St. Kitts and Nevis Maximum Residue Limits (MRLs) for Veterinary Drugs in Food Regulation

Introduction

This legislation establishes the Maximum Residue Limits (MRLs) for veterinary drugs in food products within St. Kitts and Nevis. The aim is to ensure food safety, protect public health, and facilitate international trade by aligning with the standards set by the Codex Alimentarius Commission. The St. Kitts and Nevis Bureau of Standards (SKNBS), the Ministry of Agriculture (MOA), and the Ministry of Health (MOH) shall have jurisdiction over the implementation and enforcement of these MRLs.

1 Scope

This legislation applies to all food products of animal origin intended for human consumption within St. Kitts and Nevis. It covers the establishment, monitoring, and enforcement of MRLs for residues of veterinary drugs in these food products.

2 Terms and Definitions

2.1
Codex Alimentarius Commission (Codex)
an international food standards body established by the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) to protect consumer health and ensure fair practices in the food trade

2.2
FAO
Food and Agriculture Organization

2.3
Finfish
means all fish species

2.4
maximum residue limit (MRL)
the highest concentration of a veterinary drug residue legally permitted in food and feed products, expressed in mg/kg or µg/kg

2.5
residue
any specified substance in food, agricultural commodities, or animal feed resulting from the use of veterinary drug

2.6
veterinary drug
any substance applied or administered to any food-producing animal, such as meat or dairy animals, for therapeutic, prophylactic, or diagnostic purposes

List of Abbreviations

ADI	acceptable daily intake
ARfD	acute reference dose
BMD	benchmark dose
BMDL	confidence limit for BMD
bw	body weight
CAC	Codex Alimentarius Commission
CCPR	Codex Committee on Pesticide Residues
CCRVDF	Codex Committee on Residues of Veterinary Drugs in Foods
EDI	estimated daily intake
GEADE	global estimated acute dietary exposure
GECDE	global estimated chronic dietary exposure
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JMPR	Joint FAO/WHO Expert Meeting on Pesticide Residues
LOAEL	lowest-observed-adverse-effect level
NOAEL	no-observed-adverse-effect level
LOQ	limit of quantification
mADI	microbiological acceptable daily intake
MRL	maximum residue limit
RMR	risk management recommendation
TMDI	theoretical maximum daily intake

3 General Provisions

3.1 Establishment of MRLs

3.1.1 MRLs for veterinary drugs in food products shall be established based on scientific risk assessments conducted by the European Food Safety Authority (EFSA) and the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

3.1.2 In the absence of specific MRLs, a default MRL of 0.01 mg/kg or 10 µg/kg shall apply.

3.2 Risk Assessment and Safety Evaluation

3.2.1 The safety of MRLs shall be evaluated considering the toxicity of the veterinary drug, the expected residue levels, and the dietary habits of different consumer groups.

3.2.2 Risk assessments shall be conducted in accordance with the guidelines provided by the Codex Alimentarius Commission.

3.3 Monitoring and Enforcement

3.3.1 Regular monitoring of veterinary drug residues in food products shall be conducted to ensure compliance with established MRLs.

3.3.2 Non-compliance with MRLs shall result in appropriate enforcement actions, including product recalls, fines, and other penalties as deemed necessary.

3.3.3 Non-compliant products shall be rejected, recalled, or subjected to other enforcement actions as deemed necessary.

3.4 Import and Export Regulations

3.4.1 Imported food products shall comply with the MRLs established under this legislation.

3.4.2 Imported food products shall be accompanied by documentation from a regulatory or competent authority of the exporting country, certifying that the products comply with the established MRLs. This documentation shall include:

a) The name and address of the regulatory or competent authority.
b) Details of the food product, including type, batch number, and date of production.
c) A statement confirming compliance with the MRLs.
d) Results of residue testing, if applicable.

3.4.3 Exported food products must meet the MRL requirements of the destination country.

3.5 Review and Update

3.5.1 The MRLs and related provisions shall be reviewed and updated periodically to reflect new scientific data, changes in international standards such as Codex, and advancements in veterinary medicine.

Annex A
(informative)

List of Veterinary Drugs Monitored

A.1 Introduction

Annex A provides a comprehensive list of veterinary drugs that are commonly found in food products of animal origin and are subject to monitoring by the regulatory authorities in St. Kitts and Nevis. This list is essential for ensuring food safety, protecting public health, and maintaining compliance with international standards.

A.2 Purpose

The purpose of this annex is to:

a) Identify the veterinary drugs that require monitoring due to their potential presence in food products.
b) Establish the Maximum Residue Limits (MRLs) for these drugs to ensure they are within safe levels for human consumption.
c) Provide a reference for regulatory authorities, food producers, and importers/exporters to ensure compliance with food safety regulations.

A.3 Scope

This annex applies to all food products of animal origin, including but not limited to:

a) meat (muscle, liver, kidney, fat) from cattle, sheep, goats, pigs, and poultry,
b) milk from cattle, sheep, and goats;
c) eggs from poultry; and
d) finfish.

A.4 List of Veterinary Drugs

The list includes veterinary drugs that are used for therapeutic, prophylactic, or diagnostic purposes in food-producing animals. These drugs are monitored to ensure their residues do not exceed the established MRLs. The list is based on international standards set by the Codex Alimentarius Commission.

Annex A: List of Veterinary Drugs monitored

Abamectin	Gentamicin
Albendazole	Halquinol
Amoxicillin	Imidocarb
Ampicillin	Isometamidium
Avylamycin	Ivermectin
Azaperone	Lasalocid sodium
Benzylpenicillin/Procaine benzylpenicillin	Levamisole
Carazolol	Lincomycin

Ceftiofur	Lufenuron
Chlortetracycline/Oxytetracycline/Tetracycline	Melengestrol acetate
Clenbuterol	Monensin
Closantel	Monepantel
Colistin	Moxidectin
Cyfluthrin	Narasin
Cyhalothrin	Neomycin
Cypermethrin and alpha-cypermethrin	Nicarbazin
Danofloxacin	Phoxim
Deltamethrin	Pirlimycin
Derquantel	Porcine somatotropin
Dexamethasone	Progesterone
Diclazuril	Ractopamine
Dicyclanil	Sarafloxacin
Diflubenzuron	Spectinomycin
Dihydrostreptomycin/Streptomycin	Spiramycin
Diminazene	Sulfadimidine
Doramectin	Teflubenzuron
Emamectin benzoate	Testosterone
Eprinomectin	Thiabendazole
Erythromycin	Tilmicosin
Estradiol-17beta	Trenbolone acetate
Febantel/Fenbendazole/Oxfendazole	Trichlorfon (Metrifonate)
Fluazuron	Triclabendazole
Flubendazole	Tylosin
Flumequine	Zeranol
Flumethrin	Zilpaterol hydrochloride

Annex B
(informative)

Maximum Residue Limits (MRLs) for Residues of Veterinary Drugs

B.1 Introduction

Annex B provides detailed information on the Maximum Residue Limits (MRLs) for various veterinary drugs found in food products of animal origin. This section is crucial for ensuring that the levels of veterinary drug residues in food are within safe limits, protecting consumer health and facilitating international trade.

B.2 Purpose

The purpose of this annex is to:

a) specify the MRLs for residues of veterinary drugs in different animal species and tissue parts,
b) provide the Acceptable Daily Intake (ADI) for each veterinary drug, ensuring that the consumption of residues does not pose a risk to human health;
c) identify the species of animals in which these drugs are commonly used;
d) detail the specific tissue parts (e.g., muscle, liver, kidney, fat) where residues are monitored; and
e) establish the maximum allowable dosage of residues in these tissues.

B.3 Structure

This annex is organized into a table format for clarity and ease of reference. The table includes the following columns:

1. **Veterinary Drug**: The name of the veterinary drug.
2. **Acceptable Daily Intake (ADI)**: The amount of the drug that can be ingested daily over a lifetime without appreciable health risk, expressed in µg/kg body weight.
3. **Species**: The animal species in which the drug is commonly used.
4. **Tissue Parts**: The specific parts of the animal where residues are monitored (e.g., muscle, liver, kidney, fat).
5. **MRL (µg/kg)**: The maximum allowable concentration of the drug residue in the specified tissue parts.

171 **Table B.3** – Maximum Residue Limits (MRLs) for Residues of Veterinary Drugs
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ABAMECTIN (anthelmintic agent)			
Acceptable daily intake		0–2 µg/kg bw (1997) established for the sum of abamectin and (Z)-8,9 isomer by JMPR (1997)	
Residue definition		Avermectin B1a	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Cattle	Liver	100	
Cattle	Kidney	50	
Cattle	Fat	100	

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ALBENDAZOLE (anthelmintic agent)			
Acceptable daily intake		0–50 µg/kg bw (JECFA34)	
Residue definition		Except milk, 2-aminosulfone metabolite; milk, not yet identified	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Not specified	Muscle	100	
Not specified	Liver	5,000	
Not specified	Kidney	5,000	
Not specified	Fat	100	
Not specified	Milk (µg/l)	100	

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AMOXICILLIN (antimicrobial agent)	
Microbiological acceptable daily intake	0–0.002 mg/kg bw based on the effects of amoxicillin on the intestinal microbiota
Acute reference dose	0.005 mg/kg bw based on microbiological effects on the intestinal microbiota
Estimated chronic dietary exposure	0.14 µg/kg bw per day (for the general population), which represents 7% of the upper bound of the mADI
Estimated acute dietary exposure	1.4 µg/kg bw (for the general population), which represents 28% of the microbiological ARfD 1.6 µg/kg bw (for children), which represents 31% of the microbiological ARfD
Residue definition	Amoxicillin

Species	Tissue	MRL (µg/kg)	Notes
Cattle	Muscle	50	
Cattle	Liver	50	
Cattle	Kidney	50	
Cattle	Fat	50	
Cattle	Milk	4	
Sheep and goats	Muscle	50	
Sheep and goats	Liver	50	
Sheep and goats	Kidney	50	
Sheep and goats	Fat	50	
Sheep and goats	Milk	4	
Pigs	Muscle	50	
Pigs	Liver	50	
Pigs	Kidney	50	
Pigs	Fat/Skin	50	
Finfish	Fillet	50	The term "finfish" includes all fish species. Muscle plus skin in natural proportion.
	Muscle	50	The term "finfish" includes all fish species.

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AMPICILLIN (antimicrobial agent)	
Microbiological acceptable daily intake	0–0.003 mg/kg bw based on a NOAEL equivalent to 0.025 mg/kg bw per day for increase in population(s) of ampicillin-resistant bacteria in the gastrointestinal tract in humans, and using a safety factor of 10 (for the variability in the composition of the intestinal microbiota within and between individuals)
Acute reference dose	0.012 mg/kg bw based on the microbiological end-point
Estimated chronic dietary exposure	0.29 µg/kg bw per day (for the general population), which represents 10% of the upper bound of the ADI
Estimated acute dietary exposure	1.9 µg/kg bw per day (for the general population), which represents 16% of the ARfD 1.7 µg/kg bw per day (for children), which represents 14% of the ARfD
Residue definition	Ampicillin
Note	JECFA85 recommended an MRL of 50 µg/kg for ampicillin in finfish muscle and in finfish muscle plus skin in natural proportion, the same as that recommended for amoxicillin, because the modes of action, the physicochemical properties and the toxicological and pharmacokinetic profiles of amoxicillin and ampicillin are very

		similar.		
Species	**Tissue**	**MRL (µg/kg)**	**CAC**	**Notes**
Finfish	Fillet	50	The term "finfish" includes all fish species. Muscle plus skin in natural proportion.	
	Muscle	50	The term "finfish" includes all fish species.	

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AVILAMYCIN (antimicrobial agent)			
Acceptable daily intake		0–2 mg/kg bw on the basis of a NOAEL of 150 mg avilamycin activity/kg bw per day and a safety factor of 100 and rounding to one significant figure (JECFA70)	
Residue definition		Dichloroisoeverninic acid (DIA)	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Pigs	Muscle	200	
Pigs	Liver	300	
Pigs	Kidney	200	
Pigs	Fat/Skin	200	
Chicken	Muscle	200	
Chicken	Liver	300	
Chicken	Kidney	200	
Chicken	Fat/Skin	200	
Turkey	Muscle	200	
Turkey	Liver	300	
Turkey	Kidney	200	
Turkey	Fat/Skin	200	
Rabbits	Muscle	200	
Rabbits	Liver	300	
Rabbits	Kidney	200	
Rabbits	Fat/Skin	200	

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AZAPERONE (tranquillizing agent)	
Acceptable daily intake	0–6 µg/kg bw (JECFA50)
Residue definition	Sum of azaperone and azaperol

Species	Tissue	MRL (µg/kg)	Notes
Pig	Muscle	60	
Pig	Liver	100	
Pig	Kidney	100	
Pig	Fat	60	

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BENZYLPENICILLIN/PROCAINE BENZYLPENICILLIN (antimicrobial agent)			
Acceptable daily intake		30 µg-penicillin/person/day (JECFA50). Residues of benzylpenicillin and procaine benzylpenicillin should be kept below this level	
Residue definition		Benzylpenicillin	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Cattle	Muscle	50	
Cattle	Liver	50	
Cattle	Kidney	50	
Cattle	Milk (µg/l)	4	
Chicken	Muscle	50	Applies to procaine benzylpenicillin only.
Chicken	Liver	50	Applies to procaine benzylpenicillin only.
Chicken	Kidney	50	Applies to procaine benzylpenicillin only.
Pig	Muscle	50	
Pig	Liver	50	
Pig	Kidney	50	

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CARAZOLOL (beta-adreniceptor-blocking agent)			
Acceptable daily intake		0–0.1 µg/kg bw (JECFA43). ADI based on the acute pharmacological effects of carazolol	
Residue definition		Carazolol	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Pig	Muscle	5	The concentration at the injection site two hours after treatment may result in an intake that exceeds the ARfD and therefore, an appropriate withdrawal period should be applied.
Pig	Liver	25	
Pig	Kidney	25	

Pig	Fat/Skin	5	The concentration at the injection site two hours after treatment may result in an intake that exceeds the ARfD and therefore, an appropriate withdrawal period should be applied.

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CEFTIOFUR (antimicrobial agent)			
Acceptable daily intake		0–50 µg/kg bw (JECFA45)	
Residue definition		Desfuroylceftiofur	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Cattle	Muscle	1,000	
Cattle	Liver	2,000	
Cattle	Kidney	6,000	
Cattle	Fat	2,000	
Cattle	Milk (µg/l)	100	
Pig	Muscle	1,000	
Pig	Liver	2,000	
Pig	Kidney	6,000	
Pig	Fat	2,000	

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CHLORTETRACYCLINE/OXYTETRACYCLINE/TETRACYCLINE (antimicrobial agent)			
Acceptable daily intake		Group ADI for chlortetracycline, oxytetracycline and tetracycline: 0–30 µg/kg bw (JECFA50). Group ADI for chlortetracycline, oxytetracycline and tetracycline	
Residue definition		Parent drugs, singly or in combination	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Cattle	Muscle	200	
Cattle	Liver	600	
Cattle	Kidney	1,200	
Cattle	Milk (µg/l)	100	
Fish	Muscle	200	Applies only to oxytetracycline.
Giant prawn (*Paeneus monodon*)	Muscle	200	Applies only to oxytetracycline.
Pig	Muscle	200	
Pig	Liver	600	

Pig	Kidney	1,200	
Poultry	Muscle	200	
Poultry	Liver	600	
Poultry	Kidney	1,200	
Poultry	Eggs	400	
Sheep and goats	Muscle	200	
Sheep and goats	Liver	600	
Sheep and goats	Kidney	1,200	
Sheep and goats	Milk (µg/l)	100	

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CLENBUTEROL (adrenoceptor agonist)			
Acceptable daily intake		0–0.004 µg/kg bw (JECFA47)	
Residue definition		Clenbuterol	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Cattle	Muscle	0.2	Due to the potential abuse of this drug, the MRLs are recommended only when associated with a nationally approved therapeutic use, such as tocolysis or as an adjunct therapy in respiratory diseases.
Cattle	Liver	0.6	Due to the potential abuse of this drug, the MRLs are recommended only when associated with a nationally approved therapeutic use, such as tocolysis or as an adjunct therapy in respiratory diseases.
Cattle	Kidney	0.6	Due to the potential abuse of this drug, the MRLs are recommended only when associated with a nationally approved therapeutic use, such as tocolysis or as an adjunct therapy in respiratory diseases.
Cattle	Fat	0.2	Due to the potential abuse of this drug, the MRLs are recommended only when associated with a nationally approved therapeutic use, such as tocolysis or as an adjunct therapy in respiratory diseases.
Cattle	Milk (µg/l)	0.05	Due to the potential abuse of this drug, the MRLs are recommended only when associated with a nationally approved therapeutic use, such as tocolysis or as an adjunct therapy in respiratory diseases.

Horse	Muscle	0.2	Due to the potential abuse of this drug, the MRLs are recommended only when associated with a nationally approved therapeutic use, such as tocolysis or as an adjunct therapy in respiratory diseases.
Horse	Liver	0.6	Due to the potential abuse of this drug, the MRLs are recommended only when associated with a nationally approved therapeutic use, such as tocolysis or as an adjunct therapy in respiratory diseases.
Horse	Kidney	0.6	Due to the potential abuse of this drug, the MRLs are recommended only when associated with a nationally approved therapeutic use, such as tocolysis or as an adjunct therapy in respiratory diseases.

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CLOSANTEL (anthelmintic agent)			
Acceptable daily intake		0–30 µg/kg bw (JECFA40)	
Residue definition		Closantel	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Cattle	Muscle	1,000	
Cattle	Liver	1,000	
Cattle	Kidney	3,000	
Cattle	Fat	3,000	
Sheep and goats	Muscle	1,500	
Sheep and goats	Liver	1,500	
Sheep and goats	Kidney	5,000	
Sheep and goats	Fat	2,000	

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COLISTIN (antimicrobial agent)			
Acceptable daily intake		0–7 µg/kg bw (JECFA66)	
Residue definition		Sum of colistin A and colistin B	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Cattle	Muscle	150	
Cattle	Liver	150	
Cattle	Kidney	200	

Cattle	Fat	150	
Cattle	Milk	50	
Sheep and goats	Muscle	150	
Sheep and goats	Liver	150	
Sheep and goats	Kidney	200	
Sheep and goats	Fat	150	
Sheep and goats	Milk	50	
Pig	Muscle	150	
Pig	Liver	150	
Pig	Kidney	200	
Pig	Fat	150	The MRL includes skin + fat.
Chicken	Muscle	150	
Chicken	Liver	150	
Chicken	Kidney	200	
Chicken	Fat	150	The MRL includes skin + fat.
Chicken	Eggs	300	
Turkey	Muscle	150	
Turkey	Liver	150	
Turkey	Kidney	200	
Turkey	Fat	150	The MRL includes skin + fat.
Rabbit	Muscle	150	
Rabbit	Liver	150	
Rabbit	Kidney	200	
Rabbit	Fat	150	

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CYFLUTHRIN (insecticide)			
Acceptable daily intake		0–20 µg/kg bw (JECFA48)	
Residue definition		Cyfluthrin	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Cattle	Muscle	20	
Cattle	Liver	20	
Cattle	Kidney	20	
Cattle	Fat	200	

Cattle	Milk (µg/l)	40	

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CYHALOTHRIN (insecticide)			
Acceptable daily intake		0–5 µg/kg bw (JECFA62)	
Residue definition		Cyhalothrin	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Cattle	Muscle	20	
Cattle	Liver	20	
Cattle	Kidney	20	
Cattle	Fat	400	
Cattle	Milk	30	
Pig	Muscle	20	
Pig	Liver	20	
Pig	Kidney	20	
Pig	Fat	400	
Sheep and goats	Muscle	20	
Sheep and goats	Liver	50	
Sheep and goats	Kidney	20	
Sheep and goats	Fat	400	

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CYPERMETHRIN AND ALPHA-CYPERMETHRIN (insecticide)			
Acceptable daily intake		JECFA62 established a common ADI of 0–20 µg/kg bw for both cypermethrin and alpha-cypermethrin	
Residue definition		Total of cypermethrin residues (resulting from the use of cypermethrin or alpha-cypermethrin as veterinary drugs)	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Cattle	Muscle	50	
Cattle	Liver	50	
Cattle	Kidney	50	
Cattle	Fat	1,000	
Cattle	Milk	100	
Sheep and goats	Muscle	50	

Sheep and goats	Liver	50	
Sheep and goats	Kidney	50	
Sheep and goats	Fat	1,000	

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DANOFLOXACIN (antimicrobial agent)			
Acceptable daily intake		0–20 µg/kg bw (JECFA48)	
Residue definition		Danofloxacin	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Cattle	Muscle	200	
Cattle	Liver	400	
Cattle	Kidney	400	
Cattle	Fat	100	
Chicken	Muscle	200	
Chicken	Liver	400	
Chicken	Kidney	400	
Chicken	Fat	100	Fat/skin in normal proportion.
Pig	Muscle	100	
Pig	Liver	50	
Pig	Kidney	200	
Pig	Fat	100	

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DELTAMETHRIN (insecticide)			
Acceptable daily intake		0–10 µg/kg bw (1982). Established by JMPR (1982)	
Residue definition		Deltamethrin	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Cattle	Muscle	30	
Cattle	Liver	50	
Cattle	Kidney	50	
Cattle	Fat	500	
Cattle	Milk	30	
Chicken	Muscle	30	
Chicken	Liver	50	
Chicken	Kidney	50	
Chicken	Fat	500	

Chicken	Eggs	30	
Salmon	Muscle	30	
Sheep and goats	Muscle	30	
Sheep and goats	Liver	50	
Sheep and goats	Kidney	50	
Sheep and goats	Fat	500	

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DERQUANTEL (anthelmintic agent)			
Acceptable daily intake		0–0.3 µg/kg bw on the basis of a LOAEL of 0.1 mg/kg bw per day for acute clinical observations in dogs, consistent with antagonistic activity on the nicotinic acetylcholine receptors. A safety factor of 300 was applied to the LOAEL (JECFA75)	
Estimated dietary exposure		There were insufficient data to calculate an EDI, and the TMDI approach was used. Using the model diet and the MT:TR approach, these MRLs result in an estimated dietary exposure of 6.8 µg/person, which represents approximately 38% of the upper bound of the ADI (JECFA78)	
Residue definition		Derquantel	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Sheep and goats	Muscle	0.3	
Sheep and goats	Liver	0.8	
Sheep and goats	Kidney	0.4	
Sheep and goats	Fat	7.0	

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DEXAMETHASONE (glucocorticosteroid)			
Residue definition		Dexamethasone	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Cattle	Muscle	1.0	
Cattle	Liver	2.0	
Cattle	Kidney	1.0	
Cattle	Milk (µg/l)	0.3	
Pig	Muscle	1.0	
Pig	Liver	2.0	
Pig	Kidney	1.0	
Horses	Muscle	1.0	
Horses	Liver	2.0	
Horses	Kidney	1.0	

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DICLAZURIL (antiprotozoal agent)			
Acceptable daily intake		0–30 µg/kg bw (JECFA50)	
Residue definition		Diclazuril	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Poultry	Muscle	500	
Poultry	Liver	3,000	
Poultry	Kidney	2,000	
Poultry	Fat/Skin	1,000	
Rabbit	Muscle	500	
Rabbit	Liver	3,000	
Rabbit	Kidney	2,000	
Rabbit	Fat	1,000	
Sheep and goats	Muscle	500	
Sheep and goats	Liver	3,000	
Sheep and goats	Kidney	2,000	
Sheep and goats	Fat	1,000	

DICYCLANIL (insecticide)			
Acceptable daily intake		0–7 µg/kg bw (JECFA54)	
Residue definition		Dicyclanil	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Sheep and goats	Muscle	150	
Sheep and goats	Liver	125	
Sheep and goats	Kidney	125	
Sheep and goats	Fat	200	

DIFLUBENZURON (insecticide)			
Acceptable daily intake		JECFA established an ADI of 0–0.02 mg/kg bw – based on a NOAEL of 2 mg/kg bw per day for increased methaemoglobin and sulfhaemoglobin levels in a 2-year study of toxicity and carcinogenicity in rats; and increased methaemoglobin and sulfhaemoglobin levels, platelet counts and hepatic pigmentation in a 1-year study of toxicity in dogs – applying a safety factor of 100 (10 for interspecies variability and 10 for intraspecies variability)	
Acute reference dose		JECFA reiterated the conclusion of the 81st meeting (1) that it was not necessary to establish an ARfD, in view of the low acute oral toxicity and the absence of developmental toxicity, and any other toxicological effects likely to be elicited by a single dose	
Estimated chronic dietary exposure		The GECDE for the general population is 0.84 µg/kg bw per day, which represents 4% of the upper bound of the ADI The GECDE for children is 2.85 µg/kg bw per day, which represents 14% of the upper bound of the ADI	
Estimated acute dietary exposure		The acute dietary exposure was not estimated because JECFA concluded that it was not necessary to establish an ARfD	
Residue definition		JECFA reconfirmed diflubenzuron as the marker residue (MR) and the ratio of the MR to the total radioactive residue of 0.9 established at its 81st meeting	
Maximum residue limits		JECFA recommended an MRL in salmon of 10 µg/kg in muscle plus skin in natural proportions	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Salmon	Muscle plus skin in natural proportions	10	

DIHYDROSTREPTOMYCIN / STREPTOMYCIN (antimicrobial agent)			
Acceptable daily intake		0–50 µg/kg bw (JECFA48). Group ADI for combined residues of dihydrostreptomycin and streptomycin	
Residue definition		Sum of dihydrostreptomycin and streptomycin	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Cattle	Muscle	600	
Cattle	Liver	600	
Cattle	Kidney	1,000	
Cattle	Fat	600	
Cattle	Milk	200	
Chicken	Muscle	600	
Chicken	Liver	600	

Chicken	Kidney	1,000	
Chicken	Fat	600	
Pig	Muscle	600	
Pig	Liver	600	
Pig	Kidney	1,000	
Pig	Fat	600	
Sheep and goats	Muscle	600	
Sheep and goats	Liver	600	
Sheep and goats	Kidney	1,000	
Sheep and goats	Fat	600	
Sheep and goats	Milk	200	

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DIMINAZENE (trypanocide)			
Acceptable daily intake		0-100 µg/kg bw (JECFA42)	
Residue definition		Diminazene	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Cattle	Muscle	500	
Cattle	Liver	12,000	
Cattle	Kidney	6,000	
Cattle	Milk (µg/l)	150	LOQ of the analytical method.

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DORAMECTIN (anthelmintic agent)			
Acceptable daily intake		0–1 µg/kg bw (JECFA58)	
Residue definition		Doramectin	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Cattle	Muscle	10	High concentration of residues at the injection site over a 35-day period after subcutaneous or intramuscular administration of the drug at the recommended dose.
Cattle	Liver	100	
Cattle	Kidney	30	

Cattle	Fat	150	High concentration of residues at the injection site over a 35-day period after subcutaneous or intramuscular administration of the drug at the recommended dose.
Cattle	Milk	15	Depending on the route and/or time of administration, the use of doramectin in dairy cows may result in extended withdrawal periods in milk. This may be addressed in national/regional regulatory programmes.
Pig	Muscle	5	
Pig	Liver	100	
Pig	Kidney	30	
Pig	Fat	150	

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EMAMECTIN BENZOATE (antiparasitic agent)			
Acceptable daily intake		ADI of 0–0.5 µg/kg bw established by JMPR (2011), based on an overall NOAEL of 0.25 mg/kg bw per day for neurotoxicity from 14- and 53- week studies in dogs, supported by an overall NOAEL of 0.25 mg/kg bw per day from 1- and 2-year studies in rats. An uncertainty factor of 500 was applied to the NOAEL, which includes an additional uncertainty factor of 5 to account for the steep dose–response curve and irreversible histopathological effects in neural tissues at the LOAEL in dogs, as used by JMPR and confirmed by JECFA78	
Estimated dietary exposure		11 µg/person per day, which represents approximately 37% of the upper bound of the ADI (JECFA78)	
Residue definition		Emamectin B1a	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Salmon	Muscle	100	
Salmon	Fillet	100	Muscle plus skin in natural proportion.
Trout	Muscle	100	
Trout	Fillet	100	Muscle plus skin in natural proportion.

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EPRINOMECTIN (anthelmintic agent)			
Acceptable daily intake		0–10 µg/kg bw (JECFA50)	
Residue definition		Eprinomectin B1a	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Cattle	Muscle	100	

Cattle	Liver	2,000	
Cattle	Kidney	300	
Cattle	Fat	250	
Cattle	Milk (µg/l)	20	

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ERYTHROMYCIN (antimicrobial agent)			
Acceptable daily intake		0–0.7 µg/kg bw (JECFA66)	
Residue definition		Erythromycin A	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Chicken	Muscle	100	
Chicken	Liver	100	
Chicken	Kidney	100	
Chicken	Fat	100	The MRL includes skin + fat.
Chicken	Eggs	50	
Turkey	Muscle	100	
Turkey	Liver	100	
Turkey	Kidney	100	
Turkey	Fat	100	The MRL includes skin + fat.

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ESTRADIOL-17BETA (production aid)			
Acceptable daily intake		unnecessary (JECFA32); 0–0.05 µg/kg bw (JECFA52)	
Residue definition		Estradiol-17beta	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Cattle	Muscle	Unnecessary	Residues resulting from the use of this substance as a growth promoter in accordance with good animal husbandry practice are unlikely to pose a hazard to human health.
Cattle	Liver	Unnecessary	Residues resulting from the use of this substance as a growth promoter in accordance with good animal husbandry practice are unlikely to pose a hazard to human health.
Cattle	Kidney	Unnecessary	Residues resulting from the use of this substance as a growth promoter in accordance with good animal husbandry practice are unlikely to pose a hazard to human health.
Cattle	Fat	Unnecessary	Residues resulting from the use of this substance as a growth promoter in accordance with good animal husbandry practice are unlikely to pose a hazard to human health.

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FEBANTEL/FENBENDAZOLE/OXFENDAZOLE (anthelmintic agent)			
Acceptable daily intake		Group ADI of 0–7 µg/kg bw (JECFA50)	
Residue definition		Sum of fenbendazole, oxfendazole and oxfendazole sulphone, expressed as oxfendazole sulphone equivalents	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Cattle	Muscle	100	
Cattle	Liver	500	
Cattle	Kidney	100	
Cattle	Fat	100	
Cattle	Milk (µg/l)	100	
Horse	Muscle	100	
Horse	Liver	500	
Horse	Kidney	100	
Horse	Fat	100	
Pig	Muscle	100	
Pig	Liver	500	
Pig	Kidney	100	
Pig	Fat	100	
Sheep and goats	Muscle	100	
Sheep and goats	Liver	500	
Sheep and goats	Kidney	100	
Sheep and goats	Fat	100	
Sheep and goats	Milk (µg/l)	100	

FLUAZURON (insecticide)			
Acceptable daily intake		0–40 µg/kg bw (JECFA48)	
Residue definition		Fluazuron	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Cattle	Muscle	200	
Cattle	Liver	500	
Cattle	Kidney	500	
Cattle	Fat	7 000	

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FLUBENDAZOLE (anthelmintic agent)			
Acceptable daily intake		0–12 µg/kg bw (JECFA40)	
Residue definition		Flubendazole	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Pig	Muscle	10	
Pig	Liver	10	
Poultry	Muscle	200	
Poultry	Liver	500	
Poultry	Eggs	400	

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FLUMEQUINE (antimicrobial agent)			
Acceptable daily intake		0–30 µg/kg bw (JECFA62)	
Residue definition		Flumequine	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Cattle	Muscle	500	
Cattle	Liver	500	
Cattle	Kidney	3,000	
Cattle	Fat	1,000	
Chicken	Muscle	500	
Chicken	Liver	500	
Chicken	Kidney	3,000	
Chicken	Fat	1,000	
Pig	Muscle	500	
Pig	Liver	500	
Pig	Kidney	3,000	
Pig	Fat	1,000	
Sheep and goats	Muscle	500	
Sheep and goats	Liver	500	
Sheep and goats	Kidney	3,000	
Sheep and goats	Fat	1,000	
Trout	Muscle	500	Muscle including normal proportion of skin.

FLUMETHRIN (insecticide)			
Acceptable daily intake		0–0.004 mg/kg bw based on the NOAEL of 0.37 mg/kg bw per day for skin lesions in parental animals and reduced survival and body weight gain in pups in a two-generation toxicity study in rats and using a safety factor of 100 (10 for interspecies variability and 10 for intraspecies variability)	
Acute reference dose		0.005 mg/kg bw based on the NOAEL of 0.5 mg/kg bw for salivation in dams in a developmental toxicity study in rats and using a safety factor of 100 (10 for interspecies variability and 10 for intraspecies variability)	
Estimated chronic dietary exposure		0.008 µg/kg bw per day (for the general population), which represents 0.2% of the upper bound of the ADI 0.006 µg/kg bw per day (for children), which represents 0.2% of the upper bound of the ADI Note: As Flumethrin is also used as pesticide the overall dietary exposure was estimated. The assumptions and detailed results will be displayed in the JECFA85 report. Results below are only for use as veterinary drug	
Estimated acute dietary exposure		0.1 µg/kg bw per day (for the general population), which represents 2.2% of the ARfD 0.1 µg/kg bw per day (for children), which represents 2.2% of the ARfD	
Residue definition		Flumethrin (trans-Z1 and trans-Z2 diastereomers at a ratio of approximately 60:40)	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
	Honey	Unnecessary	Residues resulting from the use of this substances as an insecticide in accordance with good practice for veterinary drug are unlikely to pose a hazard to human health.

GENTAMICIN (antimicrobial agent)			
Acceptable daily intake		0–20 µg/kg bw (JECFA50)	
Residue definition		Gentamicin	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Cattle	Muscle	100	
Cattle	Liver	2 000	
Cattle	Kidney	5 000	
Cattle	Fat	100	
Cattle	Milk (µg/l)	200	
Pig	Muscle	100	
Pig	Liver	2 000	
Pig	Kidney	5 000	
Pig	Fat	100	

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HALQUINOL (broad-spectrum antimicrobial)			
Acceptable daily intake		JECFA established an ADI of 0–0.2 mg/kg bw, based on histopathological changes in the kidney, accompanied by increases in absolute and relative renal weight in a 1-year chronic toxicity study in rats, applying a safety factor of 100 (10 for interspecies variability and 10 for intraspecies variability)	
Acute reference dose		JECFA established an ARfD of 0.3 mg/kg bw, based on a NOAEL of 30 mg/kg bw for clinical signs in dams observed in a developmental toxicity study in mice, with application of a safety factor of 100 (10 for interspecies variability and 10 for intraspecies variability)	
Estimated chronic dietary exposure		The GECDE for the general population is 5.9 µg/kg bw per day, which represents 3% of the upper bound of the ADI The GECDE for children is 6.9 µg/kg bw per day, which represents 3.4% of the upper bound of the ADI	
Estimated acute dietary exposure		The GEADE was comparable for children and adults, being 2–224 µg/kg bw per day, which represents 0.5–75% of the ARfD	
Residue definition		The marker residue (MR) is the sum of 5-chloroquinolin-8-ol (5-CL), 5,7- dichloroquinolin-8-ol 5,7-DCL (5,7-DCL) and their glucuronide metabolites: 5-CLG (expressed as 5-CL equivalents) and 5,7-DCLG (expressed as 5,7-DCL equivalents)	
Maximum residue limits		JECFA recommended MRLs in swine of 40 µg/kg for muscle, 350 µg/kg for skin plus fat, 500 µg/kg for liver and 9000 µg/kg for kidney	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Swine	Muscle	40	
Swine	Skin plus fat	350	

Swine	Liver	500	
Swine	Kidney	9 000	

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IMIDOCARB (antiprotozoal agent)			
Acceptable daily intake		0–10 µg/kg bw (JECFA50)	
Residue definition		Imidocarb	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Cattle	Muscle	300	
Cattle	Liver	1 500	
Cattle	Kidney	2 000	
Cattle	Fat	50	
Cattle	Milk	50	

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ISOMETAMIDIUM (trypanocide)			
Acceptable daily intake		0–100 µg/kg bw (JECFA40)	
Residue definition		Isometamidium	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Cattle	Muscle	100	
Cattle	Liver	500	
Cattle	Kidney	1 000	
Cattle	Fat	100	
Cattle	Milk (µg/l)	100	

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IVERMECTIN (broad-spectrum antiparasitic agent)			
Acceptable daily intake		0–10 µg/kg body weight (JECFA81)	
Acute reference dose		200 µg/kg body weight (JECFA81)	
Estimated acute dietary exposure		The GEADE for cattle muscle, applicable to children and the general population, is 69 µg/kg bw, which represents 35% of the ARfD of 200 µg/kg bw. The GEADE for sheep muscle, applicable to children and the general population, is 73 µg/kg bw, which represents 37% of the ARfD of 200 µg/kg bw. The GEADE for pig muscle, applicable to children and the general population, is 30 µg/kg bw, which represents 15% of the ARfD of 200 µg/kg bw (JECFA94)	
Estimated chronic dietary exposure		The GECDE for adults and the elderly is 0.72 µg/kg bw per day, which represents 7.2% of the upper bound of the ADI of 10 µg/kg bw. The GECDE for children and adolescents is 0.93 µg/kg bw per day, which represents 9.3% of the upper bound of the ADI of 10 µg/kg bw. The GECDE for infants and toddlers is 0.48 µg/kg bw per day, which represents 4.8% of the upper bound of the ADI of 10 µg/kg bw (JECFA94)	
Residue definition		Ivermectin B1a The marker residue in sheep, pigs and goats is ivermectin B1a (H2B1a, or *22,23*-dihydroavermectin B1a) (JECFA94)	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Cattle	Muscle	30	
Cattle	Liver	800	
Cattle	Kidney	100	
Cattle	Fat	400	
Cattle	Milk	10	
Pig	Muscle	15	
Pig	Liver	30	
Pig	Kidney	20	
Pig	Fat	50	
Sheep and goats	Muscle	30	
Sheep and goats	Liver	60	
Sheep and goats	Kidney	20	
Sheep and goats	Fat	100	

LASALOCID SODIUM (antiparasitic agent)			
Acceptable daily intake		0–5 µg/kg bw on the basis of a NOAEL of 0.5 mg/kg bw per day from a developmental toxicity study in rabbits and a multigeneration reproductive toxicity study in rats, with application of an uncertainty factor of 100 for interspecies and intraspecies variability (JECFA78)	
Estimated dietary exposure		80 µg/person per day was calculated, which represents approximately 27% of the upper bound of the ADI (JECFA78)	
Residue definition		Lasalocid A	
Note		JECFA78 extended the MRLs in chicken to turkey and quail and extrapolated the MRLs in chicken to pheasant. No information was available for duck, including on approved uses. As the compound is not registered for use in laying hens, according to the sponsor, it is not appropriate to recommend MRLs for egg.	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Chicken	Muscle	400	
Chicken	Liver	1,200	
Chicken	Kidney	600	
Chicken	Skin + Fat	600	
Turkey	Muscle	400	
Turkey	Liver	1,200	
Turkey	Kidney	600	
Turkey	Skin + Fat	600	
Quail	Muscle	400	
Quail	Liver	1,200	
Quail	Kidney	600	
Quail	Skin + Fat	600	
Pheasant	Muscle	400	
Pheasant	Liver	1,200	
Pheasant	Kidney	600	
Pheasant	Skin + Fat	600	

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LEVAMISOLE (anthelmintic agent)			
Acceptable daily intake		0–6 µg/kg bw (JECFA42)	
Residue definition		Levamisole	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Cattle	Muscle	10	
Cattle	Liver	100	
Cattle	Kidney	10	
Cattle	Fat	10	
Pig	Muscle	10	
Pig	Liver	100	
Pig	Kidney	10	
Pig	Fat	10	
Poultry	Muscle	10	
Poultry	Liver	100	
Poultry	Kidney	10	
Poultry	Fat	10	
Sheep	Muscle	10	
Sheep	Liver	100	
Sheep	Kidney	10	
Sheep	Fat	10	

LINCOMYCIN (antimicrobial agent)			
Acceptable daily intake		0–30 µg/kg bw (JECFA54)	
Residue definition		Lincomycin	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Cattle	Milk	150	
Chicken	Muscle	200	
Chicken	Liver	500	
Chicken	Kidney	500	
Chicken	Fat	100	Additional MRL for skin with adhering fat of 300 µg/kg.
Pig	Muscle	200	
Pig	Liver	500	
Pig	Kidney	1,500	
Pig	Fat	100	Additional MRL for skin with adhering fat of 300 µg/kg.

LUFENURON (insecticide)			
Acceptable daily intake		0–0.02 mg/kg bw based on the NOAEL of 1.93 mg/kg bw per day for tonic-clonic seizures and findings in lungs, gastrointestinal tract, liver and urinary tract in a 2-year dietary study in rats and using a safety factor of 100 (10 for interspecies variability and 10 for intraspecies variability)	
Acute reference dose		Unnecessary, in view of lufenuron low acute oral toxicity and the absence of developmental toxicity and other toxicological effects likely to be elicited by a single dose	
Estimated chronic dietary exposure		1.1 µg/kg bw per day (for the general population), which represents 5.5% of the upper bound of the ADI. As lufenuron is also used as pesticide, the overall dietary exposure was estimated. The assumptions and detailed results will be displayed in the JECFA85 report. Results below are only for use as veterinary drug	
Residue definition		Lufenuron	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Salmon	Fillet	1,350	Muscle plus skin in natural proportion.
Trout	Fillet	1,350	Muscle plus skin in natural proportion.

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MELENGESTROL ACETATE (production aid)			
Acceptable daily intake		0–0.03 µg/kg bw (JECFA54)	
Residue definition		Melengestrol acetate	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Cattle	Muscle	1	
Cattle	Liver	10	
Cattle	Kidney	2	
Cattle	Fat	18	

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MONENSIN (antimicrobial agent)			
Acceptable daily intake		0–10 µg/kg bw on the basis of a NOAEL of 1.14 mg/kg bw per day and a safety factor of 100 and rounding to one significant figure (JECFA70)	
Estimated dietary exposure		Using the revised MRL, the TMDI from JECFA70 was recalculated, resulting in a value of 481 µg/person, which represents 80% of the upper bound of the ADI (JECFA75)	
Residue definition		Monensin	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Cattle	Muscle	10	
Cattle	Liver	100	
Cattle	Kidney	10	
Cattle	Fat	100	
Cattle	Milk	2	
Sheep	Muscle	10	
Sheep	Liver	20	
Sheep	Kidney	10	
Sheep	Fat	100	
Goats	Muscle	10	
Goats	Liver	20	
Goats	Kidney	10	
Goats	Fat	100	
Chicken	Muscle	10	
Chicken	Liver	10	
Chicken	Kidney	10	
Chicken	Fat	100	
Turkey	Muscle	10	
Turkey	Liver	10	
Turkey	Kidney	10	
Turkey	Fat	100	
Quail	Muscle	10	
Quail	Liver	10	
Quail	Kidney	10	
Quail	Fat	100	

MONEPANTEL (anthelmintic agent)			
Acceptable daily intake		0–0.02 mg/kg bw based on the NOAEL of 1.93 mg/kg bw per day for tonic-clonic seizures and findings in lungs, gastrointestinal tract, liver and urinary tract in a 2-year dietary study in rats, and using a safety factor of 100 (10 for interspecies variability and 10 for intraspecies variability)	
Acute reference dose		Unnecessary	
Estimated chronic dietary exposure		13.7 µg per kg bw per day (for the general population), which represents 68% of the upper bound of the ADI 5.0 µg per kg bw per day (for children), which represents 22% of the upper bound of the ADI 4.4 µg per kg bw per day (for infants), which represents 25% of the upper bound of the ADI	
Residue definition		Monepantel sulfone, expressed as monepantel	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Sheep	Muscle	500	
Sheep	Liver	7,000	
Sheep	Kidney	1,700	
Sheep	Fat	13,000	
Cattle	Fat	7,000	
	Kidney	1,000	
	Liver	2,000	
	Muscle	300	

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MOXIDECTIN (anthelmintic agent)			
Acceptable daily intake		0–2 µg/kg bw (JECFA45)	
Residue definition		Moxidectin	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Cattle	Muscle	20	Very high concentration and great variation in the level of residues at the injection site in cattle over a 49-day period after dosing.
Cattle	Liver	100	
Cattle	Kidney	50	
Cattle	Fat	500	
Deer	Muscle	20	
Deer	Liver	100	
Deer	Kidney	50	
Deer	Fat	500	
Sheep	Muscle	50	
Sheep	Liver	100	
Sheep	Kidney	50	
Sheep	Fat	500	

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NARASIN (antimicrobial agent)			
Acceptable daily intake		0–5 µg/kg bw on the basis of a NOAEL of 0.5 mg/kg bw per day and a safety factor of 100 (JECFA70)	
Residue definition		Narasin A	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Cattle	Muscle	15	
Cattle	Liver	50	
Cattle	Kidney	15	
Cattle	Fat	50	
Chicken	Muscle	15	
Chicken	Liver	50	
Chicken	Kidney	15	
Chicken	Fat	50	
Pig	Muscle	15	
Pig	Liver	50	
Pig	Kidney	15	
Pig	Fat	50	

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NEOMYCIN (antimicrobial agent)			
Acceptable daily intake		0–60 µg/kg bw (JECFA47)	
Residue definition		Neomycin	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Cattle	Muscle	500	
Cattle	Liver	500	
Cattle	Kidney	10,000	
Cattle	Fat	500	
Cattle	Milk	1,500	
Chicken	Muscle	500	
Chicken	Liver	500	
Chicken	Kidney	10,000	
Chicken	Fat	500	
Chicken	Eggs	500	
Duck	Muscle	500	
Duck	Liver	500	
Duck	Kidney	10,000	
Duck	Fat	500	
Goat	Muscle	500	
Goat	Liver	500	
Goat	Kidney	10,000	
Goat	Fat	500	
Pig	Muscle	500	
Pig	Liver	500	
Pig	Kidney	10,000	
Pig	Fat	500	
Sheep	Muscle	500	
Sheep	Liver	500	
Sheep	Kidney	10,000	
Sheep	Fat	500	
Turkey	Muscle	500	
Turkey	Liver	500	
Turkey	Kidney	10,000	
Turkey	Fat	500	

NICARBAZIN (coccidiostat)			
Acceptable daily intake		0–0.9 mg/kg bw based on toxicological effects (JECFA94)	
Acute reference dose		Not necessary (JECFA94)	
Estimated chronic dietary exposure		Based on incurred DNC residues in chicken muscle, offal, and skin with fat, at 24 hours withdrawal time and 125 mg/kg feed: the GECDE for adults and the elderly is 120 µg/kg body weight (bw) per day, which represents 13% of the upper bound of the ADI of 900 µg/kg bw; the GECDE for children and adolescents is 160 µg/kg bw per day, which represents 18% of the upper bound of the ADI of 900 µg/kg bw; and the GECDE for infants and toddlers is 210 µg/kg bw per day, which represents 23% of the upper bound of the ADI of 900 µg/kg bw. Based on incurred DNC residues in chicken muscle, offal, and skin with fat, at zero days withdrawal time and 50 mg/kg feed: the GECDE for adults and the elderly is 95 µg/kg bw per day, which represents 11% of the upper bound of the ADI of 900 µg/kg bw; the GECDE for children and adolescents is 120 µg/kg bw per day, which represents 14% of the upper bound of the ADI of 900 µg/kg bw; and the GECDE for infants and toddlers is 160 µg/kg bw per day, which represents 18% of the upper bound of the ADI of 900 µg/kg bw. (JECFA94)	
Microbiological effects		Nicarbazin and/or its metabolites show no antimicrobial activity towards representative bacteria of the human intestinal microbiota	
Microbiological ADI		JECFA concluded that it was not necessary to establish an mADI for nicarbazin	
Toxicological effects		The NOAEL was 60 mg/kg bw per day (equivalent to 42.5 mg/kg bw per day of DNC) due to prominent liver lobulation, observed in a study of developmental toxicity in the rabbit	
Uncertainty factor		When considering nicarbazin, it is DNC that is the toxic component, and its absorption alone or in a mixture with HDP is substantially less (< 5%) than when formed from ingested nicarbazin. As DNC is the residue of concern and there is no nicarbazin in products from treated animals, JECFA concluded that despite limitations in the database, a reduction in the default safety factor of 100 used to account for interspecies and intraspecies variability, would be justified. JECFA was unable to quantify just how much of a reduction would be appropriate, but concluded that 50 could certainly be supported, and would still result in a conservative evaluation	
Toxicological acceptable daily intake		The tADI for nicarbazin was established at 0–0.9 mg/kg bw (DNC)	
Residue definition		The marker residue in chickens is 4,4′-dinitrocarbanilide (DNC).	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Chicken	Muscle	4 000	Broilers

Chicken	Liver	15 000	Broilers
Chicken	Kidney	8 000	Broilers
Chicken	Fat/Skin (skin with fat)	4 000	Broilers

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PHOXIM (insecticide)			
Acceptable daily intake		0–4 µg/kg bw (JECFA52)	
Residue definition		Phoxim	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Goat	Muscle	50	
Goat	Liver	50	
Goat	Kidney	50	
Goat	Fat	400	
Pig	Muscle	50	
Pig	Liver	50	
Pig	Kidney	50	
Pig	Fat	400	
Sheep	Muscle	50	
Sheep	Liver	50	
Sheep	Kidney	50	
Sheep	Fat	400	

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PIRLIMYCIN (antimicrobial agent)			
Acceptable daily intake		0–8 µg/kg bw (JECFA62)	
Residue definition		Pirlimycin	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Cattle	Muscle	100	
Cattle	Liver	1 000	
Cattle	Kidney	400	
Cattle	Fat	100	
Cattle	Milk	100	JECFA evaluated the effect of pirlimycin residues on starter cultures and for this reason recommended an MRL of 100 µg/kg of milk. Codex Members may therefore adapt national/regional MRLs in order to address this technological aspect for trade of fresh liquid milk intended for processing using starter culture.

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PORCINE SOMATOTROPIN (production aid)			
Acceptable daily intake		Not specified (JECFA52)	
Residue definition		Not applicable	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Pig	Muscle	Not specified	
Pig	Liver	Not specified	
Pig	Kidney	Not specified	
Pig	Fat	Not specified	

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PROGESTERONE (production aid)			
Acceptable daily intake		0–30 µg/kg bw (JECFA52)	
Residue definition		Progesterone	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Cattle	Muscle	Unnecessary	Residues resulting from the use of this substances as a growth promoter in accordance with good animal husbandry practice are unlikely to pose a hazard to human health.
Cattle	Liver	Unnecessary	Residues resulting from the use of this substances as a growth promoter in accordance with good animal husbandry practice are unlikely to pose a hazard to human health.
Cattle	Kidney	Unnecessary	Residues resulting from the use of this substances as a growth promoter in accordance with good animal husbandry practice are unlikely to pose a hazard to human health.
Cattle	Fat	Unnecessary	Residues resulting from the use of this substances as a growth promoter in accordance with good animal husbandry practice are unlikely to pose a hazard to human health.

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RACTOPAMINE (production aid)			
Acceptable daily intake		0–1 µg/kg bw (JECFA66)	
Residue definition		Ractopamine	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Cattle	Muscle	10	
Cattle	Liver	40	
Cattle	Kidney	90	
Cattle	Fat	10	
Pig	Muscle	10	
Pig	Liver	40	
Pig	Kidney	90	
Pig	Fat	10	The MRL includes skin + fat.

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SARAFLOXACIN (antimicrobial agent)			
Acceptable daily intake		0–0.3 µg/kg bw (JECFA50)	
Residue definition		Sarafloxacin	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Chicken	Muscle	10	
Chicken	Liver	80	
Chicken	Kidney	80	
Chicken	Fat	20	
Turkey	Muscle	10	
Turkey	Liver	80	
Turkey	Kidney	80	
Turkey	Fat	20	

SPECTINOMYCIN (antimicrobial agent)			
Acceptable daily intake		0–40 µg/kg bw (JECFA42)	
Residue definition		Spectinomycin	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Cattle	Muscle	500	
Cattle	Liver	2,000	
Cattle	Kidney	5,000	
Cattle	Fat	2,000	
Cattle	Milk (µg/l)	200	
Chicken	Muscle	500	
Chicken	Liver	2,000	
Chicken	Kidney	5,000	
Chicken	Fat	2,000	
Chicken	Eggs	2,000	
Pig	Muscle	500	
Pig	Liver	2,000	
Pig	Kidney	5,000	
Pig	Fat	2,000	
Sheep	Muscle	500	
Sheep	Liver	2,000	
Sheep	Kidney	5,000	
Sheep	Fat	2,000	

SPIRAMYCIN (antimicrobial agent)			
Acceptable daily intake		0–50 µg/kg bw (JECFA43)	
Residue definition		Cattle and chickens, sum of spiramycin and neospiramycin; pigs, spiramycin equivalents (antimicrobially active residues)	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Cattle	Muscle	200	
Cattle	Liver	600	
Cattle	Kidney	300	
Cattle	Fat	300	
Cattle	Milk (µg/l)	200	
Chicken	Muscle	200	
Chicken	Liver	600	
Chicken	Kidney	800	
Chicken	Fat	300	
Pig	Muscle	200	
Pig	Liver	600	
Pig	Kidney	300	
Pig	Fat	300	

SULFADIMIDINE (antimicrobial agent)			
Acceptable daily intake		0–50 µg/kg bw (JECFA42)	
Residue definition		Sulfadimidine	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Cattle	Milk (µg/l)	25	
Not specified	Muscle	100	
Not specified	Liver	100	
Not specified	Kidney	100	
Not specified	Fat	100	

TEFLUBENZURON (insecticide)			
Acceptable daily intake		0–5 µg/kg bw on the basis of a lower 95% confidence limit on the benchmark dose for a 10% response (BMDL10) of 0.54 mg/kg bw per day for hepatocellular hypertrophy in male mice observed in a carcinogenicity study, with application of an uncertainty factor of 100 to account for interspecies and intraspecies variability (JECFA81)	
Estimated chronic dietary exposure		The EDI is 42.9 µg/person per day, on the basis of a 60 kg individual, which represents approximately 14% of the upper bound of the ADI. The GECDE for the general population is 1.6 µg/kg bw per day, which represents 31% of the upper bound of the ADI. The GECDE for children is 2.1 µg/kg bw per day, which represents 43% of the upper bound of the ADI. The GECDE for infants is 0.9 µg/kg bw per day, which represents 18% of the upper bound of the ADI (JECFA81)	
Residue definition		Teflubenzuron	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Salmon	Muscle	400	
Salmon	Fillet	400	Muscle plus skin in natural proportion.

TESTOSTERONE (production aid)			
Acceptable daily intake		0–2 µg/kg bw (JECFA52)	
Residue definition		Testosterone	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Cattle	Muscle	Unnecessary	Residues resulting from the use of this substances as a growth promoter in accordance with good animal husbandry practice are unlikely to pose a hazard to human health.
Cattle	Liver	Unnecessary	Residues resulting from the use of this substances as a growth promoter in accordance with good animal husbandry practice are unlikely to pose a hazard to human health.
Cattle	Kidney	Unnecessary	Residues resulting from the use of this substances as a growth promoter in accordance with good animal husbandry practice are unlikely to pose a hazard to human health.
Cattle	Fat	Unnecessary	Residues resulting from the use of this substances as a growth promoter in accordance with good animal husbandry practice are unlikely to pose a hazard to human health.

THIABENDAZOLE (anthelmintic agent)			
Acceptable daily intake		0–100 µg/kg bw (JECFA40)	
Residue definition		Sum of thiabendazole and 5-hydroxythiabendazole	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Cattle	Muscle	100	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.
Cattle	Liver	100	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.
Cattle	Kidney	100	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.
Cattle	Fat	100	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.
Cattle	Milk (µg/l)	100	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.
Goat	Muscle	100	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.
Goat	Liver	100	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.
Goat	Kidney	100	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.
Goat	Fat	100	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.
Goat	Milk (µg/l)	100	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.
Pig	Muscle	100	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.
Pig	Liver	100	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.
Pig	Kidney	100	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.
Pig	Fat	100	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.
Sheep	Muscle	100	The MRL also covers residues derived from feed containing the residues resulted from agricultural

			use.
Sheep	Liver	100	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.
Sheep	Kidney	100	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.
Sheep	Fat	100	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.

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TILMICOSIN (antimicrobial agent)			
Acceptable daily intake		0–40 µg/kg bw (JECFA47)	
Residue definition		Tilmicosin	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Cattle	Muscle	100	
Cattle	Liver	1,000	
Cattle	Kidney	300	
Cattle	Fat	100	
Chicken	Muscle	150	
Chicken	Liver	2,400	
Chicken	Kidney	600	
Chicken	Skin/Fat	250	
Pig	Muscle	100	
Pig	Liver	1,500	
Pig	Kidney	1,000	
Pig	Fat	100	
Sheep	Muscle	100	
Sheep	Liver	1,000	
Sheep	Kidney	300	
Sheep	Fat	100	
Turkey	Muscle	100	
Turkey	Kidney	1,200	
Turkey	Liver	1,400	
Turkey	Skin/Fat	250	

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TRENBOLONE ACETATE (growth promoter)			
Acceptable daily intake		0–0.02 µg/kg bw (JECFA34)	
Residue definition		Cattle muscle, beta-Trenbolone; cattle liver, alpha-Trenbolone	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Cattle	Muscle	2	
Cattle	Liver	10	

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TRICHLORFON (Metrifonate) (insecticide)	
Acceptable daily intake	0–2 µg/kg bw (JECFA60)
Residue definition	JECFA54 confirmed the MRL for cows' milk and the guidance levels for muscle, liver, kidney, and fat of cattle recommended (WHO TRS 900, 2001

Species	Tissue	MRL (µg/kg)	Notes
Cattle	Milk	50	

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TRICLABENDAZOLE (anthelmintic agent)			
Acceptable daily intake		0–3 µg/kg bw (JECFA40)	
Residue definition		Ketotriclabnedazole	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Cattle	Muscle	250	
Cattle	Liver	850	
Cattle	Kidney	400	
Cattle	Fat	100	
Sheep	Muscle	200	
Sheep	Liver	300	
Sheep	Kidney	200	
Sheep	Fat	100	

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TYLOSIN (antimicrobial agent)			
Acceptable daily intake		0–30 µg/kg bw based on a microbiological end-point derived from in vitro MIC susceptibility testing and faecal binding data (MICcalc = 1.698) (JECFA70)	
Residue definition		Tylosin A	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Cattle	Muscle	100	
Cattle	Liver	100	
Cattle	Kidney	100	
Cattle	Fat	100	
Cattle	Milk	100	
Pig	Muscle	100	
Pig	Liver	100	
Pig	Kidney	100	
Pig	Fat	100	
Chicken	Muscle	100	
Chicken	Liver	100	
Chicken	Kidney	100	
Chicken	Fat/Skin	100	
Chicken	Eggs	300	

ZERANOL (growth promoter)			
Acceptable daily intake		0–0.5 µg/kg bw (JECFA32)	
Residue definition		Zeranol	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Cattle	Muscle	2	
Cattle	Liver	10	

ZILPATEROL HYDROCHLORIDE		(β2-adrenoceptor agonist)	
Acceptable daily intake		ADI is 0–0.04 µg/kg bw established at JECFA78 (WHO TRS No. 988, 2014) and reaffirmed at JECFA81 and JECFA85	
Acute reference dose		ARfD is 0.04 µg/kg bw based on a LOAEL of 0.76 µg/kg bw for acute pharmacological effects observed in a single-dose human study, with application of an uncertainty factor of 20, comprising a default uncertainty factor of 10 for human individual variability and an additional uncertainty factor of 2 to account for use of a LOAEL for a slight effect instead of a NOAEL (JECFA81)	
Global estimated acute dietary exposure		GEADE is 1.9 µg/day for the general population, which represents approximately 80% of the ARfD The GEADE is 0.57 µg/day for children, which represents approximately 94% of the ARfD (JECFA81)	
Residue definition		Zilpaterol (free base) in muscle, liver, and kidney	
Species	**Tissue**	**MRL (µg/kg)**	**Notes**
Cattle	Kidney	3.3	
Cattle	Liver	3.5	
Cattle	Muscle	0.5	

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Annex C

(informative)

Maximum Residue Limits for Residues Of Veterinary Drugs In Foods Extrapolated In Accordance With The Approach For The Extrapolation Of MRLs For Veterinary Drugs To One Or More Species

AMOXICILLIN

Species	Tissue	MRL (µg/kg)	Note
All other ruminants	Muscle	50	MRL extrapolated
All other ruminants	Fat	50	MRL extrapolated
All other ruminants	Liver	50	MRL extrapolated
All other ruminants	Kidney	50	MRL extrapolated
All other ruminants	Milk	4	MRL extrapolated

BENZYLPENICILLIN

Species	Tissue	MRL (µg/kg)	Note
All other ruminants	Muscle	50	MRL extrapolated
All other ruminants	Liver	50	MRL extrapolated
All other ruminants	Kidney	50	MRL extrapolated
All other ruminants	Milk	4	MRL extrapolated

CYHALOTHRIN

Species	Tissue	MRL (µg/kg)	Note
All other ruminants	Muscle	20	MRL extrapolated
All other ruminants	Fat	400	MRL extrapolated
All other ruminants	Liver	20	MRL extrapolated
All other ruminants	Kidney	20	MRL extrapolated
All other ruminants	Milk	30	MRL extrapolated

CYPERMETHRIN

Species	Tissue	MRL (µg/kg)	Note
All other ruminants	Muscle	50	MRL extrapolated
All other ruminants	Fat	1 000	MRL extrapolated
All other ruminants	Liver	50	MRL extrapolated
All other ruminants	Kidney	50	MRL extrapolated

DELTAMETHRIN

Species	Tissue	MRL (µg/kg)	Note
All other ruminants	Muscle	30	MRL extrapolated
All other ruminants	Fat	500	MRL extrapolated
All other ruminants	Liver	50	MRL extrapolated
All other ruminants	Kidney	50	MRL extrapolated

LEVAMISOLE

Species	Tissue	MRL (µg/kg)	Note
All other ruminants	Muscle	10	MRL extrapolated
All other ruminants	Fat	10	MRL extrapolated
All other ruminants	Liver	100	MRL extrapolated
All other ruminants	Kidney	10	MRL extrapolated

MOXIDECTIN

Species	Tissue	MRL (µg/kg)	Note
All other ruminants	Muscle	20	MRL extrapolated
All other ruminants	Fat	500	MRL extrapolated
All other ruminants	Liver	100	MRL extrapolated
All other	Kidney	50	MRL

ruminants			extrapolated

SPECTINOMYCIN

Species	Tissue	MRL (µg/kg)	Note
All other ruminants	Muscle	500	MRL extrapolated
All other ruminants	Fat	2 000	MRL extrapolated
All other ruminants	Liver	2 000	MRL extrapolated
All other ruminants	Kidney	5 000	MRL extrapolated
All other ruminants	Milk	200	MRL extrapolated

TETRACYCLINES

Species	Tissue	MRL (µg/kg)	Note
All other ruminants	Muscle	200	MRL extrapolated
All other ruminants	Liver	600	MRL extrapolated
All other ruminants	Kidney	1 200	MRL extrapolated
All other ruminants	Milk	100	MRL extrapolated

TILMICOSIN

Species	Tissue	MRL (µg/kg)	Note
All other ruminants	Muscle	100	MRL extrapolated
All other ruminants	Fat	100	MRL extrapolated
All other ruminants	Liver	1 000	MRL extrapolated
All other ruminants	Kidney	300	MRL extrapolated

DELTAMETHRIN

Species	Tissue	MRL (µg/kg)	Note
All other finfish	Muscle	30	MRL extrapolated

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Species	Tissue	MRL (µg/kg)	Note
All other finfish	Muscle	500	MRL extrapolated

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