

This document is meant purely as a documentation tool and the institutions do not assume any liability for its contents

►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

(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
► M59	Commission Regulation (EC) No 804/1999 of 16 April 1999	L 102	58	17.4.1999
► M60	Commission Regulation (EC) No 953/1999 of 5 May 1999	L 118	23	6.5.1999
► M61	Commission Regulation (EC) No 954/1999 of 5 May 1999	L 118	28	6.5.1999
► M62	Commission Regulation (EC) No 997/1999 of 11 May 1999	L 122	24	12.5.1999
► M63	Commission Regulation (EC) No 998/1999 of 11 May 1999	L 122	30	12.5.1999
► M64	Council Regulation (EC) No 1308/1999 of 15 June 1999	L 156	1	23.6.1999
► M65	Commission Regulation (EC) No 1931/1999 of 9 September 1999	L 240	3	10.9.1999
► M66	Commission Regulation (EC) No 1942/1999 of 10 September 1999	L 241	4	11.9.1999
► M67	Commission Regulation (EC) No 1943/1999 of 10 September 1999	L 241	9	11.9.1999
► M68	Commission Regulation (EC) No 2385/1999 of 10 November 1999	L 288	14	11.11.1999
► M69	Commission Regulation (EC) No 2393/1999 of 11 November 1999	L 290	5	12.11.1999
► M70	Commission Regulation (EC) No 2593/1999 of 8 December 1999	L 315	26	9.12.1999
► M71	Commission Regulation (EC) No 2728/1999 of 20 December 1999	L 328	23	22.12.1999
► M72	Commission Regulation (EC) No 2757/1999 of 22 December 1999	L 331	45	23.12.1999
► M73	Commission Regulation (EC) No 2758/1999 of 22 December 1999	L 331	49	23.12.1999
► M74	Commission Regulation (EC) No 1286/2000 of 19 June 2000	L 145	15	20.6.2000
► M75	Commission Regulation (EC) No 1295/2000 of 20 June 2000	L 146	11	21.6.2000
► M76	Commission Regulation (EC) No 1960/2000 of 15 September 2000	L 234	5	16.9.2000
► M77	Commission Regulation (EC) No 2338/2000 of 20 October 2000	L 269	21	21.10.2000
► M78	Commission Regulation (EC) No 2391/2000 of 27 October 2000	L 276	5	28.10.2000
► M79	Commission Regulation (EC) No 2535/2000 of 17 November 2000	L 291	9	18.11.2000
► M80	Commission Regulation (EC) No 2908/2000 of 29 December 2000	L 336	72	30.12.2000
► M81	Commission Regulation (EC) No 749/2001 of 18 April 2001	L 109	32	19.4.2001
► M82	Commission Regulation (EC) No 750/2001 of 18 April 2001	L 109	35	19.4.2001
► M83	Commission Regulation (EC) No 807/2001 of 25 April 2001	L 118	6	27.4.2001
► M84	Commission Regulation (EC) No 1274/2001 of 27 June 2001	L 175	14	28.6.2001

► M85	Commission Regulation (EC) No 1322/2001 of 29 June 2001	L 177	52	30.6.2001
► M86	Commission Regulation (EC) No 1478/2001 of 18 July 2001	L 195	32	19.7.2001
► M87	Commission Regulation (EC) No 1553/2001 of 30 July 2001	L 205	16	31.7.2001
► M88	Commission Regulation (EC) No 1680/2001 of 22 August 2001	L 227	33	23.8.2001
► M89	Commission Regulation (EC) No 1815/2001 of 14 September 2001	L 246	11	15.9.2001
► M90	Commission Regulation (EC) No 1879/2001 of 26 September 2001	L 258	11	27.9.2001
► M91	Commission Regulation (EC) No 2162/2001 of 7 November 2001	L 291	9	8.11.2001
► M92	Council Regulation (EC) No 2584/2001 of 19 December 2001	L 345	7	29.12.2001
► M93	Commission Regulation (EC) No 77/2002 of 17 January 2002	L 16	9	18.1.2002
► M94	Commission Regulation (EC) No 868/2002 of 24 May 2002	L 137	6	25.5.2002
► M95	Commission Regulation (EC) No 869/2002 of 24 May 2002	L 137	10	25.5.2002
► M96	Commission Regulation (EC) No 1181/2002 of 1 July 2002	L 172	13	2.7.2002
► M97	Commission Regulation (EC) No 1530/2002 of 27 August 2002	L 230	3	28.8.2002
► M98	Commission Regulation (EC) No 1752/2002 of 1 October 2002	L 264	18	2.10.2002
► M99	Commission Regulation (EC) No 1937/2002 of 30 October 2002	L 297	3	31.10.2002
► M100	Commission Regulation (EC) No 61/2003 of 15 January 2003	L 11	12	16.1.2003
► M101	Commission Regulation (EC) No 544/2003 of 27 March 2003	L 81	7	28.3.2003
► M102	Commission Regulation (EC) No 665/2003 of 11 April 2003	L 96	7	12.4.2003
► M103	Commission Regulation (EC) No 739/2003 of 28 April 2003	L 106	9	29.4.2003
► M104	Council Regulation (EC) No 806/2003 of 14 April 2003	L 122	1	16.5.2003
► M105	Commission Regulation (EC) No 1029/2003 of 16 June 2003	L 149	15	17.6.2003
► M106	Commission Regulation (EC) No 1490/2003 of 25 August 2003	L 214	3	26.8.2003
► M107	Commission Regulation (EC) No 1873/2003 of 24 October 2003	L 275	9	25.10.2003
► M108	Commission Regulation (EC) No 2011/2003 of 14 November 2003	L 297	15	15.11.2003
► M109	Commission Regulation (EC) No 2145/2003 of 8 December 2003	L 322	5	9.12.2003
► M110	Commission Regulation (EC) No 324/2004 of 25 February 2004	L 58	16	26.2.2004
► M111	Commission Regulation (EC) No 546/2004 of 24 March 2004	L 87	13	25.3.2004
► M112	Commission Regulation (EC) No 1101/2004 of 10 June 2004	L 211	3	12.6.2004
► M113	Commission Regulation (EC) No 1646/2004 of 20 September 2004	L 296	5	21.9.2004
► M114	Commission Regulation (EC) No 1851/2004 of 25 October 2004	L 323	6	26.10.2004
► M115	Commission Regulation (EC) No 1875/2004 of 28 October 2004	L 326	19	29.10.2004
► M116	Commission Regulation (EC) No 2232/2004 of 23 December 2004	L 379	71	24.12.2004
► M117	Commission Regulation (EC) No 75/2005 of 18 January 2005	L 15	3	19.1.2005
► M118	Commission Regulation (EC) No 712/2005 of 11 May 2005	L 120	3	12.5.2005
► M119	Commission Regulation (EC) No 869/2005 of 8 June 2005	L 145	19	9.6.2005
► M120	Commission Regulation (EC) No 1148/2005 of 15 July 2005	L 185	20	16.7.2005
► M121	Commission Regulation (EC) No 1299/2005 of 8 August 2005	L 206	4	9.8.2005
► M122	Commission Regulation (EC) No 1356/2005 of 18 August 2005	L 214	3	19.8.2005
► M123	Commission Regulation (EC) No 1518/2005 of 19 September 2005	L 244	11	20.9.2005
► M124	Commission Regulation (EC) No 1911/2005 of 23 November 2005	L 305	30	24.11.2005
► M125	Commission Regulation (EC) No 6/2006 of 5 January 2006	L 3	3	6.1.2006
► M126	Commission Regulation (EC) No 205/2006 of 6 February 2006	L 34	21	7.2.2006
► M127	Commission Regulation (EC) No 1055/2006 of 12 July 2006	L 192	3	13.7.2006
► M128	Commission Regulation (EC) No 1231/2006 of 16 August 2006	L 225	3	17.8.2006
► M129	Commission Regulation (EC) No 1451/2006 of 29 September 2006	L 271	37	30.9.2006
► M130	Commission Regulation (EC) No 1729/2006 of 23 November 2006	L 325	6	24.11.2006
► M131	Commission Regulation (EC) No 1805/2006 of 7 December 2006	L 343	66	8.12.2006
► M132	Commission Regulation (EC) No 1831/2006 of 13 December 2006	L 354	5	14.12.2006
► M133	Commission Regulation (EC) No 287/2007 of 16 March 2007	L 78	13	17.3.2007
► M134	Commission Regulation (EC) No 703/2007 of 21 June 2007	L 161	28	22.6.2007
► M135	Commission Regulation (EC) No 1064/2007 of 17 September 2007	L 243	3	18.9.2007

► M136	Commission Regulation (EC) No 1323/2007 of 12 November 2007	L 294	11	13.11.2007
► M137	Commission Regulation (EC) No 1353/2007 of 20 November 2007	L 303	6	21.11.2007
► M138	Commission Regulation (EC) No 61/2008 of 24 January 2008	L 22	8	25.1.2008
► M139	Commission Regulation (EC) No 203/2008 of 4 March 2008	L 60	18	5.3.2008
► M140	Commission Regulation (EC) No 542/2008 of 16 June 2008	L 157	43	17.6.2008

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 310, 28.11.2007, p. 22 (2796/95)
- **C5** Corrigendum, OJ L 271, 8.10.1998, p. 42 (1568/98)
- **C6** Corrigendum, OJ L 116, 30.4.2008, p. 86 (508/1999)
- **C7** Corrigendum, OJ L 9, 13.1.2000, p. 30 (1308/1999)
- **C8** Corrigendum, OJ L 133, 16.5.2001, p. 17 (807/2001)
- **C9** Corrigendum, OJ L 307, 18.11.2008, p. 21 (807/2001)
- **C10** Corrigendum, OJ L 268, 9.10.2001, p. 50 (1815/2001)
- **C11** Corrigendum, OJ L 251, 19.9.2002, p. 20 (1181/2002)
- **C12** Corrigendum, OJ L 45, 19.2.2003, p. 27 (1181/2002)
- **C13** Corrigendum, OJ L 62, 6.3.2003, p. 27 (1181/2002)
- **C14** Corrigendum, OJ L 337, 13.11.2004, p. 73 (1101/2004)

▼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

(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

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 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 food-stuffs 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

(¹) OJ No L 317, 6. 11. 1981, p. 16.

(²) OJ No L 15, 17. 1. 1987, p. 34.

▼B

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.

▼M64*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

▼M64

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.

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.

▼M104*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.

⁽¹⁾ OJ L 214, 24.8.1993, p. 1

⁽²⁾ OJ L 184, 17.7.1999, p. 23.

▼B*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. ►M64 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 ◀. 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.

▼M104*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.

▼B*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.

▼M64*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 ►C7 Annexes I and III. ◀

▼B*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:

▼M64

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

▼M34

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

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

▼B*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. Chemotheapeutics
 - 1.1.1. Sulfonamides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
All substances belonging to the sulphonamide group	Parent drug	All food-producing species	100 µg/kg	Muscle	
			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
Baqiloprim	Baqiloprim	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	

▼M58

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
			50 µg/kg	Kidney	
Trimethoprim	Trimethoprim	All food producing species except equidae	50 µg/kg Fat (1) Muscle (2)		Not for use in animals from which eggs are produced for human consumption

(1) For porcine and poultry species this MRL relates to 'skin and fat in natural proportions'.

(2) For fin fish this MRL relates to 'muscle and skin in natural proportions'.

▼M96

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

▼M58

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

▼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	

▼M111

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Nafcillin	Nafcillin	All ruminants ⁽¹⁾	300 µg/kg	Muscle	
			300 µg/kg	Fat	
			300 µg/kg	Liver	
			300 µg/kg	Kidney	
			30 µg/kg	Milk	
▼M58	Oxacillin	All food-producing species	300 µg/kg	Muscle	
			300 µg/kg	Fat	
			300 µg/kg	Liver	
			300 µg/kg	Kidney	
			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	
▼M72		Porcine	50 µg/kg	Muscle	
			50 µg/kg	Fat	
			50 µg/kg	Liver	
			50 µg/kg	Kidney	
▼M120	All mammalian-food producing species		50 µg/kg	Muscle	
			50 µg/kg	Fat	

▼M120

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
			50 µg/kg 50 µg/kg 4 µg/kg	Liver Kidney Milk	

▼M74

Phenoxymethylenicillin	Phenoxymethylenicillin	Porcine	25 µg/kg 25 µg/kg 25 µg/kg	Muscle Liver Kidney	
		Poultry (2)			
			25 µg/kg 25 µg/kg 25 µg/kg	Muscle Skin + fat Liver	

▼M121**▼M111**⁽¹⁾ For intramammary use only.►M121 ⁽²⁾ Not for use in animals from which eggs are produced for human consumption. ▶

1.2.2. Cephalosporins

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Cefacetile	Cefacetile	Bovine	125 µg/kg	Milk	For intramammary use only
Cefalexin	Cefalexin	Bovine	200 µg/kg 200 µg/kg 200 µg/kg	Muscle Fat Liver	

▼M58

	Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
				1 000 µg/kg 100 µg/kg	Kidney Milk	
▼M100	Cefalonium	Bovine		20 µg/kg	Milk	
▼M87	Cépirin	Sum of cephapirin and desacetylcephapirin	Bovine	50 µg/kg 50 µg/kg 100 µg/kg 60 µg/kg	Muscle Fat Kidney Milk	
▼M58	Cefazolin	Cefazolin	Bovine, ovine, caprine	50 µg/kg	Milk	
▼M83	Cefoperazone	Cefoperazone	Bovine	50 µg/kg	Milk	
▼M58	Cefquinome	Cefquinome	Bovine	50 µg/kg 50 µg/kg 100 µg/kg 200 µg/kg 20 µg/kg	Muscle Fat Liver Kidney Milk	
▼M65			Porcine	50 µg/kg 50 µg/kg 100 µg/kg 200 µg/kg	Muscle Skin + fat Liver Kidney	

▼M65	Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
▼M109		Equidae		50 µg/kg 50 µg/kg 100 µg/kg 200 µg/kg	Muscle Fat Liver Kidney	
▼M128	Ceftiofur	Sum of all residues retaining the beta-lactam structure expressed as desfuroylceftiofur	All mammalian food-producing species	1 000 µg/kg 2 000 µg/kg 2 000 µg/kg 6 000 µg/kg 100 µg/kg	Muscle Fat (¹) Liver Kidney Milk	
¹) For porcine species this MRL relates to 'skin and fat in natural proportions'.						
▼M58	1.2.3. Quinolones					
▼M96	Danofloxacin	Danofloxacin	►C11 All food species except bovine, ovine, caprine, porcine and poultry ▼	100 µg/kg 50 µg/kg 200 µg/kg 200 µg/kg	Muscle (²) Fat (¹) Liver Kidney	Other provisions

▼M96

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
	Bovine, ovine, caprine	200 µg/kg 100 µg/kg Fat 400 µg/kg Liver 400 µg/kg Kidney 30 µg/kg Milk	200 µg/kg 100 µg/kg Fat 400 µg/kg Liver 400 µg/kg Kidney 30 µg/kg Milk	Muscle	
	Poultry	200 µg/kg Muscle 100 µg/kg Skin and fat	400 µg/kg Liver 400 µg/kg Kidney	Liver Kidney	Not for use in animals from which eggs are produced for human consumption
Difloxacin	Difloxacin	All food producing species except bovine, ovine, caprine and poultry	300 µg/kg 100 µg/kg Fat 800 µg/kg Liver 600 µg/kg Kidney 400 µg/kg Muscle 100 µg/kg Fat 1 400 µg/kg Liver 800 µg/kg Kidney 400 µg/kg Muscle 100 µg/kg Skin and fat 800 µg/kg Liver 800 µg/kg Kidney 300 µg/kg Muscle 400 µg/kg Skin and fat 1 900 µg/kg Liver 600 µg/kg Kidney	Muscle (2) Fat Liver Kidney Muscle Fat Liver Kidney Muscle Skin and fat Liver Kidney Muscle Skin and fat Liver Kidney	Not for use in animals from which milk is produced for human consumption
Enrofloxacin	Sum of enrofloxacin and ciprofloxacin	All food producing species except bovine, ovine, porcine, rabbits and poultry	100 µg/kg 100 µg/kg Fat 200 µg/kg Liver 200 µg/kg Kidney	Muscle (2) Fat Liver Kidney	

▼M96

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
	Bovine, ovine, caprine	100 µg/kg	Muscle		
		100 µg/kg	Fat		
		300 µg/kg	Liver		
		200 µg/kg	Kidney		
		100 µg/kg	Milk		
		100 µg/kg	Muscle		
		100 µg/kg	Fat (1)		
		200 µg/kg	Liver		
		300 µg/kg	Kidney		
		100 µg/kg	Muscle		
		100 µg/kg	Skin and fat		
		200 µg/kg	Liver		
		300 µg/kg	Kidney		
					Not for use in animals from which eggs are produced for human consumption
Flumequine	Flumequine	All food producing species except bovine, ovine, caprine, porcine, poultry and fin fish	200 µg/kg 250 µg/kg 500 µg/kg 1 000 µg/kg 200 µg/kg 300 µg/kg 500 µg/kg 1 500 µg/kg 50 µg/kg 400 µg/kg	Muscle Fat Liver Kidney Muscle Fat (1) Liver Kidney Milk Muscle Skin and fat	
		Bovine, porcine, ovine, caprine			
		Poultry			
		Fin fish			
					Not for use in animals from which eggs are produced for human consumption

	Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
▼M96						
▼M77	Marbofloxacin	Marbofloxacin	Bovine	150 µg/kg 50 µg/kg 150 µg/kg 150 µg/kg 75 µg/kg 150 µg/kg 50 µg/kg 150 µg/kg	Muscle Fat Liver Kidney Milk Muscle Skin and fat Liver Kidney	
▼M103	Oxolinic acid	Oxolinic acid	Porcine	100 µg/kg 50 µg/kg 150 µg/kg 150 µg/kg 100 µg/kg 50 µg/kg 150 µg/kg 150 µg/kg	Muscle Skin and fat Liver Kidney Muscle Skin and fat Liver Kidney	Not for use in animals from which eggs are produced for human consumption
▼M122	All food-producing species ⁽³⁾		Fin fish	100 µg/kg	Muscle and skin in natural proportions	100 µg/kg 50 µg/kg 150 µg/kg 150 µg/kg

▼M122

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

▼M58

▼M96

- (¹) For fin fish this MRL relates to 'muscle and skin in natural proportions'.
 (²) For porcine species this MRL relates to 'skin and fat in natural proportions'.
 ►M122 (³) Not for use in animals from which milk or eggs are produced for human consumption; MRLs for fat, liver and kidney do not apply to fin fish.
 (⁴) For porcine and poultry species this MRL relates to 'skin and fat in natural proportions'. ▶M58

1.2.4. Macrolides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Erythromycin	Erythromycin A	All food producing species	200 µg/kg	Muscle (¹) Fat (²) Liver Kidney Milk	
			200 µg/kg 200 µg/kg 40 µg/kg 150 µg/kg	Eggs	

▼M137**▼M96**

	Pharmacologically active substance(s)	Marker residue	Animal species	MRL _s	Target tissues	Other provisions
▼M96						
▼M58	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	
		Spiramycin 1	Porcine	250 µg/kg	Muscle	
				2 000 µg/kg	Liver	
				1 000 µg/kg	Kidney	

▼M70

	Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
▼M70						
▼M96	Tilmicosin	Tilmicosin	All food producing species except poultry	50 µg/kg 50 µg/kg 1 000 µg/kg 1 000 µg/kg 50 µg/kg 75 µg/kg 75 µg/kg 1 000 µg/kg 250 µg/kg	Muscle (¹) Fat (²) Liver Kidney Milk Muscle Skin and fat Liver Kidney	Not for use in animals from which eggs are produced for human consumption
▼C14	Tulathromycin	(2R,3S,4R,5R,8R,10R,11R,12S,13S,14R)-2-ethyl-3,4,10,13-tetrahydroxy-3,5,8,10,12,14-hexamethyl-11-[[3,4,6-trideoxy-3-(dimethylamino)- β -D-xylo-hexopyranosyl]oxy]-1-oxa-6-azacyclopentadecan-15-one expressed as tulathromycin equivalents	Bovine (⁴)	100 µg/kg 3 000 µg/kg 3 000 µg/kg 100 µg/kg 3 000 µg/kg 3 000 µg/kg	Fat Liver Kidney Skin + fat Liver Kidney	
▼M112						

C14

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Tylosin	Tylosin A	All food producing species	100 µg/kg 100 µg/kg 100 µg/kg 100 µg/kg 50 µg/kg 200 µg/kg	Fat (2) Muscle (1) Liver Kidney Milk Eggs	
Tyvalosin	Sum of tyvalosin and 3-O-acetyltylosin	Porcine Poultry (6)	50 µg/kg 50 µg/kg 50 µg/kg 50 µg/kg 50 µg/kg 50 µg/kg	Muscle Fat (18) Liver Kidney Fat (7) Liver	

M137

(1) For fin fish this MRL relates to a 'muscle and skin in natural proportions'.

(2) For porcine species this MRI relates to 'skin and fat in natural proportions'.

For porcine and poultry species this MRI relates to 'skin and fat in natural proportions' or porcine species and mice relates to 'skin and fat in natural proportions'.

- M112 C14 (4) Not for use in animals from which milk is produced for human consumption or porcine and poultry species unless milk leaves the animal within 6 hours of last administration.

Q11 **Q12** **Q13** **Q14** **Q15** **Q16** **Q17** **Q18** **Q19** **Q20** **Q21** **Q22** **Q23** **Q24** **Q25** **Q26** **Q27** **Q28** **Q29** **Q30** **Q31** **Q32** **Q33** **Q34** **Q35** **Q36** **Q37** **Q38** **Q39** **Q40** **Q41** **Q42** **Q43** **Q44** **Q45** **Q46** **Q47** **Q48** **Q49** **Q50** **Q51** **Q52** **Q53** **Q54** **Q55** **Q56** **Q57** **Q58** **Q59** **Q60** **Q61** **Q62** **Q63** **Q64** **Q65** **Q66** **Q67** **Q68** **Q69** **Q70** **Q71** **Q72** **Q73** **Q74** **Q75** **Q76** **Q77** **Q78** **Q79** **Q80** **Q81** **Q82** **Q83** **Q84** **Q85** **Q86** **Q87** **Q88** **Q89** **Q90** **Q91** **Q92** **Q93** **Q94** **Q95** **Q96** **Q97** **Q98** **Q99** **Q100**

which milk is produced or human consumption.

MRI Not for use in animals nor which eggs are produced in natural proportions.

▼M131

1.2.5. Florfenicol and related compounds

Pharmacologically active Substance(s)	Marker residue	Animal species	MRLs	Target tissues
Thiamphenicol	Thiamphenicol	All food producing species ⁽¹⁾	50 µg/kg 50 µg/kg 50 µg/kg 50 µg/kg 50 µg/kg	Muscle ⁽²⁾ Fat ⁽³⁾ Liver Kidney Milk

⁽¹⁾ Not for use in animals from which eggs are produced for human consumption, MRLs for fat, liver and kidney do not apply to fin fish.⁽²⁾ For fin fish muscle relates to 'muscle and skin in natural proportions'.⁽³⁾ For porcine and poultry species this MRL relates to 'skin and fat in natural proportions'.**▼M58**

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 300 µg/kg 600 µg/kg 100 µg/kg 200 µg/kg	Muscle Liver Kidney Milk Eggs	
Doxycycline	Doxycycline	Bovine Not for use in animals from which milk is produced for human consumption	100 µg/kg 300 µg/kg	Muscle Liver Kidney Muscle Skin and fat Liver Kidney	

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

▼M58

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

1.2.7. Naphthalene-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
▼M71	Sum of metabolites that may be hydrolysed to 8-a-hydroxymutilin	Porcine	100 µg/kg	Muscle	
Tiamulin		Chicken	500 µg/kg	Liver	
			100 µg/kg	Muscle	
			100 µg/kg	Skin and fat	
			1 000 µg/kg	Liver	
▼M77		Rabbits	100 µg/kg	Muscle	
			500 µg/kg	Liver	
▼M83		Turkey	100 µg/kg	Muscle	
			100 µg/kg	Skin and fat	
			300 µg/kg	Liver	

	Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
▼M83						
▼M71	Tiamulin			1 000 µg/kg	Eggs	
▼M58	Vancomulin	Valnemulin	Porcine	50 µg/kg 500 µg/kg 100 µg/kg	Muscle Liver Kidney	
▼M59						
1.2.9. Lincomycinides						
	Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
▼M96	Lincomycin	All food producing species		50 µg/kg 100 µg/kg 500 µg/kg 1 500 µg/kg 150 µg/kg 50 µg/kg	Fat (1) Muscle (2) Liver Kidney Milk Eggs	
▼M77	Pirlimycin	Bovine		100 µg/kg	Muscle	
				100 µg/kg 1 000 µg/kg 400 µg/kg	Fat Liver Kidney	

▼M77

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Porcine			100 µg/kg	Milk	
			100 µg/kg	Muscle	
			50 µg/kg	Skin and fat	
			500 µg/kg	Liver	
			1 500 µg/kg	Kidney	
			100 µg/kg	Muscle	
			50 µg/kg	Skin and fat	
			500 µg/kg	Liver	
			1 500 µg/kg	Kidney	
			50 µg/kg	Eggs	

(1) For porcine and poultry species this MRL relates to 'skin and fat in natural proportions'.

(2) For fin fish this MRL relates to 'muscle and skin in natural proportions'.

▼M96

1.2.10. Aminoglycosides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Apramycin	Apramycin	Bovine	1 000 µg/kg	Muscle	Not for use in animals from which milk is produced for human consumption

▼M65

▼M65	Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
▼M134	Dihydrostreptomycin	Dihydrostreptomycin	All ruminants	500 µg/kg 500 µg/kg 500 µg/kg 1 000 µg/kg 200 µg/kg 500 µg/kg 500 µg/kg 500 µg/kg 500 µg/kg 500 µg/kg 500 µg/kg 1 000 µg/kg 500 µg/kg 500 µg/kg 500 µg/kg 500 µg/kg 500 µg/kg 1 000 µg/kg 500 µg/kg 500 µg/kg 500 µg/kg 500 µg/kg 500 µg/kg 1 000 µg/kg 1 000 µg/kg 500 µg/kg 500 µg/kg 500 µg/kg 1 000 µg/kg	Muscle Fat Liver Kidney Milk Muscle Skin + fat Liver Kidney Muscle Fat Liver Kidney	
▼M94	Gentamicin	Sum of gentamicin C1, gentamicin C1a, gentamicin C2 and gentamicin C2a	Bovine	50 µg/kg 50 µg/kg 200 µg/kg 750 µg/kg 100 µg/kg	Muscle Fat Liver Kidney Milk	

▼M94

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
		Porcine	50 µg/kg	Muscle	
			50 µg/kg	Skin and fat	
			200 µg/kg	Liver	
			750 µg/kg	Kidney	
▼M110					
Kanamycin	Kanamycin A	All food producing species except fish ⁽³⁾	100 µg/kg 100 µg/kg 600 µg/kg 2 500 µg/kg 150 µg/kg	Muscle Fat ⁽¹⁾ Liver Kidney Milk	
▼M96					
Neomycin (including framycetin)	Neomycin B	All food producing species	500 µg/kg 500 µg/kg 500 µg/kg 1 500 µg/kg 500 µg/kg	Fat ⁽¹⁾ Muscle ⁽²⁾ Liver Kidney Milk Eggs	
Paromomycin	Paromomycin	All food producing species	500 µg/kg 1 500 µg/kg 1 500 µg/kg	Muscle ⁽²⁾ Liver Kidney	Not for use in animals from which milk or eggs are produced for human consumption

M96

▼M134

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

▼M96

(¹) For porcine and poultry species this MRL relates to 'skin and fat in natural proportions'.

(²) For fin fish this MRL relates to 'muscle and skin in natural proportions'.

►M110 (³) Not for use in animals from which eggs are produced for human consumption. ▶

▼M70

1.2.11. Other antibiotics

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Novobiocin	Novobiocin	Bovine	50 µg/kg	Milk	

▼M86

1.2.12. Polyptides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Bacitracin	Sum of bacitracin A, bacitracin B, and bacitracin C	Bovine	100 µg/kg	Milk	
		Rabbits	150 µg/kg	Muscle	
			150 µg/kg	Fat	
			150 µg/kg	Liver	
			150 µg/kg	Kidney	

▼M101

▼M87

1.2.13.Beta-lactamase inhibitors

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Clavulanic acid	Clavulanic acid	Bovine	100 µg/kg	Muscle	
			100 µg/kg	Fat	
			200 µg/kg	Liver	
			400 µg/kg	Kidney	
			200 µg/kg	Milk	
			100 µg/kg	Muscle	
			100 µg/kg	Skin and fat	
			200 µg/kg	Liver	
			400 µg/kg	Kidney	

▼M96

1.2.14.Polymyxins

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Colistin	Colistin	All food producing species	150 µg/kg	Fat (1)	
			150 µg/kg	Muscle (2)	
			150 µg/kg	Liver	
			200 µg/kg	Kidney	
			50 µg/kg	Milk	
			300 µg/kg	Eggs	

(1) For porcine and poultry species this MRL relates to 'skin and fat in natural proportions'.
 (2) For fin fish this MRL relates to 'muscle and skin in natural proportions'.

▼M135

1.2.15. Orthosomycins

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Avilamycin	Dichloroisoevernic acid	Porcine	50 µg/kg	Muscle	
			100 µg/kg	Fat (1)	
		Rabbit	300 µg/kg	Liver	
			200 µg/kg	Kidney	
		Poultry (2)	50 µg/kg	Muscle	
			100 µg/kg	Fat	
			300 µg/kg	Liver	
			200 µg/kg	Kidney	
		Poultry (2)	50 µg/kg	Muscle	
			100 µg/kg	Fat (1)	
			300 µg/kg	Liver	
			200 µg/kg	Kidney	

(1) For porcine and poultry species, this MRL relates to skin and fat in natural proportions.

(2) Not for use in animals from which eggs are produced for human consumption.

▼M137

1.2.16. Ionophores

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Monensin	Monensin A	Bovine	2 µg/kg	Muscle	
			10 µg/kg	Fat	
			30 µg/kg	Liver	
			2 µg/kg	Kidney	
			2 µg/kg	Milk	

▼M137

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Lasalocid	Lasalocid A	Poultry	20 µg/kg 100 µg/kg 100 µg/kg 50 µg/kg 150 µg/kg	Muscle Fat (1) Liver Kidney Eggs	

(1) For poultry species, this MRL relates to 'skin and fat in natural proportions'.

▼M58

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	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	
▼M86					
Rafoxanide	Bovine		30 µg/kg	Muscle	
			30 µg/kg	Fat	
			10 µg/kg	Liver	
			40 µg/kg	Kidney	
	Ovine		100 µg/kg	Muscle	
			250 µg/kg	Fat	
			150 µg/kg	Liver	
			150 µg/kg	Kidney	

▼M58

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 Fat Liver Kidney	

2.1.3. Benzimidazoles and pro-benzimidazoles

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
▼M113 Albendazole	Sum of albendazole sulphoxide, albendazole sulphone, and alben-dazole 2-amino sulphone, expressed as albendazole	All ruminants	100 µg/kg 100 µg/kg 1 000 µg/kg 500 µg/kg 100 µg/kg	Muscle Fat Liver Kidney Milk	
▼M69 Albendazole oxide	Sum of albendazole oxide, albendazole sulphone and alben-dazole 2-amino-sulphone, expressed as albendazole	Bovine, ovine	100 µg/kg 100 µg/kg 1 000 µg/kg 500 µg/kg 100 µg/kg	Muscle Fat Liver Kidney Milk	

▼M69		Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
▼M113	Febantel	Sum of extractable residues which may be oxidised to oxfendazole sulphone	All ruminants	50 µg/kg 50 µg/kg 500 µg/kg 50 µg/kg 10 µg/kg	Muscle Fat Liver Kidney Milk		
▼M127	Fenbendazole	Sum of extractable residues which may be oxidised to oxfendazole sulphone	All ruminants	50 µg/kg 50 µg/kg 500 µg/kg 50 µg/kg 10 µg/kg	Muscle Fat Liver Kidney Milk		
▼M127	Flubendazole	Sum of flubendazole and (2-amino 1H-benzimidazol-5-yl) (4-fluorophenyl) methanone	Poultry, porcine	50 µg/kg 50 µg/kg 400 µg/kg 300 µg/kg	Muscle Skin + fat Liver Kidney		
▼M127	Flubendazole	Flubendazole	Poultry	400 µg/kg	Eggs		
▼M88	Mebendazole	Sum of mebendazole methyl (5-(1-hydroxy, 1-phenyl) methyl-1H-benzimidazol-2-yl) carbamate and (2-amino-1H-benzimidazol-5-yl) phenylmethanone, expressed as mebendazole equivalents	Ovine, caprine, equidae	60 µg/kg 60 µg/kg 400 µg/kg 60 µg/kg	Muscle Fat Liver Kidney	Not for use in animals from which milk is produced for human consumption	

	Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
▼M88						
▼M83	Netobimin	Sum of albendazole oxide, sulphone and alben-dazole 2-amino-sulphone, expressed as albendazole	►C8 ovine	Bovine, 100 µg/kg 100 µg/kg 1 000 µg/kg 500 µg/kg 100 µg/kg	Muscle Fat Liver Kidney Milk	For oral use only
▼M113	Oxfendazole	Sum of extractable residues which may be oxidised to oxibendazole sulphone	All ruminants	50 µg/kg 50 µg/kg 500 µg/kg 50 µg/kg 10 µg/kg	Muscle Fat Liver Kidney Milk	
▼M58	Oxibendazole	Oxibendazole	Porcine	100 µg/kg 500 µg/kg 200 µg/kg 100 µg/kg	Muscle Skin and fat Liver Kidney	
▼M113	Thiabendazole	Sum of thiabendazole and 5-hydroxythaben-dazole	Caprine	100 µg/kg 100 µg/kg 100 µg/kg 100 µg/kg	Muscle Fat Liver Kidney Milk	

▼M113

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Triclabendazole	Sum of extractable residues that may be oxidised to ketotriacobendazole	All ruminants ⁽¹⁾	225 µg/kg 100 µg/kg 250 µg/kg 150 µg/kg	Muscle Fat Liver Kidney	

▼M130

⁽¹⁾ Not for use in animals producing milk for human consumption.

▼M62

2.1.4. Phenol derivatives including salicylanides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Nitroxinil	Nitroxinil	Bovine, ovine	400 µg/kg	Muscle	
Oxyclozanide	Oxyclozanide	All ruminants	20 µg/kg 20 µg/kg 500 µg/kg 100 µg/kg	Muscle Fat Liver Kidney	

▼M113

▼M113

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

▼M66**2.1.5. Benzenesulphonamides**

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Clorsulon	Clorsulon	Bovine	35 µg/kg 100 µg/kg 200 µg/kg	Muscle Liver Kidney	

▼M94**2.1.6. Piperazine derivatives**

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Piperazine	Piperazine	Porcine	400 µg/kg 800 µg/kg 2 000 µg/kg 1 000 µg/kg 2 000 µg/kg	Muscle Skin and fat Liver Kidney Eggs	

▼M114**2.1.7. Tetrahydropyrimides**

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Morantel	Sum of residues which may be hydrolysed to N-methyl-1,3-propanediamine and expressed as morantel equivalents	Bovine, ovine	100 µg/kg 100 µg/kg 800 µg/kg 200 µg/kg 50 µg/kg	Muscle Fat Liver Kidney Milk	

▼M114

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
	All ruminants		100 µg/kg 100 µg/kg 800 µg/kg 200 µg/kg 50 µg/kg	Muscle Fat Liver Kidney Milk	

▼M122

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
	All ruminants		100 µg/kg 100 µg/kg 800 µg/kg 200 µg/kg 50 µg/kg	Muscle Fat Liver Kidney Milk	

▼M58

2.2. Agents acting against ectoparasites
 2.2.1. Organophosphates

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Coumafos	Bees		100 µg/kg	Honey	
Diazinon	Diazinon	Bovine, ovine, caprine Bovine, porcine, ovine, caprine	20 µg/kg 20 µg/kg	Milk Muscle	
Phoxim	Ovine		50 µg/kg 400 µg/kg 50 µg/kg	Muscle Fat Kidney	Not for use in animals from which milk is produced for human consumption

▼M83

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
		Porcine	20 µg/kg	Muscle	
			700 µg/kg	Skin and fat	
			20 µg/kg	Liver	
			20 µg/kg	Kidney	
▼M121					
		Chicken	25 µg/kg	Muscle	
			550 µg/kg	Skin + fat	
			50 µg/kg	Liver	
			30 µg/kg	Kidney	
			60 µg/kg	Eggs	

▼M58

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	

▼M58

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
	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	
	Bees (honey)		200 µg/kg	Honey	
			200 µg/kg	Fat	
	Caprine		100 µg/kg	Liver	
			200 µg/kg	Kidney	
			10 µg/kg	Milk	

▼M69**▼M113**

2.2.3. Pyrethroids

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
	Cyhalothrin (sum of isomers)	Bovine	500 µg/kg	Fat	Further provisions in Council Directive 94/29/EC are to be observed
			50 µg/kg	Kidney	
			50 µg/kg	Milk	

▼M58**▼M83**
▼C8

▼C8	Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
▼C9	Cyfluthrin	Cyfluthrin (sum of isomers)	Bovine, caprine	50 µg/kg 10 µg/kg 10 µg/kg 20 µg/kg	Fat Liver Kidney Milk	Further provisions in Council Directive 94/29/EC observed
▼M113	Deltamethrin	Deltamethrin	All ruminants	10 µg/kg 50 µg/kg 10 µg/kg 10 µg/kg 20 µg/kg	Muscle Fat Liver Kidney Milk	
▼M91			Fin fish	10 µg/kg	Muscle and skin in natural proportions	
▼M131	Fenvalerate	Fenvalerate (sum of RR, SS, RS and SR isomers)	Bovine	25 µg/kg 250 µg/kg 25 µg/kg 25 µg/kg 40 µg/kg	Muscle Fat Liver Kidney Milk	
▼M58	Flumethrin	Flumethrin (sum of trans-Z isomers)	Bovine	10 µg/kg 150 µg/kg 20 µg/kg 10 µg/kg	Muscle Fat Liver Kidney	

▼M58	Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
▼M78		Ovine		30 µg/kg	Milk	
				10 µg/kg	Muscle	
				150 µg/kg	Fat	
				20 µg/kg	Liver	
				10 µg/kg	Kidney	
▼M100						
	Permethrin	(sum of isomers)	Bovine	50 µg/kg	Muscle	
				500 µg/kg	Fat	
				50 µg/kg	Liver	
				50 µg/kg	Kidney	
				50 µg/kg	Milk (*)	
▼M105	Cypermethrin	(sum of isomers)	Salmonidae	50 µg/kg	Muscle and skin in natural proportions	
▼M113		All ruminants		20 µg/kg	Muscle	
				200 µg/kg	Fat	
				20 µg/kg	Liver	
				20 µg/kg	Kidney	

▼M113

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Alphacypermethrin	Cypermethrin (sum of isomers)	Bovine, ovine	20 µg/kg 200 µg/kg 20 µg/kg 20 µg/kg 20 µg/kg	Muscle Fat Liver Kidney Milk (*)	

(*) Further provisions in Commission Directive 98/82/EC are to be observed (OJ L 290, 29.10.1998, p. 25).

▼M100**▼M65**

2.2.4. Acyl urea derivatives

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Diffubenzuron		Salmonidae	1 000 µg/kg	Muscle and skin in natural proportions	
Fluazuron	Fluazuron	Bovine ⁽¹⁾	200 µg/kg 7 000 µg/kg 500 µg/kg 500 µg/kg	Muscle Fat Liver Kidney	
Teflubenzuron	Teflubenzuron	Salmonidae	500 µg/kg	Muscle and skin in natural proportions	

⁽¹⁾ Not for use in animals from which milk is produced for human consumption.**▼M129**

▼M76

2.2.5. Pyrimidines derivatives

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Dicyclanil	Sum of dicyclanil and 2, 4, 6-triamino-pyrimidine-5-carbonitrile	Ovine	200 µg/kg ►M78 150 µg/kg	Muscle Fat	Not for use in animals from which milk is produced for human consumption

▼M86

2.2.6. Triazine derivatives

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Cyromazine	Cyromazine	Ovine	300 µg/kg 300 µg/kg 300 µg/kg	Muscle Fat Liver	Not for use in animals from which milk is produced for human consumption

▼M58

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
Abamectin	Avermectin B1a	Bovine	10 µg/kg	Fat	

▼M58

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
▼M94		Ovine	20 µg/kg	Liver	Not for use in animals from which milk is produced for human consumption
			20 µg/kg	Muscle	
			50 µg/kg	Fat	
			25 µg/kg	Liver	
			20 µg/kg	Kidney	
▼M132	Doramectin	All mammalian food producing species (1)	40 µg/kg 150 µg/kg 100 µg/kg 60 µg/kg	Muscle Fat Liver Kidney	
	Doramectin				
▼M106	Emanectin	Fin fish	100 µg/kg	Muscle and skin in natural proportions	
	Emanectin				
▼M58	Eprinomectin	Bovine	►M67 50 µg/kg ►M67 250 µg/kg ►M67 1 500 µg/kg ►M67 300 µg/kg ►M67 20 µg/kg	Muscle Fat Liver Kidney Milk	
	Eprinomectin				

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
ivermectin	22, 23-Dihydro-avermectin B1a	Bovine Porcine, ovine, equidae Deer, reindeer All mammalian food-producing species ⁽¹⁾	40 µg/kg 100 µg/kg Liver 20 µg/kg Fat 15 µg/kg Liver 20 µg/kg Muscle 100 µg/kg Fat 50 µg/kg Liver 20 µg/kg Kidney 100 µg/kg Fat 100 µg/kg Liver 30 µg/kg Kidney	Fat Liver Fat Liver Muscle Fat Liver Kidney Fat Liver Kidney	
Moxidectin	Moxidectin	Bovine, ovine Bovine Equidae	50 µg/kg 500 µg/kg 100 µg/kg 50 µg/kg 40 µg/kg 50 µg/kg 500 µg/kg 100 µg/kg 50 µg/kg 40 µg/kg Milk	Muscle Fat Liver Kidney Milk	

1) Not for use in animals from which milk is produced for human consumption.

▼M58
 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	
			200 µg/kg	Skin and fat	
			600 µg/kg	Liver	
		Turkey	400 µg/kg	Kidney	
			100 µg/kg	Muscle	
			200 µg/kg	Skin and fat	
			600 µg/kg	Liver	
			400 µg/kg	Kidney	
		Porcine	100 µg/kg	Muscle	
			150 µg/kg	Skin and fat	
			500 µg/kg	Liver	
			250 µg/kg	Kidney	
All mammalian food producing species (1)			100 µg/kg	Muscle	
			150 µg/kg	Fat (2)	

▼M80

▼M126

▼M126

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
		Poultry ⁽³⁾	500 µg/kg 250 µg/kg 100 µg/kg	Liver Kidney Muscle	
			200 µg/kg 600 µg/kg 400 µg/kg	Skin + fat Liver Kidney	

⁽¹⁾ Not for use in animals from which milk is produced for human consumption.⁽²⁾ For porcine species this MRL relates to 'skin and fat in natural proportions'.⁽³⁾ Not for use in animals from which eggs are produced for human consumption.**▼M80****2.4.2. Quinazolone derivatives**

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Halofuginone	Halofuginone	Bovine	10 µg/kg 25 µg/kg 30 µg/kg 30 µg/kg	Muscle Fat Liver Kidney	

▼M91**2.4.3. Carbamides**

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Imidocarb	Imidocarb	Bovine	300 µg/kg 50 µg/kg	Muscle Fat	

▼M91

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
			2 000 µg/kg	Liver	
			1 500 µg/kg	Kidney	
			50 µg/kg	Milk	
▼M109					
	Ovine (¹)		300 µg/kg	Muscle	
			50 µg/kg	Fat	
			2 000 µg/kg	Liver	
			1 500 µg/kg	Kidney	

(¹) Not for use in ovine from which milk is produced for human consumption.

▼M118

2.4.4. Ionophores

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
▼M137					

▼M58

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 azapetrol	Porcine	100 µg/kg	Muscle	

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 5 µg/kg 25 µg/kg 25 µg/kg	Muscle Skin and fat Liver Kidney	

▼M72

▼M78

3.2.2. β_2 sympathomimetic agents

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Clenbuterol hydrochloride	Clenbuterol	Bovine	0,1 µg/kg 0,5 µg/kg 0,5 µg/kg 0,05 µg/kg	Muscle Liver Kidney Milk	

▼M58

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
Carprofen	Carprofen	Bovine Not for use in animals from which milk is produced for human consumption Equidae	500 µg/kg 1 000 µg/kg 1 000 µg/kg 500 µg/kg 1 000 µg/kg 1 000 µg/kg	Muscle Fat Liver Kidney Muscle Fat Liver Kidney	

▼M65

▼M65						
Pharmacologically active substance(s)		Marker residue	Animal species	MRLs	Target tissues	Other provisions
▼M58		Vedaprofen	Equidae	50 µg/kg 20 µg/kg 100 µg/kg 1 000 µg/kg	Muscle Fat Liver Kidney	
▼M119		Carprofen	Sum of carprofen and carprofen glucuronide conjugate	500 µg/kg 1 000 µg/kg 1 000 µg/kg 1 000 µg/kg	Muscle Fat Liver Kidney	
4.1.2. Fenamate group derivatives						
▼M71						
Pharmacologically active substance(s)		Marker residue	Animal species	MRLs	Target tissues	Other provisions
Flunixin		Bovine		20 µg/kg 30 µg/kg 300 µg/kg 100 µg/kg 40 µg/kg 50 µg/kg 10 µg/kg 200 µg/kg 30 µg/kg	Muscle Fat Liver Kidney Milk Muscle Skin and fat Liver Kidney	
5-Hydroxyflunixin		Porcine				

	Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
▼M71						
▼M80		Equidae		10 µg/kg 20 µg/kg 100 µg/kg 200 µg/kg	Muscle Fat Liver Kidney	
▼M58	Tolfenamic acid	Bovine		50 µg/kg 400 µg/kg	Muscle Liver	
				100 µg/kg 50 µg/kg 50 µg/kg	Kidney Milk Muscle	
		Porcine		400 µg/kg	Liver	
				100 µg/kg	Kidney	

▼M97 4.1.3. Enolic acid derivates

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Meloxicam	Meloxicam	Equidae	20 µg/kg 65 µg/kg 65 µg/kg	Muscle Liver Kidney	

▼M69

4.1.4. Oxican derivatives

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
▼M131 Meloxicam		Porcine, equidae, rabbit Bovine, caprine	20 µg/kg 65 µg/kg 65 µg/kg 20 µg/kg 65 µg/kg 65 µg/kg 15 µg/kg	Muscle Liver Kidney Muscle Liver Kidney Milk	

M108

4.1.5. Pyrazolone derivatives

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Metamizole	4-Methylaminoantipyrin	Bovine	100 µg/kg	Muscle	
			100 µg/kg	Fat	
			100 µg/kg	Liver	
			100 µg/kg	Kidney	
			50 µg/kg	Milk	
			100 µg/kg	Muscle	
			100 µg/kg	Skin and fat	
			100 µg/kg	Liver	
			100 µg/kg	Kidney	
			100 µg/kg	Muscle	
			100 µg/kg	Fat	
			100 µg/kg	Liver	
			100 µg/kg	Kidney	

M110

4.16 Phenyl acetic acid derivatives

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Diclofenac	Diclofenac	Bovine ⁽¹⁾	5 µg/kg 1 µg/kg 5 µg/kg 10 µg/kg 5 µg/kg	Muscle Fat Liver Kidney Muscle	
		Porcine	1 µg/kg 5 µg/kg 10 µg/kg	Skin + fat Liver Kidney	

(1) Not for use in animals from which milk is produced for human consumption.

▼M136 4.1.7. Sulphonated fenyldactones

Firocoxib					
Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
	Firocoxib	<i>Equidae</i>	10 µg/kg 15 µg/kg 60 µg/kg 10 µg/kg	Muscle Fat Liver Kidney	
▼M58					
5. Corticoids					
5.1. Glucocorticoides					
M70					
Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Betamethasone	Bovine		0,75 µg/kg 2,0 µg/kg	Muscle Liver	
			0,75 µg/kg 0,3 µg/kg	Kidney Milk	
			0,75 µg/kg 2,0 µg/kg	Muscle Liver	
			0,75 µg/kg	Kidney	
▼M58					
Dexamethasone	Bovine Bovine, <i>equidae</i>	porcine,	0,3 µg/kg 0,75 µg/kg	Milk Muscle	
			2 µg/kg 0,75 µg/kg	Liver Kidney	
			0,75 µg/kg 2 µg/kg	Muscle Liver	
			0,75 µg/kg 0,3 µg/kg	Kidney Milk	

	Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
▼M58						
▼M93	Methylprednisolone	Methylprednisolone	Bovine	10 µg/kg 10 µg/kg 10 µg/kg 10 µg/kg	Muscle Fat Liver Kidney	Not for use in animals from which milk is produced for human consumption
▼M79	Prednisolone	Prednisolone	Bovine	4 µg/kg 4 µg/kg 10 µg/kg 10 µg/kg 6 µg/kg	Muscle Fat Liver Kidney Milk	
▼M92	6. Agents acting on the reproductive system					
6.1. Progestogens	Chlormadinone	Marker residue	Animal species	MRLs	Target tissues	Other provisions
	Chlormadinone	Bovine		4 µg/kg 2 µg/kg 2,5 µg/kg	Fat Liver Milk	For zootechnical use only

▼M92	Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Flugestone acetate	Flugestone acetate	Ovine		1 µg/kg	Milk	For intravaginal use for zootechnical purposes only
▼M103		Caprine		1 µg/kg	Milk	For intravaginal use for zootechnical purposes only
▼M124		Ovine, caprine		0,5 µg/kg 0,5 µg/kg 0,5 µg/kg 0,5 µg/kg	Muscle Fat Liver Kidney	For therapeutic and zootechnical purposes only
▼M116	Altrenogest ⁽¹⁾	Porcine		1 µg/kg	Skin and fat	
		Equidae		0,4 µg/kg 1 µg/kg 0,9 µg/kg	Liver Fat Liver	
▼M121	Norgestomet ⁽²⁾	Bovine		0,2 µg/kg	Muscle	
				0,2 µg/kg 0,2 µg/kg 0,2 µg/kg 0,12 µg/kg	Fat Liver Kidney Milk	
▼M116						

⁽¹⁾ Only for zootechnical use and in accordance with the provisions of Directive 96/22/EC.

► **M21** ⁽²⁾ For therapeutic and zootechnical purposes only. ▶

▼M58*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	
▼M99		
Aluminium salicylate, basic	Bovine	For oral use only; Not for use in animals from which milk is produced for human consumption
▼M58		
Aluminium tristearate	All food-producing species	
Ammonium chloride	All food-producing species	
▼M72		
Barium selenate	Bovine, ovine	
▼M58		
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

	Pharmacologically active substance(s)	Animal species	Other provisions
Boric acid and borates	All food-producing species		
▼M65			
Bromide, potassium salt	All food producing species		
▼M58			
Bromide, sodium salt	All mammalian food-producing species	For topical use only	
▼M58			
Calcium acetate	All food-producing species		
Calcium benzoate			
Calcium carbonate			
Calcium chloride			
Calcium gluconate			
Calcium hydroxide			
Calcium hypophosphate			
Calcium malate			
Calcium oxide			
Calcium phosphate			
Calcium polyphosphates			
Calcium propionate			
Calcium silicate			
Calcium stearate			
Calcium sulphate			

▼M58

Pharmacologically active substance(s)	Animal species	Other provisions
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	
▼M80		
Calcium glycerophosphate	All food producing species	
▼M58		
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	
Copper methionate	All food-producing species	
Copper oxide	All food-producing species	

▼M58

Pharmacologically active substance(s)	Animal species	Other provisions
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:	All food-producing species	
— Sodium and potassium-iodide		
— Sodium and potassium-iodate		
— Iodophors including polyvinylpyrrolidone-iodine		
Iron dichloride	All food-producing species	
Iron sulphate	All food-producing species	
Magnesium	All food-producing species	
Magnesium sulphate		
Magnesium hydroxide		
Magnesium stearate		
Magnesium glutamate		
Magnesium orotate		
Magnesium aluminium silicate		
Magnesium oxide		
Magnesium carbonate		
Magnesium phosphate		

▼M58

Pharmacologically active substance(s)	Animal species	Other provisions
Magnesium glycerophosphate		
Magnesium aspartate		
Magnesium citrate		
Magnesium acetate		
Magnesium trisilicate		
Nickel gluconate	All food-producing species	
Nickel sulphate	All food-producing species	
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 chloride	Bovine	For topical use only
Sodium dichloroisocyanurate	Bovine, ovine, caprine	For topical use only
▼M62		
Sodium glycerophosphate	All food producing species	
▼M58		
Sodium hypophosphite	All food-producing species	
Sodium nitrite	Bovine	For topical use only
▼M129		
Sodium propionate	All food producing species	
Sodium selenate	All food-producing species	
▼M77		
Sodium propionate		
▼M58		
Sodium selenate		

▼M58

	Pharmacologically active substance(s)	Animal species	Other provisions
Sodium selenite	All food-producing species		
Sulphur	►M101 All food producing species ▼		
Zinc acetate	All food-producing species		
Zinc chloride			
Zinc gluconate			
Zinc oleate			
Zinc stearate			

2. Organic compounds

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

▼ M58

	Pharmacologically active substance(s)	Animal species	Other provisions
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
Buserein	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		
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
Chlorotresol	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		

▼M58

	Pharmacologically active substance(s)	Animal species	Other provisions
Denaverine hydrochloride	Bovine		
Detomidine	Bovine, equidae	For therapeutic uses only	
▼M112			
Diclazuril	All ruminants ⁽¹⁾ Porcine ⁽¹⁾		
▼M58			
Diethyl phthalate	All food-producing species		
Diethylene glycol monoethyl ether	Bovine, porcine		
Dimanganeze trioxide	All food-producing species	For oral use only	
Dimethyl phthalate	All food-producing species		
Dinoprost	All mammalian food-producing species		
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		

Pharmacologically active substance(s)	Animal species	Other provisions
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	
Isobutane	All food-producing species	
Isoflurane	Equidae	For use as anaesthetic only
Ioxsuprime	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	
Lactic acid	All food-producing species	For use as excipient
Lecirelin	Bovine, equidae, rabbits	
Lobeline	All food-producing species	
Luprotilol	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

▼M58

Pharmacologically active substance(s)	Animal species	Other provisions
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
Manganese sulphate	All food-producing species	For oral use only
Mecillinam	Bovine	For intraterine 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 nicotine	Bovine, equidae	For topical use only
	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	
Nicoboxid	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	

▼M58

	Pharmacologically active substance(s)	Animal species	Other provisions
Pancreatin	All mammalian food-producing species		For topical use only
Papain	All food-producing species		
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		
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

	Pharmacologically active substance(s)	Animal species	Other provisions
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 ceteostearyl sulphate	All food-producing species		For topical use only
Somatotaxim	Salmon		
Tanninum	All food-producing species		
Tau fluvinate			
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		
Wool alcohols	All food-producing species		For topical use only
▼M59			
1-Methyl-2-pyrrolidone	Equidae		
Cefaceftrile	Bovine		For intramammary use only and for all tissues except milk

▼M59

	Pharmacologically active substance(s)	Animal species	Other provisions
Eniconazole	Bovine, equidae		For topical use only
Etamsylate	All food producing species		
Strychnine	Bovine		For oral use only at dose to 0,1 mg/kg bw
▼M60			
Parconazole	Guinea fowl		
▼M62			
Biotin	All food producing species		
Bromhexine	Bovine Not for use in animals from which milk is produced for human consumption		
	Porcine		
	Poultry Not for use in animals from which eggs are produced for human consumption		
Mercaptamine hydrochloride	All mammalian food-producing species		
Praziquantel	Ovine		
Pyrantel embonate	Equidae		
Vitamin B1	All food-producing species		
Vitamin B12	All food-producing species		
Vitamin B2	All food-producing species		
Vitamin B3	All food-producing species		
Vitamin B5	All food-producing species		
Vitamin B6	All food-producing species		

	Pharmacologically active substance(s)	Animal species	Other provisions
Vitamin E	All food-producing species		
▼M63			
Tiaprost	Bovine, ovine, porcine, equidae		
▼M65			
Apramycin	Porcine, rabbit Ovine	For oral use only	
			Not for use in animals from which milk is produced for human consumption
	Chicken		
			Not for use in animals from which eggs are produced for human consumption
Azamethiphos	Salmonidae		
Doxapram	All mammalian food producing species		
Piperonyl butoxide	Bovine, ovine, caprine, equidae	For topical use only	
Sulfogaiacol	All food producing species		
Vetrabutine hydrochloride	Porcine		
▼M66			
Fenpipramide hydrochloride	Equidae	For intravenous use only	
Hydrochlorothiazide	Bovine		
Levomethadone	Equidae	For intravenous use only	
Tricaine mesilate	Fin fish	For water borne use only	
Trichlormethiazide	All mammalian food producing species		Not for use in animals from which milk is produced for human consumption

	Pharmacologically active substance(s)	Animal species	Other provisions
Vincamine	Bovine		For use in newborn animals only
▼M67	All food producing species		
Atropine			
Cefoperazone	Bovine		For intramammary use in lactating cows only and for all tissues except milk
▼M69			
2-aminoethanol glucuronate	All food-producing species		
Betaine glucuronate	All food-producing species		
▼M118			
Bituminosulfonates, ammonium and sodium salts	All mammalian food producing species		For topical use only
▼M69			
Chlorphenamine	All mammalian food-producing species		
Humic acids and their sodium salts	All food-producing species		For oral use only
Paracetamol	Porcine		For oral use only
Tosylchloramide sodium	Fin fish		For water-borne use only
▼M88			
	Bovine		For topical use only
▼M125			
	Equidae		For topical use only
▼M70			
1-methyl-1,2-pyrrolidone	All food-producing species		
Ergometrine maleate	All mammalian food-producing species		For use in parturient animals only
<i>Jecoris oleum</i>	All food-producing species		For topical use only

▼M70

Pharmacologically active substance(s)	Animal species	Other provisions
Mepivacaine	Equidae	For intra-articular and epidural use as local anaesthetic only
Novobiocin	Bovine	For intrammary use only and for all tissues except milk
Piperazine dihydrochloride	Chicken	For all tissues except eggs
Polyoxyl castor oil with 30 to 40 oxyethylene units	All food-producing species	For use as excipient
Polyoxyl hydrogenated castor oil with 40 to 60 oxyethylene units	All food-producing species	For use as excipient
Xylazine hydrochloride	Bovine, equidae	Not for use in animals from which milk is produced for human consumption
▼M71		
Butafosfan	Bovine	►M78 For intravenous use only ▶
Cefalonium	Bovine	For intramammary use and eye treatment only, and for all tissues except milk
Furosemide	Bovine, equidae	For intravenous administration only
Lidocaine	Equidae	For local-regional anaesthesia only
▼M72		
3,5-Diiodo-L-thyrosine	All mammalian food-producing species	
Levothyroxine	All mammalian food-producing species	
▼M74		
Aluminium salicylate, basic	All food producing species except fish For topical use only	
Bismuth subnitrate	Bovine	For intramammary use only
Calcium aspartate	All food producing species	
Methyl salicylate	All food producing species except fish	For topical use only

	Pharmacologically active substance(s)	Animal species	Other provisions
Salicylic acid	All food producing species except fish	For topical use only	
▼M115	Sodium salicylate	Bovine, porcine (2)	
▼M74	Zinc aspartate	All food producing species	
▼M75	Toldimfos	All food producing species	
▼M77	Decoquinate	Bovine, ovine	For oral use only. Not for use in animals from which milk is produced for human consumption
	Sodium boroformiate	All food producing species	
▼M81	Thiamylal	All mammalian food producing species	For intravenous administration only
	Thiopental sodium	All food-producing species	For intravenous administration only
▼M105	Acetylsalicylic acid	All food producing species except fish	Not for use in animals from which milk or eggs are produced for human consumption
	Acetylsalicylic acid DL-lysine	All food producing species except fish	Not for use in animals from which milk or eggs are produced for human consumption
	Carbasalate calcium	All food producing species except fish	Not for use in animals from which milk or eggs are produced for human consumption

	Pharmacologically active substance(s)	Animal species	Other provisions
Sodium acetylsalicylate	All food producing species except fish		Not for use in animals from which milk or eggs are produced for human consumption
▼M83			
Linear alkyl benzene sulphonic acids with alkyl chain lengths ranging from C ₉ to C ₁₃ , containing less than 2,5 % of chains longer than C ₁₃	Bovine		For topical use only
	Ovine (4)		
▼M86			
Amprolium	Poultry		For oral use only
Tiludronic acid, disodium salt	Equidae		For intravenous use only
▼M89			
Sorbitan trioleate	All food-producing species		
▼M90			
Vitamin A	All food producing species		
▼M91			
Ammonium lauryl sulphate	All food-producing species		
Bronopol	Fin fish		
Calcium pantothenate	All food-producing species		
▼M94			
Allantoin	All food producing species		For topical use only
Benzocaine	Salmonidae		
▼M95			
Dexpanthenol	All food producing species		

	Pharmacologically active substance(s)	Animal species	Other provisions
▼M97	Azagly-nafarelin	Salmonidae	Not for use in fish from which eggs are produced for human consumption
	Deslorelin acetate	Equidae	
▼M98	Hydroxyethylsalicylate Xylazine hydrochloride	All food producing species except fish Bovine, equidae	For topical use only
▼M99	Omeprazole	Equidae	For oral use only
▼M100	Trichlomethiazide	All mammalian food producing species	
▼M107	Progesterone (*)	Bovine, ovine, caprine, Equidae (female)	
▼M116	Beclometasone dipropionate	Equidae (¹)	
	Cloprostenol	Caprine	
	R-cloprostenol	Caprine	
	Sorbitan sesquioleate	All food producing species	
▼M126	Diethylene glycol monoethyl ether	All ruminants and porcine	
▼M129	Peforelin	Porcine	

	Pharmacologically active substance(s)	Animal species	Other provisions
▼M129			
▼M138			
Dinoprostone	All mammalian species		
▼M107	(*) Only for intravaginal therapeutic or zootechnical use and in accordance with the provisions of Directive 96/22/EC. ► M112 (*) For oral use only. ▼ ► M115 (?) For oral use; not for use in animals from which milk is produced for human consumption. ▼ ► M116 (?) For inhalation use only. ▼ ► M117 (?) For topical use only. ▼		

▼M58

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		
►C6 Benzyl 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 aceramide	All food-producing species		
Dimethyl sulphoxide	All food-producing species		
Epinephrine	All food-producing species		
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		

▼M58

Pharmacologically active substance(s)	Animal species	Other provisions
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	
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	

	Pharmacologically active substance(s)	Animal species	Other provisions
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 diocylsulphosuccinate	All food-producing species		
Sodium formaldehydesulfoxylate	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		
Tragacanth	All food-producing species		
Urea	All food-producing species		
Zinc oxide	All food-producing species		
Zinc sulphate	All food-producing species		
▼M58			
Adenosine and its 5'-mono-, 5'-di- and 5'-triphosphates	All food producing species		
Alanine	All food producing species		
Arginine	All food producing species		
▼M65			

▼M65

	Pharmacologically active substance(s)	Animal species	Other provisions
Asparagine	All food producing species		
Aspartic acid	All food producing species		
Carnitine	All food producing species		
Choline	All food producing species		
Chymotrypsin	All food producing species		
Citrulline	All food producing species		
Cysteine	All food producing species		
Cytidine and its 5'-mono-, 5'-di- and 5'-triphosphates	All food producing species		
Glutamic acid	All food producing species		
Glutamine	All food producing species		
Glycine	All food producing species		
Guanosine and its 5'-mono-, 5'-di- and 5'-triphosphates	All food producing species		
Histidine	All food producing species		
Hyaluronic acid	All food producing species		
Inosine and its 5'-mono-, 5'-di- and 5'-triphosphates	All food producing species		
Inositol	All food producing species		
Isoleucine	All food producing species		
Leucine	All food producing species		
Lysine	All food producing species		
Methionine	All food producing species		
Ornithine	All food producing species		
Orotic acid	All food producing species		
Pepsin	All food producing species		

▼M65

	Pharmacologically active substance(s)	Animal species	Other provisions
Phenylalanine	All food producing species		
Proline	All food producing species		
Serine	All food producing species		
Thioctic acid	All food producing species		
Threonine	All food producing species		
Thymidine	All food producing species		
Trypsin	All food producing species		
Tryptophan	All food producing species		
Tyrosine	All food producing species		
Uridine and its 5'-mono-, 5'-di- and 5'-triphosphates	All food producing species		
Valine	All food producing species		
▼M126			
Polyoxyethylene sorbitan monoleate	All food producing species		
▼M128			
Polyoxyethylene sorbitan monooleate and trioleate	All food-producing species		

M58 ▼ 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 <i>Adonis vernalis</i>	All food-producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias, at concentrations in the products not exceeding one part per hundred only
 <i>Acqua levici</i>	All food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias only
 <i>Atropa belladonna</i>	All food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias, at concentrations in the products not exceeding one part per hundred only
 <i>Convallaria majalis</i>	All food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias, at concentrations in the products not exceeding one part per thousand only For oral use only
 <i>Apocynum cannabinum</i>	All food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias, at concentrations in the products not exceeding one part per hundred only For oral use only
 <i>Harungana madagascariensis</i>	All food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias, at concentrations in the products not exceeding one part per hundred only
 <i>Selenicereus grandiflorus</i>	All food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias, at concentrations in the products not exceeding one part per hundred only

▼M66

Pharmacologically active substance(s)	Animal species	Other provisions
<i>Thuja occidentalis</i>	All food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias, at concentrations in the products not exceeding one part per hundred only
<i>Virola sebifera</i>	All food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias, at concentrations in the products not exceeding one part per thousand only
▼M68		
<i>Ruta graveolens</i>	All food-producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias, at concentrations in the products not exceeding one part per thousand only. Not for use in animals from which milk is produced for human consumption
▼M71		
<i>Aesculus hippocastanum</i>	All-food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations in the products not exceeding one part per ten only
<i>Agnus castus</i>	All-food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof only
<i>Ailanthus altissima</i>	All-food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof only
<i>Allium cepa</i>	All-food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof only

▼M71

Pharmacologically active substance(s)	Animal species	Other provisions
<i>Arnicae radix</i>	All-food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding in the products not exceeding one part per ten only
<i>Artemisia abrotanum</i>	All-food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof only
<i>Bellis perennis</i>	All-food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof only
<i>Calendula officinalis</i>	All-food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding in the products not exceeding one part per ten only
<i>Camphora</i>	All-food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations in the products not exceeding one part per hundred only.
<i>Cardiospermum halicacabum</i>	All-food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof only
<i>Crataegus</i>	All-food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof only
<i>Echinacea</i>	All-food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof only. For topical use only. For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding in the products not exceeding one part per ten only

▼M71

Pharmacologically active substance(s)	Animal species	Other provisions
<i>Eucalyptus globulus</i>	All-food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof only
<i>Euphrasia officinalis</i>	All-food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof only
<i>Ginkgo biloba</i>	All-food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations in the products not exceeding one part per thousand only.
<i>Ginseng</i>	All-food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof only
<i>Hamamelis virginiana</i>	All-food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations in the products not exceeding one part per ten only
<i>Harpagophytum procumbens</i>	All-food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof only
<i>Hypericum perforatum</i>	All-food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof only
<i>Lachnanthes tinctoria</i>	All-food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations in the products not exceeding one part per thousand only.
<i>Lobaria pulmonaria</i>	All-food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof only

▼M71

Pharmacologically active substance(s)	Animal species	Other provisions
<i>Okoubaka aubrevillei</i>	All-food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof only
<i>Prunus laurocerasus</i>	All-food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations in the products not exceeding one part per thousand only.
<i>Serenoa repens</i>	All-food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof only
<i>Silybum marianum</i>	All-food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof only
<i>Solidago virgaurea</i>	All-food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof only
<i>Syzygium cumini</i>	All-food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof only
<i>Turnera diffusa</i>	All-food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof only
<i>Viscum album</i>	All-food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof only

▼M71

Pharmacologically active substance(s)	Animal species	Other provisions
---------------------------------------	----------------	------------------

▼M72

<i>Phytolacca americana</i>	All food-producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias, at concentrations in the products not exceeding one part per thousand only
<i>Urginea maritima</i>	All food-producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias, at concentrations in the products not exceeding one part per hundred only For oral use only

▼M58 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
Aloe vera gel and whole leaf extract of Aloe vera	All food-producing species	For topical use only
<i>Aloes, Barbados and Capae, their standardised dry extract and preparations thereof</i>	All food-producing species	

▼M73**▼M71**

▼M71	Pharmacologically active substance(s)	Animal species	Other provisions
▼M58			
<i>Angelicae radix aetheroleum</i>	All food-producing species		
<i>Anisi aetheroleum</i>	All food-producing species		
▼M77			
<i>Anisi stellatae fructus</i> , standardised extracts and preparations thereof	All food producing species		
▼M71			
<i>Arnica montana (arnicae flos and arnicae planta tota)</i>	All food-producing species	For topical use only	
▼M58			
<i>Balsamum peruvianum</i>	All food-producing species	For topical use only	
▼M71			
<i>Boldo folium</i>	All food-producing species		
▼M70			
<i>Calendulae flos</i>	All food-producing species	For topical use only	
▼M68			
<i>Capsici fructus acer</i>	All food-producing species		
▼M71			
<i>Carlinae radix</i>	All food-producing species	For topical use only	
▼M58			
<i>Carvi aetheroleum</i>	All food-producing species		
<i>Caryophylli aetheroleum</i>	All food-producing species		
▼M59			
<i>Centellae asiaticaer extractum</i>	All food producing species	For topical use only	
▼M58			
<i>Chrysanthemi cinerariifoli flos</i>	All food-producing species	For topical use only	

▼M58	Pharmacologically active substance(s)	Animal species	Other provisions
▼M70	<i>Cimicifugae racemosae rhizoma</i>	All food-producing species	Not for use in animals from which milk is produced for human consumption
▼M77	<i>Cinchonae cortex</i> , standardised extracts and preparations thereof	All food producing species	
▼M58	<i>Cinnamomi cassiae aetheroleum</i>	All food-producing species	
▼M77	<i>Cinnamomi cassiae cortex</i> , standardised extracts and preparations thereof	All food producing species	
▼M58	<i>Cinnamomi ceylanici aetheroleum</i>	All food-producing species	
▼M77	<i>Cinnamomi ceylanici cortex</i> , standardised extracts and preparations thereof	All food producing species	
▼M58	<i>Citri aetheroleum</i>	All food-producing species	
▼M77	<i>Citronellae aetheroleum</i>	All food-producing species	
▼M58	<i>Condurango cortex</i> , standardised extracts and preparations thereof	All food producing species	
▼M77	<i>Coriandri aetheroleum</i>	All food-producing species	
▼M58	<i>Cupressi aetheroleum</i>	All food-producing species	For topical use only
▼M71			

▼M71	Pharmacologically active substance(s)	Animal species	Other provisions
▼M58			
<i>Echinacea purpurea</i>	All food-producing species	For topical use only	
<i>Eucalypti aetheroleum</i>	All food-producing species		
<i>Foeniculi aetheroleum</i>	All food-producing species		
▼M77			
<i>Frangulae cortex</i> , standardised extracts and preparations thereof	All food producing species		
<i>Genitiae radix</i> , standardised extracts and preparations thereof	All food producing species		
▼M133			
<i>Ginseng</i> , standardised extracts and preparations thereof	All food-producing species		
▼M58			
<i>Hamamelis virginiana</i>	All food-producing species	For topical use only	
▼M68			
<i>Hippocastani semen</i>	All food-producing species	For topical use only	
▼M58			
<i>Hyperici olorum</i>	All food-producing species	For topical use only	
▼M68			
<i>Juniperi fructus</i>	All food-producing species		
<i>Lauri folii aetheroleum</i>	All food-producing species		
<i>Lauri fructus</i>	All food-producing species		
▼M71			
<i>Lavandulae aetheroleum</i>	All food-producing species	For topical use only	
▼M58			
<i>Lespedeza capitata</i>	All food-producing species		
<i>Lini oleum</i>	All food-producing species		
<i>Majoranae herba</i>	All food-producing species		
▼M74			
<i>Matricaria recutita</i> and preparations thereof	All food producing species		

▼M74	Pharmacologically active substance(s)	Animal species	Other provisions
▼M58	<i>Matricariae flos</i>	All food-producing species	
	<i>Medicago sativa extractum</i>	All food-producing species	For topical use only
▼M59	<i>Melissae aetheroleum</i>	All food producing species	
▼M58	<i>Melissae folium</i>	All food-producing species	
▼M91	<i>Menthae arvensis aetheroleum</i>	All food-producing species	
▼M58	<i>Menthae piperitae aetheroleum</i>	All food-producing species	
	<i>Millefolii herba</i>	All food-producing species	
	<i>Myristicæ aetheroleum</i>	All food-producing species	For use in newborn animals only
▼M140	Lectin extracted from red kidney beans <i>Phaseolus vulgaris</i>	Porcine	For oral use only
▼M125	<i>Piceae turiones recentes extractum</i>	All food producing species	For oral use only
▼M58	Oxidation products of <i>Terebinthinae oleum</i>	Bovine, porcine, ovine, caprine	
	<i>Pyrethrum extract</i>	All food-producing species	For topical use only
	<i>Quercus cortex</i>	All food-producing species	
	<i>Quillaia saponins</i>	All food-producing species	
▼M74	<i>Rhei radix</i> , standardised extracts and preparations thereof	All food producing species	
▼M58	<i>Ricini oleum</i>	All food-producing species	For use as excipient
	<i>Rosmarini aetheroleum</i>	All food-producing species	

	Pharmacologically active substance(s)	Animal species	Other provisions
▼M58	<i>Rosmarini folium</i>	All food-producing species	
▼M68	<i>Ruscus aculeatus</i>	All food-producing species	For topical use only
▼M58	<i>Salviae folium</i>	All food-producing species	
	<i>Sambuci flos</i>	All food-producing species	
	<i>Sinapis nigrae semen</i>	All food-producing species	
▼M68	<i>Strychni semen</i>	Bovine, ovine, caprine	For oral use only at doses up to the equivalent of 0,1 mg strychnine/kg bw
▼M71	<i>Symphyti radix</i>	All food-producing species	For topical use on intact skin only
▼M58	<i>Terebinthinae aetheroleum rectificatum</i>	All food-producing species	For topical use only
	<i>Terebinthinae laricina</i>	All food-producing species	For topical use only
	<i>Thymi aetheroleum</i>	All food-producing species	
	<i>Tiliae flos</i>	All food-producing species	
	<i>Urticae herba</i>	All food-producing species	
▼M111	7. Anti-infectious agents		
	Pharmacologically active substance(s)	Animal species	Other provisions
	Oxalic acid	Honey bees	

▼M119 8. Anti-inflammatory agents

	Pharmacologically active substance(s)	Animal species	Other provisions
Carprofen		Bovine ⁽¹⁾	

(1) For bovine milk only.

▼M58*ANNEX III*

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

Pharmacologically active substance(s)							Marker residue			Animal species			MRLs			Target tissues			Other provisions		
Clorsulon				Clorsulon		Bovine				50 µg/kg	Muscle								Provisional MRLs expire on 1 January 2000		
										150 µg/kg	Liver										
										400 µg/kg	Kidney										
1.2.	Antibiotics																				
1.2.1.	Beta-lactamase inhibitors																				
		Clavulanic acid					Marker residue			Animal species			MRLs			Target tissues			Other provisions		
										Bovine, ovine			200 µg/kg	Milk							
										Bovine, ovine, porcine			200 µg/kg	Muscle					► M67 Provisional MRLs expire on 1 July 2001 ▶		
													200 µg/kg	Fat							
													200 µg/kg	Liver							
													200 µg/kg	Kidney							

1.2.2. Macrolides

	Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
▼M58	Acetylisovaleryltylosin	Sum of acetylisovaleryltylosin and 3-O-acetyltylosin	Porcine	100 µg/kg 100 µg/kg 100 µg/kg 100 µg/kg	Muscle Skin and fat Liver Kidney	Provisional MRLs expire on 1.7.2001
▼M117	Acetylisovaleryltylosin ⁽¹⁾	Sum of acetyl-isovaleryltylosin and 3-O-acetyltylosin	Poultry ⁽²⁾	50 µg/kg 50 µg/kg	Skin and fat Liver	
▼M58	Erythromycin	MRLs apply to all microbiological active residues expressed as erythromycin equivalent	Bovine, ovine poultry	40 µg/kg	Milk	Provisional MRLs expire on 1 June 2000
	Josamycin		Bovine, ovine, porcine, poultry	400 µg/kg 400 µg/kg 400 µg/kg 200 µg/kg	Muscle Fat Liver Kidney Eggs	►M77 Provisional MRLs expire on 1.7.2002 ▶

▼M58	Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
▼M60	Sum of the microbiologically active metabolites, expressed as josamycin	Porcine		200 µg/kg	Eggs	Provisional MRLs expire on 1.7.2002
▼M70	Tilmicosin	Bovine		40 µg/kg	Milk	Provisional MRLs expire on 1.1.2001
▼M99	Tulathromycin	(2R,3S,4R,5R,8R,10R,11R,12S, 13S,14R)-2-ethyl-3,4,10,13-tetrahydroxy-3,5,8,10,12,14-hexamethyl-11-[[3,4,6-trideoxy-3-(dimethylamino)-β-D-xylohexopyranosyloxy]-1-oxa-6-azacyclopent-decan-15-one expressed as tulathromycin equivalents	Bovine	100 µg/kg 3 000 µg/kg 3 000 µg/kg	Fat Liver Kidney	Provisional MRLs expire on 1 July 2004; not for use in animals from which milk is produced for human consumption
▼M139	Ganithromycin			20 µg/kg 200 µg/kg 100 µg/kg	Fat Liver Kidney	Provisional MRLs will expire on 1 July 2009. (?) Not for use in animals producing milk for human consumption
▼M117						

(¹) Provisional MRLs expire on 1 July 2006.
(²) Not for use in animals from which eggs are produced for human consumption.

▼M59
1.2.4. Cephalosporins

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Cefacetnile	Cefacetnile	Bovine	125 µg/kg	Milk	►M83 Provisional MRLs expire on 1.1.2002 ▼ For intramammary use only
▼M71	Cefalonium	Bovine	10 µg/kg	Milk	►M85 Provisional MRLs expire on 1.1.2003 ▼
▼M67	Cefoperazone	Bovine	50 µg/kg	Milk	Provisional MRLs expire on 1 January 2001
▼M61	Cefquinome	Porcine	50 µg/kg	Muscle Skin + fat	Provisional MRLs expire on 1.1.2000
			50 µg/kg	Liver	
			100 µg/kg	Kidney	
			200 µg/kg		
▼M59	Sum of cephapirin and desacetylcephapirin	Bovine	50 µg/kg	Muscle Fat	Provisional MRLs expire on 1.1.2001
			50 µg/kg	Liver	
			100 µg/kg	Kidney	
			10 µg/kg	Milk	

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 For use in non-lactating cattle only	1 000 µg/kg 1 000 µg/kg	Muscle Fat	Provisional MRLs expire on 1 July 1999
			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	
Dihydrostreptomycin	Dihydrostreptomycin	Bovine, ovine	500 µg/kg	Muscle	Provisional MRLs expire on 1.6.2002
			500 µg/kg	Fat	
			500 µg/kg	Liver	
		Porcine	1 000 µg/kg	Kidney	
			200 µg/kg	Milk	
			500 µg/kg	Muscle	
			500 µg/kg	Skin and fat	
			500 µg/kg	Liver	
			1 000 µg/kg	Kidney	

▼M76**▼M58**

▼M76

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Gentamicin	Gentamicin	Bovine	100 µg/kg	Milk	Provisional MRLs expire on 1.6.2002
		Bovine, porcine	50 µg/kg	Muscle	
			50 µg/kg	Fat	
			200 µg/kg	Liver	
			750 µg/kg	Kidney	
					►M91 Provisional MRLs expire on 1.1.2004 ▼
Kanamycin	Kanamycin	Rabbits	100 µg/kg	Muscle	
			100 µg/kg	Fat	
			600 µg/kg	Liver	
			2 500 µg/kg	Kidney	
		Bovine, ovine	100 µg/kg	Muscle	
			100 µg/kg	Fat	

▼M65

▼M65

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
			600 µg/kg	Liver	
			2 500 µg/kg	Kidney	
			150 µg/kg	Milk	
			100 µg/kg	Muscle	
			100 µg/kg	Skin + fat	
			600 µg/kg	Liver	
			2 500 µg/kg	Kidney	
▼M76					
Neomycin (including framycetin)	Neomycin B	Bovine, porcine, chicken	500 µg/kg	Muscle	Provisional MRLs expire on 1.6.2002
			500 µg/kg	Fat	
			500 µg/kg	Liver	
			5 000 µg/kg	Kidney	
			500 µg/kg	Milk	
			500 µg/kg	Eggs	
▼M58					
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	

▼M58	Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
▼M71		Ovine Not for use in animals from which milk is produced for human consumption		300 µg/kg	Muscle	Provisional MRLs expire on 1.1.2002
				500 µg/kg	Fat	
				2 000 µg/kg	Liver	
				5 000 µg/kg	Kidney	
		Chicken		200 µg/kg	Eggs	
▼M76	Streptomycin	Bovine, ovine		500 µg/kg	Muscle	Provisional MRLs expire on 1.6.2002
				500 µg/kg	Fat	
				500 µg/kg	Liver	
				1 000 µg/kg	Kidney	
				200 µg/kg	Milk	
		Porcine		500 µg/kg	Muscle	
				500 µg/kg	Skin and fat	
				500 µg/kg	Liver	
				1 000 µg/kg	Kidney	

▼M58 1.2.6. Quinolones

	Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
▼M60	Danofloxacin	Danofloxacin	Porcine	100 µg/kg 50 µg/kg 200 µg/kg 200 µg/kg	Muscle Skin and fat Liver Kidney	Provisional MRLs expire on 1.1.2000
▼M58	Decoquinate	Decoquinate	Bovine, ovine	500 µg/kg	Muscle	Provisional MRLs expire on 1 July 2000
				500 µg/kg 500 µg/kg 500 µg/kg	Fat Liver Kidney	
▼M62	Difloxacain	Difloxacain	Bovine Not for use in animals from which milk is produced for human consumption Porcine	400 µg/kg	Muscle	Provisional MRLs expire on 1.1.2001
				100 µg/kg 1 400 µg/kg 800 µg/kg 400 µg/kg 100 µg/kg 800 µg/kg	Fat Liver Kidney Muscle Skin and fat Liver	
				800 µg/kg	Kidney	

▼M62

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
▼M58					
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	

▼M58

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
			75 µg/kg	Milk	
		Porcine	150 µg/kg	Muscle	
			50 µg/kg	Skin and fat	
			150 µg/kg	Liver	
			150 µg/kg	Kidney	
▼M111	Oxolinic acid ⁽¹⁾	Bovine ⁽²⁾	100 µg/kg	Muscle	
			50 µg/kg	Fat	
			150 µg/kg	Liver	
			150 µg/kg	Kidney	
▼M59		Porcine	100 µg/kg	Muscle	
			50 µg/kg	Skin + fat	
			150 µg/kg	Liver	
			150 µg/kg	Kidney	
		Chicken	100 µg/kg	Muscle	
			50 µg/kg	Skin + fat	
			150 µg/kg	Liver	
			150 µg/kg	Kidney	
			50 µg/kg	Eggs	
		Fin fish	300 µg/kg	Muscle and skin in natural proportions	

⁽¹⁾ Provisional MRLs expire 1 January 2006.

⁽²⁾ Not for use in animals from which milk is produced for human consumption.

▼M111

▼M58

1.2.9. Polymyxins

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Colistin	Colistin	Bovine, ovine Bovine, ovine, porcine, chicken, rabbits	50 µg/kg 150 µg/kg 150 µg/kg 150 µg/kg 200 µg/kg	Milk Muscle Fat Liver Kidney	►M77 Provisional MRLs expire on 1.7.2002 ▼

1.2.10. Penicillins

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Nafcillin	Nafcillin	Bovine	300 µg/kg 300 µg/kg 300 µg/kg 30 µg/kg	Muscle Fat Liver Kidney Milk	Provisional MRLs expire on 1.1.2001
Penethamate	Benzylpenicillin	Ovine	50 µg/kg	Muscle	Provisional MRLs expire on 1 January 2000

▼M59**▼M58**

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

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
▼M59	Thiamphenicol	Ovine	50 µg/kg	Muscle	Provisional MRLs expire on 1.1.2001
			50 µg/kg	Fat	
			50 µg/kg	Liver	
			50 µg/kg	Kidney	
		Porcine	50 µg/kg	Muscle	
			50 µg/kg	Skin + fat	
			50 µg/kg	Liver	
			50 µg/kg	Kidney	
		Fin fish	50 µg/kg	Muscle and skin in natural proportions	

▼M59

▼M58

▼M59

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Thiamphenicol (1)	Thiamphenicol	Porcine	50 µg/kg 50 µg/kg 50 µg/kg 50 µg/kg	Muscle Skin + fat Liver Kidney	

(1) Provisional MRLs expire on 1 January 2007.

▼M121

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions

1.2.12. Polypeptides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Bacitracin	Bacitracin	Bovine	150 µg/kg	Milk	Provisional MRLs expire on 1.7.2001

▼M59

1.2.13. Lincosamides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Lincomycin	Lincomycin	Ovine	100 µg/kg 50 µg/kg 500 µg/kg 1 500 µg/kg 150 µg/kg	Muscle Fat Liver Kidney Milk	Provisional MRLs expire on 1.1.2001
		Porcine	100 µg/kg 50 µg/kg 500 µg/kg 1 500 µg/kg	Muscle Skin + fat Liver Kidney	

▼M59

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
	Chicken		100 µg/kg	Muscle	
			50 µg/kg	Skin + fat	
			500 µg/kg	Liver	
			1 500 µg/kg	Kidney	
			50 µg/kg	Eggs	
					Provisional MRLs expire on 1.7.2000
Pirlimycin	Bovine		100 µg/kg	Muscle	
			100 µg/kg	Fat	
			1 000 µg/kg	Liver	
			400 µg/kg	Kidney	
			100 µg/kg	Milk	

▼M60

▼M71

1.2.14. Pleuromutilines

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Tiamulin	Sum of metabolites that may be hydrolysed to 8- α -hydroxymutilin	Turkey	100 µg/kg 100 µg/kg	Muscle Skin and fat	Provisional MRLs expire on 1.7.2001

▼M58

2. Antiparasitic agents
 2.1. Agents acting against endoparasites

▼M62

2.1.1. Phenol derivatives including salicylanides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Oxyclozanide	Oxyclozanide	Bovine	20 µg/kg 20 µg/kg 500 µg/kg 100 µg/kg 10 µg/kg 20 µg/kg 20 µg/kg	Muscle Fat Liver Kidney Milk Muscle Fat Liver Kidney	▲M77 Provisional MRLs expire on 1.7.2002 ▼

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 sulphoxide, alben-dazole sulphone, and albendazole 2-amino sulphone, expressed as albendazole	Bovine, ovine	100 µg/kg	Milk	Provisional MRLs expire on 1 January 2000
▼M71	Mebendazole	Ovine, caprine, equidae Not for use in animals from which milk is produced for human consumption	60 µg/kg 60 µg/kg 400 µg/kg 60 µg/kg	Muscle Fat Liver Kidney	Provisional MRLs expire on 1.1.2002
▼M58	Netobimbin	Sum of netobimin and albendazole and metabolites of albendazole measured as 2-amino-benzimidazole sulphone	Bovine, ovine, caprine 	100 µg/kg 1 000 µg/kg 500 µg/kg	Provisional MRLs expire on 31 July 1999

▼M58

▼M58

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

▼M62

2.1.3. Tetrahydropyrimidines

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Morantel	Sum of residues which may be hydrolysed to N-Methyl-1,3-propanediamine and expressed as morantel equivalents	Bovine, ovine Porcine	100 µg/kg 100 µg/kg 800 µg/kg 200 µg/kg 100 µg/kg 100 µg/kg 100 µg/kg 100 µg/kg 800 µg/kg 200 µg/kg	Muscle Fat Liver Kidney Milk Muscle Skin and fat Liver Kidney	▲ M85 Provisional MRLs expire on 1.7.2003 ▼

▼M70

2.1.5. Piperazine derivatives

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Piperazine	Piperazine	Porcine Chicken	400 µg/kg 800 µg/kg 2 000 µg/kg 1 000 µg/kg 2 000 µg/kg	Muscle Skin and fat Liver Kidney Eggs	▲ M86 Provisional MRLs expire on 1.7.2003 ▼

▼M71

2.1.6. Salicylanilides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Rafoxanide	Rafoxanide	Bovine Not for use in animals from which milk is produced for human consumption	30 µg/kg 30 µg/kg 10 µg/kg 40 µg/kg	Muscle Fat Liver Kidney	Provisional MRLs expire on 1.7.2001

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Ovine Not for use in animals from which milk is produced for human consumption			100 µg/kg 250 µg/kg 150 µg/kg 150 µg/kg	Muscle Fat Liver Kidney	

▼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 moiety, 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	▲M65 Provisional MRLs expire on 1.7.2001 ▼

▼M58

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	Muscle	Provisional MRLs expire on 1 January 2001
			50 µg/kg 10 µg/kg 10 µg/kg 20 µg/kg	Fat Liver Kidney Milk	Further provisions in Council Directive 94/29/EC are to be observed (OJ L 189, 23.7.1994, p. 67)

▼M61

Alphacypermethrin	Cypermethrin (sum of isomers)	Bovine, ovine	20 µg/kg 200 µg/kg 20 µg/kg	Muscle Fat Liver	►M95 Provisional MRLs expire on 1.7.2003 Further provisions in Directive 93/57/ EC are to be observed ▼
-------------------	-------------------------------	---------------	-----------------------------------	------------------------	---

▼M61	Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
		Chicken		50 µg/kg 50 µg/kg 50 µg/kg 50 µg/kg 50 µg/kg	Muscle Skin + fat Liver Kidney Eggs	
▼M95	Cypermethrin Cypermethrin (sum of isomers)	Bovine		20 µg/kg 200 µg/kg 20 µg/kg 20 µg/kg 20 µg/kg	Muscle Fat Liver Kidney Milk	Provisional MRLs expire on 1.7.2003 Further provisions in Directive 93/57/EC are to be observed
	Cypermethrin (sum of isomers)	Ovine		20 µg/kg 200 µg/kg 20 µg/kg 20 µg/kg	Muscle Fat Liver Kidney	Provisional MRLs expire on 1.7.2003 Not for use in animals from which milk is produced for human consumption
		Porcine		20 µg/kg 200 µg/kg 20 µg/kg 20 µg/kg	Muscle Skin + fat Liver Kidney	

▼M61

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
		Chicken	50 µg/kg	Muscle	
			50 µg/kg	Skin + fat	
			50 µg/kg	Liver	
			50 µg/kg	Kidney	
			50 µg/kg	Eggs	
		Salmonidae	50 µg/kg	Muscle and skin in natural proportions	►M93 Provisional MRLs expire on 1.7.2003 ▼
			10 µg/kg		
			50 µg/kg	Fat	
			10 µg/kg	Liver	
			10 µg/kg	Kidney	
			20 µg/kg	Milk	
			10 µg/kg	Muscle	
		Ovine Not for use in animals from which milk is produced for human consumption	50 µg/kg	Fat	
			10 µg/kg	Liver	
			10 µg/kg	Kidney	

▼M66

M66

▼M83

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
	Bovine, caprine	50 µg/kg	Muscle Fat		Provisional MRLs expire on 1.1.2003

(1) Provisional MRLs expire on 1 July 2006.

▼M115**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

▼M58	Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
▼M65	Coumafos	Coumafos	Bees	100 µg/kg	Honey	Provisional MRLs expire on 1.7.2001
▼M68	Phoxim	Phoxim	Porcine	20 µg/kg	Muscle	Provisional MRLs expire on 1 January 2001
				700 µg/kg	Skin and fat	
				20 µg/kg	Liver	
				20 µg/kg	Kidney	
▼M78	Ovine			50 µg/kg	Muscle	Provisional MRLs expire on 1.7.2001; not for use in animals from which milk is produced for human consumption
				400 µg/kg	Fat	
				50 µg/kg	Kidney	
▼M108	Chicken			50 µg/kg	Muscle	Provisional MRLs expire on 1.7.2005.
				550 µg/kg	Skin and fat	
				25 µg/kg	Liver	
				50 µg/kg	Kidney	
				60 µg/kg	Eggs	
▼M71	Propetamphos	Sum of residues of propetamphos and desisopropyl-propetamphos	Ovine Not for use in animals from which milk is produced for human consumption	90 µg/kg	Fat	Provisional MRLs expire on 1.1.2001
				90 µg/kg	Kidney	

▼M58

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
Diflubenzuron	Diflubenzuron	Salmonidae	1 000 µg/kg	Muscle and skin in natural proportions	Provisional MRLs expire on 1.7.2000
Fluazuron (¹)	Fluazuron	Bovine (²)	200 µg/kg	Muscle	
			7 000 µg/kg	Fat	
			500 µg/kg	Liver	
			500 µg/kg	Kidney	

(¹) Provisional MRLs expire on 1.1.2007.(²) Not for use in animals from which milk is produced for human consumption.**▼M62****▼M123**

2.2.6. Pyrimidines derivatives

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Dicyclanil	Sum of dicyclanil and 2,4,6-triamino-pyrimidine-5-carbonitrile	Ovine	200 µg/kg 50 µg/kg 400 µg/kg 400 µg/kg	Muscle Fat Liver Kidney	Provisional MRLs expire on 1 July 2000; Not for use in animals from which milk is produced for human consumption

▼M69

▼M70 2.2.7. Triazine derivatives

	Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Cyromazine	Cyromazine	Ovine	300 µg/kg 300 µg/kg 300 µg/kg 300 µg/kg	Muscle Fat Liver Kidney	Provisional MRLs expire on 1.7.2001 Not for use in animals from which milk is produced for human consumption	
▼M58	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
▼M71	Abamectin	Avermectin B1a	Ovine	20 µg/kg 50 µg/kg 25 µg/kg 20 µg/kg	Muscle Fat Liver Kidney	Provisional MRLs expire on 1.1.2001
Doramectin	Doramectin	Deer, reindeer	including	20 µg/kg 100 µg/kg 50 µg/kg 30 µg/kg	Muscle Fat Liver Kidney	Provisional MRLs expire on 1.7.2001

▼M71

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
▼M58 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

▼M60

2.4. Agents acting against protozoa

2.4.1. Carbanilides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Imidocarb		Bovine, ovine	300 µg/kg 50 µg/kg 2 000 µg/kg 1 500 µg/kg 50 µg/kg	Muscle Fat Liver Kidney Milk	Provisional MRLs expire on 1.1.2002

2.4.2. Quinazolone derivatives

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Haloquinone	Halofuginone	Bovine	10 µg/kg 25 µg/kg 30 µg/kg	Muscle Fat Liver	Provisional MRL's expire on 1.1.2001

▼M62

▼M62

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

▼M70**2.4.3. Triazinetrione derivatives**

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Toltrazuril	Toltrazuril sulfone	Porcine	100 µg/kg	Muscle	Provisional MRLs expire on 1.1.2001
			150 µg/kg	Skin and fat	
			500 µg/kg	Liver	
			250 µg/kg	Kidney	

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Toltrazuril (¹)	Toltrazuril sulfone	Bovine	100 µg/kg	Muscle	
			150 µg/kg	Fat	
			500 µg/kg	Liver	
			250 µg/kg	Kidney	

(¹) Provisional MRLs expire on 1 July 2006. Not for use in animals from which milk is produced for human consumption.

▼M75**2.4.4. Other anti-protozoal agents**

Pharmacologically active substance(s)	Marker residue	Animal species	MRL	Target tissues	Other provisions
Ampriolum	Ampriolum	Chicken, turkey	200 µg/kg	Muscle	Provisional MRLs expire on 1.1.2002
			200 µg/kg	Skin and fat	
			200 µg/kg	Liver	
			400 µg/kg	Kidney	
			1 000 µg/kg	Eggs	

▼M127

2.4.5. Ionophores

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Lasalocid	Lasalocid A	Poultry	150 µg/kg	Eggs ⁽¹⁾	

⁽¹⁾ Provisional MRLs expire on 1 January 2008.**▼M58**

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
		Equidae Indications: tocolysis and the treatment of respiratory ailments	0,05 µg/kg 0,1 µg/kg 0,5 µg/kg	Milk Muscle Liver	
			0,5 µg/kg	Kidney	

▼M60

3.2.2. Anti-adrenergics

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Carazolol	Bovine	5 µg/kg	Muscle		Provisional MRLs expire on 1.1.2000

▼M58

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	Bovine	500 µg/kg	Muscle		Provisional MRLs expire on 1 January 2000

▼M58

5.1.2. Enolic acid derivates

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

▼M71

5.1.3. Pyrazolone derivatives

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Metamizole	4-Methylaminoantipyrin	Bovine, equidae porcine,	200 µg/kg 200 µg/kg 200 µg/kg 200 µg/kg	Muscle Fat Liver Kidney	Provisional MRLs expire on 1.7.2003. Not for use in animals from which milk is produced for human consumption

▼M130

5.1.4. Sulfonated phenyl lactones

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Firocoxib		<i>Equidae</i>	10 µg/kg 15 µg/kg 60 µg/kg 10 µg/kg	Muscle Fat Liver Kidney	Provisional MRLs expire on 1 July 2007

M92

Agents acting on the reproductive system

Progesterone

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Altrenogest	Altrenogest	Porcine	3 µg/kg 3 µg/kg 3 µg/kg 3 µg/kg 3 µg/kg	►M97 Skin and fat Liver Kidney Fat Liver Kidney	►M97 Provisional MRLs expire on 1.1.2005; for zootechnical use only
		Equidae			
Flugestone acetate	Flugestone acetate	Ovine, caprine	0,5 µg/kg 0,5 µg/kg 0,5 µg/kg 0,5 µg/kg	Muscle Fat Liver Kidney	Provisional MRLs expire on 1.1.2008; for therapeutic or zootechnical use only
Norgestomet	Norgestomet	Bovine	0,5 µg/kg 0,5 µg/kg 0,5 µg/kg 0,5 µg/kg	Muscle Fat Liver Kidney Milk	Provisional MRLs expire on 1.1.2008; for therapeutic or zootechnical use only

M102

71 Classification

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Methylprednisolone	Methylprednisolone	Bovine	10 µg/kg	Muscle	Provisional MRLs expire on 1.7.2001. Not for use in animals from which milk is produced for human consumption

▼M58

ANNEX IV

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

Pharmacologically active substance(s)
<i>Aristolochia</i> 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.

▼M2

- 3.4.1 Study of the effects on reproduction.
- 3.4.2 Embryotoxicity/fetotoxicity, including teratogenicity.
- 3.5 Mutagenicity.
- 3.6 Carcinogenicity.
- 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).
- B.3 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.