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► **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

► <u>M31</u>	Commission Regulation (EC) No 17/97 of 8 January 1997	L 5	12	9.1.1997
► <u>M32</u>	Commission Regulation (EC) No 211/97 of 4 February 1997	L 35	1	5.2.1997
► <u>M33</u>	Commission Regulation (EC) No 270/97 of 14 February 1997	L 45	8	15.2.1997
► <u>M34</u>	Council Regulation (EC) No 434/97 of 3 March 1997	L 67	1	7.3.1997
► <u>M35</u>	Commission Regulation (EC) No 716/97 of 23 April 1997	L 106	10	24.4.1997
► <u>M36</u>	Commission Regulation (EC) No 748/97 of 25 April 1997	L 110	21	26.4.1997
► <u>M37</u>	Commission Regulation (EC) No 749/97 of 25 April 1997	L 110	24	26.4.1997
► <u>M38</u>	Commission Regulation (EC) No 1836/97 of 24 September 1997	L 263	6	25.9.1997
► <u>M39</u>	Commission Regulation (EC) No 1837/97 of 24 September 1997	L 263	9	25.9.1997
► <u>M40</u>	Commission Regulation (EC) No 1838/97 of 24 September 1997	L 263	14	25.9.1997
► <u>M41</u>	Commission Regulation (EC) No 1850/97 of 25 September 1997	L 264	12	26.9.1997
► <u>M42</u>	Commission Regulation (EC) No 121/98 of 16 January 1998	L 11	11	17.1.1998
► <u>M43</u>	Commission Regulation (EC) No 426/98 of 23 February 1998	L 53	3	24.2.1998
► <u>M44</u>	Commission Regulation (EC) No 613/98 of 18 March 1998	L 82	14	19.3.1998
► <u>M45</u>	Commission Regulation (EC) No 1000/98 of 13 May 1998	L 142	18	14.5.1998
► <u>M46</u>	Commission Regulation (EC) No 1076/98 of 27 May 1998	L 154	14	28.5.1998
► <u>M47</u>	Commission Regulation (EC) No 1191/98 of 9 June 1998	L 165	6	10.6.1998
► <u>M48</u>	Commission Regulation (EC) No 1568/98 of 17 July 1998	L 205	1	22.7.1998
► <u>M49</u>	Commission Regulation (EC) No 1569/98 of 17 July 1998	L 205	7	22.7.1998
► <u>M50</u>	Commission Regulation (EC) No 1570/98 of 17 July 1998	L 205	10	22.7.1998
► <u>M51</u>	Commission Regulation (EC) No 1916/98 of 9 September 1998	L 250	8	10.9.1998
► <u>M52</u>	Commission Regulation (EC) No 1917/98 of 9 September 1998	L 250	13	10.9.1998
► <u>M53</u>	Commission Regulation (EC) No 1958/98 of 15 September 1998	L 254	7	16.9.1998
► <u>M54</u>	Commission Regulation (EC) No 2560/98 of 27 November 1998	L 320	28	28.11.1998
► <u>M55</u>	Commission Regulation (EC) No 2686/98 of 11 December 1998	L 337	20	12.12.1998
► <u>M56</u>	Commission Regulation (EC) No 2692/98 of 14 December 1998	L 338	5	15.12.1998
► <u>M57</u>	Commission Regulation (EC) No 2728/98 of 17 December 1998	L 343	8	18.12.1998
► <u>M58</u>	Commission Regulation (EC) No 508/1999 of 4 March 1999	L 60	16	9.3.1999
► <u>M59</u>	Commission Regulation (EC) No 804/1999 of 16 April 1999	L 102	58	17.4.1999
► <u>M60</u>	Commission Regulation (EC) No 953/1999 of 5 May 1999	L 118	23	6.5.1999
► <u>M61</u>	Commission Regulation (EC) No 954/1999 of 5 May 1999	L 118	28	6.5.1999
► <u>M62</u>	Commission Regulation (EC) No 997/1999 of 11 May 1999	L 122	24	12.5.1999
► <u>M63</u>	Commission Regulation (EC) No 998/1999 of 11 May 1999	L 122	30	12.5.1999
► <u>M64</u>	Council Regulation (EC) No 1308/1999 of 15 June 1999	L 156	1	23.6.1999
► <u>M65</u>	Commission Regulation (EC) No 1931/1999 of 9 September 1999	L 240	3	10.9.1999
► <u>M66</u>	Commission Regulation (EC) No 1942/1999 of 10 September 1999	L 241	4	11.9.1999
► <u>M67</u>	Commission Regulation (EC) No 1943/1999 of 10 September 1999	L 241	9	11.9.1999
► <u>M68</u>	Commission Regulation (EC) No 2385/1999 of 10 November 1999	L 288	14	11.11.1999
► <u>M69</u>	Commission Regulation (EC) No 2393/1999 of 11 November 1999	L 290	5	12.11.1999
► <u>M70</u>	Commission Regulation (EC) No 2593/1999 of 8 December 1999	L 315	26	9.12.1999
► <u>M71</u>	Commission Regulation (EC) No 2728/1999 of 20 December 1999	L 328	23	22.12.1999
► <u>M72</u>	Commission Regulation (EC) No 2757/1999 of 22 December 1999	L 331	45	23.12.1999
► <u>M73</u>	Commission Regulation (EC) No 2758/1999 of 22 December 1999	L 331	49	23.12.1999
► <u>M74</u>	Commission Regulation (EC) No 1286/2000 of 19 June 2000	L 145	15	20.6.2000

▶ <u>M75</u>	Commission Regulation (EC) No 1295/2000 of 20 June 2000	L 146	11	21.6.2000
▶ <u>M76</u>	Commission Regulation (EC) No 1960/2000 of 15 September 2000	L 234	5	16.9.2000
▶ <u>M77</u>	Commission Regulation (EC) No 2338/2000 of 20 October 2000	L 269	21	21.10.2000
▶ <u>M78</u>	Commission Regulation (EC) No 2391/2000 of 27 October 2000	L 276	5	28.10.2000
▶ <u>M79</u>	Commission Regulation (EC) No 2535/2000 of 17 November 2000	L 291	9	18.11.2000
▶ <u>M80</u>	Commission Regulation (EC) No 2908/2000 of 29 December 2000	L 336	72	30.12.2000
▶ <u>M81</u>	Commission Regulation (EC) No 749/2001 of 18 April 2001	L 109	32	19.4.2001
▶ <u>M82</u>	Commission Regulation (EC) No 750/2001 of 18 April 2001	L 109	35	19.4.2001
▶ <u>M83</u>	Commission Regulation (EC) No 807/2001 of 25 April 2001	L 118	6	27.4.2001
▶ <u>M84</u>	Commission Regulation (EC) No 1274/2001 of 27 June 2001	L 175	14	28.6.2001
▶ <u>M85</u>	Commission Regulation (EC) No 1322/2001 of 29 June 2001	L 177	52	30.6.2001
▶ <u>M86</u>	Commission Regulation (EC) No 1478/2001 of 18 July 2001	L 195	32	19.7.2001
▶ <u>M87</u>	Commission Regulation (EC) No 1553/2001 of 30 July 2001	L 205	16	31.7.2001
▶ <u>M88</u>	Commission Regulation (EC) No 1680/2001 of 22 August 2001	L 227	33	23.8.2001
▶ <u>M89</u>	Commission Regulation (EC) No 1815/2001 of 14 September 2001	L 246	11	15.9.2001
▶ <u>M90</u>	Commission Regulation (EC) No 1879/2001 of 26 September 2001	L 258	11	27.9.2001
▶ <u>M91</u>	Commission Regulation (EC) No 2162/2001 of 7 November 2001	L 291	9	8.11.2001
▶ <u>M92</u>	Council Regulation (EC) No 2584/2001 of 19 December 2001	L 345	7	29.12.2001
▶ <u>M93</u>	Commission Regulation (EC) No 77/2002 of 17 January 2002	L 16	9	18.1.2002
▶ <u>M94</u>	Commission Regulation (EC) No 868/2002 of 24 May 2002	L 137	6	25.5.2002
▶ <u>M95</u>	Commission Regulation (EC) No 869/2002 of 24 May 2002	L 137	10	25.5.2002
▶ <u>M96</u>	Commission Regulation (EC) No 1181/2002 of 1 July 2002	L 172	13	2.7.2002
▶ <u>M97</u>	Commission Regulation (EC) No 1530/2002 of 27 August 2002	L 230	3	28.8.2002
▶ <u>M98</u>	Commission Regulation (EC) No 1752/2002 of 1 October 2002	L 264	18	2.10.2002
▶ <u>M99</u>	Commission Regulation (EC) No 1937/2002 of 30 October 2002	L 297	3	31.10.2002
▶ <u>M100</u>	Commission Regulation (EC) No 61/2003 of 15 January 2003	L 11	12	16.1.2003
▶ <u>M101</u>	Commission Regulation (EC) No 544/2003 of 27 March 2003	L 81	7	28.3.2003

Corrected by:

- ▶ **C1** Corrigendum, OJ L 222, 20.9.1995, p. 17 (1442/95)
- ▶ **C2** Corrigendum, OJ L 316, 5.12.1996, p. 37 (1442/95)
- ▶ **C3** Corrigendum, OJ L 76, 18.3.1997, p. 34 (1442/95)
- ▶ **C4** Corrigendum, OJ L 271, 8.10.1998, p. 42 (1568/98)
- ▶ **C5** Corrigendum, OJ L 9, 13.1.2000, p. 30 (1308/1999)
- ▶ **C6** Corrigendum, OJ L 133, 16.5.2001, p. 17 (807/2001)
- ▶ **C7** Corrigendum, OJ L 268, 9.10.2001, p. 50 (1815/2001)
- ▶ **C8** Corrigendum, OJ L 251, 19.9.2002, p. 20 (1181/2002)
- ▶ **C9** Corrigendum, OJ L 45, 19.2.2003, p. 27 (1181/2002)
- ▶ **C10** Corrigendum, OJ L 62, 6.3.2003, p. 27 (1181/2002)

▼B**COUNCIL REGULATION (EEC) No 2377/90****of 26 June 1990****laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin**

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 43 thereof,

Having regard to the proposal from the Commission ⁽¹⁾,

Having regard to the opinion of the European Parliament ⁽²⁾,

Having regard to the opinion of the Economic and Social Committee ⁽³⁾,

Whereas the use of veterinary medicinal products in food-producing animals may result in the presence of residues of foodstuffs obtained from treated animals;

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

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

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

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

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

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

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

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

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

⁽¹⁾ OJ No C 61, 10. 3. 1989, p. 5.

⁽²⁾ OJ No C 96, 17. 4. 1990, p. 273.

⁽³⁾ OJ No C 201, 17. 8. 1989, p. 1.

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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 been established shall be contained in Annex I, which shall be adopted in accordance with the procedure laid down in Article 8. Except as provided for in Article 9, any amendments to Annex I shall be adopted in accordance with the same procedure.

⁽¹⁾ OJ No L 317, 6. 11. 1981, p. 16.

⁽²⁾ OJ No L 15, 17. 1. 1987, p. 34.

▼**B***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 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.

⁽¹⁾ OJ L 214, 24.8.1993, p. 1

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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.

▼B*Article 8***▼M64**

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

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2. The representative of the Commission shall submit a draft of the measures to be adopted to the ►**M64** Standing Committee ◀ for Adaptation to Technical Progress. The ►**M64** Standing Committee ◀ shall deliver its opinion on the draft within a time limit set by the chairman, having regard to the urgency of the matter. It shall act by a qualified majority, the votes of the Member States being weighted as provided for in Article 148 (2) of the Treaty. The chairman shall not vote.
3. (a) The Commission shall adopt the measures envisaged where they are in accordance with the opinion of the ►**M64** Standing Committee ◀.
- (b) Where the measures envisaged are not in accordance with the opinion of the ►**M64** Standing Committee ◀, or if no opinion is adopted, the Commission shall without delay propose to the

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Council the measures to be adopted. The Council shall act by a qualified majority.

- (c) If, after a period of three months of the proposal being referred to it, the Council has not acted, the proposed measures shall be adopted by the Commission, unless the Council has voted against them by a simple majority.

Article 9

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

2. ►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.

Article 10

1. Where the procedure laid down in this Article is to be followed, the chairman shall, without delay, refer the matter to the ►M64 Standing Committee ◀ either on his own initiative or at the request of a representative of a Member State.

2. The representative of the Commission shall submit to the ►M64 Standing Committee ◀ a draft of the measures to be adopted. The ►M64 Standing Committee ◀ shall deliver its opinion on the draft within a time limit set by the chairman, having regard to the urgency of the matter. It shall act by a qualified majority, the votes of the Member States being weighted as provided for in Article 148 (2) of the Treaty. The chairman shall not vote.

3. (a) The Commission shall adopt the measures envisaged, where they are in accordance with the opinion of the ►M64 Standing Committee ◀.

(b) Where the measures envisaged are not in accordance with the opinion of the ►M64 Standing Committee ◀, or if no opinion is adopted, the Commission shall without delay propose to the Council the measures to be adopted. The Council shall act by a qualified majority.

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

▼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 ►**C5** 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.

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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:

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

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— 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.

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

ANNEX I

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

1. Anti-infectious agents
 - 1.1. Chemotherapeutics
 - 1.1.1. Sulfonamides

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

- 1.1.2. Diamino pyrimidine derivatives

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Baquloprim	Baquloprim	Bovine	10 µg/kg	Fat	
			300 µg/kg	Liver	
			150 µg/kg	Kidney	
			30 µg/kg	Milk	
			40 µg/kg	Skin and fat	
		Porcine			
Trimethoprim	Trimethoprim	All food producing species except equidae	50 µg/kg	Fat (1)	Not for use in animals from which eggs are produced for human consumption
			50 µg/kg	Muscle (2)	
			50 µg/kg	Liver	
			50 µg/kg	Kidney	

▼ **M96**

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

▼ **M58**

- 1.2. Antibiotics
1.2.1. Penicillins

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

▼ M58

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Cloxacillin	Cloxacillin	All food-producing species	50 µg/kg 4 µg/kg	Kidney Milk	
			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	
Nafcillin	Nafcillin	Bovine	300 µg/kg 300 µg/kg 300 µg/kg 300 µg/kg 30 µg/kg	Muscle Fat Liver Kidney Milk	For intramammary use only
Oxacillin	Oxacillin	All food-producing species	300 µg/kg 300 µg/kg 300 µg/kg 300 µg/kg 30 µg/kg	Muscle Fat Liver Kidney Milk	

▼ M83

▼ M58

▼ **M58**

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Penethamate	Benzylpenicillin	Bovine	50 µg/kg 50 µg/kg 50 µg/kg 50 µg/kg 4 µg/kg	Muscle Fat Liver Kidney Milk	
		Porcine	50 µg/kg 50 µg/kg 50 µg/kg 50 µg/kg	Muscle Fat Liver Kidney	
Phenoxymethylpenicillin	Phenoxymethylpenicillin	Porcine	25 µg/kg 25 µg/kg 25 µg/kg	Muscle Liver Kidney	

▼ **M72**▼ **M74**▼ **M58**

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	Muscle	
			200 µg/kg 200 µg/kg 1 000 µg/kg 100 µg/kg	Fat Liver Kidney Milk	
Cefalonium	Cefalonium	Bovine	20 µg/kg	Milk	

▼ **M91**▼ **M71**▼ **M100**

▼ <u>M100</u>	Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
▼ <u>M87</u>	Cefapirin	Sum of cefapirin and desacetylcefapirin	Bovine	50 µg/kg 50 µg/kg 100 µg/kg 60 µg/kg	Muscle Fat Kidney Milk	
▼ <u>M58</u>	Cefazolin	Cefazolin	Bovine, ovine, caprine	50 µg/kg	Milk	
▼ <u>M83</u>	Cefoperazone	Cefoperazone	Bovine	50 µg/kg	Milk	
▼ <u>M58</u>	Cefquinome	Cefquinome	Bovine	50 µg/kg 50 µg/kg 100 µg/kg 200 µg/kg 20 µg/kg	Muscle Fat Liver Kidney Milk	
▼ <u>M65</u>			Porcine	50 µg/kg 50 µg/kg 100 µg/kg 200 µg/kg	Muscle Skin + fat Liver Kidney	
▼ <u>M59</u>	Ceftiofur	Sum of all residues retaining the betalactam structure expressed as desfuroylceftiofur	Bovine Porcine	1 000 µg/kg 2 000 µg/kg 2 000 µg/kg 6 000 µg/kg 100 µg/kg 1 000 µg/kg 2 000 µg/kg 2 000 µg/kg	Muscle Fat Liver Kidney ► <u>M98</u> Milk ◀ Muscle Fat Liver	

▼ **M59**

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
			6 000 µg/kg	Kidney	

▼ **M58**

1.2.3. Quinolones

▼ **M96**

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Danofloxacin	Danofloxacin	<p>► C8 All food producing species except bovine, ovine, caprine, porcine and poultry ▼</p> <p>Bovine, ovine, caprine</p> <p>Poultry</p>	<p>100 µg/kg</p> <p>50 µg/kg</p> <p>200 µg/kg</p> <p>200 µg/kg</p> <p>200 µg/kg</p> <p>100 µg/kg</p> <p>400 µg/kg</p> <p>400 µg/kg</p> <p>30 µg/kg</p> <p>200 µg/kg</p> <p>100 µg/kg</p> <p>400 µg/kg</p> <p>400 µg/kg</p>	<p>Muscle (2)</p> <p>Fat (1)</p> <p>Liver</p> <p>Kidney</p> <p>Muscle</p> <p>Fat</p> <p>Liver</p> <p>Kidney</p> <p>Milk</p> <p>Muscle</p> <p>Skin and fat</p> <p>Liver</p> <p>Kidney</p>	<p>Not for use in animals from which eggs are produced for human consumption</p>

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

▼ **M96**

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Flumequine	Flumequine	All food producing species except bovine, ovine, caprine, porcine, poultry and fin fish Bovine, porcine, ovine, caprine	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 250 µg/kg 800 µg/kg 1 000 µg/kg 600 µg/kg	Muscle Fat Liver Kidney Muscle Fat (')	
		Poultry		Muscle Skin and fat	Not for use in animals from which eggs are produced for human consumption
		Fin fish		Liver Kidney Muscle and skin in natural proportion	
Marbofloxacin	Marbofloxacin	Bovine Porcine	150 µg/kg 50 µg/kg 150 µg/kg 150 µg/kg 75 µg/kg 150 µg/kg 50 µg/kg 150 µg/kg 150 µg/kg	Muscle Fat Liver Kidney Milk Muscle Skin and fat Liver Kidney	

▼ **M77**

▼ M77	Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
▼ M58	Sarafloxacin	Sarafloxacin	Chicken Salmonidae	10 µg/kg 100 µg/kg 30 µg/kg	Skin and fat Liver Muscle and skin in natural proportions	
▼ 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'.					
▼ M58	1.2.4. Macrolides					
▼ M93	Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
▼ M96	Acetylisovalerytylosin	Sum of acetyl-isovalerytylosin and 3-O-acetyltylosin	Porcine	50 µg/kg 50 µg/kg 50 µg/kg 50 µg/kg	Muscle Skin and fat Liver Kidney	
▼ M96	Erythromycin	Erythromycin A	All food producing species	200 µg/kg 200 µg/kg 200 µg/kg 200 µg/kg 40 µg/kg 150 µg/kg	Muscle (1) Fat (2) Liver Kidney Milk Eggs	
▼ M58	Spiramycin	Sum of spiramycin and neospiramycin	Bovine	200 µg/kg 300 µg/kg 300 µg/kg 300 µg/kg	Muscle Fat Liver Kidney	

▼ **M58**

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
		Chicken	200 µg/kg 200 µg/kg 300 µg/kg 400 µg/kg	Milk Muscle Skin and fat Liver	
	Spiramycin 1	Porcine	250 µg/kg 2 000 µg/kg 1 000 µg/kg	Muscle Liver Kidney	
Tilmicosin	Tilmicosin	All food producing species except poultry 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 Sin and fat Liver Kidney	Not for use in animals from which eggs are produced for human consumption
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 ⁽³⁾ Muscle ⁽¹⁾ Liver Kidney Milk Eggs	

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

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

⁽³⁾ For porcine and poultry species this MRL relates to 'skin and fat in natural proportions'.

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

1.2.6. Tetracyclines

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

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

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	

▼ **M58**

1.2.8. Pleuromutilines

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Tiamulin	Sum of metabolites that may be hydrolysed to 8- a-hydroxymutilin	Porcine	100 µg/kg 500 µg/kg	Muscle Liver	
		Chicken	100 µg/kg 100 µg/kg 1 000 µg/kg	Muscle Skin and fat Liver	
		Rabbits	100 µg/kg 500 µg/kg	Muscle Liver	
		Turkey	100 µg/kg 100 µg/kg 300 µg/kg	Muscle Skin and fat Liver	
			1 000 µg/kg	Eggs	
Valnemulin	Valnemulin	Porcine	50 µg/kg 500 µg/kg 100 µg/kg	Muscle Liver Kidney	

▼ **M59**

1.2.9. Lincosamides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Lincomycin	Lincomycin	All food producing species	50 µg/kg 100 µg/kg 500 µg/kg 1 500 µg/kg 150 µg/kg	Fat (1) Muscle (2) Liver Kidney Milk	

▼ **M96**

▼ **M96**

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

▼ **M77**▼ **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'.

▼ **M65**

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
			1 000 µg/kg	Fat	
			10 000 µg/kg	Liver	
			20 000 µg/kg	Kidney	

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
▼ <u>M65</u> Dihydrostreptomycin	Dihydrostreptomycin	Bovine, ovine	500 µg/kg	Muscle	
			500 µg/kg	Fat	
▼ <u>M97</u>		Porcine	500 µg/kg	Liver	
			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	
▼ <u>M94</u> Gentamicin	Sum of gentamicin C1, gentamicin C1a, gentamicin C2 and gentamicin C2a	Bovine	50 µg/kg	Muscle	
			50 µg/kg	Fat	
			200 µg/kg	Liver	
			750 µg/kg	Kidney	
			100 µg/kg	Milk	
			50 µg/kg	Muscle	
			50 µg/kg	Skin and fat	
			200 µg/kg	Liver	
			750 µg/kg	Kidney	
			▼ <u>M96</u> Neomycin (including framycetin)	Neomycin B	All food producing species
500 µg/kg	Muscle (2)				
500 µg/kg	Liver				
5 000 µg/kg	Kidney				
1 500 µg/kg	Milk				
500 µg/kg	Eggs				

▼ **M96**

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Paromomycin	Paromomycin	All food producing species	500 µg/kg 1 500 µg/kg 1 500 µg/kg	Muscle ⁽¹⁾ Liver Kidney	Not for use in animals from which milk or eggs are produced for human consumption
Spectinomycin	Spectinomycin	All food producing species except ovine Ovine	500 µg/kg 300 µg/kg 1 000 µg/kg 5 000 µg/kg 200 µg/kg 300 µg/kg 500 µg/kg 2 000 µg/kg 5 000 µg/kg 200 µg/kg	Fat ⁽¹⁾ Muscle ⁽²⁾ Liver Kidney Milk Muscle Fat Liver Kidney Milk	Not for use in animals from which eggs are produced for human consumption
Streptomycin	Streptomycin	Bovine, ovine Porcine	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 1 000 µg/kg	Muscle Fat Liver Kidney Milk Muscle Skin and fat Liver Kidney	

▼ **M97**▼ **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'.

▼ **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. Polypeptides

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	
		Porcine	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 150 µg/kg 150 µg/kg 200 µg/kg 50 µg/kg 300 µg/kg	Fat ⁽¹⁾ Muscle ⁽²⁾ Liver Kidney Milk 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'.

▼ **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	Closantel	Bovine	1 000 µg/kg 3 000 µg/kg 1 000 µg/kg 3 000 µg/kg 1 500 µg/kg 2 000 µg/kg 1 500 µg/kg 5 000 µg/kg	Muscle Fat Liver Kidney Muscle Fat Liver Kidney	
Rafoxanide	Rafoxanide	Bovine Ovine	30 µg/kg 30 µg/kg 10 µg/kg 40 µg/kg 100 µg/kg 250 µg/kg 150 µg/kg 150 µg/kg	Muscle Fat Liver Kidney Muscle Fat Liver Kidney	Not for use in animals from which milk is produced for human consumption

▼ **M86**▼ **M58**

- 2.1.2. Tetra-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 10 µg/kg 100 µg/kg 10 µg/kg	Muscle Fat Liver Kidney	

▼ **M58**

2.1.3. Benzimidazoles and pro-benzimidazoles

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Albendazole	Sum of albendazole sulphoxide, albendazole sulphone, and albendazole 2-amino sulphone, expressed as albendazole	Bovine, ovine	100 µg/kg 100 µg/kg 1 000 µg/kg 500 µg/kg 100 µg/kg	Muscle Fat Liver Kidney Milk	
Albendazole oxide	Sum of albendazole oxide, albendazole sulphone and albendazole 2-aminosulphone, 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	
Febantel	Sum of extractable residues which may be oxidised to oxfendazole	Bovine, ovine Bovine, ovine, porcine, equidae	10 µg/kg 50 µg/kg 50 µg/kg 500 µg/kg 50 µg/kg	Milk Muscle Fat Liver Kidney	
Fenbendazole	Sum of extractable residues which may be oxidised to oxfendazole sulphone	Bovine, ovine Bovine, ovine, porcine, equide	10 µg/kg 50 µg/kg 50 µg/kg	Milk Muscle Fat	

▼ **M69**▼ **M58**

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Flubendazole	Sum of flubendazole and (2-amino 1H-benzimidazol-5-yl) (4-fluorophenyl) methanone	Porcine, chicken, game birds Turkey Chicken	500 µg/kg 50 µg/kg 50 µg/kg 400 µg/kg 300 µg/kg 50 µg/kg 50 µg/kg 400 µg/kg 300 µg/kg 400 µg/kg	Liver Kidney Muscle Skin and fat Liver Kidney Muscle Skin and fat Liver Kidney Eggs	
Mebendazole	Flubendazole 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
Netobimin	Sum of albendazole oxide, albendazole sulphone and albendazole 2-aminosulphone, expressed as albendazole	► <u>C6</u> Bovine, ovine ▼	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

▼ M58▼ M68▼ M58▼ M88▼ M83

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

▼ **M62**

2.1.4. Phenol derivatives including salicylanides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Nitroximil	Nitroximil	Bovine, ovine	400 µg/kg 200 µg/kg 20 µg/kg 400 µg/kg	Muscle Fat Liver Kidney	
Oxyclozanide	Oxyclozanide	Bovine Ovine	20 µg/kg 20 µg/kg 500 µg/kg 100 µg/kg 10 µg/kg 20 µg/kg 20 µg/kg 500 µg/kg 100 µg/kg	Muscle Fat Liver Kidney Milk Muscle Fat Liver Kidney	Not for use in animals from which milk is produced for human consumption

▼ **M96**▼ **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	Muscle Skin and fat	

▼ **M94**

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
		Chicken	2 000 µg/kg 1 000 µg/kg 2 000 µg/kg	Liver Kidney Eggs	

▼ **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	Coumafos	Bees	100 µg/kg	Honey	
Diazinon	Diazinon	Bovine, ovine, caprine Bovine, porcine, ovine, caprine	20 µg/kg 20 µg/kg 700 µg/kg 20 µg/kg 20 µg/kg	Milk Muscle Fat Liver Kidney	
Phoxim	Phoxim	Ovine Porcine	50 µg/kg 400 µg/kg 50 µg/kg 20 µg/kg 700 µg/kg 20 µg/kg 20 µg/kg	Muscle Fat Kidney Muscle Skin and fat Liver Kidney	Not for use in animals from which milk is produced for human consumption

▼ **M83**

▼ **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	
		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	

▼ **M69**

▼ **M58**

2.2.3. Pyrethroids

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Cyhalothrin	Cyhalothrin (sum of isomers)	Bovine	500 µg/kg 50 µg/kg 50 µg/kg	Fat Kidney Milk	Further provisions in Council Directive 94/29/EC are to be observed
Cyfluthrin	Cyfluthrin (sum of isomers)	Bovine	10 µg/kg 50 µg/kg 10 µg/kg 10 µg/kg 20 µg/kg	Muscle Fat Liver Kidney Milk	
Deltamethrin	Deltamethrin	Bovine Ovine Fin fish	10 µg/kg 50 µg/kg 10 µg/kg 10 µg/kg 20 µg/kg 10 µg/kg 50 µg/kg 10 µg/kg 10 µg/kg 10 µg/kg	Muscle Fat Liver Kidney Milk Muscle Fat Liver Kidney Muscle and skin in natural proportions	Not for use in animals from which milk is produced for human consumption
Flumethrin	Flumethrin (sum of trans-Z isomers)	Bovine	10 µg/kg	Muscle	

▼ **M83**
▼ **C6**▼ **M89**
▼ **C7**▼ **M91**▼ **M58**

▼ **M58**

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
			150 µg/kg 20 µg/kg 10 µg/kg 30 µg/kg	Fat Liver Kidney Milk	
		Ovine	10 µg/kg	Muscle	Not for use in animals from which milk is produced for human consumption
			150 µg/kg 20 µg/kg 10 µg/kg	Fat Liver Kidney	
Permethrin	Permethrin (sum of isomers)	Bovine	50 µg/kg 500 µg/kg 50 µg/kg 50 µg/kg 50 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).

▼ **M65**

2.2.4. Acyl urea derivatives

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Diflubenzuron	Diflubenzuron	Salmonidae	1 000 µg/kg	Muscle and skin in natural proportions	
Teflubenzuron	Teflubenzuron	Salmonidae	500 µg/kg	Muscle and skin in natural proportions	

▼ **M70**▼ **M65**

▼ **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 ▼ 400 µg/kg 400 µg/kg	Muscle Fat Liver Kidney	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 300 µg/kg	Muscle Fat Liver Kidney	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 Ovine	10 µg/kg 20 µg/kg 20 µg/kg 50 µg/kg 25 µg/kg 20 µg/kg	Fat Liver Muscle Fat Liver Kidney	Not for use in animals from which milk is produced for human consumption

▼ **M94**

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Doramectin	Doramectin	Bovine	10 µg/kg 150 µg/kg 100 µg/kg 30 µg/kg 20 µg/kg	Muscle Fat Liver Kidney Muscle	Not for use in bovine from which milk is produced for human consumption
		Porcine, ovine	100 µg/kg 50 µg/kg 30 µg/kg	Fat Liver Kidney	Not for use in ovine from which milk is produced for human consumption
Emamectin	Emamectin B1a	Deer, including reindeer	20 µg/kg 100 µg/kg 50 µg/kg 30 µg/kg	Muscle Fat Liver Kidney	
		Salmonidae	100 µg/kg	Muscle and skin in natural proportions	
Eprinomectin	Eprinomectin B1a	Bovine	► <u>M67</u> 50 µg/kg ▼ ► <u>M67</u> 250 µg/kg ▼ ► <u>M67</u> 1 500 µg/kg ▼ ► <u>M67</u> 300 µg/kg ▼	Muscle Fat Liver Kidney	

▼ M94▼ M58▼ M86▼ M65▼ M58

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Ivermectin	22, 23-Dihydro-avermectin B1a	Bovine Porcine, ovine, equidae Deer, including reindeer	► M67 20 µg/kg ▼	Milk Fat Liver Fat Liver Muscle 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	Muscle Fat Liver Kidney Milk Muscle Fat Liver Kidney	

▼ **M58**▼ **M87**▼ **M66**

▼ **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	Not for use in animals from which eggs are produced for human consumption
			200 µg/kg	Skin and fat	
			600 µg/kg	Liver	
			400 µg/kg	Kidney	
		Turkey	100 µg/kg	Muscle	
			200 µg/kg	Skin and fat	
			600 µg/kg	Liver	
			400 µg/kg	Kidney	
		Porcine	100 µg/kg	Muscle	
			150 µg/kg	Skin and fat	
			500 µg/kg	Liver	
			250 µg/kg	Kidney	

▼ **M80**

2.4.2. Quimazolone derivatives

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

▼ **M91**

2.4.3. Carbamylides

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

▼ **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
	Azaperone	Sum of azaperone and azaperol	Porcine	100 µg/kg 100 µg/kg 100 µg/kg 100 µg/kg	Muscle Skin and fat Liver Kidney
					Other provisions

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
	Carazolol	Carazolol	Porcine Bovine	5 µg/kg 5 µg/kg 25 µg/kg 25 µg/kg 5 µg/kg 5 µg/kg 15 µg/kg 15 µg/kg 1 µg/kg	Muscle Skin and fat Liver Kidney Muscle Fat Liver Kidney Milk
					Other provisions

▼ **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 μ g/kg 0,5 μ g/kg 0,5 μ g/kg 0,05 μ g/kg 0,1 μ g/kg 0,5 μ g/kg 0,5 μ g/kg	Muscle Liver Kidney Milk Muscle Liver Kidney	

▼ **M58**

4. Anti-inflammatory agents
 4.1. Nonsteroidal anti-inflammatory agents
 4.1.1. Arylpropionic acid derivative

▼ **M65**

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 μ g/kg 1 000 μ g/kg 1 000 μ g/kg 1 000 μ g/kg 500 μ g/kg 1 000 μ g/kg 1 000 μ g/kg 1 000 μ g/kg	Muscle Fat Liver Kidney Muscle Fat Liver Kidney	
Vedaprofen	Vedaprofen	Equidae	50 μ g/kg 20 μ g/kg 100 μ g/kg 1 000 μ g/kg	Muscle Fat Liver Kidney	

▼ **M58**

▼ **M58**
4.1.2. Fenamate group derivatives

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Flunixin	Flunixin	Bovine	20 µg/kg 30 µg/kg 300 µg/kg	Muscle Fat Liver	
	5-Hydroxyflunixin Flunixin	Porcine	100 µg/kg 40 µg/kg 50 µg/kg 10 µg/kg 200 µg/kg 30 µg/kg	Kidney Milk Muscle Skin and fat Liver Kidney	
Tolfenamic acid	Tolfenamic acid	Equidae	10 µg/kg 20 µg/kg 100 µg/kg 200 µg/kg	Muscle Fat Liver Kidney	
		Bovine	50 µg/kg 400 µg/kg 100 µg/kg 50 µg/kg 50 µg/kg 400 µg/kg 100 µg/kg	Muscle Liver Kidney Milk Muscle Liver Kidney	
		Porcine			

▼ **M71**

▼ **M80**

▼ **M58**

▼ **M97**

4.1.3. Enolic acid derivatives

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
Meloxicam	Meloxicam	Bovine	► <u>M71</u> 20 µg/kg ▼ ► <u>M71</u> 65 µg/kg ▼ ► <u>M71</u> 65 µg/kg ▼ ► <u>M71</u> 15 µg/kg ▼	Muscle Liver Kidney ► <u>M71</u> Milk ◀	
		Porcine	20 µg/kg 65 µg/kg 65 µg/kg	Muscle Liver Kidney	

▼ **M84**

▼ **M58**

5. Corticoïdes

5.1. Glucocorticoides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Betamethasone	Betamethasone	Bovine Porcine	0,75 µg/kg 2,0 µg/kg 0,75 µg/kg 0,3 µg/kg 0,75 µg/kg 2,0 µg/kg 0,75 µg/kg	Muscle Liver Kidney Milk Muscle Liver Kidney	
Dexamethasone	Dexamethasone	Bovine Bovine, porcine, equidae	0,3 µg/kg 0,75 µg/kg 2 µg/kg 0,75 µg/kg	Milk Muscle Liver Kidney	
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
Prednisolone	Prednisolone	Bovine	4 µg/kg 4 µg/kg 10 µg/kg 10 µg/kg 6 µg/kg	Muscle Fat Liver Kidney Milk	

▼ **M70**▼ **M58**▼ **M93**▼ **M79**

▼ **M92**

6. Agents acting on the reproductive system

6.1. Progestogens

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Chlormadinone	Chlormadinone	Bovine	4 µg/kg 2 µg/kg 2,5 µg/kg	Fat Liver Milk	For zootechnical use only
Flugestone acetate	Flugestone acetate	Ovine	1 µg/kg	Milk	For intravaginal use for zootechnical purposes only

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	
▼ <u>M99</u>	Aluminium salicylate, basic	Bovine	For oral use only; Not for use in animals from which milk is produced for human consumption
▼ <u>M58</u>	Aluminium tristearate	All food-producing species	
	Ammonium chloride	All food-producing species	
▼ <u>M72</u>	Barium selenate	Bovine, ovine	
▼ <u>M58</u>	Bismuth subcarbonate	All food-producing species	For oral use only
	Bismuth subgallate	All food-producing species	For oral use only
	Bismuth subnitrate	All food-producing species	For oral use only
	Bismuth subsalicylate	All food-producing species	For oral use only
	Boric acid and borates	All food-producing species	
▼ <u>M65</u>	Bromide, potassium salt	All food producing species	
▼ <u>M58</u>	Bromide, sodium salt	All mammalian food-producing species	For topical use only

▼ **M58**

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

▼ **M80**▼ **M58**

▼ M58

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

▼ M58

Pharmacologically active substance(s)	Animal species	Other provisions
Nickel gluconate	All food-producing species	
Nickel sulphate	All food-producing species	
Potassium DL-aspartate	All food-producing species	
Potassium gluconate	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
Sodium glycerophosphate	All food producing species	
Sodium hypophosphite	All food-producing species	
Sodium propionate	All food producing species	
Sodium selenate	All food-producing species	
Sodium selenite	All food-producing species	
Sulphur	► M101 All food producing species ◄	
Zinc acetate Zinc chloride Zinc gluconate Zinc oleate Zinc stearate	All food-producing species	

▼ M62▼ M58▼ M77▼ M58

▼ M58

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-Aminoethanol	All food-producing species	
2-Aminoethyl 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
Benzylalcohol	All food-producing species	For use as excipient
Betaine	All food-producing species	
Bronopol	Salmonidae	For use only on farmed fertilised eggs
Brotizolam	Bovine	For therapeutic uses only
Buserelin	All food-producing species	
Butorphanol tartrate	Equidae	For intravenous administration only
Butyl 4-hydroxybenzoate	All food-producing species	

▼ M58

Pharmacologically active substance(s)	Animal species	Other provisions
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
Chloroeresol	All food-producing species	
Clazuril	Pigeon	
Cloprostenol	Bovine, porcine, equidae	
Coco alkyl dimethyl betaines	All food-producing species	For use as excipient
Corticotropin	All food-producing species	
D-Phe 6 -luteinising-hormone releasing hormone	All food-producing species	
Dembrexine	Equidae	
Denaverine hydrochloride	Bovine	
Detomidine	Bovine, equidae	For therapeutic uses only
Diclazuril	Ovine	For oral use in lambs only
Diethyl phthalate	All food-producing species	
Diethylene glycol monoethyl ether	Bovine, porcine	

Pharmacologically active substance(s)	Animal species	Other provisions
Dimanganese 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	
Hesperidin	Equidae	
Hesperidin methyl chalcone	Equidae	
Hexetidine	Equidae	For topical use only
Human chorion gonadotrophin	All food-producing species	
Human menopausal urinary gonadotrophin	Bovine	

▼ M58

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

▼ M58

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

Pharmacologically active substance(s)	Animal species	Other provisions
Oxytocin	All mammalian food-producing species	
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	
Poliresulen	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 (crothamide and cropropamide)	All mammalian food-producing species	
Procaine	All food-producing species	
Propane	All food-producing species	
Propylene glycol	All food-producing species	

▼ M58

Pharmacologically active substance(s)	Animal species	Other provisions
Quatresin	All food-producing species	For use as preservative only at concentrations of up to 0,5 %
R-CloprostenoI	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
Romifidine	Equidae	For therapeutic uses only
Sodium 2-methyl-2-phenoxy-propanoate	Bovine, porcine, caprine, equidae	
Sodium benzyl 4-hydroxybenzoate	All food-producing species	
Sodium butyl 4-hydroxybenzoate	All food-producing species	
Sodium cetostearyl sulphate	All food-producing species	For topical use only
Somatosalm	Salmon	
Tanninum	All food-producing species	
Tau flualinate		
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 multidosed vaccines at a concentration not exceeding 0,02 %
Thymol	All food-producing species	
Timerfonate	All food-producing species	For use only as preservatives in multidosed vaccines at a concentration not exceeding 0,02 %

▼ M58

Pharmacologically active substance(s)	Animal species	Other provisions
Trimethylphloroglucinol	All food-producing species	
Vitamin D	All food-producing species	
Wool alcohols	All food-producing species	For topical use only
1-Methyl-2-pyrrolidone	Equidae	
Cefacetrile	Bovine	For intramammary use only and for all tissues except milk
Enilconazole	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
Parconazole	Guinea fowl	
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	

▼ M59▼ M60▼ M62

▼ **M62**

Pharmacologically active substance(s)	Animal species	Other provisions
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	
Vitamin E	All food-producing species	

▼ **M63**

Tiaprost	Bovine, ovine, porcine, equidae	
Apramycin	Porcine, rabbits Ovine 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	For oral use only

▼ **M65**

Azamethiphos	Salmonidae	
Doxapram	All mammalian food producing species	
Piperonyl butoxide	Bovine, ovine, caprine, equidae	For topical use only
Sulfogaiacol	All food producing species	
Vetabutine hydrochloride	Porcine	
Fenpipramide hydrochloride	Equidae	For intravenous use only
Hydrochlorothiazide	Bovine	

▼ **M66**

▼ M66	Pharmacologically active substance(s)	Animal species	Other provisions
	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
	Vincamine	Bovine	For use in newborn animals only
▼ M67	Atropine	All food producing species	
	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	
	Bituminosulfonates, ammonium and sodium salts	All mammalian food-producing species	For topical use only Not for use in animals from which milk is produced for human consumption
	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
▼ M70	1-methyl-2-pyrrolidone	All food-producing species	
	Ergometrine maleate	All mammalian food-producing species	For use in parturient animals only

▼ **M70**

Pharmacologically active substance(s)	Animal species	Other provisions
<i>Jecoris oleum</i>	All food-producing species	For topical use only
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
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
3,5-Diiodo-L-tyrosine	All mammalian food-producing species	
Levothyroxine	All mammalian food-producing species	
Aluminium salicylate, basic	All food producing species except fish For topical use only	
Bismuth subnitrate	Bovine	For intramammary use only

▼ **M71**▼ **M72**▼ **M74**

▼ M74	Pharmacologically active substance(s)	Animal species	Other provisions
	Calcium aspartate	All food producing species	
	Methyl salicylate	All food producing species except fish	For topical use only
	Salicylic acid	All food producing species except fish	For topical use only
	Sodium salicylate	All food producing species except fish	For topical use only
	Zinc aspartate	All food producing species	
	Toldimfos	All food producing species	
	Decoquinat	Bovine, ovine	For oral use only. Not for use in animals from which milk is produced for human consumption
	Sodium boroforniat	All food producing species	
	Thiamylal	All mammalian food producing species	For intravenous administration only
	Thiopental sodium	All food-producing species	For intravenous administration only
	Acetylsalicylic acid	Bovine Porcine Chicken	Not for use in animals from which milk is produced for human consumption Not for use in animals from which eggs are produced for human consumption
	Acetylsalicylic acid DL-lysine	Bovine Porcine Chicken	Not for use in animals from which milk is produced for human consumption Not for use in animals from which eggs are produced for human consumption

▼ **M75**▼ **M77**▼ **M81**▼ **M82**

▼ M82	Pharmacologically active substance(s)	Animal species	Other provisions
	Carbasalate calcium	Bovine Porcine Chicken	Not for use in animals from which milk is produced for human consumption Not for use in animals from which eggs are produced for human consumption
	Sodium acetylsalicylate	Bovine Porcine Chicken	Not for use in animals from which milk is produced for human consumption Not for use in animals from which 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
▼ 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	

▼ <u>M95</u>	Pharmacologically active substance(s)	Animal species	Other provisions
▼ <u>M97</u>	Azagly-nafarelin	Salmonidae	Not for use in fish from which eggs are produced for human consumption
▼ <u>M98</u>	Deslorelin acetate	Equidae	
▼ <u>M99</u>	Hydroxyethylsalicylate	All food producing species except fish	For topical use only
▼ <u>M99</u>	Xylazine hydrochloride	Bovine, equidae	
▼ <u>M100</u>	Omeprazole	Equidae	For oral use only
▼ <u>M58</u>	Trichlormethiazide	All mammalian food producing species	
3.	Substances generally recognised as safe		
	Pharmacologically active substance(s)	Animal species	Other provisions
	Absinthium extract	All food-producing species	
	Acetylmethionine	All food-producing species	
	Aluminium hydroxide	All food-producing species	
	Aluminium monostearate	All food-producing species	
	Ammonium sulfate	All food-producing species	
	Benzoyl benzoate	All food-producing species	
	Benzyl p-hydroxybenzoate	All food-producing species	
	Calcium borogluconate	All food-producing species	
	Calcium citrate	All food-producing species	

▼ M58

Pharmacologically active substance(s)	Animal species	Other provisions
Camphor	All food-producing species	External use only
Cardamon extract	All food-producing species	
Diethyl sebacate	All food-producing species	
Dimethicone	All food-producing species	
Dimethyl acetamide	All food-producing species	
Dimethyl sulphoxide	All food-producing species	
Epinephrine	All food-producing species	
Ethyl oleate	All food-producing species	
Ethylene diaminetetraacetic acid and salts	All food-producing species	
Eucalyptol	All food-producing species	
Follicle stimulating hormone (natural FSH from all species and their synthetic analogues)	All food-producing species	
Formaldehyde	All food-producing species	
Formic acid	All food-producing species	
Glutaraldehyde	All food-producing species	
Guaiacol	All food-producing species	
Heparin and its salts	All food-producing species	
Human chorionic gonadotropin (natural HCG and its synthetic analogues)	All food-producing species	
Iron ammonium citrate	All food-producing species	
Iron dextran	All food-producing species	

▼ M58

Pharmacologically active substance(s)	Animal species	Other provisions
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	
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	

▼ **M58**

Pharmacologically active substance(s)	Animal species	Other provisions
Sodium cromoglycate	All food-producing species	
Sodium dioctylsulphosuccinate	All food-producing species	
Sodium formaldehydesulphoxylate	All food-producing species	
Sodium lauryl sulphate	All food-producing species	
Sodium pyrosulphite	All food-producing species	
Sodium stearate	All food-producing species	
Sodium thiosulphate	All food-producing species	
Tragacanth	All food-producing species	
Urea	All food-producing species	
Zinc oxide	All food-producing species	
Zinc sulphate	All food-producing species	
Adenosine and its 5'-mono-, 5'-di- and 5'-triphosphates	All food producing species	
Alanine	All food producing species	
Arginine	All food producing species	
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	

▼ **M65**

▼ M65

Pharmacologically active substance(s)	Animal species	Other provisions
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	
Phenylalanine	All food producing species	
Proline	All food producing species	

▼ **M65**

Pharmacologically active substance(s)	Animal species	Other provisions
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	

▼ **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	All food-producing species	
Adonis vernalis	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
Acqua levici	All food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias only
Atropa belladonna	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

▼ **M63**

Pharmacologically active substance(s)	Animal species	Other provisions
<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
<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>Hanunga 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
<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
<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
<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

▼ **M63**▼ **M66**▼ **M68**▼ **M71**



M71

Pharmacologically active substance(s)	Animal species	Other provisions
<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
<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 halitacabum</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



M71

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



M71

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

Pharmacologically active substance(s)	Animal species	Other provisions
<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
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	
<i>Angelicae radix aetheroleum</i>	All food-producing species	
<i>Anisi aetheroleum</i>	All food-producing species	
<i>Anisi stellati fructus, standardised extracts and preparations thereof</i>	All food producing species	

▼ **M71**▼ **M72**▼ **M58**▼ **M73**▼ **M71**▼ **M58**▼ **M77**

	Pharmacologically active substance(s)	Animal species	Other provisions
▼ <u>M77</u>			
▼ <u>M71</u>	<i>Arnica montana (arnicae flos and arnicae planta tota)</i>	All food-producing species	For topical use only
▼ <u>M58</u>	<i>Balsamum peruvianum</i>	All food-producing species	For topical use only
▼ <u>M71</u>	<i>Boldo folium</i>	All food-producing species	
▼ <u>M70</u>	<i>Catendulae flos</i>	All food-producing species	For topical use only
▼ <u>M68</u>	<i>Capsici fructus acer</i>	All food-producing species	
▼ <u>M71</u>	<i>Carlinae radix</i>	All food-producing species	For topical use only
▼ <u>M58</u>	<i>Carvi aetheroleum</i>	All food-producing species	
	<i>Caryophylli aetheroleum</i>	All food-producing species	
▼ <u>M59</u>	<i>Centellae asiaticaer extractum</i>	All food producing species	For topical use only
▼ <u>M58</u>	<i>Chrysanthemi cinerariifolii flos</i>	All food-producing species	For topical use only
▼ <u>M70</u>	<i>Cimicifugae racemosae rhizoma</i>	All food-producing species	Not for use in animals from which milk is produced for human consumption
▼ <u>M77</u>	<i>Cinchonae cortex</i> , standardised extracts and preparations thereof	All food producing species	

	Pharmacologically active substance(s)	Animal species	Other provisions
▼ <u>M77</u>			
▼ <u>M58</u>	<i>Cinnamomi cassiae aetheroleum</i>	All food-producing species	
▼ <u>M77</u>	<i>Cinnamomi cassiae cortex</i> , standardised extracts and preparations thereof	All food producing species	
▼ <u>M58</u>	<i>Cinnamomi ceylanici aetheroleum</i>	All food-producing species	
▼ <u>M77</u>	<i>Cinnamomi ceylanici cortex</i> , standardised extracts and preparations thereof	All food producing species	
▼ <u>M58</u>	<i>Citri aetheroleum</i>	All food-producing species	
	<i>Citronellae aetheroleum</i>	All food-producing species	
▼ <u>M77</u>	<i>Condurango cortex</i> , standardised extracts and preparations thereof	All food producing species	
▼ <u>M58</u>	<i>Coriandri aetheroleum</i>	All food-producing species	
▼ <u>M71</u>	<i>Cupressi aetheroleum</i>	All food-producing species	For topical use only
▼ <u>M58</u>	<i>Echinaceae 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	

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

	Pharmacologically active substance(s)	Animal species	Other provisions
▼ <u>M74</u>			
▼ <u>M58</u>	<i>Matricariae flos</i>	All food-producing species	
▼ <u>M59</u>	<i>Medicago sativa extractum</i>	All food-producing species	For topical use only
▼ <u>M58</u>	<i>Melissae aetheroleum</i>	All food-producing species	
▼ <u>M58</u>	<i>Melissae folium</i>	All food-producing species	
▼ <u>M91</u>	<i>Menthae arvensis aetheroleum</i>	All food-producing species	
▼ <u>M58</u>	<i>Menthae piperitae aetheroleum</i>	All food-producing species	
	<i>Millefolii herba</i>	All food-producing species	
	<i>Myrsiticae aetheroleum</i>	All food-producing species	For use in newborn animals only
	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>Quillaiia saponins</i>	All food-producing species	
▼ <u>M74</u>	<i>Rhei radix</i> , standardised extracts and preparations thereof	All food-producing species	

	Pharmacologically active substance(s)	Animal species	Other provisions
▼ <u>M74</u>	<i>Ricini oleum</i>	All food-producing species	For use as excipient
▼ <u>M58</u>	<i>Rosmarini aetheroleum</i>	All food-producing species	
▼ <u>M68</u>	<i>Rosmarini folium</i>	All food-producing species	
▼ <u>M58</u>	<i>Ruscus aculeatus</i>	All food-producing species	For topical use only
▼ <u>M58</u>	<i>Salviae folium</i>	All food-producing species	
▼ <u>M68</u>	<i>Sambuci flos</i>	All food-producing species	
▼ <u>M71</u>	<i>Sinapis nigrae semen</i>	All food-producing species	
▼ <u>M68</u>	<i>Strychni semen</i>	Bovine, ovine, caprine	For oral use only at doses up to the equivalent of 0,1 mg strychnine/kg bw
▼ <u>M71</u>	<i>Symphyti radix</i>	All food-producing species	For topical use on intact skin only
▼ <u>M58</u>	<i>Terebinthinae aetheroleum rectificatum</i>	All food-producing species	For topical use only
▼ <u>M58</u>	<i>Terebinthinae laricina</i>	All food-producing species	For topical use only
▼ <u>M58</u>	<i>Thymi aetheroleum</i>	All food-producing species	
▼ <u>M58</u>	<i>Tiliae flos</i>	All food-producing species	
▼ <u>M58</u>	<i>Urticae herba</i>	All food-producing species	

ANNEX III

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

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

▼ **M58**

1.2.2. Macrolides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
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
Erythromycin	MRLs apply to all microbiological active residues expressed as erythromycin equivalent	Bovine, ovine Bovine, ovine, porcine, poultry Poultry	40 µg/kg 400 µg/kg 400 µg/kg 400 µg/kg 400 µg/kg 200 µg/kg	Milk Muscle Fat Liver Kidney Eggs	Provisional MRLs expire on 1 June 2000
Josamycin	Josamycin	Chicken	200 µg/kg 200 µg/kg 200 µg/kg 400 µg/kg 200 µg/kg	Muscle Fat Liver Kidney Eggs	► M77 Provisional MRLs expire on 1.7.2002 ◀

▼ **M74**▼ **M58**

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
	Sum of the microbiologically active metabolites, expressed as josamycin	Porcine	200 µg/kg 200 µg/kg 200 µg/kg 400 µg/kg	Muscle Skin and fat Liver Kidney	Provisional MRLs expire on 1.7.2002
Tilmicosin	Tilmicosin	Bovine	40 µg/kg	Milk	Provisional MRLs expire on 1.1.2001
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-azacyclopent-decan-15-one expressed as tulathromycin equivalents	Bovine Porcine	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 and fat Liver Kidney	Provisional MRLs expire on 1 July 2004; not for use in animals from which milk is produced for human consumption Provisional MRLs expire on 1 July 2004

▼ **M58**▼ **M60**▼ **M70**▼ **M99**

▼ **M59**

1.2.4. Cephalosporins

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

▼ **M58**

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 1 500 µg/kg 1 500 µg/kg	Muscle Liver Kidney	Provisional MRLs expire on 1 July 2000

▼ M58

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Apramycin	Apramycin	Bovine For use in non-lactating cattle only Porcine	1 000 µg/kg 1 000 µg/kg 10 000 µg/kg 20 000 µg/kg 1 000 µg/kg 1 000 µg/kg 1 000 µg/kg 5 000 µg/kg	Muscle Fat Liver Kidney Muscle Skin and fat Liver Kidney	Provisional MRLs expire on 1 July 1999
Dihydrostreptomycin	Dihydrostreptomycin	Bovine, ovine Porcine	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 1 000 µg/kg	Muscle Fat Liver Kidney Milk Muscle Skin and fat Liver Kidney	Provisional MRLs expire on 1.6.2002
Gentamicin	Gentamicin	Bovine Bovine, porcine	100 µg/kg 50 µg/kg 50 µg/kg 200 µg/kg 750 µg/kg	Milk Muscle Fat Liver Kidney	Provisional MRLs expire on 1.6.2002

▼ M76

▼ M76

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions						
Kanamycin	Kanamycin	Rabbits	100 µg/kg 100 µg/kg 600 µg/kg 2 500 µg/kg	Muscle Fat Liver Kidney	► M91 Provisional MRLs expire on 1.1.2004 ◄						
		Bovine, ovine	100 µg/kg 100 µg/kg 600 µg/kg 2 500 µg/kg	Muscle Fat Liver Kidney							
		Porcine, chicken	150 µg/kg 100 µg/kg 100 µg/kg 600 µg/kg 2 500 µg/kg	Milk Muscle Skin + fat Liver Kidney							
		Neomycin (including framycetin)	Neomycin B	Bovine, porcine, chicken		500 µg/kg 500 µg/kg 500 µg/kg 5 000 µg/kg 500 µg/kg 500 µg/kg	Muscle Fat Liver Kidney Milk Eggs	Provisional MRLs expire on 1.6.2002			
				Bovine Chicken		200 µg/kg 300 µg/kg 500 µg/kg 2 000 µg/kg 5 000 µg/kg	Milk Muscle Fat Liver Kidney				
				Spectinomycin		Spectinomycin	Bovine Bovine, porcine, poultry		200 µg/kg 300 µg/kg 500 µg/kg 2 000 µg/kg 5 000 µg/kg	Milk Muscle Fat Liver Kidney	Provisional MRLs expire on 1 July 2000
							Bovine		200 µg/kg 300 µg/kg 500 µg/kg 2 000 µg/kg 5 000 µg/kg	Milk Muscle Fat Liver Kidney	
							Bovine, porcine, poultry		200 µg/kg 300 µg/kg 500 µg/kg 2 000 µg/kg 5 000 µg/kg	Milk Muscle Fat Liver Kidney	
							Bovine		200 µg/kg 300 µg/kg 500 µg/kg 2 000 µg/kg 5 000 µg/kg	Milk Muscle Fat Liver Kidney	

▼ M76▼ M58

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	300 µg/kg 500 µg/kg 2 000 µg/kg 5 000 µg/kg 200 µg/kg	Muscle Fat Liver Kidney Eggs	Provisional MRLs expire on 1.1.2002
Streptomycin	Streptomycin	Bovine, ovine Porcine	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 1 000 µg/kg	Muscle Fat Liver Kidney Milk Muscle Skin and fat Liver Kidney	Provisional MRLs expire on 1.6.2002

▼ **M58**▼ **M71**▼ **M76**

▼ **M58**

1.2.6. Quinolones

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
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
Decoquinatone	Decoquinatone	Bovine, ovine	500 µg/kg 500 µg/kg 500 µg/kg 500 µg/kg	Muscle Fat Liver Kidney	Provisional MRLs expire on 1 July 2000
Difloxacin	Difloxacin	Bovine Not for use in animals from which milk is produced for human consumption Porcine	400 µg/kg 100 µg/kg 1 400 µg/kg 800 µg/kg 400 µg/kg 100 µg/kg 800 µg/kg 800 µg/kg	Muscle Fat Liver Kidney Muscle Skin and fat Liver Kidney	Provisional MRLs expire on 1.1.2001
Enrofloxacin	Sum of enrofloxacin and ciprofloxacin	Ovine	100 µg/kg 100 µg/kg 300 µg/kg 200 µg/kg	Muscle Fat Liver Kidney	Provisional MRLs expire on 1 July 1999
Flumequine	Flumequine	Bovine, ovine, porcine, chicken	50 µg/kg 50 µg/kg 100 µg/kg	Muscle Fat or skin and fat Liver	Provisional MRLs expire on 1 January 2000

▼ **M60**▼ **M58**▼ **M62**▼ **M58**

▼ **M58**

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Marbofloxacin	Marbofloxacin	Salmonidae	300 µg/kg 150 µg/kg	Kidney Muscle and skin	
Marbofloxacin	Marbofloxacin	Bovine	150 µg/kg 50 µg/kg 150 µg/kg 150 µg/kg	Muscle Fat Liver Kidney	Provisional MRLs expire on 1 July 2000
		Porcine	75 µg/kg 150 µg/kg 50 µg/kg 150 µg/kg 150 µg/kg	Milk Muscle Skin and fat Liver Kidney	
Oxolinic acid	Oxolinic acid	Bovine	100 µg/kg 50 µg/kg 150 µg/kg	Muscle Fat Liver	► M83 Provisional MRLs expire on 1.1.2003 Not for use in animals from which milk is produced for human consumption ▼
		Porcine	150 µg/kg 100 µg/kg 50 µg/kg 150 µg/kg	Kidney Muscle Skin + fat Liver	
		Chicken	150 µg/kg 100 µg/kg 50 µg/kg 150 µg/kg	Kidney Muscle Skin + fat Liver	
		Fin fish	150 µg/kg 50 µg/kg 300 µg/kg	Kidney Eggs Muscle and skin in natural proportions	

▼ **M59**

▼ **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 Chicken	50 µg/kg 150 µg/kg 150 µg/kg 150 µg/kg 200 µg/kg 300 µg/kg	Milk Muscle Fat Liver Kidney Eggs	► M77 Provisional MRLs expire on 1.7.2002 ◀

1.2.10. Pencilins

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 300 µg/kg 30 µg/kg	Muscle Fat Liver Kidney Milk	Provisional MRLs expire on 1.1.2001
Penethamate	Benzylopenicillin	Ovine Porcine	50 µg/kg 50 µg/kg 50 µg/kg 50 µg/kg 4 µg/kg 50 µg/kg 50 µg/kg 50 µg/kg 50 µg/kg	Muscle Fat Liver Kidney Milk Muscle Fat Liver Kidney	Provisional MRLs expire on 1 January 2000

▼ **M59**▼ **M58**

▼ **M58**

1.2.11. Florfenicol and related compounds

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Florfenicol	Sum of florfenicol and its metabolites measured as florfenicol-amine	Fish	1 000 µg/kg	Muscle and skin in natural proportions	Provisional MRLs expire on 1 July 2001
Thiamphenicol	Thiamphenicol	Ovine	50 µg/kg 50 µg/kg 50 µg/kg 50 µg/kg	Muscle Fat Liver Kidney	Provisional MRLs expire on 1.1.2001
		Porcine	50 µg/kg	Muscle	
		Fin fish	50 µg/kg 50 µg/kg 50 µg/kg	Skin + fat Liver Kidney Muscle and skin in natural proportions	

▼ **M59**▼ **M60**

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	Muscle	Provisional MRLs expire on 1.1.2001
			50 µg/kg	Fat	
			500 µg/kg	Liver	
		Porcine	1 500 µg/kg	Kidney	
			150 µg/kg	Milk	
			100 µg/kg	Muscle	
			50 µg/kg	Skin + fat	
		Chicken	500 µg/kg	Liver	
			1 500 µg/kg	Kidney	
			100 µg/kg	Muscle	
			50 µg/kg	Skin + fat	
			500 µg/kg	Liver	
			1 500 µg/kg	Kidney	
Pirlimycin	Pirlimycin	Bovine	100 µg/kg	Muscle	Provisional MRLs expire on 1.7.2000
			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 $\mu\text{g}/\text{kg}$ 100 $\mu\text{g}/\text{kg}$ 300 $\mu\text{g}/\text{kg}$	Muscle Skin and fat Liver	Provisional MRLs expire on 1.7.2001

▼ **M58**

2. Antiparasitic agents

2.1. Agents acting against endoparasites

▼ **M62**

2.1.1. Phenol derivatives including salicylamides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Oxyclozanide	Oxyclozanide	Bovine	20 $\mu\text{g}/\text{kg}$ 20 $\mu\text{g}/\text{kg}$ 500 $\mu\text{g}/\text{kg}$ 100 $\mu\text{g}/\text{kg}$ 10 $\mu\text{g}/\text{kg}$ 20 $\mu\text{g}/\text{kg}$ 20 $\mu\text{g}/\text{kg}$ 500 $\mu\text{g}/\text{kg}$ 100 $\mu\text{g}/\text{kg}$	Muscle Fat Liver Kidney Milk Muscle Fat Liver Kidney	► M77 Provisional MRLs expire on 1.7.2002 ◄
		Ovine			

▼ **M58**

2.1.2. Benzimidazoles and pro-benzimidazoles

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Albendazole sulphoxide	Sum of albendazole, albendazole sulphoxide, albendazole sulphone, and albendazole 2-amino sulphone, expressed as albendazole	Bovine, ovine	100 $\mu\text{g}/\text{kg}$	Milk	Provisional MRLs expire on 1 January 2000

▼ **M58**

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

▼ **M71**▼ **M58**

▼ **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 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 Ovine 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 100 µg/kg 250 µg/kg 150 µg/kg 150 µg/kg	Muscle Fat Liver Kidney Muscle Fat Liver Kidney	Provisional MRLs expire on 1.7.2001

▼ **M58**

2.2. Agents acting against ectoparasites

2.2.1. Formamidines

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Amtraz	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 50 µg/kg 10 µg/kg 10 µg/kg 20 µg/kg	Muscle Fat Liver Kidney Milk Further provisions in Council Directive 94/29/EC are to be observed (OJ L 189, 23.7.1994, p. 67)	Provisional MRLs expire on 1 January 2001
Alphacypermethrin	Cypermethrin (sum of isomers)	Bovine, ovine Chicken	20 µg/kg 200 µg/kg 20 µg/kg 20 µg/kg 20 µg/kg 50 µg/kg 50 µg/kg 50 µg/kg 50 µg/kg 50 µg/kg	Muscle Fat Liver Kidney Milk Muscle Skin + fat Liver Kidney Eggs	► M95 Provisional MRLs expire on 1.7.2003 Further provisions in Directive 93/57/EC are to be observed ◄

▼ **M61**

▼ **M61**

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

▼ **M95**▼ **M61**

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
▼ <u>M61</u> ▼ <u>M66</u> Deltamethrin	Deltamethrin	Bovine	10 µg/kg 50 µg/kg 10 µg/kg 10 µg/kg 20 µg/kg 10 µg/kg	Muscle Fat Liver Kidney Milk Muscle	Provisional MRLs expire on 1 July 2001
		Ovine Not for use in animals from which milk is produced for human consumption Chicken	50 µg/kg 10 µg/kg 10 µg/kg 10 µg/kg 10 µg/kg 50 µg/kg 10 µg/kg 10 µg/kg 50 µg/kg 10 µg/kg	Muscle Skin + fat Liver Kidney Muscle Skin + fat Liver Kidney Eggs Muscle and skin in natural proportions	
▼ <u>M76</u> 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	Provisional MRLs expire on 1 July 2004; ► <u>M89</u> Provisional MRLs expire on 1.7.2003 ◄
▼ <u>M99</u> Permethrin	Permethrin (sum of isomers)	Chicken, porcine	50 µg/kg 500 µg/kg 50 µg/kg 50 µg/kg	Muscle Skin and fat Liver Kidney	Provisional MRLs expire on 1.1.2002
▼ <u>M83</u>					

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
		Bovine, caprine	50 µg/kg 500 µg/kg 50 µg/kg 50 µg/kg 50 µg/kg	Muscle Fat Liver Kidney Milk	Provisional MRLs expire on 1.1.2003 Further provisions in Commission Directive 98/82/EC are to be observed (OJ L 290, 29.10.1998, p. 25) Provisional MRLs expire on 1.1.2003
		Chicken	50 µg/kg	Eggs	

▼ **M58**

2.2.4. Organophosphates

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Azamethiphos	Azamethiphos	Salmonidae	100 µg/kg	Muscle and skin in natural proportions	Provisional MRLs expire on 1 June 1999
Coumafos	Coumafos	Bees	100 µg/kg	Honey	Provisional MRLs expire on 1.7.2001
Phoxim	Phoxim	Porcine	20 µg/kg 700 µg/kg	Muscle Skin and fat	Provisional MRLs expire on 1 January 2001
		Ovine	20 µg/kg 20 µg/kg	Liver Kidney	
			50 µg/kg 400 µg/kg 50 µg/kg	Muscle Fat Kidney	Provisional MRLs expire on 1.7.2001; not for use in animals from which milk is produced for human consumption
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 90 µg/kg	Fat Kidney	Provisional MRLs expire on 1.1.2001

▼ **M71**▼ **M58**

2.2.5. Acyl urea derivatives

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

▼ **M62**

▼ **M69**

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

▼ **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
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, including reindeer	20 µg/kg 100 µg/kg 50 µg/kg 30 µg/kg	Muscle Fat Liver Kidney	Provisional MRLs expire on 1.7.2001
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

▼ **M58**▼ **M60**

2.4. Agents acting against protozoa

2.4.1. Carbamides

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

▼ **M62**

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	Provisional MRL's expire on 1.1.2001

▼ **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 150 µg/kg 500 µg/kg 250 µg/kg	Muscle Skin and fat Liver Kidney	Provisional MRLs expire on 1.1.2001

▼ **M75**

2.4.4. Other anti-protozoal agents

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

▼ **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 $\mu\text{g}/\text{kg}$	Muscle	Provisional MRLs expire on 1 July 2000
			0,5 $\mu\text{g}/\text{kg}$	Liver	
		Equidae Indications: tocolysis and the treatment of respiratory ailments	0,5 $\mu\text{g}/\text{kg}$	Kidney	
			0,05 $\mu\text{g}/\text{kg}$	Milk	
			0,1 $\mu\text{g}/\text{kg}$	Muscle	
			0,5 $\mu\text{g}/\text{kg}$	Liver	
0,5 $\mu\text{g}/\text{kg}$	Kidney				

▼ **M60**

- 3.2.2. Anti-adrenergics

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Carazolol	Carazolol	Bovine	5 $\mu\text{g}/\text{kg}$	Muscle	Provisional MRLs expire on 1.1.2000
			5 $\mu\text{g}/\text{kg}$	Fat	
			15 $\mu\text{g}/\text{kg}$	Liver	
			15 $\mu\text{g}/\text{kg}$	Kidney	
			1 $\mu\text{g}/\text{kg}$	Milk	

▼ **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	Carprofen	Bovine	500 µg/kg	Muscle	Provisional MRLs expire on 1 January 2000
			500 µg/kg	Fat	
			1 000 µg/kg	Liver	
		Equidae	1 000 µg/kg	Kidney	
			50 µg/kg	Muscle	
			100 µg/kg	Fat	
			1 000 µg/kg	Liver	
1 000 µg/kg	Kidney				

- 5.1.2. Enolic acid derivatives

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

▼ **M71**

- 5.1.3. Pyrazolone derivatives

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Metamizole	4-Methylaminoantipyrin	Bovine, porcine, equidae	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

▼ **M85**

▼ **M92**

6. Agents acting on the reproductive system

6.1. Progestogens

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 3 µg/kg	► M97 Skin and fat ◀ Liver Kidney Fat Liver Kidney	► M97 Provisional MRLs expire on 1.1.2005; for zootechnical use only ◀
Flugestone acetate	Flugestone acetate	Caprine	1 µg/kg	Milk	Provisional MRLs expire on 01/01/2003; For intravaginal use for zootechnical purposes only

▼ **M74**

7. Corticoids

7.1. Glucocorticoids

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Methylprednisolone	Methylprednisolone	Bovine	10 µg/kg 10 µg/kg 10 µg/kg 10 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***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.
 - 3.4.1 Study of the effects on reproduction.
 - 3.4.2 Embryotoxicity/fetotoxicity, including teratogenicity.
- 3.5 Mutagenicity.
- 3.6 Carcinogenicity.

▼ M2

A.4. Studies of other effects

- 4.1 Immunotoxicity.
- 4.2 Microbiological properties of residues.
 - 4.2.1 On the human gut flora;
 - 4.2.2 On the organisms and microorganisms used for industrial food-processing.
- 4.3 Observations in humans.

B. *Residue documentation*

B.0 Expert report

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

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

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

B.2. Residue studies

2.1 Pharmacokinetics

(absorption, distribution, biotransformation, excretion).

2.2 Depletion of residues.

2.3 Elaboration of maximum residue limits (MRLS).

B3. Routine analytical method for the detection of residues

- 3.1 Description of the method.
- 3.2 Validation of the method.
 - 3.2.1 specificity;
 - 3.2.2 accuracy, including sensitivity;
 - 3.2.3 precision;
 - 3.2.4 limit of detection;
 - 3.2.5 limit of quantitation;
 - 3.2.6 practicability and applicability under normal laboratory conditions;
 - 3.2.7 susceptibility to interference.