

## SUBSIDIARY LEGISLATION 231.34

### MAXIMUM RESIDUE LIMITS IN VETERINARY MEDICINAL PRODUCTS REGULATIONS

1st October, 1998

*Legal Notice 162 of 1998.*

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| <p><b>1.</b> The title of these Regulations is Maximum Residue Limits in Veterinary Medicinal Products Regulations.</p>   | Title.                                   |
| <p><b>2.</b> (1) In these regulations, unless the context otherwise -</p> <p>"Director" means the Director for Veterinary Services;</p> <p>"maximum residue limit" or "MRL" means the maximum concentration of residue resulting from the use of a veterinary medicinal product (expressed in mg/Kg or u/Kg on a fresh weight basis) which may be legally permitted or recognised as acceptable in food. This limit is either 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 utilises an additional safety factor. In order to assess this limit one also takes into account other relevant public health risks as well as food technology aspects. When establishing a maximum residue limit consideration is also given to residues that are found 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;</p> <p>"residues of veterinary medicinal products" means all pharmacologically active substances, whether active principals, excipients or degradation products, and their metabolites which remain in foodstuffs made from animals to which the veterinary medicinal product in question has been administered.</p> <p>(2) These regulations 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.</p> | Interpretation.                          |
| <p><b>3.</b> 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 the First Schedule.</p>   | Substances subject to MRL.               |
| <p><b>4.</b> 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 the Second Schedule.</p>   | Substances not subject to MRL.           |
| <p><b>5.</b> 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 the Third Schedule.</p>   | Substances subject to a provisional MRL. |

Substances where  
MRL cannot be  
fixed.

**6.** (1) 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 the Fourth Schedule.

(2) The administration of the substances listed in the Fourth Schedule to food-producing animals shall be prohibited.

How to establish  
MRL.

**7.** (1) In establishing maximum residue limits for residues of veterinary medicinal products used in foodstuffs of animal origin, it is necessary to specify the animal species in which such residues may be present, the levels which may be present in each of the relevant meat tissues obtained from the treated animal (target tissue), and the nature of the residue which is relevant for the monitoring of residues (marker residue).

(2) In order to control for residues, maximum residue limits shall be established for the target tissue of liver or kidney; however, since liver and kidney are frequently removed from the carcasses marketed in the international trade, maximum residue limits should therefore also always be established for muscle or fat tissues.

(3) In the case of veterinary medicinal products intended to be used for laying birds, lactating animals or honey bees, maximum residue limits shall also be established for eggs, milk, or honey.

Listing of  
products.

**8.** (1) A new pharmacologically active substance, intended to be used in veterinary medicinal products administered to food producing animals, may only be included in the First, Second and Third Schedules if the person responsible for marketing submits a relative application to the Director. Such application shall contain the information and particulars referred to in the Fifth Schedule.

(2) The Director may, after assessing new information or after reassessing existing information, amend any provision contained in the First, Second, Third and Fourth Schedules if it is necessary for the protection of human or animal health.

(3) The Director may not prohibit or impede the trade of foodstuffs of animal origin and originating in other countries on the ground that they contain residues of veterinary medicinal products if the quantity of residue does not exceed the maximum residue limit found in the First Schedule or in the Third Schedule, or if the substance concerned is listed in the Second Schedule.

Food-producing  
animals.

**9.** The administration to food-producing animals of veterinary medicinal products containing pharmacologically active substances which are not mentioned in the First, Second or Third Schedules shall be prohibited, except in the case of clinical trials accepted by the competent authorities and provided that foodstuffs obtained from livestock used in such trials do not contain residues which constitute a hazard to human health.

Saving.  
S.L.231.32

**10.** Nothing in these regulations shall operate against the provisions of the Residues in Meat Regulations, prohibiting the use, in livestock farming, of certain substances which have a

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hormonal action.

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FIRST SCHEDULE

(Regulation 3)

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
All substances belonging to the sulfonamide group	Parent drug	All food producing species	100 µg/kg	Muscle, liver, kidney, fat
		Bovine, Ovine, Caprine	100 µg/kg	Milk

Other provisions: The combined total residues of all substances within the sulfonamide group should not exceed 100 µg/kg

1.2. Antibiotics

1.2.1. Penicillins

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues
1.2.1.1. Benzylpenicillin	Benzylpenicillin	All food producing species	50 µg/kg	Muscle, liver, kidney, fat
			4 µg/kg	Milk
1.2.1.2. Ampicillin	Ampicillin	All food producing species	50 µg/kg	Muscle, liver, kidney, fat
			4 µg/kg	Milk
1.2.1.3. Amoxicillin	Amoxicillin	All food producing species	50 µg/kg	Muscle, liver, kidney, fat
			4 µg/kg	Milk
1.2.1.4. Oxacillin	Oxacillin	All food producing species	300 µg/kg	Muscle, liver, kidney, fat
			30 µg/kg	Milk
1.2.1.5. Cloxacillin	Cloxacillin	All food producing species	300 µg/kg	Muscle, liver, kidney, fat
			30 µg/kg	Milk
1.2.1.6. Dicloxacillin	Dicloxacillin	All food producing species	300 µg/kg	Muscle, liver, kidney, fat
			30 µg/kg	Milk
1.2.1.7. Penethamate	Benzylpenicillin	Bovine	50 µg/kg	Muscle, liver, kidney, fat
			4 µg/kg	Milk

1.2.2. Cephalosporins

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues
1.2.2.1. Cefquinome	Cefquinome	Bovine	200 µg/kg 100 µg/kg 50 µg/kg 50 µg/kg 20 µg/kg	Kidney Liver Muscle Fat Milk

1.2.3. Quinolones

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues
1.2.3.1. Enrofloxacin	Sum of enrofloxacin and ciprofloxacin	Bovine, porcine, poultry	30 µg/kg	Muscle, liver kidney
1.2.3.2. Sarafloxacin	Sarafloxacin	Chicken	100 µg/kg 10 µg/kg	Liver Skin and fat
1.2.3.3. Difloxacin	Difloxacin	Chicken, turkey	200 µg/kg 150 µg/kg 50 µg/kg 200 µg/kg	Liver Kidney Muscle Skin and fat

1.2.4. Macrolides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues
1.2.4.1. Tilmicosin	Tilmicosin	Bovine, ovine, porcine	1000 µg/kg 50 µg/kg	Liver, kidney Muscle, fat
		Ovine	50 µg/kg	Milk
1.2.4.2. Spiramycin	Sum of spiramycin and neospiramycin	Bovine	300 µg/kg 200 µg/kg 200 µg/kg	Liver, kidney, fat Muscle Milk
		Chicken	400 µg/kg 300 µg/kg 200 µg/kg	Liver Skin and fat Muscle

1.2.5. Florfenicol and related compounds

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues
1.2.5.1. Florfenicol	Sum of Florfenicol and its metabolites measured as Florfenicol-amine	Bovine	200 µg/kg 300 µg/kg 3000 µg/kg	Muscle Kidney Liver

## 1.2.6. Tetracyclines

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues
1.2.6.1. Tetracycline	Sum of parent drug and its 4-epimer	All food producing species	600 µg/kg 300 µg/kg 100 µg/kg 100 µg/kg 200 µg/kg	Kidney Liver Muscle Milk Eggs
1.2.6.2. Oxytetracycline	Sum of parent drug and its 4-epimer	All food producing species	600 µg/kg 300 µg/kg 100 µg/kg 100 µg/kg 200 µg/kg	Kidney Liver Muscle Milk Eggs
1.2.6.3. Chlortetracycline	Sum of parent drug and its 4-epimer	All food producing species	600 µg/kg 300 µg/kg 100 µg/kg 100 µg/kg 200 µg/kg	Kidney Liver Muscle Milk Eggs

## 2. Antiparasitic agents

## 2.1. Agents acting against endoparasites

## 2.1.1. Avermectins

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues
2.1.1.1. Ivermectin	22, 23-Dihydro-avermectin B 1a	Bovine	100 µg/kg 40 µg/kg	Liver Fat
		Porcine, ovine, equidae	15 µg/kg 20 µg/kg	Liver Fat
2.1.1.2. Abamectin	Avermectin B 1a	Bovine	20 µg/kg 10 µg/kg	Liver Fat
2.1.1.3. Doramectin	Doramectin	Bovine	15 µg/kg 25 µg/kg	Liver Fat

## 2.1.2. Salicylanilides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues
2.1.2.1. Closantel	Closantel	Bovine	1000 µg/kg 3000 µg/kg	Muscle, liver Kidney, fat
		Ovine	1500 µg/kg 5000 µg/kg 2000 µg/kg	Muscle, liver Kidney Fat

## 2.1.3. Tetra-hydro-imidazoles (imidazolthiazoles)

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues
2.1.2.1. Levamisole	Levamisole	Bovine, ovine, porcine, poultry	10 µg/kg 100 µg/kg	Muscle, kidney, fat Liver

2.2. Agents acting against ectoparasites

2.2.1. Organophosphates

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues
2.2.1.1. Diazinon	Diazinon	Bovine, ovine	700 µg/kg 20 µg/kg	Fat Kidney, liver, muscle
		Bovine, ovine, caprine	20 µg/kg	Milk

2.2.2. Formamidines

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues
2.2.2.1. Amitraz	Sum of amitraz and all metabolites containing the 2,4-DMA moiety, expressed as amitraz	Porcine	400 µg/kg 200 µg/kg	Fat and skin Kidney, liver

3. Agents acting on the nervous system

3.1. Agents acting on the autonomic nervous system

3.1.1. Anti-adrenergics

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues
3.1.1.1. Carazolol	Carazolol	Porcine	25 µg/kg 5 µg/kg	Liver, kidney Muscle, fat and skin

SECOND SCHEDULE

(Regulation 4)

List of substances not subject to maximum residue limits

1. Inorganic chemicals

Pharmacologically active substance(s)	Animal species
1.1. Hydrogen peroxide	All food producing species
1.2. Sulphur	Bovine, porcine, ovine, caprine, equidae
1.3. Iodine and iodine inorganic compounds including: - Sodium and potassium-iodide - Sodium and potassium-iodate - Iodophors including Polyvinylpyrrolidone-iodine	All food producing species
1.4. Sodium chlorite	Bovine (for topical use only)

1.5.	Calcium acetate Calcium benzoate Calcium carbonate Calcium chloride Calcium gluconate Calcium hydroxide Calcium hypophosphite Calcium malate Calcium oxide Calcium phosphate Calcium polyphosphates Calcium propionate Calcium silicate Calcium stearate Calcium sulphate	All food producing species
1.6.	Hydrochloric acid	All food producing species (for use as excipient)
1.7.	Sodium dichloroisocyanurate	Bovine, ovine, caprine (for topical use only)
1.8.	Boric acid and borates	All food producing species
1.9.	Magnesium	All food producing species
1.10.	Magnesium sulphate	All food producing species
1.11.	Magnesium hydroxide	All food producing species
1.12.	Magnesium stearate	All food producing species
1.13.	Magnesium glutamate	All food producing species
1.14.	Magnesium orotate	All food producing species
1.15.	Magnesium aluminium silicate	All food producing species
1.16.	Magnesium oxide	All food producing species
1.17.	Magnesium carbonate	All food producing species
1.18.	Magnesium phosphate	All food producing species
1.19.	Magnesium glycerophosphate	All food producing species
1.20.	Magnesium aspartate	All food producing species
1.21.	Magnesium citrate	All food producing species
1.22.	Magnesium acetate	All food producing species
1.23.	Magnesium trisilicate	All food producing species
2.	Organic Compounds	
Pharmacologically active substance(s)		Animal species
2.1.	Etiproston tromethamine	Bovine, porcine
2.2.	Ketanserin tartrate	Equidae
2.3.	Fertireline acetate	Bovine
2.4.	Human menopausal urinary gonadotrophin	Bovine
2.5.	Lactic acid	All food producing species
2.6.	Melatonin	Ovine, caprine
2.7.	Iodine organic compounds - Iodoform	All food producing species
2.8.	Acetyl cysteine	All food producing species



2.9. Gonadotrophin releasing hormone	All food producing species
2.10. Pregnant Mare Serum Gonadotrophine	All food producing species
2.11. 17β-Oestradiol	All food producing mammals (for therapeutic and zootechnical uses only)
2.12. Romifidine	Equidae (for therapeutic uses only)
2.13. Detomidine	Bovine, Equidae (for therapeutic uses only)
2.14. Brotizolam	Bovine, (for therapeutic uses only)
2.15. Human chorion gonadotrophin (HCG)	All food producing species
2.16. Oxytocin	All food producing mammals
2.17. Lecirelin	Bovine, equidae, rabbit
2.18. Dinoprost tromethamine	All mammalian species
2.19. Malic acid	All food producing species (for use as excipient)
2.20. L-tartaric acid and its mono-and dibasic salt of sodium, potassium and calcium	All food producing species (for use as excipient)
2.21. Benzylalcohol	All food producing species (for use as excipient)
2.22. Ethanol	All food producing species (for use as excipient)
2.23. N-butanol	All food producing species (for use as excipient)
2.24. 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)
2.25. Buserelin	All food producing species
2.26. Ketoprofen	Bovine, equidae
2.27. Caffeine	All food producing species
2.28. Theophylline	All food producing species
2.29. Theobromine	All food producing species
2.30. Ketoprofen	Porcine
2.31. Propane	All food producing species
2.32. n-butane	All food producing species
2.33. Isobutane	All food producing species
2.34. Polysulphated glycosaminoglycan	Equidae
2.35. Rifaximin	Bovine (for intramammary use - except if the udder may be used as food for human consumption - and intrauterine use only)
2.36. Tau fluvalinate	Honey bees
2.37. Phenol	All food producing species
2.38. Papaverine	Bovine (newborn calves)
2.39. Policresuline	All food producing species (for topical use only)
2.40. Papain	All food producing species
2.41. Dimethyl phthalate	All food producing species
2.42. Diethyl phthalate	All food producing species
2.43. Ethyl lactate	All food producing species

2.44. Heptaminol	All food producing species
2.45. Menthol	All food producing species
2.46. Phloroglucinol	All food producing species
2.47. Trimethylphloroglucinol	All food producing species
2.48. Peracetic acid	All food producing species
2.49. Carbetocin	All mammalian food producing species
2.50. Quillaia sapocin	All food producing species
2.51. Butyl 4-hydroxybenzoate	All food producing species
2.52. Sodium butyl 4-hydroxybenzoate	All food producing species
2.53. Sodium benzyl 4-hydroxybenzoate	All food producing species
2.54. Cetrimide	All food producing species
2.55. Lobeline	All food producing species
2.56. Pancreatin	All mammalian food producing species (for topical use only)
2.57. Chlorocresol	All food producing species
2.58. Thymol	All food producing species
2.59. Dembrexine	Equidae
2.60. Diclazuril	Ovine (for oral use in lambs only)
2.61. Etamiphylline camsylate	All food producing species
3. Substances generally recognized as safe	
Pharmacologically active substance(s)	Animal species
3.1. Absinthium extract	All food producing species
3.2. Acetylmethionine	All food producing species
3.3. Aluminium hydroxide	All food producing species
3.4. Aluminium monostearate	All food producing species
3.5. Ammonium sulfate	All food producing species
3.6. Benzoyl benzoate	All food producing species
3.7. Benzyl p-hydroxybenzoate	All food producing species
3.8. Calcium borogluconate	All food producing species
3.9. Calcium citrate	All food producing species
3.10. Camphor	All food producing species (external use only)
3.11. Cardamon extract	All food producing species
3.12. Diethyl sebacate	All food producing species
3.13. Dimethicone	All food producing species
3.14. Dimethyl acetamide	All food producing species
3.15. Dimethyl sulphoxide	All food producing species
3.16. Ethylenediaminetetraacetic acid and salts	All food producing species
3.17. Eucalyptol	All food producing species
3.18. Epinephrine	All food producing species
3.19. Ethyl oleate	All food producing species
3.20. Formaldehyde	All food producing species
3.21. Formic acid	All food producing species
3.22. Follicle stimulating hormone (natural FSH from all species and their synthetic analogues)	All food producing species

3.23. Glutaraldehyde	All food producing species
3.24. Guaiacol	All food producing species
3.25. Heparin and its salts	All food producing species
3.26. Human chorionic gonadotropin (natural HCG and its synthetic analogues)	All food producing species
3.27. Iron ammonium citrate	All food producing species
3.28. Iron dextran	All food producing species
3.29. Iron glucoheptonate	All food producing species
3.30. Isopropanol	All food producing species
3.31. Lanolin	All food producing species
3.32. Luteinizing hormone (natural LH from all species and their synthetic analogues)	All food producing species
3.33. Magnesium chloride	All food producing species
3.34. Magnesium gluconate	All food producing species
3.35. Magnesium hypophosphite	All food producing species
3.36. Mannitol	All food producing species
3.37. Montanide	All food producing species
3.38. Methylbenzoate	All food producing species
3.39. Monothioglycerol	All food producing species
3.40. Myglyol	All food producing species
3.41. Orgotein	All food producing species
3.42. Poloxalene	All food producing species
3.43. Poloxamer	All food producing species
3.44. Polyethylene glycol 200	All food producing species
3.45. Polyethylene glycol 400	All food producing species
3.46. Polyethylene glycol 600	All food producing species
3.47. Polyethylene glycol 3500	All food producing species
3.48. Polysorbate 80	All food producing species
3.49. Serotonin	All food producing species
3.50. Sodium chloride	All food producing species
3.51. Sodium cromoglycate	All food producing species
3.52. Sodium dioctylsulphosuccinate	All food producing species
3.53. Sodium formaldehydesulphoxylate	All food producing species
3.54. Sodium lauryl sulphate	All food producing species
3.55. Sodium pyrosulphite	All food producing species
3.56. Sodium stearate	All food producing species
3.57. Sodium thiosulphate	All food producing species
3.58. Tragacanth	All food producing species
3.59. Urea	All food producing species
3.60. Zinc sulphate	All food producing species
3.61. Zinc oxide	All food producing species
3.62. Polyethylene glycols (molecular weight ranging from 200 to 10000)	All food producing species

4. Substances used in homeopathic veterinary medicinal products	
Pharmacologically active substance(s)	Animal species
4.1. All substances used in homeopathic veterinary medicinal products provided that their concentration in the product does not exceed one part per ten thousand	All food producing species
5.1. Substances used as food additives in foodstuffs for human consumption	
Pharmacologically active substance(s)	Animal species
5.1. Substances with an E number	All food producing species (only substances approved as additives in foodstuffs for human consumption).

## THIRD SCHEDULE

(Regulation 5)

List of pharmacologically active substances used in veterinary medicinal products for which provisional maximum residue limits have been fixed

1. Anti-infectious agents
  - 1.1. Chemotherapeutics
    - 1.1.1. Diamino pyrimidine derivatives

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues
1.1.1.1. Trimethoprim	Trimethoprim	All food producing species	50 µg/kg	Muscle, liver kidney, fat, milk

## 1.1.2. Benzenesulphonamides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues
1.1.2.1. Clorsulon	Clorsulon	Bovine	50 µg/kg 150 µg/kg 400 µg/kg	Muscle Liver Kidney
1.1.2.2. Baquiloprim	Baquiloprim	Bovine	300 µg/kg 150 µg/kg 10 µg/kg 30 µg/kg	Liver Kidney Fat Milk
		Porcine	50 µg/kg 40 µg/kg	Liver, kidney Fat and skin

## 1.2. Antibiotics

## 1.2.2. Macrolides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues
1.2.2.1. Spiramycin	Spiramycin	Porcine	600 µg/kg 300 µg/kg 200 µg/kg	Liver Kidney, muscle Fat

1.2.2.2. Tylosin	Tylosin	Bovine, porcine, poultry	100 µg/kg	Muscle, liver kidney
		Bovine	50 µg/kg	Milk
1.2.2.3. Erythromycin	Erythromycin	Bovine, ovine, porcine, poultry	400 µg/kg	Liver, kidney, muscle, fat
		Bovine, ovine	40 µg/kg	Milk
		Poultry	200 µg/kg	Eggs
1.2.2.4. Josamycin	Josamycin	Chicken	400 µg/kg 200 µg/kg 200 µg/kg	Kidney Liver, muscle, fat Eggs

1.2.3. Thiamphenicol and related compounds

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues
1.2.3.1. Thiamphenicol	Thiamphenicol	Bovine, poultry	40 µg/kg	Muscle, liver kidney, fat

1.2.4. Cephalosporins

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues
1.2.4.1. Ceftiofur	Sum of all resi- dues retaining the betalactam structure expressed as des- furoylceftiofur	Bovine	2000 µg/kg 200 µg/kg 600 µg/kg 100 µg/kg	Kidney, liver Muscle Fat Milk
		Porcine	4000 µg/kg 3000 µg/kg 500 µg/kg 600 µg/kg	Kidney Liver Muscle Fat

1.2.5. Aminoglycosides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues
1.2.5.1. Spectinomycin	Spectinomycin	Bovine, porcine, poultry	5000 µg/kg 2000 µg/kg 300 µg/kg 500 µg/kg	Kidney Liver Muscle Fat
		Bovine	200 µg/kg	Milk
1.2.5.2. Streptomycin	Spectinomycin	Bovine, ovine, porcine, poultry	1000 µg/kg 500 µg/kg	Kidney Muscle, liver, fat
		Bovine, ovine	200 µg/kg	Milk
1.2.5.3. Dihydrostrepto- mycin	Dihydrostrepto- mycin	Bovine, ovine, porcine, poultry	1000 µg/kg 500 µg/kg	Kidney Muscle, liver, fat
		Bovine, ovine	200 µg/kg	Milk

1.2.5.4. Gentamicin	Gentamicin	Bovine, porcine	1000 µg/kg 200 µg/kg 100 µg/kg	Kidney Liver Muscle, fat
		Bovine	100 µg/kg	Milk
1.2.5.5. Neomycin (including framyc- etin)	Neomycin	Bovine, ovine, caprine, porcine, chicken, turkey, duck	5000 µg/kg 500 µg/kg	Kidney Muscle, liver, fat
		Bovine, ovine, caprine	500 µg/kg	Milk
		Chicken	500 µg/kg	Eggs
1.2.5.6. Aminosidine	Aminosidine	Bovine, porcine, rabbits, chicken	1500 µg/kg 500 µg/kg	Liver, kidney Muscle

## 1.2.6. Quinolones

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues
1.2.6.1. Danofloxacin	Danofloxacin	Bovine	900 µg/kg 500 µg/kg 300 µg/kg 200 µg/kg	Liver Kidney Muscle Fat
		Chicken	1200 µg/kg 600 µg/kg 300 µg/kg	Liver, kidney Skin and fat Muscle
1.2.6.2. Decoquinat	Decoquinat	Bovine, ovine	500 µg/kg	Muscle, liver Kidney, fat
1.2.6.3. Marbofloxacin	Marbofloxacin	Bovine	150 µg/kg 75 µg/kg 50 µg/kg	Muscle, liver, kidney Milk Fat
		Porcine	150 µg/kg 50 µg/kg	Muscle, liver, kidney Fat and skin

## 1.2.7. Naphtalene-ringed ansamycin

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues
1.2.7.1. Rifaximin	Rifaximin	Bovine	600 µg/kg	Milk

## 1.2.8. Polymyxins

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues
1.2.8.1. Colistin	Colistin	Bovine, ovine, porcine, chicken, rabbits	200 µg/kg 150 µg/kg	Kidney Liver, muscle, fat
		Bovine, ovine	50 µg/kg	Milk
		Chicken	300 µg/kg	Eggs

1.2.9. Penicillins

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues
1.2.9.1. Penethamate	Benzylpenicillin	Ovine	50 µg/kg 4 µg/kg	Liver, kidney, muscle, fat Milk
		Porcine	50 µg/kg	Liver, kidney, muscle, fat

2. Antiparasitic agents

2.1. Agents acting against endo-parasites

2.1.1. Benzimidazoles and pro-benzimidazoles

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues
2.1.1.1. Febantel	Combined residues of oxfendazole, oxfendazole sulfone and fenbendazole	All food producing species	1000 µg/kg 10 µg/kg 10 µg/kg	Liver Muscle, kidney, fat Milk

Other provisions: The MRLs cover all residues of febantel, fenbendazole and oxfendazole

2.1.1.2. Fenbendazole	Combined residues of oxfendazole, oxfendazole sulfone and fenbendazole	All food producing species	1000 µg/kg 10 µg/kg 10 µg/kg	Liver Muscle, kidney, fat Milk
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Other provisions: The MRLs cover all residues of febantel, fenbendazole and oxfendazole

2.1.1.3. Oxfendazole	Combined residues of oxfendazole, oxfendazole sulfone and fenbendazole	All food producing species	1000 µg/kg 10 µg/kg 10 µg/kg	Liver Muscle, kidney, fat Milk
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Other provisions: The MRLs cover all residues of febantel, fenbendazole and oxfendazole

2.1.1.4. Albendazole	Sum of albendazole and metabolites which are measured as 2-amino-benzimidazole sulphone	Bovine, Ovine	100 µg/kg 500 µg/kg 1000 µg/kg	Muscle, fat, milk Kidney Liver
2.1.1.5. Thiabendazole	Sum of thiabendazole and 5-hydroxythiabendazole	Bovine, ovine, caprine	100 µg/kg	Muscle, liver kidney, fat, milk
2.1.1.6. Triclabendazole	Sum of extractable residues that may be oxidized to ketatriclabendazole	Bovine, ovine	150 µg/kg 50 µg/kg	Muscle, liver, kidney, Fat

2.1.1.7. Flubendazole	Flubendazole	Poultry, game birds	500 µg/kg 200 µg/kg 400 µg/kg	Liver Muscle Eggs
		Porcine	10 µg/kg	Muscle, liver kidney, fat
2.1.1.8. Oxibendazole	Oxibendazole	Bovine, ovine, porcine, equidae	100 µg/kg	Muscle, liver kidney, fat
		Bovine, ovine	50 µg/kg	Milk
2.1.1.9. Netobimin	Sum of neto-bimin and albendazole and metabolites of albendazole measured as 2-amino-benzimidazole sulphone	Bovine, ovine, caprine	1000 µg/kg 500 µg/kg 100 µg/kg 100 µg/kg	Liver Kidney Muscle, fat Milk

## 2.2. Agents acting against ectoparasites

## 2.2.1. Formamidines

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues
2.2.1.1. Amitraz	Sum of amitraz and metabolites which are measured as 2,4-dimethylaniline	Bovine	200 µg/kg 10 µg/kg	Kidney, liver, fat Milk
		Ovine	400 µg/kg 200 µg/kg	Fat Kidney, liver

## 2.2.2. Organophosphates

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues
2.2.2.1. Azamethiphos	Azamethiphos	Salmonidae	100 µg/kg	Muscle and skin in natural proportions

## 2.2.3. Iminophenyl thiazolidine derivative

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues
2.2.3.1. Cymiazole	Cymiazole	Bees	1000 µg/kg	Honey

## 2.3. Agents acting against endo- and ectoparasites

## 2.3.1. Avermectins

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues
2.3.1.1. Moxidectin	Moxidectin	Bovine, ovine	200 µg/kg 20 µg/kg	Fat Kidney, liver



3. Agents acting on the nervous system  
 3.1. Agents acting on the central nervous system  
 3.1.1. Butyrophenone tranquillizers

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues
3.1.1.1. Azaperone	Azaperol	All food producing species	100 µg/kg 50 µg/kg	Kidney Liver, muscle, fat

- 3.2. Agents acting on the automatic nervous system  
 3.2.1.  $\beta_2$ sympathomimetic agents

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues
3.2.1.1. Clenbuterol hydrochloride	Clenbuterol	Bovine (Indication: solely for tocolysis in parturient cows)	0,5 µg/kg 0,1 µg/kg 0,05 µg/kg	Liver, kidney Muscle Milk
		Equidae (Indications: tocolysis and the treatment of respiratory ailments)	0,5 µg/kg 0,1 µg/kg	Liver, kidney Muscle

4. Corticoids  
 4.1. Glucocorticoids

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues
4.1.1. Dexamethasone	Dexamethasone	Bovine, porcine, equidae	2,5 µg/kg 0,5 µg/kg	Liver Muscle, kidney
		Bovine	0,3 µg/kg	Milk

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
5.1.1.1. Vedaprofen	Vedaprofen	Equidae	100 µg/kg 1000 µg/kg 50 µg/kg	Liver Kidney Muscle
5.1.1.2. Carprofen	Carprofen	Bovine	1000 µg/kg 500 µg/kg	Liver, kidney Muscle, fat
		Equidae	1000 µg/kg 50 µg/kg 100 µg/kg	Liver, kidney Muscle Fat

## FOURTH SCHEDULE

(Regulation 6)

List of pharmacologically active substances for which no maximum levels can be fixed

1. Nitrofurans, except furazolidone
  2. Ronidazole
  3. Dapsone
  4. Chloramphenicol
  5. Furazolidone
  6. Dimetridazole
  7. Colchicine
  8. Avoparcin
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## FIFTH SCHEDULE

(Regulation 8)

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 Organisation (WHO), where such name exists.
  - 4) Manufacturing authorization, if any.
  - 5) Marketing authorizations, if any.
  - 6) Summary of the characteristics of the veterinary medicinal product(s).
- A) Safety documentation
- A.0 Expert report
- A.1) Precise identification of the substance concerned by the application
- 1.1) International non-proprietary name.
  - 1.2) International Union of Pure and Applied Chemistry (IUPAC) name.
  - 1.3) Chemical Abstract Service (CAS) name.
  - 1.4) Classification:
    - therapeutic

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- 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:
    - fusion point
    - boiling point
    - vapour pressure
    - solubility in water and organic solvents expressed in g/l, 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.
  
  - 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 micro-organisms 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 item 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 of the final product;
- specific activity and radio-purity of labelled substances;
- position of labelled atoms on the molecule.

## B.2) Residue studies

## 2.1) Pharmacokinetics

(absorption, distribution, biotransformation, excretion).

## 2.2) Depletion of residues.

## 2.3) Elaboration of maximum residue limits (MRLs).

## B.3) Routine analytical method for the detection of residues

## 3.1) Description of the method.

## 3.2) Validation of the method.

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