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

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

Corrected by:

- ▶ **C1** Corrigendum, OJ L 222, 20.9.1995, p. 17 (1442/95)
- ▶ **C2** Corrigendum, OJ L 316, 5.12.1996, p. 37 (1442/95)
- ▶ **C3** Corrigendum, OJ L 76, 18.3.1997, p. 34 (1442/95)
- ▶ **C4** Corrigendum, OJ L 271, 8.10.1998, p. 42 (1568/98)
- ▶ **C5** Corrigendum, OJ L 9, 13.1.2000, p. 30 (1308/1999)

▼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 <sup>(1)</sup>,

Having regard to the opinion of the European Parliament <sup>(2)</sup>,

Having regard to the opinion of the Economic and Social Committee <sup>(3)</sup>,

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

<sup>(1)</sup> OJ No C 61, 10. 3. 1989, p. 5.

<sup>(2)</sup> OJ No C 96, 17. 4. 1990, p. 273.

<sup>(3)</sup> OJ No C 201, 17. 8. 1989, p. 1.

**▼B**

rapid procedure which ensures close cooperation between the Commission and the Member States through the Committee set up under Council Directive 81/852/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products <sup>(1)</sup>, as last amended by Directive 87/20/EEC <sup>(2)</sup>; 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.

<sup>(1)</sup> OJ No L 317, 6. 11. 1981, p. 16.

<sup>(2)</sup> 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.

**▼M60***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<sup>(1)</sup>, 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.

<sup>(1)</sup> 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***▼M60**

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 ►**M60** Standing Committee ◀ for Adaptation to Technical Progress. The ►**M60** 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 ►**M60** Standing Committee ◀.
- (b) Where the measures envisaged are not in accordance with the opinion of the ►**M60** 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. ►**M60** 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 ►**M60** 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 ►**M60** Standing Committee ◀ a draft of the measures to be adopted. The ►**M60** 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 ►**M60** Standing Committee ◀.

(b) Where the measures envisaged are not in accordance with the opinion of the ►**M60** 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.

**▼M60***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           |  |

- 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           |                  |
| Trimethoprim                          | Trimethoprim   | Bovine         | 40 µg/kg  | Skin and fat   |                  |
|                                       |                |                | 50 µg/kg  | Liver          |                  |
|                                       |                |                | 50 µg/kg  | Kidney         |                  |

## ▼ M58

| Pharmacologically active substance(s) | Marker residue | Animal species  | MRLs   | Target tissues                                    | Other provisions |
|---------------------------------------|----------------|---|--|---|------------------|
|                                       |                | Porcine   | 50 µg/kg<br>50 µg/kg<br>50 µg/kg<br>50 µg/kg<br>50 µg/kg | Kidney<br>Milk<br>Muscle<br>Skin and fat<br>Liver |                  |
|                                       |                | Equidae   | 50 µg/kg<br>100 µg/kg<br>100 µg/kg<br>100 µg/kg          | Kidney<br>Muscle<br>Fat<br>Liver                  |                  |
|                                       |                | Poultry<br>Not for use in animals<br>from which eggs are<br>produced for human<br>consumption | 100 µg/kg<br>50 µg/kg<br>50 µg/kg                        | Kidney<br>Muscle<br>Skin and fat                  |                  |
|                                       |                | Fin fish  | 50 µg/kg   | Muscle and skin in<br>natural proportions         |                  |
| 1.2. Antibiotics                      |                |   |  |   |                  |
| 1.2.1. Pencilins                      |                |   |  |   |                  |
|                                       |                |   |  |   |                  |
| Pharmacologically active substance(s) | Marker residue | Animal species  | MRLs   | Target tissues                                    | Other provisions |
| Amoxicyllin                           | Amoxicyllin    | All food-producing<br>species   | 50 µg/kg<br>50 µg/kg<br>50 µg/kg<br>50 µg/kg<br>4 µg/kg  | Muscle<br>Fat<br>Liver<br>Kidney<br>Milk          |                  |

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

| Pharmacologically active substance(s) | Marker residue    | Animal species             | MRLs   | Target tissues                           | Other provisions |
|---------------------------------------|-------------------|----------------------------|--|--|------------------|
| Oxacillin                             | Oxacillin         | All food-producing species | 300 µg/kg<br>300 µg/kg<br>300 µg/kg<br>300 µg/kg<br>30 µg/kg | Muscle<br>Fat<br>Liver<br>Kidney<br>Milk |                  |
| Penethamate                           | Benzylopenicillin | Bovine                     | 50 µg/kg<br>50 µg/kg<br>50 µg/kg<br>50 µg/kg<br>4 µg/kg      | Muscle<br>Fat<br>Liver<br>Kidney<br>Milk |                  |

## 1.2.2. Cephalosporins

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

▼ **M58**

| Pharmacologically active substance(s) | Marker residue   | Animal species | MRLs  | Target tissues   | Other provisions |
|---------------------------------------|--|----------------|---|--|------------------|
|                                       |  | Porcine        | 50 µg/kg<br>50 µg/kg<br>100 µg/kg<br>200 µg/kg                        | Muscle<br>Skin + fat<br>Liver<br>Kidney                            |                  |
| Ceftiofur                             | Sum of all residues retaining the betalactam structure expressed as desfuroylceftiofur | Bovine         | 1 000 µg/kg<br>2 000 µg/kg<br>2 000 µg/kg<br>6 000 µg/kg<br>100 µg/kg | Muscle<br>Fat<br>Liver<br>Kidney<br>Milk, not for intramammary use |                  |
|                                       |  | Porcine        | 1 000 µg/kg<br>2 000 µg/kg<br>2 000 µg/kg<br>6 000 µg/kg              | Muscle<br>Fat<br>Liver<br>Kidney                                   |                  |

▼ **M58**

## 1.2.3. Quinolones

| Pharmacologically active substance(s) | Marker residue | Animal species  | MRLs   | Target tissues                           | Other provisions |
|---------------------------------------|----------------|-----------------|--|--|------------------|
| Danofloxacin                          | Danofloxacin   | Bovine          | 200 µg/kg<br>100 µg/kg<br>400 µg/kg<br>400 µg/kg<br>30 µg/kg | Muscle<br>Fat<br>Liver<br>Kidney<br>Milk |                  |
| Difloxacin                            | Difloxacin     | Chicken, turkey | 300 µg/kg<br>400 µg/kg                                       | Muscle<br>Skin and fat                   |                  |

▼ **M64**▼ **M58**

| Pharmacologically active substance(s) | Marker residue                        | Animal species   | MRLs   | Target tissues  | Other provisions |
|---------------------------------------|---------------------------------------|--|--|---|------------------|
| Enrofloxacin                          | Sum of enrofloxacin and ciprofloxacin | Bovine   | 1 900 µg/kg<br>600 µg/kg   | Liver<br>Kidney   |                  |
|                                       |                                       | Rabbits  | 100 µg/kg<br>100 µg/kg<br>300 µg/kg<br>200 µg/kg<br>100 µg/kg<br>100 µg/kg<br>200 µg/kg<br>300 µg/kg<br>100 µg/kg<br>100 µg/kg<br>200 µg/kg<br>300 µg/kg<br>100 µg/kg<br>100 µg/kg | Muscle<br>Fat<br>Liver<br>Kidney<br>Milk<br>Muscle<br>Fat<br>Liver<br>Kidney<br>Muscle<br>Skin and fat<br>Liver<br>Kidney<br>Muscle<br>Skin and fat |                  |
|                                       |                                       | Porcine  | 100 µg/kg<br>200 µg/kg<br>300 µg/kg<br>100 µg/kg<br>100 µg/kg  | Liver<br>Kidney<br>Muscle<br>Skin and fat<br>Liver<br>Kidney<br>Muscle<br>Skin and fat  |                  |
|                                       |                                       | Poultry<br>Not for use in animals from which eggs are produced for human consumption | 100 µg/kg<br>100 µg/kg<br>200 µg/kg<br>300 µg/kg<br>100 µg/kg<br>300 µg/kg   | Liver<br>Kidney<br>Muscle<br>Skin and fat<br>Liver<br>Kidney<br>Muscle<br>Skin and fat  |                  |
| Sarafloxacin                          | Sarafloxacin                          | Chicken<br>Salmonidae  | 10 µg/kg<br>100 µg/kg<br>30 µg/kg  | Skin and fat<br>Liver<br>Muscle and skin in natural proportions   |                  |

## ▼ M58

## 1.2.4. Macrolides

| Pharmacologically active substance(s) | Marker residue                      | Animal species                                 | MRLs   | Target tissues  | Other provisions  |
|---------------------------------------|-------------------------------------|--|--|---|---|
| Spiramycin                            | Sum of spiramycin and neospiramycin | Bovine<br><br>Chicken                          | 200 µg/kg<br>300 µg/kg<br>300 µg/kg<br>300 µg/kg<br>200 µg/kg<br>200 µg/kg<br>300 µg/kg<br>400 µg/kg               | Muscle<br>Fat<br>Liver<br>Kidney<br>Milk<br>Muscle<br>Skin and fat<br>Liver           |   |
| Tilmicosin                            | Tilmicosin                          | Bovine, ovine, porcine<br><br>Ovine<br>Chicken | 50 µg/kg<br>50 µg/kg<br>1 000 µg/kg<br>1 000 µg/kg<br>50 µg/kg<br>75 µg/kg<br>75 µg/kg<br>1 000 µg/kg<br>250 µg/kg | Muscle<br>Fat<br>Liver<br>Kidney<br>Milk<br>Muscle<br>Skin and fat<br>Liver<br>Kidney | Not for use in animals from which eggs are produced for human consumption |
| Tylosin                               | Tylosin A                           | Bovine<br><br>Porcine                          | 100 µg/kg<br>100 µg/kg<br>100 µg/kg<br>100 µg/kg<br>50 µg/kg<br>100 µg/kg<br>100 µg/kg<br>100 µg/kg                | Muscle<br>Fat<br>Liver<br>Kidney<br>Milk<br>Muscle<br>Skin and fat<br>Liver           |   |



| Pharmacologically active substance(s) | Marker residue | Animal species  | MRLs  | Target tissues  | Other provisions |
|---------------------------------------|----------------|---|---|---|------------------|
|                                       |                | Poultry<br>Not for use in hens producing eggs for human consumption | 100 µg/kg<br>100 µg/kg<br>100 µg/kg<br><br>100 µg/kg<br>100 µg/kg | Kidney<br>Muscle<br>Skin and fat<br><br>Liver<br>Kidney |                  |

## 1.2.5. Florfenicol and related compounds

| Pharmacologically active substance(s) | Marker residue   | Animal species   | MRLs   | Target tissues  | Other provisions |
|---------------------------------------|--|--|--|---|------------------|
| Florfenicol                           | Sum of florfenicol and its metabolites measured as florfenicol-amine | Bovine   | 200 µg/kg<br><br>3 000 µg/kg<br>300 µg/kg  | Muscle<br><br>Liver<br>Kidney   |                  |
| Thiamphenicol                         | Thiamphenicol  | Bovine<br><br>Chicken<br>Not for use in animals from which eggs are produced for human consumption | 50 µg/kg<br>50 µg/kg<br>50 µg/kg<br>50 µg/kg<br>50 µg/kg<br>50 µg/kg<br><br>50 µg/kg<br>50 µg/kg | Muscle<br>Fat<br>Liver<br>Kidney<br>Milk<br>Muscle<br>Skin and fat<br><br>Liver<br>Kidney |                  |

## ▼ M58

## 1.2.6. Tetracyclines

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

| Pharmacologically active substance(s) | Marker residue                      | Animal species             | MRLs  | Target tissues                            | Other provisions |
|---------------------------------------|-------------------------------------|----------------------------|---|---|------------------|
| Tetracycline                          | Sum of parent drug and its 4-epimer | All food-producing species | 100 µg/kg<br>300 µg/kg<br>600 µg/kg<br>100 µg/kg<br>200 µg/kg | Muscle<br>Liver<br>Kidney<br>Milk<br>Eggs |                  |

## 1.2.7. Naphtalene-ringed ansamycin

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

## 1.2.8. Pleuromutilines

| Pharmacologically active substance(s) | Marker residue | Animal species | MRLs                               | Target tissues            | Other provisions |
|---------------------------------------|----------------|----------------|------------------------------------|---------------------------|------------------|
| Valnemulin                            | Valnemulin     | Porcine        | 50 µg/kg<br>500 µg/kg<br>100 µg/kg | Muscle<br>Liver<br>Kidney |                  |

▼ **M59**

## 1.2.9. Lincosamides

| Pharmacologically active substance(s) | Marker residue | Animal species | MRLs   | Target tissues                           | Other provisions |
|---------------------------------------|----------------|----------------|--|--|------------------|
| Lincomycin                            | Lincomycin     | Bovine         | 100 µg/kg<br>50 µg/kg<br>500 µg/kg<br>1 500 µg/kg<br>150 µg/kg | Muscle<br>Fat<br>Liver<br>Kidney<br>Milk |                  |

▼ **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<br>1 000 µg/kg<br>10 000 µg/kg<br>20 000 µg/kg | Muscle<br>Fat<br>Liver<br>Kidney | Not for use in animals from which milk is produced for human consumption |

▼ **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<br><br>Ovine | 1 000 µg/kg<br>3 000 µg/kg<br>1 000 µg/kg<br>3 000 µg/kg<br>1 500 µg/kg<br>2 000 µg/kg | Muscle<br>Fat<br>Liver<br>Kidney<br>Muscle<br>Fat |                  |

## ▼ M58

| Pharmacologically active substance(s) | Marker residue | Animal species | MRLs                       | Target tissues  | Other provisions |
|---------------------------------------|----------------|----------------|----------------------------|-----------------|------------------|
|                                       |                |                | 1 500 µg/kg<br>5 000 µg/kg | Liver<br>Kidney |                  |

## 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<br>10 µg/kg<br>100 µg/kg<br>10 µg/kg | Muscle<br>Fat<br>Liver<br>Kidney |                  |

## 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<br><br>100 µg/kg<br>1 000 µg/kg<br>500 µg/kg<br>100 µg/kg | Muscle<br><br>Fat<br>Liver<br>Kidney<br>Milk |                  |
| Febantel                              | Sum of extractable residues which may be oxidised to oxfendazole  | Bovine, ovine<br><br>Bovine, ovine, porcine, equidae | 10 µg/kg<br><br>50 µg/kg<br>50 µg/kg                                | Milk<br><br>Muscle<br>Fat                    |                  |

| Pharmacologically active substance(s) | Marker residue  | Animal species                                       | MRLs   | Target tissues  | Other provisions |
|---------------------------------------|---|--|--|---|------------------|
| Fenbendazole                          | Sum of extractable residues which may be oxidised to oxfendazole sulphone                             | Bovine, ovine<br><br>Bovine, ovine, porcine, equidae | 500 µg/kg<br>50 µg/kg<br><br>10 µg/kg<br><br>50 µg/kg<br>50 µg/kg<br>500 µg/kg<br>50 µg/kg | Liver<br>Kidney<br><br>Milk<br><br>Muscle<br>Fat<br>Liver<br>Kidney |                  |
| Flubendazole                          | Sum of flubendazole and (2-amino 1H-benzimidazol-5-yl) (4-fluorophenyl) methanone<br><br>Flubendazole | Porcine, chicken, game birds<br><br>Chicken          | 50 µg/kg<br><br>50 µg/kg<br>400 µg/kg<br>300 µg/kg<br>400 µg/kg                            | Muscle<br><br>Skin and fat<br>Liver<br>Kidney<br>Eggs               |                  |
| Oxfendazole                           | Sum of extractable residues which may be oxidised to oxfendazole sulphone                             | Bovine, ovine<br><br>Bovine, ovine, porcine, equidae | 10 µg/kg<br><br>50 µg/kg<br>50 µg/kg<br>500 µg/kg<br>50 µg/kg                              | Milk<br><br>Muscle<br>Fat<br>Liver<br>Kidney                        |                  |
| Oxibendazole                          | Oxibendazole  | Porcine  | 100 µg/kg<br>500 µg/kg<br>200 µg/kg  | Muscle<br>Skin and fat<br>Liver                                     |                  |

▼ **M58**

| Pharmacologically active substance(s) | Marker residue  | Animal species | MRLs  | Target tissues                                     | Other provisions   |
|---------------------------------------|---|----------------|---|--|--|
| Thiabendazole                         | Sum of thiabendazole and 5-hydroxythiabendazole                         | Bovine         | 100 µg/kg<br>100 µg/kg<br>100 µg/kg<br>100 µg/kg<br>100 µg/kg | Kidney<br>Muscle<br>Fat<br>Liver<br>Kidney<br>Milk |  |
| Triclabendazole                       | Sum of extractable residues that may be oxidised to ketotriclabendazole | Bovine, ovine  | 100 µg/kg<br>100 µg/kg<br>100 µg/kg                           | Muscle<br>Liver<br>Kidney                          | Not for use in animals from which milk is produced for human consumption |

▼ **M63**

## 2.1.4. Phenol derivatives including salicylamides

| Pharmacologically active substance(s) | Marker residue | Animal species | MRLs  | Target tissues                   | Other provisions |
|---------------------------------------|----------------|----------------|---|----------------------------------|------------------|
| Nitroximil                            | Nitroximil     | Bovine, ovine  | 400 µg/kg<br>200 µg/kg<br>20 µg/kg<br>400 µg/kg | Muscle<br>Fat<br>Liver<br>Kidney |                  |

▼ **M58**

## 2.2. Agents acting against ectoparasites

## 2.2.1. Organophosphates

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

## 2.2.2. Formamidines

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



▼ **M58**

## 2.2.3. Pyrethroids

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

▼ **M65**

## 2.2.4. 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 |                  |

▼ **M58**

## 2.3. Agents acting against endo- and ectoparasites

## 2.3.1. Avermectins

| Pharmacologically active substance(s) | Marker residue | Animal species | MRLs   | Target tissues                             | Other provisions  |
|---------------------------------------|----------------|----------------|--|--|---|
| Abamectin                             | Avermectin B1a | Bovine         | 10 µg/kg<br>20 µg/kg                                       | Fat<br>Liver                               |   |
| Doramectin                            | Doramectin     | Bovine         | 10 µg/kg<br>150 µg/kg<br>100 µg/kg<br>30 µg/kg<br>20 µg/kg | Muscle<br>Fat<br>Liver<br>Kidney<br>Muscle | Not for use in bovine from which milk is produced for human consumption<br><br>Not for use in ovine from which milk is produced for human consumption |

| Pharmacologically active substance(s) | Marker residue                | Animal species  | MRLs   | Target tissues   | Other provisions |
|---------------------------------------|-------------------------------|---|--|--|------------------|
|                                       |                               |   | 100 µg/kg<br>50 µg/kg<br>30 µg/kg  | Fat<br>Liver<br>Kidney   |                  |
| Emamectin                             | Emamectin B1a                 | Salmonidae  | 100 µg/kg  | Muscle and skin in natural proportions                           |                  |
| Eprinomectin                          | Eprinomectin B1a              | Bovine  | 30 µg/kg<br>30 µg/kg<br>600 µg/kg<br>100 µg/kg<br>30 µg/kg                                     | Muscle<br>Fat<br>Liver<br>Kidney<br>Milk                         |                  |
| Ivermectin                            | 22, 23-Dihydro-avermectin B1a | Bovine<br>Porcine, ovine, equidae<br>Deer, including reindeer | 40 µg/kg<br>100 µg/kg<br>20 µg/kg<br>15 µg/kg<br>20 µg/kg<br>100 µg/kg<br>50 µg/kg<br>20 µg/kg | Fat<br>Liver<br>Fat<br>Liver<br>Muscle<br>Fat<br>Liver<br>Kidney |                  |
| Moxidectin                            | Moxidectin                    | Bovine, ovine   | 50 µg/kg<br>500 µg/kg<br>100 µg/kg<br>50 µg/kg   | Muscle<br>Fat<br>Liver<br>Kidney                                 |                  |

▼ **M58**▼ **M65**▼ **M58**

## ▼ 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          |   |
|                                       |                     | Turkey         | 400 µg/kg | Kidney         |   |
|                                       |                     |                | 100 µg/kg | Muscle         |   |
|                                       |                     |                | 200 µg/kg | Skin and fat   |   |
| 600 µg/kg                             | Liver               |                |           |                |   |
| 400 µg/kg                             | Kidney              |                |           |                |   |

## 3. Agents acting on the nervous system

## 3.1. Agents acting on the central nervous system

## 3.1.1. Butyrophenone tranquilisers

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

## 3.2. Agents acting on the autonomic nervous system

## 3.2.1. Anti-adrenergics

| Pharmacologically active substance(s) | Marker residue | Animal species | MRLs    | Target tissues | Other provisions |
|---------------------------------------|----------------|----------------|---------|----------------|------------------|
| Carazolol                             | Carazolol      | Porcine        | 5 µg/kg | Muscle         |                  |

▼ **M58**

| Pharmacologically active substance(s) | Marker residue | Animal species | MRLs                            | Target tissues                  | Other provisions |
|---------------------------------------|----------------|----------------|---------------------------------|---------------------------------|------------------|
|                                       |                |                | 5 µg/kg<br>25 µg/kg<br>25 µg/kg | Skin and fat<br>Liver<br>Kidney |                  |

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<br>Not for use in animals from which milk is produced for human consumption<br>Equidae | 500 µg/kg<br>1 000 µg/kg<br>1 000 µg/kg<br>1 000 µg/kg<br>500 µg/kg<br>1 000 µg/kg<br>1 000 µg/kg<br>1 000 µg/kg | Muscle<br>Fat<br>Liver<br>Kidney<br>Muscle<br>Fat<br>Liver<br>Kidney |                  |
| Vedaprofen                            | Vedaprofen     | Equidae   | 50 µg/kg<br>20 µg/kg<br>100 µg/kg<br>1 000 µg/kg   | Muscle<br>Fat<br>Liver<br>Kidney                                     |                  |

▼ **M58**

- 4.1.2. Fenamate group derivatives

| Pharmacologically active substance(s) | Marker residue  | Animal species | MRLs     | Target tissues | Other provisions |
|---------------------------------------|-----------------|----------------|----------|----------------|------------------|
| Tolfenamic acid                       | Tolfenamic acid | Bovine         | 50 µg/kg | Muscle         |                  |

## ▼ M58

| Pharmacologically active substance(s) | Marker residue | Animal species | MRLs   | Target tissues                                       | Other provisions |
|---------------------------------------|----------------|----------------|--|--|------------------|
|                                       |                | Porcine        | 400 µg/kg<br>100 µg/kg<br>50 µg/kg<br>50 µg/kg<br>400 µg/kg<br>100 µg/kg | Liver<br>Kidney<br>Milk<br>Muscle<br>Liver<br>Kidney |                  |

## 5. Corticoïdes

## 5.1. Glucocorticoides

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

▼ **M58**

## ANNEX II

## LIST OF SUBSTANCES NOT SUBJECT TO MAXIMUM RESIDUE LIMITS

| 1. Inorganic chemicals | Pharmacologically active substance(s) | Animal species                       | Other provisions     |
|------------------------|---------------------------------------|--------------------------------------|----------------------|
|                        | Aluminium distearate                  | All food-producing species           |                      |
|                        | Aluminium hydroxide acetate           | All food-producing species           |                      |
|                        | Aluminium phosphate                   | All food-producing species           |                      |
|                        | Aluminium tristearate                 | All food-producing species           |                      |
|                        | Ammonium chloride                     | All food-producing species           |                      |
|                        | Bismuth subcarbonate                  | All food-producing species           | For oral use only    |
|                        | Bismuth subgallate                    | All food-producing species           | For oral use only    |
|                        | Bismuth subnitrate                    | All food-producing species           | For oral use only    |
|                        | Bismuth subsalicylate                 | All food-producing species           | For oral use only    |
|                        | Boric acid and borates                | All food-producing species           |                      |
|                        | Bromide, potassium salt               | All food producing species           |                      |
|                        | Bromide, sodium salt                  | All mammalian food-producing species | For topical use only |

▼ **M65**▼ **M58**

## ▼ M58

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

## ▼ M58

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



▼ **M58**

| Pharmacologically active substance(s) | Animal species                           | Other provisions     |
|---------------------------------------|--|----------------------|
| 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 chlorite                       | 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 selenate                       | All food-producing species               |                      |
| Sodium selenite                       | All food-producing species               |                      |
| Sulphur                               | Bovine, porcine, ovine, caprine, equidae |                      |
| Zinc acetate                          | All food-producing species               |                      |
| Zinc chloride                         |  |                      |
| Zinc gluconate                        |  |                      |
| Zinc oleate                           |  |                      |
| Zinc stearate                         |  |                      |

## 2. Organic compounds

| Pharmacologically active substance(s) | Animal species                       | Other provisions                           |
|---------------------------------------|--------------------------------------|--|
| 17 $\beta$ -Oestradiol                | All mammalian food-producing species | For therapeutic and zootechnical uses only |

▼ **M63**▼ **M58**

## ▼ M58

| Pharmacologically active substance(s) | Animal species                       | Other provisions  |
|---------------------------------------|--------------------------------------|---|
| 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<br>Bovine, porcine, equidae  |   |
| Bacitracin                            | Bovine                               | For intramammary use in lactating cows only and for all tissues except milk |
| Benzalkonium chloride                 | All food-producing species           | For use as an excipient at concentrations up to 0,05 % only                 |
| Benzocaine                            | All food-producing species           | For use as local anaesthetic only   |
| Benzylalcohol                         | All food-producing species           | For use as excipient  |
| Betaine                               | All food-producing species           |   |
| Bronopol                              | Salmonidae                           | For use only on farmed fertilised eggs                                      |
| Brotizolam                            | Bovine                               | For therapeutic uses only   |
| Buserelin                             | All food-producing species           |   |
| Butorphanol tartrate                  | Equidae                              | For intravenous administration only   |
| Butyl 4-hydroxybenzoate               | All food-producing species           |   |
| Butylscopolaminium bromide            | All food-producing species           |   |
| Caffeine                              | All food-producing species           |   |

## ▼ M58

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

## ▼ M58

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

## ▼ M58

| Pharmacologically active substance(s)  | Animal species             | Other provisions  |
|--|----------------------------|---|
| Iodine organic compounds<br>— 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   |
| Manganese oxide  | All food-producing species | For oral use only   |

## ▼ M58

| Pharmacologically active substance(s)  | Animal species                           | Other provisions                                    |
|--|--|---|
| 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                                |
| Nomivamide   | Equidae                                  | For topical use only                                |
| Oleyloleate  | All food-producing species               | For topical use only                                |
| Oxytocin   | All mammalian food-producing species     |   |

## ▼ M58

| Pharmacologically active substance(s)                     | Animal species                       | Other provisions  |
|---|--------------------------------------|---|
| Pancreatin  | All mammalian food-producing species | For topical use only  |
| Papain  | All food-producing species           |   |
| Papaverine  | Bovine                               | Newborn calves only   |
| Paracetamol   | All food-producing species           |   |
| Phenol  | All food-producing species           |   |
| Phloroglucinol  | All food-producing species           |   |
| Phytomenadione  | All food-producing species           |   |
| Policresulen  | All food-producing species           | For topical use only  |
| Polyethylene glycol 15 hydroxystearate                    | All food-producing species           | For use as excipient  |
| Polyethylene glycol 7 glyceryl cocoate                    | All food-producing species           | For topical use only  |
| Polyethylene glycol stearates with 8-40 oxyethylene units | All food-producing species           | For use as excipient  |
| Polysulphated glycosaminoglycan                           | Equidae                              |   |
| Praziquantel  | Ovine<br>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           |   |
| Quatresin   | All food-producing species           | For use as preservative only at concentrations of up to 0,5 % |

## ▼ M58

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



▼ **M58**

| Pharmacologically active substance(s) | Animal species   | Other provisions  |
|---------------------------------------|--|---|
| 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 |
| Emiconazole                           | 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<br>Not for use in animals from which milk is produced for human consumption   |   |
|                                       | Porcine  |   |
|                                       | Poultry<br>Not for use in animals from which eggs are produced for human consumption |   |
| Mercaptamine hydrochloride            | All mammalian food-producing species   |   |
| Praziquantel                          | Ovine  |   |
| Pyrantel embonate                     | Equidae  |   |
| Vitamin B1                            | All food-producing species   |   |

▼ **M59**▼ **M61**▼ **M63**

▼ **M63**

| Pharmacologically active substance(s) | Animal species  | Other provisions     |
|---------------------------------------|---|----------------------|
| 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  |                      |
| Tiaprost                              | Bovine, ovine, porcine, equidae   |                      |
| Apramycin                             | Porcine, rabbits<br>Ovine<br>Not for use in animals from which milk is produced for human consumption<br>Chicken<br>Not for use in animals from which eggs are produced for human consumption | For oral use only    |
| Azamethiphos                          | Salmonidae  |                      |
| Doxapram                              | All mammalian food producing species  |                      |
| Piperonyl butoxide                    | Bovine, ovine, caprine, equidae   | For topical use only |
| Sulfogaiacol                          | All food producing species  |                      |
| Vetrabutine hydrochloride             | Porcine   |                      |

▼ **M64**▼ **M65**

## ▼ M58

## 3. Substances generally recognised as safe

| Pharmacologically active substance(s)      | Animal species             | Other provisions  |
|--|----------------------------|-------------------|
| Absinthium extract                         | All food-producing species |                   |
| AcetylImethionine                          | All food-producing species |                   |
| Aluminium hydroxide                        | All food-producing species |                   |
| Aluminium monostearate                     | All food-producing species |                   |
| Ammonium sulfate                           | All food-producing species |                   |
| Benzoyl benzoate                           | All food-producing species |                   |
| Benzyl p-hydroxybenzoate                   | All food-producing species |                   |
| Calcium borogluconate                      | All food-producing species |                   |
| Calcium citrate                            | All food-producing species |                   |
| Camphor                                    | All food-producing species | External use only |
| Cardamon extract                           | All food-producing species |                   |
| Diethyl sebacate                           | All food-producing species |                   |
| Dimethicone                                | All food-producing species |                   |
| Dimethyl acetamide                         | All food-producing species |                   |
| Dimethyl sulphoxide                        | All food-producing species |                   |
| Epinephrine                                | All food-producing species |                   |
| Ethyl oleate                               | All food-producing species |                   |
| Ethylene diaminetetraacetic acid and salts | All food-producing species |                   |
| Eucalyptol                                 | All food-producing species |                   |

## ▼ M58

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

## ▼ M58

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

▼ **M58**

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

▼ **M65**

## ▼ M65

| Pharmacologically active substance(s)                 | Animal species             | Other provisions |
|---|----------------------------|------------------|
| 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 |                  |
| 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 |   |
| <i>Adonis vernalis</i>  | All food producing species | For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias, at concentrations in the products not exceeding one part per hundred only  |
| <i>Acqua levici</i>   | All food producing species | For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias only  |
| <i>Atropa belladonna</i>  | All food producing species | For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias, at concentrations in the products not exceeding one part per hundred only  |
| <i>Convallaria majalis</i>  | All food producing species | For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias, at concentrations in the products not exceeding one part per thousand only |

▼ **M58**

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

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

## 6. Substances of vegetable origin

| Pharmacologically active substance(s) | Animal species             | Other provisions |
|---------------------------------------|----------------------------|------------------|
| <i>Angelicae radix aetheroleum</i>    | All food-producing species |                  |



▼ **M58**

| Pharmacologically active substance(s)   | Animal species             | Other provisions     |
|---|----------------------------|----------------------|
| <i>Anisi aetheroleum</i>                | All food-producing species |                      |
| <i>Balsamum peruvianum</i>              | All food-producing species | For topical use only |
| <i>Carvi aetheroleum</i>                | All food-producing species |                      |
| <i>Caryophylli aetheroleum</i>          | All food-producing species |                      |
| <i>Centellae asiaticaer extractum</i>   | All food producing species | For topical use only |
| <i>Chrysanthemi cinerariifolii flos</i> | All food-producing species | For topical use only |
| <i>Cinnamomi cassiae aetheroleum</i>    | All food-producing species |                      |
| <i>Cinnamomi ceylanici aetheroleum</i>  | All food-producing species |                      |
| <i>Citri aetheroleum</i>                | All food-producing species |                      |
| <i>Citronellae aetheroleum</i>          | All food-producing species |                      |
| <i>Coriandri aetheroleum</i>            | All food-producing species |                      |
| <i>Echinacea purpurea</i>               | All food-producing species | For topical use only |
| <i>Eucalypti aetheroleum</i>            | All food-producing species |                      |
| <i>Foeniculi aetheroleum</i>            | All food-producing species |                      |
| <i>Hamamelis virginiana</i>             | All food-producing species | For topical use only |
| <i>Hyperici oleum</i>                   | All food-producing species | For topical use only |
| <i>Lespedeza capitata</i>               | All food-producing species |                      |
| <i>Lini oleum</i>                       | All food-producing species |                      |
| <i>Majoranae herba</i>                  | All food-producing species |                      |

▼ **M59**▼ **M58**

▼ **M58**

| Pharmacologically active substance(s)            | Animal species                  | Other provisions                |
|--|---------------------------------|---------------------------------|
| <i>Matricariae flos</i>                          | All food-producing species      |                                 |
| <i>Medicago sativa extractum</i>                 | All food-producing species      | For topical use only            |
| <i>Melissae aetheroleum</i>                      | All food producing species      |                                 |
| <i>Melissae folium</i>                           | All food-producing species      |                                 |
| <i>Menthae piperitae aetheroleum</i>             | All food-producing species      |                                 |
| <i>Millefolii herba</i>                          | All food-producing species      |                                 |
| <i>Myristicae 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>Quillaia saponins</i>                         | All food-producing species      |                                 |
| <i>Ricini oleum</i>                              | All food-producing species      | For use as excipient            |
| <i>Rosmarini aetheroleum</i>                     | All food-producing species      |                                 |
| <i>Rosmarini folium</i>                          | All food-producing species      |                                 |
| <i>Salviae folium</i>                            | All food-producing species      |                                 |
| <i>Sambuci flos</i>                              | All food-producing species      |                                 |
| <i>Sinapis nigrae semen</i>                      | All food-producing species      |                                 |
| <i>Terebinthinae aetheroleum rectificatum</i>    | All food-producing species      | For topical use only            |
| <i>Terebinthinae laricina</i>                    | All food-producing species      | For topical use only            |

▼ **M59**▼ **M58**

▼ **M58**

| Pharmacologically active substance(s) | Animal species             | Other provisions |
|---------------------------------------|----------------------------|------------------|
| <i>Thymi aetheroleum</i>              | All food-producing species |                  |
| <i>Tiliae flos</i>                    | All food-producing species |                  |
| <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
    - 1.1.2. Benzenesulphonamides

| Pharmacologically active substance(s) | Marker residue | Animal species | MRLs                               | Target tissues            | Other provisions                          |
|---------------------------------------|----------------|----------------|------------------------------------|---------------------------|---|
| Clorsulon                             | Clorsulon      | Bovine         | 50 µg/kg<br>150 µg/kg<br>400 µg/kg | Muscle<br>Liver<br>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<br>Bovine, ovine, porcine | 200 µg/kg<br>200 µg/kg<br>200 µg/kg<br>200 µg/kg<br>200 µg/kg | Milk<br>Muscle<br>Fat<br>Liver<br>Kidney | Provisional MRLs expire on 1 July 1999 |

▼ **M58**

## 1.2.2. Macrolides

| Pharmacologically active substance(s) | Marker residue   | Animal species  | MRLs  | Target tissues  | Other provisions  |
|---------------------------------------|--|---|---|---|---|
| Erythromycin                          | MRLs apply to all microbiological active residues expressed as erythromycin equivalent   | Bovine, ovine<br><br>Bovine, ovine, porcine, poultry<br><br>Poultry | 40 µg/kg<br><br>400 µg/kg<br>400 µg/kg<br>400 µg/kg<br>200 µg/kg  | Milk<br><br>Muscle<br>Fat<br>Liver<br>Kidney<br>Eggs                                      | Provisional MRLs expire on 1 June 2000  |
| Josamycin                             | Josamycin<br><br>Sum of the microbiologically active metabolites, expressed as josamycin | Chicken<br><br>Porcine  | 200 µg/kg<br>200 µg/kg<br>200 µg/kg<br>400 µg/kg<br>200 µg/kg<br><br>200 µg/kg<br>200 µg/kg<br>200 µg/kg<br>400 µg/kg | Muscle<br>Fat<br>Liver<br>Kidney<br>Eggs<br><br>Muscle<br>Skin and fat<br>Liver<br>Kidney | Provisional MRLs expire on 1 July 2000<br><br>Provisional MRLs expire on 1.7.2002 |

▼ **M61**

▼ **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                                     | Provisional MRLs expire on 1.1.2001<br>For intramammary use only |
| Cefquinome                            | Cefquinome                                | Porcine        | 50 µg/kg<br>50 µg/kg<br>100 µg/kg<br>200 µg/kg            | Muscle<br>Skin + fat<br>Liver<br>Kidney  | Provisional MRLs expire on 1.1.2000                              |
| Cephapirin                            | Sum of cephapirin and desacetylcephapirin | Bovine         | 50 µg/kg<br>50 µg/kg<br>50 µg/kg<br>100 µg/kg<br>10 µg/kg | Muscle<br>Fat<br>Liver<br>Kidney<br>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<br>1 500 µg/kg<br>1 500 µg/kg                    | Muscle<br>Liver<br>Kidney        | Provisional MRLs expire on 1 July 2000 |
| Apramycin                             | Apramycin      | Bovine<br>For use in non-lactating cattle only | 1 000 µg/kg<br>1 000 µg/kg<br>10 000 µg/kg<br>20 000 µg/kg | Muscle<br>Fat<br>Liver<br>Kidney | Provisional MRLs expire on 1 July 1999 |

| Pharmacologically active substance(s) | Marker residue      | Animal species                                      | MRLs  | Target tissues                            | Other provisions                       |
|---------------------------------------|---------------------|---|---|---|--|
|                                       |                     | Porcine   | 1 000 µg/kg<br>1 000 µg/kg<br>1 000 µg/kg<br>5 000 µg/kg        | Muscle<br>Skin and fat<br>Liver<br>Kidney |  |
| Dihydrostreptomycin                   | Dihydrostreptomycin | Bovine, ovine<br>Bovine, ovine, porcine,<br>poultry | 200 µg/kg<br>500 µg/kg<br>500 µg/kg<br>500 µg/kg<br>1 000 µg/kg | Milk<br>Muscle<br>Fat<br>Liver<br>Kidney  | Provisional MRLs expire on 1 June 2000 |
| Gentamicin                            | Gentamicin          | Bovine<br>Bovine, porcine                           | 100 µg/kg<br>100 µg/kg<br>100 µg/kg<br>200 µg/kg<br>1 000 µg/kg | Milk<br>Muscle<br>Fat<br>Liver<br>Kidney  | Provisional MRLs expire on 1 June 2000 |

▼ **M58**

| Pharmacologically active substance(s) | Marker residue | Animal species   | MRLs   | Target tissues                                   | Other provisions                       |
|---------------------------------------|----------------|--|--|--|--|
| Kanamycin                             | Kanamycin      | Rabbits  | 100 µg/kg<br>100 µg/kg<br>600 µg/kg<br>2 500 µg/kg                           | Muscle<br>Fat<br>Liver<br>Kidney                 | Provisional MRLs expire on 1.1.2002    |
|                                       |                | Bovine, ovine  | 100 µg/kg<br>100 µg/kg<br>600 µg/kg<br>2 500 µg/kg                           | Muscle<br>Fat<br>Liver<br>Kidney                 |  |
| Neomycin (including framycetin)       | Neomycin       | Porcine, chicken   | 150 µg/kg<br>100 µg/kg<br>100 µg/kg<br>600 µg/kg<br>2 500 µg/kg              | Milk<br>Muscle<br>Skin + fat<br>Liver<br>Kidney  | Provisional MRLs expire on 1 June 2000 |
|                                       |                | Bovine, ovine, caprine<br>Bovine, ovine, caprine,<br>porcine, chicken, turkey,<br>duck | 500 µg/kg<br>500 µg/kg<br>500 µg/kg<br>500 µg/kg<br>5 000 µg/kg<br>500 µg/kg | Milk<br>Muscle<br>Fat<br>Liver<br>Kidney<br>Eggs |  |
| Spectinomycin                         | Spectinomycin  | Chicken  | 200 µg/kg<br>300 µg/kg<br>500 µg/kg<br>2 000 µg/kg<br>5 000 µg/kg            | Milk<br>Muscle<br>Fat<br>Liver<br>Kidney         | Provisional MRLs expire on 1 July 2000 |
| Streptomycin                          | Streptomycin   | Bovine   | 200 µg/kg  | Milk   | Provisional MRLs expire on 1 June 2000 |
|                                       |                | Bovine, porcine, poultry   | 300 µg/kg<br>500 µg/kg<br>2 000 µg/kg<br>5 000 µg/kg                         | Muscle<br>Fat<br>Liver<br>Kidney                 |  |
|                                       |                | Bovine, ovine  | 200 µg/kg  | Milk   |  |

▼ **M65**▼ **M58**



▼ **M58**

| Pharmacologically active substance(s) | Marker residue | Animal species                  | MRLs   | Target tissues                   | Other provisions |
|---------------------------------------|----------------|---------------------------------|--|----------------------------------|------------------|
|                                       |                | Bovine, ovine, porcine, poultry | 500 µg/kg<br>500 µg/kg<br>500 µg/kg<br>1 000 µg/kg | Muscle<br>Fat<br>Liver<br>Kidney |                  |

## 1.2.6. Quinolones

▼ **M61**

| Pharmacologically active substance(s) | Marker residue | Animal species | MRLs  | Target tissues                            | Other provisions                    |
|---------------------------------------|----------------|----------------|---|---|-------------------------------------|
| Danofloxacin                          | Danofloxacin   | Porcine        | 100 µg/kg<br>50 µg/kg<br>200 µg/kg<br>200 µg/kg | Muscle<br>Skin and fat<br>Liver<br>Kidney | Provisional MRLs expire on 1.1.2000 |

▼ **M58**

|            |            |               |  |                                  |  |
|------------|------------|---------------|--|----------------------------------|--|
| Decoquinat | Decoquinat | Bovine, ovine | 500 µg/kg<br>500 µg/kg<br>500 µg/kg<br>500 µg/kg | Muscle<br>Fat<br>Liver<br>Kidney | Provisional MRLs expire on 1 July 2000 |
|------------|------------|---------------|--|----------------------------------|--|

▼ **M63**

|            |            |   |  |   |                                     |
|------------|------------|---|--|---|-------------------------------------|
| Difloxacin | Difloxacin | Bovine<br>Not for use in animals from which milk is produced for human consumption<br>Porcine | 400 µg/kg<br>100 µg/kg<br>1 400 µg/kg<br>800 µg/kg<br>400 µg/kg<br>100 µg/kg<br>800 µg/kg<br>800 µg/kg | Muscle<br>Fat<br>Liver<br>Kidney<br>Muscle<br>Skin and fat<br>Liver<br>Kidney | Provisional MRLs expire on 1.1.2001 |
|------------|------------|---|--|---|-------------------------------------|

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

▼ **M58**

| Pharmacologically active substance(s) | Marker residue | Animal species | MRLs                   | Target tissues                                 | Other provisions                    |
|---------------------------------------|----------------|----------------|------------------------|--|-------------------------------------|
| Oxolinic acid                         | Oxolinic acid  | Bovine         | 100 µg/kg<br>50 µg/kg  | Muscle<br>Fat                                  | Provisional MRLs expire on 1.1.2001 |
|                                       |                | Porcine        | 150 µg/kg<br>150 µg/kg | Liver<br>Kidney                                |                                     |
|                                       |                | Chicken        | 100 µg/kg<br>50 µg/kg  | Muscle<br>Skin + fat                           |                                     |
|                                       |                |                | 150 µg/kg<br>150 µg/kg | Liver<br>Kidney                                |                                     |
|                                       |                |                | 100 µg/kg<br>50 µg/kg  | Muscle<br>Skin + fat                           |                                     |
|                                       |                |                | 150 µg/kg<br>150 µg/kg | Liver<br>Kidney                                |                                     |
|                                       |                |                | 50 µg/kg<br>300 µg/kg  | Eggs<br>Muscle and skin in natural proportions |                                     |
|                                       |                | Fin fish       |                        |  |                                     |
|                                       |                |                |                        |  |                                     |
|                                       |                |                |                        |  |                                     |

▼ **M59**▼ **M58**

## 1.2.9. Polymyxins

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

▼ **M58**

## 1.2.10. Penicillins

| Pharmacologically active substance(s) | Marker residue    | Animal species | MRLs   | Target tissues                           | Other provisions                          |
|---------------------------------------|-------------------|----------------|--|--|---|
| Nafcillin                             | Nafcillin         | Bovine         | 300 µg/kg<br>300 µg/kg<br>300 µg/kg<br>300 µg/kg<br>30 µg/kg | Muscle<br>Fat<br>Liver<br>Kidney<br>Milk | Provisional MRLs expire on 1.1.2001       |
| Penethamate                           | Benzylopenicillin | Ovine          | 50 µg/kg<br>50 µg/kg<br>50 µg/kg<br>50 µg/kg<br>4 µg/kg      | Muscle<br>Fat<br>Liver<br>Kidney<br>Milk | Provisional MRLs expire on 1 January 2000 |
|                                       |                   | Porcine        | 50 µg/kg<br>50 µg/kg<br>50 µg/kg<br>50 µg/kg                 | Muscle<br>Fat<br>Liver<br>Kidney         |   |

▼ **M58**

## 1.2.11. Florfenicol and related compounds

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

▼ **M58**

| Pharmacologically active substance(s) | Marker residue | Animal species | MRLs   | Target tissues                         | Other provisions                    |
|---------------------------------------|----------------|----------------|--|--|-------------------------------------|
| Thiamphenicol                         | Thiamphenicol  | Ovine          | 50 µg/kg<br>50 µg/kg<br>50 µg/kg<br>50 µg/kg | Muscle<br>Fat<br>Liver<br>Kidney       | Provisional MRLs expire on 1.1.2001 |
|                                       |                | Porcine        | 50 µg/kg<br>50 µg/kg                         | Muscle<br>Skin + fat                   |                                     |
|                                       |                | Fin fish       | 50 µg/kg<br>50 µg/kg                         | Liver<br>Kidney                        |                                     |
|                                       |                |                | 50 µg/kg                                     | Muscle and skin in natural proportions |                                     |

▼ **M61**

## 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         |                                     |
|                                       |                | Chicken        | 50 µg/kg    | Skin + fat     |                                     |
|                                       |                |                | 500 µg/kg   | Liver          |                                     |
|                                       |                |                | 1 500 µg/kg | Kidney         |                                     |
|                                       |                |                | 100 µg/kg   | Muscle         |                                     |
|                                       |                |                | 50 µg/kg    | Skin + fat     |                                     |
|                                       |                |                | 500 µg/kg   | Liver          |                                     |
| 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           |                                     |

▼ **M61**

▼ **M58**

2. Antiparasitic agents
- 2.1. Agents acting against endoparasites
- 2.1.1. Phenol derivatives including salicylanilides

▼ **M63**

| Pharmacologically active substance(s) | Marker residue | Animal species | MRLs   | Target tissues                           | Other provisions                    |
|---------------------------------------|----------------|----------------|--|--|-------------------------------------|
| Oxyclozanide                          | Oxyclozanide   | Bovine         | 20 µg/kg<br>20 µg/kg<br>500 µg/kg<br>100 µg/kg             | Muscle<br>Fat<br>Liver<br>Kidney         | Provisional MRLs expire on 1.7.2000 |
|                                       |                | Ovine          | 10 µg/kg<br>20 µg/kg<br>20 µg/kg<br>500 µg/kg<br>100 µg/kg | Milk<br>Muscle<br>Fat<br>Liver<br>Kidney |                                     |

▼ **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, and albendazole 2-amino sulphone, expressed as albendazole | Bovine, ovine           | 100 µg/kg  | Milk                             | Provisional MRLs expire on 1 January 2000 |
|                                       |  | Bovine, ovine, pheasant | 100 µg/kg<br>100 µg/kg<br>1 000 µg/kg<br>500 µg/kg | Muscle<br>Fat<br>Liver<br>Kidney |   |

▼ **M58**

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

▼ **M63**

## 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<br><br>Porcine | 100 µg/kg<br>100 µg/kg<br>800 µg/kg<br>200 µg/kg<br>100 µg/kg<br>100 µg/kg<br>100 µg/kg<br>800 µg/kg<br>200 µg/kg | Muscle<br>Fat<br>Liver<br>Kidney<br>Milk<br>Muscle<br>Skin and fat<br>Liver<br>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                       |
|---------------------------------------|--|----------------|-----------|----------------|--|
| Amitraz                               | Sum of amitraz and all metabolites containing the 2,4-DMA moiety, expressed as amitraz | Bees           | 200 µg/kg | Honey          | Provisional MRLs expire on 1 July 1999 |

## 2.2.2. Iminophenyl thiazolidine derivative

| Pharmacologically active substance(s) | Marker residue | Animal species | MRLs        | Target tissues | Other provisions                           |
|---------------------------------------|----------------|----------------|-------------|----------------|--|
| Cymiazole                             | Cymiazole      | Bees           | 1 000 µg/kg | Honey          | ►M65 Provisional MRLs expire on 1.7.2001 ◀ |

## 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<br>50 µg/kg<br>10 µg/kg<br>10 µg/kg<br>20 µg/kg | Muscle<br>Fat<br>Liver<br>Kidney<br>Milk<br>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 |

| Pharmacologically active substance(s) | Marker residue                | Animal species         | MRLs  | Target tissues  | Other provisions                    |
|---------------------------------------|-------------------------------|------------------------|---|---|-------------------------------------|
| Alphacypermethrin                     | Cypermethrin (sum of isomers) | Bovine, ovine          | 20 µg/kg<br>200 µg/kg<br>20 µg/kg<br>20 µg/kg<br>20 µg/kg | Muscle<br>Fat<br>Liver<br>Kidney<br>Milk<br>Further provisions in Council Directive 93/57/EC (OJ L 211, 23.8.1992, p. 1) are to be observed | Provisional MRLs expire on 1.1.2002 |
|                                       |                               | Chicken                | 50 µg/kg<br>50 µg/kg<br>50 µg/kg<br>50 µg/kg<br>50 µg/kg  | Muscle<br>Skin + fat<br>Liver<br>Kidney<br>Eggs   |                                     |
| Cypermethrin                          | Cypermethrin (sum of isomers) | Bovine, ovine, caprine | 20 µg/kg<br>200 µg/kg<br>20 µg/kg<br>20 µg/kg<br>20 µg/kg | Muscle<br>Fat<br>Liver<br>Kidney<br>Milk<br>Further provisions in Council Directive 93/57/EC (OJ L 211, 23.8.1992, p. 1) are to be observed | Provisional MRLs expire on 1.1.2002 |
|                                       |                               | Porcine                | 20 µg/kg<br>200 µg/kg<br>20 µg/kg<br>20 µg/kg             | Muscle<br>Skin + fat<br>Liver<br>Kidney   |                                     |
|                                       |                               | Chicken                | 50 µg/kg<br>50 µg/kg                                      | Muscle<br>Skin + fat  |                                     |

▼ **M58**▼ **M62**

▼ **M62**

| Pharmacologically active substance(s) | Marker residue | Animal species | MRLs   | Target tissues  | Other provisions |
|---------------------------------------|----------------|----------------|--|---|------------------|
|                                       |                | Salmonidae     | 50 µg/kg<br>50 µg/kg<br>50 µg/kg<br>50 µg/kg | Liver<br>Kidney<br>Eggs<br>Muscle and skin in natural proportions |                  |

▼ **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    |

▼ **M65**▼ **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    |

▼ **M63**

▼ **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                          |
|---------------------------------------|----------------|----------------|--|----------------------------------|---|
| Moxidectin                            | Moxidectin     | Equidae        | 50 µg/kg<br>500 µg/kg<br>100 µg/kg<br>50 µg/kg | Muscle<br>Fat<br>Liver<br>Kidney | Provisional MRLs expire on 1 January 2000 |

▼ **M61**

## 2.4. Agents acting against protozoa

## 2.4.1. Carbamitides

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

▼ **M63**

## 2.4.2. Quinazolone derivatives

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

▼ **M58**

3. Agents acting on the nervous system
- 3.2. Agents acting on the autonomic nervous system
- 3.2.1.  $\beta$  2 sympathomimetic agents

| Pharmacologically active substance(s) | Marker residue | Animal species   | MRLs   | Target tissues   | Other provisions                       |
|---------------------------------------|----------------|--|--|--|--|
| Clenbuterol hydrochloride             | Clenbuterol    | Bovine<br>Indication: solely for tocolysis in parturient cows<br><br>Equidae<br>Indications: tocolysis and the treatment of respiratory ailments | 0,1 µg/kg<br>0,5 µg/kg<br><br>0,5 µg/kg<br>0,05 µg/kg<br>0,1 µg/kg<br>0,5 µg/kg<br><br>0,5 µg/kg | Muscle<br>Liver<br><br>Kidney<br>Milk<br>Muscle<br>Liver<br><br>Kidney | Provisional MRLs expire on 1 July 2000 |

▼ **M61**

## 3.2.2. Anti-adrenergics

| Pharmacologically active substance(s) | Marker residue | Animal species | MRLs  | Target tissues                           | Other provisions                    |
|---------------------------------------|----------------|----------------|---|--|-------------------------------------|
| Carazolol                             | Carazolol      | Bovine         | 5 µg/kg<br>5 µg/kg<br>15 µg/kg<br>15 µg/kg<br>1 µg/kg | Muscle<br>Fat<br>Liver<br>Kidney<br>Milk | Provisional MRLs expire on 1.1.2000 |

▼ **M58**

5. Anti-inflammatory agents
- 5.1. Nonsteroidal anti-inflammatory agents
- 5.1.1. Arylpropionic acid derivative

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

## 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<br>60 µg/kg | Muscle<br>Liver | Provisional MRLs expire on 1 January 2000 |

▼ M58

| Pharmacologically active substance(s) | Marker residue | Animal species | MRLs     | Target tissues | Other provisions |
|---------------------------------------|----------------|----------------|----------|----------------|------------------|
|                                       |                |                | 35 µg/kg | Kidney         |                  |

▼ **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.