dihydrostreptomycin	Bovine, ovine	200 µg/kg	Milk	Provisional MRLs expire on 1 June 2000
		Bovine, ovine, porcine, poultry	500 µg/kg	Muscle	
			500 µg/kg	Fat	
			500 µg/kg	Liver	
			1 000 µg/kg	Kidney	
Gentamicin	Gentamicin	Bovine	100 µg/kg	Milk	Provisional MRLs expire on 1 June 2000
		Bovine, porcine	100 µg/kg	Muscle	
			100 µg/kg	Fat	
			200 µg/kg	Liver	
			1 000 µg/kg	Kidney	
Neomycin (including framycetin)	Neomycin	Bovine, ovine, caprine	500 µg/kg	Milk	Provisional MRLs expire on 1 June 2000
		Bovine, ovine, caprine, porcine, chicken, turkey, duck	500 µg/kg	Muscle	
			500 µg/kg	Fat	
			500 µg/kg	Liver	
			5 000 µg/kg	Kidney	
		Chicken	500 µg/kg	Eggs	
Spectinomycin	Spectinomycin	Bovine	200 µg/kg	Milk	Provisional MRLs expire on 1 July 2000
		Bovine, porcine, poultry	300 µg/kg	Muscle	
			500 µg/kg	Fat	
			2 000 µg/kg	Liver	
			5 000 µg/kg	Kidney	
Streptomycin	Streptomycin	Bovine, ovine	200 µg/kg	Milk	Provisional MRLs expire on 1 June 2000
		Bovine, ovine, porcine, poultry	500 µg/kg	Muscle	
			500 µg/kg	Fat	

▼M58

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
			500 µg/kg	Liver	
			1 000 µg/kg	Kidney	

1.2.6. Quinolones

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Decoquinate	Decoquinate	Bovine, ovine	500 µg/kg	Muscle	Provisional MRLs expire on 1 July 2000
			500 µg/kg	Fat	
			500 µg/kg	Liver	
			500 µg/kg	Kidney	
Enrofloxacin	Sum of enrofloxacin and ciprofloxacin	Ovine	100 µg/kg	Muscle	Provisional MRLs expire on 1 July 1999
			100 µg/kg	Fat	
			300 µg/kg	Liver	
			200 µg/kg	Kidney	
Flumequine	Flumequine	Bovine, ovine, porcine, chicken	50 µg/kg	Muscle	Provisional MRLs expire on 1 January 2000
			50 µg/kg	Fat or skin and fat	
			100 µg/kg	Liver	
			300 µg/kg	Kidney	
		Salmonidae	150 µg/kg	Muscle and skin	
Marbofloxacin	Marbofloxacin	Bovine	150 µg/kg	Muscle	Provisional MRLs expire on 1 July 2000
			50 µg/kg	Fat	
			150 µg/kg	Liver	
			150 µg/kg	Kidney	
			75 µg/kg	Milk	
		Porcine	150 µg/kg	Muscle	
			50 µg/kg	Skin and fat	

▼M58

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
			150 µg/kg	Liver	
			150 µg/kg	Kidney	

1.2.9. Polymyxins

Phamarcologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Colistin	Colistin	Bovine, ovine	50 µg/kg	Milk	Provisional MRLs expire on 1 July 2000
		Bovine, ovine, porcine, chicken, rabbits	150 µg/kg	Muscle	
			150 µg/kg	Fat	
			150 µg/kg	Liver	
			200 µg/kg	Kidney	
		Chicken	300 µg/kg	Eggs	

1.2.10. Penicillins

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Penethamate	Benzylpenicillin	Ovine	50 µg/kg	Muscle	Provisional MRLs expire on 1 January 2000
			50 µg/kg	Fat	
			50 µg/kg	Liver	
			50 µg/kg	Kidney	
			4 µg/kg	Milk	
		Porcine	50 µg/kg	Muscle	
			50 µg/kg	Fat	
			50 µg/kg	Liver	
			50 µg/kg	Kidney	

▼M58

1.2.11. Florfenicol and related compounds

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Florfenicol	Sum of florfenicol and its metabolites measured as florfenicol-amine	Fish	1 000 µg/kg	Muscle and skin in natural proportions	Provisional MRLs expire on 1 July 2001

2. Antiparasitic agents

2.1. Agents acting against endoparasites

2.1.2. Benzimidazoles and pro-benzimidazoles

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Albendazole sulphoxide	Sum of albendazole, albendazole sulphoxide, albendazole sulphone, and albendazole 2-amino sulphone, expressed as albendazole	Bovine, ovine	100 µg/kg	Milk	Provisional MRLs expire on 1 January 2000
		Bovine, ovine, pheasant	100 µg/kg	Muscle	
			100 µg/kg	Fat	
			1 000 µg/kg	Liver	
			500 µg/kg	Kidney	
Netobimin	Sum of netobimin and albendazole and metabolites of albendazole measured as 2-amino-benzimidazole sulphone	Bovine, ovine, caprine	100 µg/kg	Muscle	Provisional MRLs expire on 31 July 1999
			100 µg/kg	Fat	
			1 000 µg/kg	Liver	
			500 µg/kg	Kidney	
			100 µg/kg	Milk	

▼M58

2.2. Agents acting against ectoparasites

2.2.1. Formamidines

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Amitraz	Sum of amitraz and all metabolites containing the 2,4-DMA moeity, expressed as amitraz	Bees	200 µg/kg	Honey	Provisional MRLs expire on 1 July 1999

2.2.2. Iminophenyl thiazolidine derivative

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Cymiazole	Cymiazole	Bees	1 000 µg/kg	Honey	Provisional MRLs expire on 1 July 1999

2.2.3. Pyretrin and pyrethroids

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Cyfluthrin	Cyfluthrin	Bovine	10 µg/kg 50 µg/kg 10 µg/kg 10 µg/kg 20 µg/kg	Muscle Fat Liver Kidney Milk Further provisions in Council Directive 94/29/EC are to be observed (OJ L 189, 23.7.1994, p. 67)	Provisional MRLs expire on 1 January 2001

▼M58

2.2.4. Organophosphates

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Azamethiphos	Azamethiphos	Salmonidae	100 µg/kg	Muscle and skin in natural proportions	Provisional MRLs expire on 1 June 1999

2.2.5. Acyl urea derivates

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Teflubenzuron	Teflubenzuron	Salmonidae	500 µg/kg	Muscle and skin in natural proportions	Provisional MRLs expire on 1 July 1999

2.3. Agents acting against endo- and ectoparasites

2.3.1. Avermectins

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Moxidectin	Moxidectin	Equidae	50 µg/kg 500 µg/kg 100 µg/kg 50 µg/kg	Muscle Fat Liver Kidney	Provisional MRLs expire on 1 January 2000

3. Agents acting on the nervous system

3.2. Agents acting on the autonomic nervous system

3.2.1. β 2 sympathomimetic agents

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Clenbuterol hydrochloride	Clenbuterol	Bovine Indication: solely for tocolysis in parturient cows	0,1 µg/kg 0,5 µg/kg	Muscle Liver	Provisional MRLs expire on 1 July 2000

▼M58

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
			0,5 µg/kg	Kidney	
			0,05 µg/kg	Milk	
		Equidae	0,1 µg/kg	Muscle	
		Indications: tocolysis and the treatment of respiratory ailments	0,5 µg/kg	Liver	
			0,5 µg/kg	Kidney	

5. Anti-inflammatory agents

5.1. Nonsteroidal anti-inflammatory agents

5.1.1. Arylpropionic acid derivative

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Carprofen	Carprofen	Bovine	500 µg/kg	Muscle	Provisional MRLs expire on 1 January 2000
			500 µg/kg	Fat	
			1 000 µg/kg	Liver	
			1 000 µg/kg	Kidney	
		Equidae	50 µg/kg	Muscle	
			100 µg/kg	Fat	
			1 000 µg/kg	Liver	
			1 000 µg/kg	Kidney	

▼M58

5.1.2. Enolic acid derivates

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Meloxicam	Meloxicam	Bovine	25 µg/kg 60 µg/kg 35 µg/kg	Muscle Liver Kidney	Provisional MRLs expire on 1 January 2000

▼**M58**

ANNEX IV

LIST OF PHARMACOLOGICALLY ACTIVE SUBSTANCES FOR WHICH NO MAXIMUM LEVELS CAN BE FIXED

Pharmacologically active substance(s)
Aristolochia spp. and preparations thereof
Chloramphenicol
Chloroform
Chlorpromazine
Colchicine
Dapsone
Dimetridazole
Metronidazole
Nitrofurans (including furazolidone)
Ronidazole

▼M2

ANNEX V

Information and particulars to be included in an application for the establishment of a maximum residue limit for a pharmacologically active substance used in veterinary medicinal products

Administrative particulars

1 Name or corporate name and permanent address of the applicant.

2 Name of the veterinary medicinal product.

3 Qualitative and quantitative composition in terms of active principles, with mention of the international non-proprietary name recommended by the World Health Organization, where such name exists.

4 Manufacturing authorization, if any.

5 Marketing authorization, if any.

6 Summary of the characteristics of the veterinary medicinal product(s) prepared in accordance with Article 5a of Directive 81/851/EEC.

A. *Safety documentation*

A.0. Expert report

A.1. Precise identification of the substance concerned by the application

1.1 International non-proprietary name (INN).

1.2 International Union of Pure and Applied Chemistry (IUPAC) name.

1.3 Chemical Abstract Service (CAS) name.

1.4 Classification:

— therapeutic;
— pharmacological.

1.5 Synonyms and abbreviations.

1.6 Structural formula.

1.7 Molecular formula.

1.8 Molecular weight.

1.9 Degree of impurity.

1.10 Qualitative and quantitative composition of impurities.

1.11 Description of physical properties:

— melting point;
— boiling point;
— vapour pressure;
— solubility in water and organic solvents, expressed in grams per litre, with indication of temperature;
— density;
— refractive index, rotation, etc.

A.2. Relevant pharmacological studies

2.1 Pharmacodynamics.

2.2 Pharmacokinetics.

A.3. Toxicological studies

3.1 Single dose toxicity.

3.2 Repeated dose toxicity.

3.3 Tolerance in the target species of animal.

3.4 Reproductive toxicity, including teratogenicity.

3.4.1 Study of the effects on reproduction.

3.4.2 Embryotoxicity/fetotoxicity, including teratogenicity.

3.5 Mutagenicity.

3.6 Carcinogenicity.

▼**M2**

A.4. Studies of other effects

4.1 Immunotoxicity.

4.2 Microbiological properties of residues.

4.2.1 On the human gut flora;

4.2.2 On the organisms and microorganisms used for industrial food-processing.

4.3 Observations in humans.

B. *Residue documentation*

B.0 Expert report

B.1. Precise identification of the substance concerned by the application

The substance concerned should be identified in accordance with point A.1. However, where the application relates to one or more veterinary medicinal products, the product itself should be identified in detail, including:

— qualitative and quantitative composition;
— purity;
— identification of the manufacturer's batch used in the studies; relationship to the final product;
— specific activity and radio-purity of labelled substances;
— position of labelled atoms on the molecule.

B.2. Residue studies

2.1 Pharmacokinetics

(absorption, distribution, biotransformation, excretion).

2.2 Depletion of residues.

2.3 Elaboration of maximum residue limits (MRLS).

B3. Routine analytical method for the detection of residues

3.1 Description of the method.

3.2 Validation of the method.

3.2.1 specificity;

3.2.2 accuracy, including sensitivity;

3.2.3 precision;

3.2.4 limit of detection;

3.2.5 limit of quantitation;

3.2.6 practicability and applicability under normal laboratory conditions;

3.2.7 susceptibility to interference.