CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - Fax: (+39) 06 5705 4593 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 6 **RVDF/24 INF/1**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Twenty-fourth Session

SUPPORT DOCUMENT TO THE DISCUSSION ON THE MRLs AND RMRs FOR RESIDUES OF VETERINARY DRUGS

Prepared by the Codex Secretariat

INTRODUCTION

This working document is in support to the discussion on the residues of veterinary drugs in foods of the 24th 3rd Session of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF). The document includes:

- Part 1 - Codex Maximum Residue Limits (MRLs) and Risk Management Recommendations (RMRs) for Veterinary Drugs as adopted by the Codex Alimentarius Commission as its 40th Session (July 2017); and
- Part 2 - Draft and proposed draft MRLs and RMRs.

Part 1

A) MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS IN FOODS

ABAMECTIN (anthelmintic agent)

JECFA Evaluation: 45 (1995); 47 (1996)

Acceptable Daily Intake : 0-2 µg/kg body weight (1997) Established for the sum of abamectin and (Z)-8,9 isomer by the 1997 JMPR.

Residue Definition: Avermectin B1a.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Liver	100	26th (2003)	
Cattle	Kidney	50	26th (2003)	
Cattle	Fat	100	26th (2003)	

ALBENDAZOLE (anthelmintic agent)

JECFA Evaluation: 34 (1989)

Acceptable Daily Intake: 0-50 µg/kg body weight (34th JECFA, 1989).

Residue Definition: Except milk, 2-aminosulfone metabolite; Milk, not yet identified.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Not specified	Muscle	100	20th (1993)	
Not specified	Liver	5000	20th (1993)	
Not specified	Kidney	5000	20th (1993)	
Not specified	Fat	100	20th (1993)	
Not specified	Milk (µg/l)	100	20th (1993)	

AMOXICILLIN (antimicrobial agent)

JECFA Evaluation: 75 (2011)

Acceptable Daily Intake: 0-0.07 µg/kg body weight on the basis of microbiological effects (75th JECFA, 2011).

Estimated Dietary Exposure The 75th JECFA (2001) did not calculate an EDI for amoxicillin owing to the small number of quantifiable residue data points. Using the model diet of 300 g muscle, 100 g live, 50 g kidney, 50 g fat and 1.5 liter of milk with the MRLs recommended, the theoretical maximum daily intake (TMDI) is 31 µg/person, which represents 74% of the upper bound of the ADI.

Residue Definition: Amoxicillin

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Muscle	50	35th (2012)	
Cattle	Liver	50	35th (2012)	
Cattle	Kidney	50	35th (2012)	
Cattle	Fat	50	35th (2012)	
Cattle	Milk	4	35th (2012)	
Sheep	Muscle	50	35th (2012)	
Sheep	Liver	50	35th (2012)	
Sheep	Kidney	50	35th (2012)	
Sheep	Fat	50	35th (2012)	
Sheep	Milk	4	35th (2012)	
Pigs	Muscle	50	35th (2012)	
Pigs	Liver	50	35th (2012)	
Pigs	Kidney	50	35th (2012)	
Pigs	Fat/Skin	50	35th (2012)	

AVILAMYCIN (antimicrobial agent)

JECFA Evaluation: 70 (2008)

Acceptable Daily Intake: 0-2 mg/kg body weight on the basis of a NOAEL of 150 mg avilamycin activity/kg body weight per day and a safety factor of 100 and rounding to one significant figure (70th JECFA, 2008).

Residue Definition: Dichloroisoeverninic acid (DIA).

Species	Tissue	MRL (µg/kg)	CAC	Notes
Pigs	Muscle	200	32nd (2009)	
Pigs	Liver	300	32nd (2009)	
Pigs	Kidney	200	32nd (2009)	
Pigs	Fat/Skin	200	32nd (2009)	
Chicken	Muscle	200	32nd (2009)	
Chicken	Liver	300	32nd (2009)	
Chicken	Kidney	200	32nd (2009)	
Chicken	Fat/Skin	200	32nd (2009)	
Turkey	Muscle	200	32nd (2009)	
Turkey	Liver	300	32nd (2009)	
Turkey	Kidney	200	32nd (2009)	
Turkey	Fat/Skin	200	32nd (2009)	
Rabbits	Muscle	200	32nd (2009)	
Rabbits	Liver	300	32nd (2009)	
Rabbits	Kidney	200	32nd (2009)	
Rabbits	Fat/Skin	200	32nd (2009)	

AZAPERONE (tranquilizing agent)

JECFA Evaluation: 38 (1991); 43 (1994); 50 (1998); 52 (1999)

Acceptable Daily Intake: 0-6 µg/kg body weight (50th JECFA, 1998).

Residue Definition: Sum of azaperone and azaperol.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Pig	Muscle	60	23rd (1999)	
Pig	Liver	100	23rd (1999)	
Pig	Kidney	100	23rd (1999)	
Pig	Fat	60	23rd (1999)	

BENZYLPENICILLIN/PROCAINE BENZYLPENICILLIN (antimicrobial agent)

JECFA Evaluation: 36 (1990); 50 (1998)

Acceptable Daily Intake: 30 µg-penicillin/person/day (50th JECFA, 1998). Residues of benzylpenicillin and procaine benzylpenicillin should be kept below this level.

Residue Definition: Benzylpenicillin.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Muscle	50	23rd (1999)	
Cattle	Liver	50	23rd (1999)	
Cattle	Kidney	50	23rd (1999)	
Cattle	Milk (µg/l)	4	23rd (1999)	
Chicken	Muscle	50	23rd (1999)	Applies to procaine benzylpenicillin only.
Chicken	Liver	50	23rd (1999)	Applies to procaine benzylpenicillin only.
Chicken	Kidney	50	23rd (1999)	Applies to procaine benzylpenicillin only.
Pig	Muscle	50	23rd (1999)	
Pig	Liver	50	23rd (1999)	
Pig	Kidney	50	23rd (1999)	

CARAZOLOL (beta-adreniceptor-blocking agent)

JECFA Evaluation: 38 (1991); 43 (1994); 52 (1999)

Acceptable Daily Intake: 0-0.1 µg/kg body weight (43rd JECFA, 1994). ADI based on the acute pharmacological effects of carazolol.

Residue Definition: Carazolol**.**

Species	Tissue	MRL (µg/kg)	CAC	Notes
Pig	Muscle	5	26th (2003)	The concentration at the injection site two hours after treatment may result in an intake that exceeds the acute RfD and therefore, an appropriate withdrawal period should be applied.
Pig	Liver	25	26th (2003)	
Pig	Kidney	25	26th (2003)	
Pig	Fat/Skin	5	26th (2003)	The concentration at the injection site two hours after treatment may result in an intake that exceeds the acute RfD and therefore, an appropriate withdrawal period should be applied.

CEFTIOFUR (antimicrobial agent)

JECFA Evaluation: 45 (1995); 48 (1997)

Acceptable Daily Intake: 0-50 µg/kg body weight (45th JECFA, 1995).

Residue Definition: Desfuroylceftiofur.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Muscle	1000	23rd (1999)	
Cattle	Liver	2000	23rd (1999)	
Cattle	Kidney	6000	23rd (1999)	
Cattle	Fat	2000	23rd (1999)	
Cattle	Milk (µg/l)	100	23rd (1999)	
Pig	Muscle	1000	23rd (1999)	
Pig	Liver	2000	23rd (1999)	
Pig	Kidney	6000	23rd (1999)	
Pig	Fat	2000	23rd (1999)	

CHLORTETRACYCLINE/OXYTETRACYCLINE/TETRACYCLINE (antimicrobial agent)

JECFA Evaluation: 45 (1995); 47 (1996); 50 (1998); 58 (2002)

Acceptable Daily Intake: 0-30 µg/kg body weight (50th JECFA, 1998). Group ADI for chlortetracycline, oxytetracycline and tetracycline.

Residue Definition: Parent drugs, singly or in combination.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Muscle	200	26th (2003)	
Cattle	Liver	600	26th (2003)	
Cattle	Kidney	1200	26th (2003)	
Cattle	Milk (µg/l)	100	26th (2003)	
Fish	Muscle	200	26th (2003)	Applies only to oxytetracycline.
Giant prawn (*Paeneus monodon*)	Muscle	200	26th (2003)	Applies only to oxytetracycline.
Pig	Muscle	200	26th (2003)	
Pig	Liver	600	26th (2003)	
Pig	Kidney	1200	26th (2003)	
Poultry	Muscle	200	26th (2003)	
Poultry	Liver	600	26th (2003)	
Poultry	Kidney	1200	26th (2003)	
Poultry	Eggs	400	26th (2003)	
Sheep	Muscle	200	26th (2003)	
Sheep	Liver	600	26th (2003)	
Sheep	Kidney	1200	26th (2003)	
Sheep	Milk (µg/l)	100	26th (2003)	

CLENBUTEROL (adrenoceptor agonist)

JECFA Evaluation: 47 (1996)

Acceptable Daily Intake: 0-0.004 µg/kg body weight (47th JECFA, 1996).

Residue Definition: Clenbuterol.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Muscle	0.2	26th (2003)	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 adjunt therapy in respiratory diseases.
Cattle	Liver	0.6	26th (2003)	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 adjunt therapy in respiratory diseases.
Cattle	Kidney	0.6	26th (2003)	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 adjunt therapy in respiratory diseases.
Cattle	Fat	0.2	26th (2003)	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 adjunt therapy in respiratory diseases.
Cattle	Milk (µg/l)	0.05	26th (2003)	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 adjunt therapy in respiratory diseases.
Horse	Muscle	0.2	26th (2003)	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 adjunt therapy in respiratory diseases.
Horse	Liver	0.6	26th (2003)	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 adjunt therapy in respiratory diseases.
Horse	Kidney	0.6	26th (2003)	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 adjunt therapy in respiratory diseases.
Horse	Fat	0.2	26th (2003)	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 adjunt therapy in respiratory diseases.

CLOSANTEL (anthelmintic agent)

JECFA Evaluation: 36 (1990); 40 (1992)

Acceptable Daily Intake: 0-30 µg/kg body weight (40th JECFA, 1992).

Residue Definition: Closantel.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Muscle	1000	20th (1993)	
Cattle	Liver	1000	20th (1993)	
Cattle	Kidney	3000	20th (1993)	
Cattle	Fat	3000	20th (1993)	
Sheep	Muscle	1500	20th (1993)	
Sheep	Liver	1500	20th (1993)	
Sheep	Kidney	5000	20th (1993)	
Sheep	Fat	2000	20th (1993)	

COLISTIN (antimicrobial agent)

JECFA Evaluation: 66 (2006)

Acceptable Daily Intake: 0-7 µg/kg body weight (66th JECFA, 2006).

Residue Definition: Sum of colistin A and colistin B.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Muscle	150	31st (2008)	
Cattle	Liver	150	31st (2008)	
Cattle	Kidney	200	31st (2008)	
Cattle	Fat	150	31st (2008)	
Cattle	Milk	50	31st (2008)	
Sheep	Muscle	150	31st (2008)	
Sheep	Liver	150	31st (2008)	
Sheep	Kidney	200	31st (2008)	
Sheep	Fat	150	31st (2008)	
Sheep	Milk	50	31st (2008)	
Goat	Muscle	150	31st (2008)	
Goat	Liver	150	31st (2008)	
Goat	Kidney	200	31st (2008)	
Goat	Fat	150	31st (2008)	
Pig	Muscle	150	31st (2008)	
Pig	Liver	150	31st (2008)	
Pig	Kidney	200	31st (2008)	
Pig	Fat	150	31st (2008)	The MRL includes skin + fat
Chicken	Muscle	150	31st (2008)	
Chicken	Liver	150	31st (2008)	
Chicken	Kidney	200	31st (2008)	
Chicken	Fat	150	31st (2008)	The MRL includes skin + fat
Chicken	Eggs	300	31st (2008)	
Turkey	Muscle	150	31st (2008)	
Turkey	Liver	150	31st (2008)	
Turkey	Kidney	200	31st (2008)	
Turkey	Fat	150	31st (2008)	The MRL includes skin + fat
Rabbit	Muscle	150	31st (2008)	
Rabbit	Liver	150	31st (2008)	
Rabbit	Kidney	200	31st (2008)	
Rabbit	Fat	150	31st (2008)	

CYFLUTHRIN (insecticide)

JECFA Evaluation: 48 (1997)
Acceptable Daily Intake: 0-20 µg/kg body weight (48th JECFA, 1997).
Residue Definition: Cyfluthrin.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Muscle	20	26th (2003)	
Cattle	Liver	20	26th (2003)	
Cattle	Kidney	20	26th (2003)	
Cattle	Fat	200	26th (2003)	
Cattle	Milk (µg/l)	40	26th (2003)	

CYHALOTHRIN (insecticide)

JECFA Evaluation: 54 (2000); 58 (2002); 62 (2004)
Acceptable Daily Intake: 0-5 µg/kg body weight (62nd JECFA, 2004).
Residue Definition: Cyhalothrin.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Muscle	20	28th (2005)	
Cattle	Liver	20	28th (2005)	
Cattle	Kidney	20	28th (2005)	
Cattle	Fat	400	28th (2005)	
Cattle	Milk	30	28th (2005)	
Pig	Muscle	20	28th (2005)	
Pig	Liver	20	28th (2005)	
Pig	Kidney	20	28th (2005)	
Pig	Fat	400	28th (2005)	
Sheep	Muscle	20	28th (2005)	
Sheep	Liver	50	28th (2005)	
Sheep	Kidney	20	28th (2005)	
Sheep	Fat	400	28th (2005)	

CYPERMETHRIN AND ALPHA-CYPERMETHRIN (insecticide)

JECFA Evaluation: 62 (2004)

Acceptable Daily Intake: JECFA established a common ADI of 0-20 µg/kg bw for both cypermethrin and alpha-cypermethrin (62nd JECFA, 2004)..

Residue Definition: Total of cypermethrin residues (resulting from the use of cypermethrin or alpha-cypermethrin as veterinary drugs).

Species	Tissue	MRLs(µg/kg)	CAC	Note
Cattle	Muscle	50	29th (2006)	
Cattle	Liver	50	29th (2006)	
Cattle	Kidney	50	29th (2006)	
Cattle	Fat	1000	29th (2006)	
Cattle	Milk	100	29th (2006)	
Sheep	Muscle	50	29th (2006)	
Sheep	Liver	50	29th (2006)	
Sheep	Kidney	50	29th (2006)	
Sheep	Fat	1000	29th (2006)	

DANOFLOXACIN (antimicrobial agent)

JECFA Evaluation: 48 (1997)

Acceptable Daily Intake: 0-20 µg/kg body weight (48th JECFA, 1997).

Residue Definition: Danofloxacin.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Muscle	200	24th (2001)	
Cattle	Liver	400	24th (2001)	
Cattle	Kidney	400	24th (2001)	
Cattle	Fat	100	24th (2001)	
Chicken	Muscle	200	24th (2001)	
Chicken	Liver	400	24th (2001)	
Chicken	Kidney	400	24th (2001)	
Chicken	Fat	100	24th (2001)	Fat/skin in normal proportion.
Pig	Muscle	100	24th (2001)	
Pig	Liver	50	24th (2001)	
Pig	Kidney	200	24th (2001)	
Pig	Fat	100	24th (2001)	

DELTAMETHRIN (insecticide)

JECFA Evaluation: 52 (1999); 60 (2003)

Acceptable Daily Intake: 0-10 µg/kg body weight (1982). Established by the 1982 JMPR.

Residue Definition: Deltamethrin.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Muscle	30	26th (2003)	
Cattle	Liver	50	26th (2003)	
Cattle	Kidney	50	26th (2003)	
Cattle	Fat	500	26th (2003)	
Cattle	Milk	30	26th (2003)	
Chicken	Muscle	30	26th (2003)	
Chicken	Liver	50	26th (2003)	
Chicken	Kidney	50	26th (2003)	
Chicken	Fat	500	26th (2003)	
Chicken	Eggs	30	26th (2003)	
Salmon	Muscle	30	26th (2003)	
Sheep	Muscle	30	26th (2003)	
Sheep	Liver	50	26th (2003)	
Sheep	Kidney	50	26th (2003)	
Sheep	Fat	500	26th (2003)	

DERQUANTEL (anthelmintic agent)

JECFA Evaluation: 75 (2011); 78 (2013)

Acceptable Daily Intake: 0-0.3 µg/kg body weight on the basis of a lowest-observed-adverse-effect level (LOAEL) of 0.1 mg/kg body weight 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 (75th JECFA, 2011).

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 (78th JECFA, 2013).

Residue Definition: Derquantel.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Sheep	Muscle	0.3	38th (2015)	
Sheep	Liver	0.8	38th (2015)	
Sheep	Kidney	0.4	38th (2015)	
Sheep	Fat	7.0	38th (2015)	

DEXAMETHASONE (glucocorticosteroid)

JECFA Evaluation: 70 (2008)
Acceptable Daily Intake: 0-0.015 µg/kg body weight (42nd JECFA, 1995).
Residue Definition: Dexamethasone.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Muscle	1.0	32nd (2009)	
Cattle	Liver	2.0	32nd (2009)	
Cattle	Kidney	1.0	32nd (2009)	
Cattle	Milk (µg/l)	0.3	32nd (2009)	
Pig	Muscle	1.0	32nd (2009)	
Pig	Liver	2.0	32nd (2009)	
Pig	Kidney	1.0	32nd (2009)	
Horses	Muscle	1.0	32nd (2009)	
Horses	Liver	2.0	32nd (2009)	
Horses	Kidney	1.0	32nd (2009)	

DICLAZURIL (antiprotozoal agent)

JECFA Evaluation: 45 (1995); 50 (1998)
Acceptable Daily Intake: 0-30 µg/kg body weight (50th JECFA, 1998).
Residue Definition: Diclazuril.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Poultry	Muscle	500	23rd (1999)	
Poultry	Liver	3000	23rd (1999)	
Poultry	Kidney	2000	23rd (1999)	
Poultry	Fat/Skin	1000	23rd (1999)	
Rabbit	Muscle	500	23rd (1999)	
Rabbit	Liver	3000	23rd (1999)	
Rabbit	Kidney	2000	23rd (1999)	
Rabbit	Fat	1000	23rd (1999)	
Sheep	Muscle	500	23rd (1999)	
Sheep	Liver	3000	23rd (1999)	
Sheep	Kidney	2000	23rd (1999)	
Sheep	Fat	1000	23rd (1999)	

DICYCLANIL (insecticide)

JECFA Evaluation: 54 (2000); 60 (2003)

Acceptable Daily Intake: 0-7 µg/kg body weight (54th JECFA, 2000).

Residue Definition: Dicyclanil.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Sheep	Muscle	150	28th (2005)	
Sheep	Liver	125	28th (2005)	
Sheep	Kidney	125	28th (2005)	
Sheep	Fat	200	28th (2005)	

DIHYDROSTREPTOMYCIN/STREPTOMYCIN (antimicrobial agent)

JECFA Evaluation: 43 (1994); 48 (1997); 52 (1999); 58 (2002)

Acceptable Daily Intake: 0-50 µg/kg body weight (48th JECFA, 1997). Group ADI for combined residues of dihydrostreptomycin and streptomycin.

Residue Definition: Sum of dihydrostreptomycin and streptomycin.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Muscle	600	24th (2001)	
Cattle	Liver	600	24th (2001)	
Cattle	Kidney	1000	24th (2001)	
Cattle	Fat	600	24th (2001)	
Cattle	Milk	200	26th (2003)	
Chicken	Muscle	600	24th (2001)	
Chicken	Liver	600	24th (2001)	
Chicken	Kidney	1000	24th (2001)	
Chicken	Fat	600	24th (2001)	
Pig	Muscle	600	24th (2001)	
Pig	Liver	600	24th (2001)	
Pig	Kidney	1000	24th (2001)	
Pig	Fat	600	24th (2001)	
Sheep	Muscle	600	24th (2001)	
Sheep	Liver	600	24th (2001)	
Sheep	Kidney	1000	24th (2001)	
Sheep	Fat	600	24th (2001)	
Sheep	Milk	200	26th (2003)	

DIMINAZENE (trypanocide)

JECFA Evaluation: 34 (1989); 42 (1994)

Acceptable Daily Intake: 0-100 µg/kg body weight (42nd JECFA, 1994).

Residue Definition: Diminazene.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Muscle	500	22nd (1997)	
Cattle	Liver	12000	22nd (1997)	
Cattle	Kidney	6000	22nd (1997)	
Cattle	Milk (µg/l)	150	22nd (1997)	Limit of quantitation of the analytical method.

DORAMECTIN (anthelmintic agent)

JECFA Evaluation: 45 (1995); 52 (1999); 58 (2002); 62 (2004)

Acceptable Daily Intake: 0-1 µg/kg body weight (58th JECFA, 2002).

Residue Definition: Doramectin.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Muscle	10	22nd (1997)	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	22nd (1997)	
Cattle	Kidney	30	22nd (1997)	
Cattle	Fat	150	22nd (1997)	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	29th (2006)	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	24th (2001)	
Pig	Liver	100	24th (2001)	
Pig	Kidney	30	24th (2001)	
Pig	Fat	150	24th (2001)	

EMAMECTIN BENZOATE (antiparasitic agent)

JECFA Evaluation: 78 (2013)

Acceptable Daily Intake: ADI of 0–0.5 µg/kg body weight established by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) in 2011, based on an overall no-observed-adverse effect level (NOAEL) of 0.25 mg/kg body weight per day for neurotoxicity from 14- and 53-week studies in dogs, supported by an overall NOAEL of 0.25 mg/kg body weight 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 lowest-observed-adverse-effect level (LOAEL) in dogs, as used by JMPR and confirmed by the current Committee (78th JECFA, 2013).

Estimated Dietary Exposure: 11 µg/person per day, which represents approximately 37% of the upper bound of the ADI (78th JECFA, 2013).

Residue Definition: Emamectin B1a.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Salmon	Muscle	100	38th (2015)	
Salmon	Fillet	100	38th (2015)	Muscle plus skin in natural proportion
Trout	Muscle	100	38th (2015)	
Trout	Fillet	100	38th (2015)	Muscle plus skin in natural proportion

EPRINOMECTIN (anthelmintic agent)

JECFA Evaluation: 50 (1998)

Acceptable Daily Intake: 0-10 µg/kg body weight (50th JECFA, 1998).

Residue Definition: Eprinomectin B1a.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Muscle	100	26th (2003)	
Cattle	Liver	2000	26th (2003)	
Cattle	Kidney	300	26th (2003)	
Cattle	Fat	250	26th (2003)	
Cattle	Milk (µg/l)	20	26th (2003)	

ERYTHROMYCIN (antimicrobial agent)

JECFA Evaluation: 66 (2006)

Acceptable Daily Intake: 0-0.7 µg/kg body weight (66th JECFA, 2006).

Residue Definition: Erythromycin A

Species	Tissue	MRL (µg/kg)	CAC	Notes
Chicken	Muscle	100	31st (2008)	
Chicken	Liver	100	31st (2008)	
Chicken	Kidney	100	31st (2008)	
Chicken	Fat	100	31st (2008)	The MRL includes skin + fat
Chicken	Eggs	50	31st (2008)	
Turkey	Muscle	100	31st (2008)	
Turkey	Liver	100	31st (2008)	
Turkey	Kidney	100	31st (2008)	
Turkey	Fat	100	31st (2008)	The MRL includes skin + fat

ESTRADIOL-17BETA (production aid)

JECFA Evaluation: 25 (1981); 32 (1987); 52 (1999)

Acceptable Daily Intake: unnecessary (32nd JECFA, 1987); 0-0.05 µg/kg body weight (52nd JECFA, 1999).

Residue Definition: Estradiol-17beta.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Muscle	unnecessary	21st (1995)	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	21st (1995)	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	21st (1995)	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	21st (1995)	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.

FEBANTEL/FENBENDAZOLE/OXFENDAZOLE (anthelmintic agent)

JECFA Evaluation: 38 (1991); 45 (1995); 50 (1998)

Acceptable Daily Intake: 0-7 µg/kg body weight (50th JECFA, 1998). Group ADI

Residue Definition: Sum of fenbendazole, oxfendazole and oxfendazole sulphone, expressed as oxfendazole sulphone equivalents.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Muscle	100	23rd (1999)	
Cattle	Liver	500	23rd (1999)	
Cattle	Kidney	100	23rd (1999)	
Cattle	Fat	100	23rd (1999)	
Cattle	Milk (µg/l)	100	23rd (1999)	
Goat	Muscle	100	23rd (1999)	
Goat	Liver	500	23rd (1999)	
Goat	Kidney	100	23rd (1999)	
Goat	Fat	100	23rd (1999)	
Horse	Muscle	100	23rd (1999)	
Horse	Liver	500	23rd (1999)	
Horse	Kidney	100	23rd (1999)	
Horse	Fat	100	23rd (1999)	
Pig	Muscle	100	23rd (1999)	
Pig	Liver	500	23rd (1999)	
Pig	Kidney	100	23rd (1999)	
Pig	Fat	100	23rd (1999)	
Sheep	Muscle	100	23rd (1999)	
Sheep	Liver	500	23rd (1999)	
Sheep	Kidney	100	23rd (1999)	
Sheep	Fat	100	23rd (1999)	
Sheep	Milk (µg/l)	100	23rd (1999)	

FLUAZURON (insecticide)

JECFA Evaluation: 48 (1997)

Acceptable Daily Intake: 0-40 µg/kg body weight (48th JECFA, 1997).

Residue Definition: Fluazuron.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Muscle	200	23rd (1999)	
Cattle	Liver	500	23rd (1999)	
Cattle	Kidney	500	23rd (1999)	
Cattle	Fat	7000	23rd (1999)	

FLUBENDAZOLE (anthelmintic agent)

JECFA Evaluation: 40 (1992)
Acceptable Daily Intake: 0-12 µg/kg body weight (40th JECFA, 1992).
Residue Definition: Flubendazole.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Pig	Muscle	10	21st (1995)	
Pig	Liver	10	21st (1995)	
Poultry	Muscle	200	21st (1995)	
Poultry	Liver	500	21st (1995)	
Poultry	Eggs	400	21st (1995)	

FLUMEQUINE (antimicrobial agent)

JECFA Evaluation: 42 (1994); 48 (1997); 54 (2000); 60 (2002); 62 (2004); 66 (2006)
Acceptable Daily Intake: 0-30 µg/kg body weight (62nd JECFA, 2004).
Residue Definition: Flumequine.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Muscle	500	28th (2005)	
Cattle	Liver	500	28th (2005)	
Cattle	Kidney	3000	28th (2005)	
Cattle	Fat	1000	28th (2005)	
Chicken	Muscle	500	28th (2005)	
Chicken	Liver	500	28th (2005)	
Chicken	Kidney	3000	28th (2005)	
Chicken	Fat	1000	28th (2005)	
Pig	Muscle	500	28th (2005)	
Pig	Liver	500	28th (2005)	
Pig	Kidney	3000	28th (2005)	
Pig	Fat	1000	28th (2005)	
Sheep	Muscle	500	28th (2005)	
Sheep	Liver	500	28th (2005)	
Sheep	Kidney	3000	28th (2005)	
Sheep	Fat	1000	28th (2005)	
Trout	Muscle	500	28th (2005)	Muscle including normal proportion of skin

GENTAMICIN (antimicrobial agent)

JECFA Evaluation: 43 (1994); 48 (1997); 50 (1998)
Acceptable Daily Intake: 0-20 µg/kg body weight (50th JECFA, 1998).
Residue Definition: Gentamicin.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Muscle	100	24th (2001)	
Cattle	Liver	2000	24th (2001)	
Cattle	Kidney	5000	24th (2001)	
Cattle	Fat	100	24th (2001)	
Cattle	Milk (µg/l)	200	24th (2001)	
Pig	Muscle	100	24th (2001)	
Pig	Liver	2000	24th (2001)	
Pig	Kidney	5000	24th (2001)	
Pig	Fat	100	24th (2001)	

IMIDOCARB (antiprotozoal agent)

JECFA Evaluation: 50 (1998); 60 (2003)
Acceptable Daily Intake: 0-10 µg/kg body weight (50th JECFA, 1998).
Residue Definition: Imidocarb.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Muscle	300	28th (2005)	
Cattle	Liver	1500	28th (2005)	
Cattle	Kidney	2000	28th (2005)	
Cattle	Fat	50	28th (2005)	
Cattle	Milk	50	28th (2005)	

ISOMETAMIDIUM (trypanocide)

JECFA Evaluation: 34 (1989); 40 (1992)
Acceptable Daily Intake: 0-100 µg/kg body weight (40th JECFA, 1992).
Residue Definition: Isometamidium.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Muscle	100	21st (1995)	
Cattle	Liver	500	21st (1995)	
Cattle	Kidney	1000	21st (1995)	
Cattle	Fat	100	21st (1995)	
Cattle	Milk (µg/l)	100	21st (1995)	

IVERMECTIN (anthelmintic agent)

JECFA Evaluation: 36 (1990); 40 (1992); 54 (2000); 58 (2002); 81 (2015)

Acceptable Daily Intake: 0-10 µg/kg body weight on the basis of a no-observed-adverse-effect level (NOAEL) of 0.5 mg/kg body weight per day for neurological effects (mydriasis) and retardation of weight gain in a 14-week dog study, with application of an uncertainty factor of 50 (5 for interspecies differences based on pharmacokinetic studies in dogs and humans and 10 for intraspecies differences). The previous ADI of 0-1 µg/kg body weight was withdrawn. (81st JECFA, 2015)

Acute Reference dose (ARfD): 0.2 mg/kg body weight, based on a NOAEL of 1.5 mg/kg body weight, the highest dose tested in a safety, tolerability and pharmacokinetics study in healthy human subjects, with application of an uncertainty factor of 10 for intraspecies variability. (81st JECFA, 2015)

Estimated chronic dietary exposure (GECDE): The estimated daily intake (EDI) is 38 µg/person per day, based on a 60 kg individual, which represents 6% of the upper bound of the ADI. The global estimate of chronic dietary exposure (GECDE) for the general population is 0.9 µg/kg body weight per day, which represents 9% of the upper bound of the ADI. The GECDE for children is 1.5 µg/kg body weight per day, which represents 15% of the upper bound of the ADI. The GECDE for infants is 1.3 µg/kg body weight per day, which represents 13% of the upper bound of the ADI. (81st JECFA, 2015)

Estimated Acute Dietary Exposure (GEADE): A combined analysis of all studies submitted showed that after 14 days, the maximum values of residues found at injection sites led to a Global Estimate of Acute Dose Exposure (GEADE) of 52 µg/kg bw for the general population and 87 µg/kg bw for children, corresponding, respectively, to 27% and 43% of the ARfD. (81st JECFA, 2015)

Residue Definition: Ivermectin B_{1a}

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Muscle	30	40th (2017)	
Cattle	Liver	800	40th (2017)	
Cattle	Kidney	100	40th (2017)	
Cattle	Fat	400	40th (2017)	
Cattle	Milk	10	26th (2003)	
Pig	Liver	15	20th (1993)	
Pig	Fat	20	20th (1993)	
Sheep	Liver	15	20th (1993)	
Sheep	Fat	20	20th (1993)	

LASALOCID SODIUM (antiparasitic agent)

JECFA Evaluation: 78 (2013)

Acceptable Daily Intake: 0-5 µg/kg body weight on the basis of a NOAEL of 0.5 mg/kg body weight 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 (78th JECFA, 2013).

Estimated Dietary Exposure (EDI): 80 µg/person per day was calculated, which represents approximately 27% of the upper bound of the ADI (78th JECFA, 2013).

Residue Definition: Lasalocid A.

Note: the 78th JECFA 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)	CAC	Notes
Chicken	Muscle	400	40th (2017)	
Chicken	Liver	1200	40th (2017)	
Chicken	Kidney	600	40th (2017)	
Chicken	Skin + Fat	600	40th (2017)	
Turkey	Muscle	400	40th (2017)	
Turkey	Liver	1200	40th (2017)	
Turkey	Kidney	600	40th (2017)	
Turkey	Skin + Fat	600	40th (2017)	
Quail	Muscle	400	40th (2017)	
Quail	Liver	1200	40th (2017)	
Quail	Kidney	600	40th (2017)	
Quail	Skin + Fat	600	40th (2017)	
Pheasant	Muscle	400	40th (2017)	
Pheasant	Liver	1200	40th (2017)	
Pheasant	Kidney	600	40th (2017)	
Pheasant	Skin + Fat	600	40th (2017)	

LEVAMISOLE (anthelmintic agent)

JECFA Evaluation: 36 (1990); 42 (1994)

Acceptable Daily Intake: 0-6 µg/kg body weight (42nd JECFA, 1994).

Residue Definition: Levamisole.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Muscle	10	22nd (1997)	
Cattle	Liver	100	22nd (1997)	
Cattle	Kidney	10	22nd (1997)	
Cattle	Fat	10	22nd (1997)	
Pig	Muscle	10	22nd (1997)	
Pig	Liver	100	22nd (1997)	
Pig	Kidney	10	22nd (1997)	
Pig	Fat	10	22nd (1997)	
Poultry	Muscle	10	22nd (1997)	
Poultry	Liver	100	22nd (1997)	
Poultry	Kidney	10	22nd (1997)	
Poultry	Fat	10	22nd (1997)	
Sheep	Muscle	10	22nd (1997)	
Sheep	Liver	100	22nd (1997)	
Sheep	Kidney	10	22nd (1997)	
Sheep	Fat	10	22nd (1997)	

LINCOMYCIN (antimicrobial agent)

JECFA Evaluation: 54 (2000); 58 (2002); 62 (2004)

Acceptable Daily Intake: 0-30 µg/kg body weight (54th JECFA, 2000).

Residue Definition: Lincomycin.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Milk	150	26th (2003)	
Chicken	Muscle	200	26th (2003)	
Chicken	Liver	500	26th (2003)	
Chicken	Kidney	500	26th (2003)	
Chicken	Fat	100	26th (2003)	Additional MRL for skin with adhering fat of 300 µg/kg.
Pig	Muscle	200	26th (2003)	
Pig	Liver	500	26th (2003)	
Pig	Kidney	1500	26th (2003)	
Pig	Fat	100	26th (2003)	Additional MRL for skin with adhering fat of 300 µg/kg.

MELENGESTROL ACETATE (production aid)

JECFA Evaluation: 54 (2000); 58 (2002); 62 (2004); 66 (2006) 70 (2008)

Acceptable Daily Intake: 0-0.03 µg/kg body weight (54th JECFA, 2000).

Residue Definition: Melengestrol acetate.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Muscle	1	32nd (2009)	
Cattle	Liver	10	32nd (2009)	
Cattle	Kidney	2	32nd (2009)	
Cattle	Fat	18	32nd (2009)	

MONENSIN (antimicrobial agent)

JECFA Evaluation: 70 (2008); 75 (2011)

Acceptable Daily Intake: 0–10 µg/kg body weight on the basis of a NOAEL of 1.14 mg/kg body weight per day and a safety factor of 100 and rounding to one significant figure (70th JECFA, 2008).

Estimated Dietary Exposure: Using the revised MRL, the theoretical maximum daily intake (TMDI) from the 70th JECFA was recalculated, resulting in a value of 481 µg/person, which represents 80% of the upper bound of the ADI (75thJECFA, 2011).

Residue Definition: Monensin.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Muscle	10	32nd (2009)	
Cattle	Liver	100	35th (2012)	
Cattle	Kidney	10	32nd (2009)	
Cattle	Fat	100	32nd (2009)	
Cattle	Milk	2	32nd (2009)	
Sheep	Muscle	10	32nd (2009)	
Sheep	Liver	20	32nd (2009)	
Sheep	Kidney	10	32nd (2009)	
Sheep	Fat	100	32nd (2009)	
Goats	Muscle	10	32nd (2009)	
Goats	Liver	20	32nd (2009)	
Goats	Kidney	10	32nd (2009)	
Goats	Fat	100	32nd (2009)	
Chicken	Muscle	10	32nd (2009)	
Chicken	Liver	10	32nd (2009)	
Chicken	Kidney	10	32nd (2009)	
Chicken	Fat	100	32nd (2009)	
Turkey	Muscle	10	32nd (2009)	
Turkey	Liver	10	32nd (2009)	
Turkey	Kidney	10	32nd (2009)	
Turkey	Fat	100	32nd (2009)	
Quail	Muscle	10	32nd (2009)	
Quail	Liver	10	32nd (2009)	
Quail	Kidney	10	32nd (2009)	
Quail	Fat	100	32nd (2009)	

MONEPANTEL (anthelmintic agent)

JECFA Evaluation: 75 (2011); 78 (2013)

Acceptable Daily Intake: 0-20 µg/kg body weight on the basis of a no-observed-adverse-effect level (NOAEL) of 1.8 mg/kg body weight per day considering liver effects in mice, and a safety factor of 100, with rounding to one significant figure (75th JECFA, 2011).

Estimated Dietary Exposure: Using the model diet and marker residue to total residue ratios of 1.00 for muscle and 0.66 for fat, liver and kidney, and applying a correction factor of 0.94 to account for the mass difference between monepantel sulfone (the marker residue) and monepantel, the EDI is 446 µg/person per day, which represents approximately 37% of the upper bound of the ADI (78th JECFA, 2013).

Residue Definition: Monepantel sulfone, expressed as monepantel.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Sheep	Muscle	500	38th (2015)	
Sheep	Liver	7000	38th (2015)	
Sheep	Kidney	1700	38th (2015)	
Sheep	Fat	13000	38th (2015)	

MOXIDECTIN (anthelmintic agent)

JECFA Evaluation: 45 (1995); 47 (1996); 48 (1998); 50 (1998)

Acceptable Daily Intake: 0-2 µg/kg body weight (45th JECFA, 1995).

Residue Definition: Moxidectin.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Muscle	20	22nd (1997)	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	22nd (1997)	
Cattle	Kidney	50	22nd (1997)	
Cattle	Fat	500	22nd (1997)	
Deer	Muscle	20	23rd (1999)	
Deer	Liver	100	23rd (1999)	
Deer	Kidney	50	23rd (1999)	
Deer	Fat	500	23rd (1999)	
Sheep	Muscle	50	22nd (1997)	
Sheep	Liver	100	22nd (1997)	
Sheep	Kidney	50	22nd (1997)	
Sheep	Fat	500	22nd (1997)	

NARASIN (antimicrobial agent)

JECFA Evaluation: 70 (2008); 75 (2011)

Acceptable Daily Intake: 0-5 µg/kg body weight on the basis of a NOAEL of 0.5 mg/kg body weight per day and a safety factor of 100 (70th JECFA, 2008).

Residue Definition: Narasin A.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Muscle	15	35th (2012)	
Cattle	Liver	50	35th (2012)	
Cattle	Kidney	15	35th (2012)	
Cattle	Fat	50	35th (2012)	
Chicken	Muscle	15	32nd (2009)	
Chicken	Liver	50	32nd (2009)	
Chicken	Kidney	15	32nd (2009)	
Chicken	Fat	50	32nd (2009)	
Pig	Muscle	15	34th (2011)	
Pig	Liver	50	34th (2011)	
Pig	Kidney	15	34th (2011)	
Pig	Fat	50	34th (2011)	

NEOMYCIN (antimicrobial agent)

JECFA Evaluation: 43 (1994); 47 (1996); 52 (1999); 58 (2002); 60 (2003)

Acceptable Daily Intake: 0-60 µg/kg body weight (47th JECFA, 1996).

Residue Definition: Neomycin.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Muscle	500	23rd (1999)	
Cattle	Liver	500	28th (2005)	
Cattle	Kidney	10000	28th (2005)	
Cattle	Fat	500	23rd (1999)	
Cattle	Milk	1500	28th (2005)	
Chicken	Muscle	500	23rd (1999)	
Chicken	Liver	500	23rd (1999)	
Chicken	Kidney	10000	23rd (1999)	
Chicken	Fat	500	23rd (1999)	
Chicken	Eggs	500	23rd (1999)	
Duck	Muscle	500	23rd (1999)	
Duck	Liver	500	23rd (1999)	
Duck	Kidney	10000	23rd (1999)	
Duck	Fat	500	23rd (1999)	
Goat	Muscle	500	23rd (1999)	
Goat	Liver	500	23rd (1999)	
Goat	Kidney	10000	23rd (1999)	
Goat	Fat	500	23rd (1999)	
Pig	Muscle	500	23rd (1999)	
Pig	Liver	500	23rd (1999)	
Pig	Kidney	10000	23rd (1999)	
Pig	Fat	500	23rd (1999)	
Sheep	Muscle	500	23rd (1999)	
Sheep	Liver	500	23rd (1999)	
Sheep	Kidney	10000	23rd (1999)	
Sheep	Fat	500	23rd (1999)	
Turkey	Muscle	500	23rd (1999)	
Turkey	Liver	500	23rd (1999)	
Turkey	Kidney	10000	23rd (1999)	
Turkey	Fat	500	23rd (1999)	

NICARBAZIN (antiprotozoal agent)

JECFA Evaluation: 50 (1998)
Acceptable Daily Intake: 0-400 µg/kg body weight (50th JECFA, 1998).
Residue Definition: N,N'-bis(4-nitropheyl)urea.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Chicken	Muscle	200	23rd (1999)	Broilers.
Chicken	Liver	200	23rd (1999)	Broilers.
Chicken	Kidney	200	23rd (1999)	Broilers.
Chicken	Fat/Skin	200	23rd (1999)	Broilers.

PHOXIM (insecticide)

JECFA Evaluation: 52 (1999); 62 (2004)
Acceptable Daily Intake: 0-4 µg/kg body weight (52nd JECFA, 1999).
Residue Definition: Phoxim

Species	Tissue	MRL (µg/kg)	CAC	Notes
Goat	Muscle	50	26th (2003)	
Goat	Liver	50	26th (2003)	
Goat	Kidney	50	26th (2003)	
Goat	Fat	400	26th (2003)	
Pig	Muscle	50	26th (2003)	
Pig	Liver	50	26th (2003)	
Pig	Kidney	50	26th (2003)	
Pig	Fat	400	26th (2003)	
Sheep	Muscle	50	26th (2003)	
Sheep	Liver	50	26th (2003)	
Sheep	Kidney	50	26th (2003)	
Sheep	Fat	400	26th (2003)	

PIRLIMYCIN (antimicrobial agent)

JECFA Evaluation: 62 (2004)

Acceptable Daily Intake: 0-8 µg/kg bw (62nd JECFA, 2004).

Residue Definition: Pirlimycin.

Species	Tissue	MRLs (µg/kg)	CAC	Note
Cattle	Muscle	100	29th (2006)	
Cattle	Liver	1000	29th (2006)	
Cattle	Kidney	400	29th (2006)	
Cattle	Fat	100	29th (2006)	
Cattle	Milk	100	29th (2006)	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.

PORCINE SOMATOTROPIN (production aid)

JECFA Evaluation: 52 (1999)

Acceptable Daily Intake: Not Specified (52nd JECFA, 1999).

Residue Definition: Not applicable.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Pig	Muscle	not specified	26th (2003)	
Pig	Liver	not specified	26th (2003)	
Pig	Kidney	not specified	26th (2003)	
Pig	Fat	not specified	26th (2003)	

PROGESTERONE (production aid)

JECFA Evaluation: 25 (1981); 32 (1987); 52 (1999)

Acceptable Daily Intake: 0-30 µg/kg body weight (52nd JECFA, 1999).

Residue Definition: Progesterone.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Muscle	unnecessary	21st (2005)	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	21st (2005)	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	21st (2005)	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	21st (2005)	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

RACTOPAMINE (production aid)

JECFA Evaluation: 40 (1992); 62 (2004); 66 (2006)

Acceptable Daily Intake: 0-1 µg/kg body weight (66th JECFA, 2006).

Residue Definition: Ractopamine.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Muscle	10	35th (2012)	
Cattle	Liver	40	35th (2012)	
Cattle	Kidney	90	35th (2012)	
Cattle	Fat	10	35th (2012)	
Pig	Muscle	10	35th (2012)	
Pig	Liver	40	35th (2012)	
Pig	Kidney	90	35th (2012)	
Pig	Fat	10	35th (2012)	The MRL includes skin + fat

SARAFLOXACIN (antimicrobial agent)

JECFA Evaluation: 50 (1998)
Acceptable Daily Intake: 0-0.3 µg/kg body weight (50th JECFA, 1998).
Residue Definition: Sarafloxacin.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Chicken	Muscle	10	24th (2001)	
Chicken	Liver	80	24th (2001)	
Chicken	Kidney	80	24th (2001)	
Chicken	Fat	20	24th (2001)	
Turkey	Muscle	10	24th (2001)	
Turkey	Liver	80	24th (2001)	
Turkey	Kidney	80	24th (2001)	
Turkey	Fat	20	24th (2001)	

SPECTINOMYCIN (antimicrobial agent)

JECFA Evaluation: 42 (1994); 50 (1998)
Acceptable Daily Intake: 0-40 µg/kg body weight (42nd JECFA, 1994).
Residue Definition: Spectinomycin.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Muscle	500	23rd (1999)	
Cattle	Liver	2000	23rd (1999)	
Cattle	Kidney	5000	23rd (1999)	
Cattle	Fat	2000	23rd (1999)	
Cattle	Milk (µg/l)	200	23rd (1999)	
Chicken	Muscle	500	23rd (1999)	
Chicken	Liver	2000	23rd (1999)	
Chicken	Kidney	5000	23rd (1999)	
Chicken	Fat	2000	23rd (1999)	
Chicken	Eggs	2000	23rd (1999)	
Pig	Muscle	500	23rd (1999)	
Pig	Liver	2000	23rd (1999)	
Pig	Kidney	5000	23rd (1999)	
Pig	Fat	2000	23rd (1999)	
Sheep	Muscle	500	23rd (1999)	
Sheep	Liver	2000	23rd (1999)	
Sheep	Kidney	5000	23rd (1999)	
Sheep	Fat	2000	23rd (1999)	

SPIRAMYCIN (antimicrobial agent)

JECFA Evaluation: 38 (1991); 43 (1994); 47 (1996); 48 (1997)

Acceptable Daily Intake: 0-50 µg/kg body weight (43rd JECFA, 1994).

Residue Definition: Cattle and chickens, sum of spiramycin and neospiramycin; Pigs, spiramycin equivalents (antimicrobially active residues).

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Muscle	200	22nd (1997)	
Cattle	Liver	600	22nd (1997)	
Cattle	Kidney	300	22nd (1997)	
Cattle	Fat	300	22nd (1997)	
Cattle	Milk (µg/l)	200	22nd (1997)	
Chicken	Muscle	200	22nd (1997)	
Chicken	Liver	600	22nd (1997)	
Chicken	Kidney	800	22nd (1997)	
Chicken	Fat	300	22nd (1997)	
Pig	Muscle	200	22nd (1997)	
Pig	Liver	600	22nd (1997)	
Pig	Kidney	300	22nd (1997)	
Pig	Fat	300	22nd (1997)	

SULFADIMIDINE (antimicrobial agent)

JECFA Evaluation: 34 (1989); 38 (1991); 42 (1994)

Acceptable Daily Intake: 0-50 µg/kg body weight (42nd JECFA, 1994).

Residue Definition: Sulfadimidine.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Milk (µg/l)	25	21st (1995)	
Not specified	Muscle	100	21st (1995)	
Not specified	Liver	100	21st (1995)	
Not specified	Kidney	100	21st (1995)	
Not specified	Fat	100	21st (1995)	

TEFLUBENZURON (insecticide)

JECFA Evaluation: 81 (2015)

Acceptable Daily Intake: 0-5 µg/kg body weight on the basis of a lower 95% confidence limit on the benchmark dose for a 10% response (BMDL10) of 0.54 mg/kg body weight 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. (81st JECFA, 2015).

Estimated chronic dietary exposure (GECDE): 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 body weight per day, which represents 31% of the upper bound of the ADI. The GECDE for children is 2.1 µg/kg body weight per day, which represents 43% of the upper bound of the ADI. The GECDE for infants is 0.9 µg/kg body weight per day, which represents 18% of the upper bound of the ADI. (81st JECFA, 2015)

Residue Definition: Teflubenzuron.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Salmon	Muscle	400	40th (2017)	
Salmon	Fillet	400	40th (2017)	Muscle plus skin in natural proportion

TESTOSTERONE (production aid)

JECFA Evaluation: 25 (1981); 32 (1987); 52 (1999)

Acceptable Daily Intake: 0-2 µg/kg body weight (52nd JECFA, 1999).

Residue Definition: Testosterone.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Muscle	unnecessary	21st (1995)	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	21st (1995)	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	21st (1995)	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	21st (1995)	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)

JECFA Evaluation: 40 (1992); 48 (1997); 58 (2002)

Acceptable Daily Intake: 0-100 µg/kg body weight (40th JECFA, 1992).

Residue Definition: Sum of thiabendazole and 5-hydroxythiabendazole.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Muscle	100	21st (1995)	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.
Cattle	Liver	100	21st (1995)	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.
Cattle	Kidney	100	21st (1995)	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.
Cattle	Fat	100	21st (1995)	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.
Cattle	Milk (µg/l)	100	21st (1995)	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.
Goat	Muscle	100	21st (1995)	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.
Goat	Liver	100	21st (1995)	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.
Goat	Kidney	100	21st (1995)	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.
Goat	Fat	100	21st (1995)	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.
Goat	Milk (µg/l)	100	21st (1995)	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.
Pig	Muscle	100	21st (1995)	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.
Pig	Liver	100	21st (1995)	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.
Pig	Kidney	100	21st (1995)	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.
Pig	Fat	100	21st (1995)	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.
Sheep	Muscle	100	21st (1995)	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.

Sheep	Liver	100	21st (1995)	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.
Sheep	Kidney	100	21st (1995)	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.
Sheep	Fat	100	21st (1995)	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.

TILMICOSIN (antimicrobial agent)

JECFA Evaluation: 47 (1996); 54 (2000); 70 (2008)

Acceptable Daily Intake: 0-40 µg/kg body weight (47th JECFA, 1996).

Residue Definition: Tilmicosin.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Muscle	100	23rd (1999)	
Cattle	Liver	1000	23rd (1999)	
Cattle	Kidney	300	23rd (1999)	
Cattle	Fat	100	23rd (1999)	
Chicken	Muscle	150	34th (2011)	
Chicken	Liver	2400	34th (2011)	
Chicken	Kidney	600	34th (2011)	
Chicken	Skin/Fat	250	34th (2011)	
Pig	Muscle	100	23rd (1999)	
Pig	Liver	1500	23rd (1999)	
Pig	Kidney	1000	23rd (1999)	
Pig	Fat	100	23rd (1999)	
Sheep	Muscle	100	23rd (1999)	
Sheep	Liver	1000	23rd (1999)	
Sheep	Kidney	300	23rd (1999)	
Sheep	Fat	100	23rd (1999)	
Turkey	Muscle	100	34th (2011)	
Turkey	Kidney	1200	34th (2011)	
Turkey	Liver	1400	34th (2011)	
Turkey	Skin/Fat	250	34th (2011)	

TRENBOLONE ACETATE (growth promoter)

JECFA Evaluation: 26 (1982); 27 (1983); 32 (1987); 34 (1989)

Acceptable Daily Intake: 0-0.02 µg/kg body weight (34th JECFA, 1989).

Residue Definition: Cattle muscle, beta-Trenbolone; Cattle liver, alpha-Trenbolone.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Muscle	2	21st (1995)	
Cattle	Liver	10	21st (1995)	

TRICHLORFON (Metrifonate) (insecticide)

JECFA Evaluation: 54 (2000); 60 (2003); 66 (2006)

Acceptable Daily Intake: 0-2 µg/kg bw (60th JECFA, 2003)

Residue Definition: JECFA confirmed the MRL for cows's milk and the guidance levels for muscle, liver, kidney and fat of cattle recommended at the 54th meeting (WHO TRS 900, 2001)

Species	Tissue	MRLs (µg/kg)	CAC	Notes
Cattle	Milk	50	29th (2006)	

TRICLABENDAZOLE (anthelmintic agent)

JECFA Evaluation: 40 (1992); 66 (2006); 70 (2008)

Acceptable Daily Intake: 0-3 µg/kg body weight (40th JECFA, 1993).

Residue Definition: Ketotriclabnedazole

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Muscle	250	32nd (2009)	
Cattle	Liver	850	32nd (2009)	
Cattle	Kidney	400	32nd (2009)	
Cattle	Fat	100	32nd (2009)	
Sheep	Muscle	200	32nd (2009)	
Sheep	Liver	300	32nd (2009)	
Sheep	Kidney	200	32nd (2009)	
Sheep	Fat	100	32nd (2009)	

TYLOSIN (antimicrobial agent)

JECFA Evaluation: 70 (2008)

Acceptable Daily Intake : 0-30 µg/kg body weight based on a microbiological end-point derived from in vitro MIC susceptibility testing and faecal binding data (MICcalc = 1.698) (70th JECFA, 2008).

Residue Definition: Tylosin A.

Species	Tissue	MRLs (µg/kg)	CAC	Notes
Cattle	Muscle	100	32nd (2009)	
Cattle	Liver	100	32nd (2009)	
Cattle	Kidney	100	32nd (2009)	
Cattle	Fat	100	32nd (2009)	
Cattle	Milk	100	32nd (2009)	
Pig	Muscle	100	32nd (2009)	
Pig	Liver	100	32nd (2009)	
Pig	Kidney	100	32nd (2009)	
Pig	Fat	100	32nd (2009)	
Chicken	Muscle	100	32nd (2009)	
Chicken	Liver	100	32nd (2009)	
Chicken	Kidney	100	32nd (2009)	
Chicken	Fat/Skin	100	32nd (2009)	
Chicken	Eggs	300	32nd (2009)	

ZERANOL (growth promoter)

JECFA Evaluation: 26 (1982); 27 (1983); 32 (1987)

Acceptable Daily Intake : 0-0.5 µg/kg body weight (32nd JECFA, 1987).

Residue Definition: Zeranol**.**

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Muscle	2	21st (1995)	
Cattle	Liver	10	21st (1995)	

B) RISK MANAGEMENT RECOMMENDATIONS (RMRs) FOR RESIDUES OF VETERINARY DRUGS

CARBADOX (growth promoter)

JECFA evaluation: 36th (1990) and 60th (2003) JECFA

CAC37 (2014)

Recommended risk management measures

In view of the JECFA conclusions on the available scientific information, there is no safe level of residues of carbadox or its metabolites in food that represents an acceptable risk to consumers. For this reason, competent authorities should prevent residues of carbadox in food. This can be accomplished by not using carbadox in food producing animals.

CHLORAMPHENICOL (antimicrobial agent)

JECFA evaluation: 12th (1968), 32nd (1987), 42nd (1994) and 62nd (2004) JECFA

CAC37 (2014)

Recommended risk management measures

In view of the JECFA conclusions on the available scientific information, there is no safe level of residues of chloramphenicol or its metabolites in food that represents an acceptable risk to consumers. For this reason, competent authorities should prevent residues of chloramphenicol in food. This can be accomplished by not using chloramphenicol in food producing animals.

CHLORPROMAZINE (tranquilliser agent)

JECFA evaluation: 38th (1991) JECFA

CAC37 (2014)

Recommended risk management measures

In view of the JECFA conclusions, although insufficient data were available or there was a lack of data to establish a safe level of residues of chlorpromazine or its metabolites in food representing an acceptable risk to consumers, significant health concerns were identified. For this reason, competent authorities should prevent residues of chlorpromazine in food. This can be accomplished by not using chlorpromazine in food producing animals.

DIMETRIDAZOLE (antiprotozoal agent)

JECFA evaluation: 34th (1989) JECFA

CAC38 (2015)

Recommended risk management measures

In view of the JECFA conclusions, although insufficient data were available or there was a lack of data to establish a safe level of residues of dimetridazole or its metabolites in food representing an acceptable risk to consumers, significant health concerns were identified. For this reason, competent authorities should prevent residues of dimetridazole in food. This can be accomplished by not using dimetridazole in food producing animals.

FURAZOLIDONE (antimicrobial agent)

JECFA evaluation: 40th (1992) JECFA

CAC37 (2014)

Recommended risk management measures

In view of the JECFA conclusions on the available scientific information, there is no safe level of residues of furazolidone or its metabolites in food that represents an acceptable risk to consumers. For this reason, competent authorities should prevent residues of furazolidone in food. This can be accomplished by not using furazolidone in food producing animals.

IPRONIDAZOLE (antiprotozoal agent)

JECFA evaluation: 34th (1989) JECFA

CAC38 (2015)

Recommended risk management measures

In view of the JECFA conclusions, although insufficient data were available or there was a lack of data to establish a safe level of residues of ipronidazole or its metabolites in food representing an acceptable risk to consumers, significant health concerns were identified. For this reason, competent authorities should prevent residues of ipronidazole in food. This can be accomplished by not using ipronidazole in food producing animals.

MALACHITE GREEN (antifungal and antiprotozoal agent)

JECFA evaluation: 70th (2008) JECFA

CAC37 (2014)

Recommended risk management measures

In view of the JECFA conclusions on the available scientific information, there is no safe level of residues of malachite green or its metabolites in food that represents an acceptable risk to consumers. For this reason, competent authorities should prevent residues of malachite green in food. This can be accomplished by not using malachite green in food producing animals.

METRONIDAZOLE (antiprotozoal agent)

JECFA evaluation: 34th (1989) JECFA

CAC38 (2015)

Recommended risk management measures

In view of the JECFA conclusions, although insufficient data were available or there was a lack of data to establish a safe level of residues of metronidazole or its metabolites in food representing an acceptable risk to consumers, significant health concerns were identified. For this reason, competent authorities should prevent residues of metronidazole in food. This can be accomplished by not using metronidazole in food producing animals.

NITROFURAL (antimicrobial agent)

JECFA evaluation: 40th (1992) JECFA

CAC37 (2014)

Recommended risk management measures

In view of the JECFA conclusions, although insufficient data were available or there was a lack of data to establish a safe level of residues of nitrofural or its metabolites[1] in food representing an acceptable risk to consumers, significant health concerns were identified. For this reason, competent authorities should prevent residues of nitrofural in food. This can be accomplished by not using nitrofural in food producing animals.

[1] Semicarbazide is not a unique indicator of nitrofural use and low levels can be associated with other legitimate sources.

OLAQUINDOX (antibacterial agent)

JECFA evaluation: 36th (1990) and 42nd (1994) JECFA

CAC37 (2014)

Recommended risk management measures

In view of the JECFA conclusions, although insufficient data were available or there was a lack of data to establish a safe level of residues of olaquindox or its metabolites in food representing an acceptable risk to consumers, significant health concerns were identified. For this reason, competent authorities should prevent residues of olaquindox in food. This can be accomplished by not using olaquindox in food producing animals.

RONIDAZOLE (antiprotozoal agent)

JECFA evaluation: 34th (1989) and 42nd (1994) JECFA

CAC38 (2015)

Recommended risk management measures

In view of the JECFA conclusions, although insufficient data were available or there was a lack of data to establish a safe level of residues of ronidazole or its metabolites in food representing an acceptable risk to consumers, significant health concerns were identified. For this reason, competent authorities should prevent residues of ronidazole in food. This can be accomplished by not using ronidazole in food producing animals.

STILBENES (growth promoter)

JECFA evaluation: 5th (1960) JECFA

IARC evaluation: monograph 100A (2012)

CAC37 (2014)

Recommended risk management measures

In view of the available scientific information, there is no safe level of residues of stilbenes or their metabolites in food that represents an acceptable risk to consumers. For this reason, competent authorities should prevent residues of stilbenes in food. This can be accomplished by not using stilbenes in food producing animals.

Part 2

A) PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS IN FOODS CURRENTLY UNDER CONSIDERATION BY CCRVDF

AMOXICILLIN (antimicrobial agent)

Microbiological Acceptable Daily Intake (mADI)	0–0.002 mg/kg body weight (bw) based on the effects of amoxicillin on the intestinal microbiota.
Acute Reference Dose (ARfD):	0.005 mg/kg bw based on microbiological effects on the intestinal microbiota
Estimated Chronic Dietary Exposure (GECDE):	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 (GEADE):	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**	**MRLs (µg/kg) recommended by the 85th JECFA**	**Step**	**JECFA**
Finfish[a]	Fillet[b]	50	3	85
	Muscle	50	3	85

[a] The term “finfish” includes all fish species.

[b] Muscle plus skin in natural proportion.

AMPICILLIN (antimicrobial agent)

Microbiological Acceptable Daily Intake (mADI)	0–0.003 mg/kg bw based on a no-observed-adverse-effect level (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 (ARfD):	0.012 mg/kg bw based on the microbiological end-point.
Estimated Chronic Dietary Exposure (GECDE):	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 (GEADE):	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.

Species	**Tissue**	**MRLs (µg/kg) recommended by the 85th JECFA**	**Step**	**JECFA**
Finfish[a]	Fillet[b]	50	3	85
	Muscle	50	3	85

[a] The term “finfish” includes all fish species.

[b] Muscle plus skin in natural proportion.

Note: The 85th JECFA 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.

FLUMETHRIN (insecticide)

Acceptable Daily Intake (ADI)	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 (ARfD):	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 (GECDE):	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 JECFA 85 report. Results below are only for use as veterinary drug.
Estimated Acute Dietary Exposure (GEADE):	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	MRLs (µg/kg) recommended by the 85th JECFA	Step	JECFA
	Honey	6	3	85

Note: the 85th JECFA set an MRL for honey of 6 µg/kg, which is twice the limit of quantification (LOQ; 3 µg/kg) of the most reliable analytical method (liquid chromatography coupled with tandem mass spectrometry; LC–MS/MS) used in the residues studies

LUFENURON (insecticide)

Acceptable Daily Intake (ADI)	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 (ARfD):	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 (GECDE):	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 JECFA 85 report. Results below are only for use as veterinary drug.
Residue Definition:	Lufenuron

Species	Tissue	MRLs (µg/kg) recommended by the 85th JECFA	Step	JECFA
Salmon	Fillet[a]	1 350	3	85
Trout	Fillet[a]	1 350	3	85

[a] Muscle plus skin in natural proportion.

MONEPANTEL (anthelminthic)

Acceptable Daily Intake (ADI)	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 (ARfD):	Unnecessary
Estimated chronic dietary exposure (GECDE):	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	MRLs (µg/kg) recommended by the 85th JECFA	Step	JECFA
Cattle	Fat	7 000	3	85
	Kidney	1 000	3	85
	Liver	2 000	3	85
	Muscle	300	3	85

ZILPATEROL HYDROCHLORIDE (β2-adrenoceptor agonist)

Acceptable Daily Intake (ADI)	0-0.04 µg/kg body weight established at the seventy-eighth meeting (WHO TRS No. 988, 2014) and reaffirmed at the eighty-first meeting. (81st JECFA, 2015)
Acute Reference dose (ARfD):	0.04 µg/kg body weight based on a lowest-observed-adverse-effect level (LOAEL) of 0.76 µg/kg body weight 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. (81st JECFA, 2015)
Estimated Acute Dietary Exposure (GEADE):	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. (81st JECFA, 2015)
Residue Definition:	Zilpaterol (free base) in muscle, liver and kidney.

Species	**Tissue**	**MRLs (µg/kg) recommended by the 81st JECFA**	**Step**	**JECFA**
Cattle	Kidney	3.3	4	81
	Liver	3.5	4	81
	Muscle	0.5	4	81

B) DRAFT RISK MANAGEMENT RECOMMENDATIONS FOR VETERINARY DRUGS IN FOODS CURRENTLY UNDER CONSIDERATION BY CCRVDF

(at Step 6)

GENTIAN VIOLET (antibacterial, antifungal and anthelminthic agent)

JECFA evaluation: 78th (2013) JECFA

Recommended risk management measures

In view of the JECFA conclusions on the available scientific information, there is no safe level of residues of gentian violet or its metabolites in food that represents an acceptable risk to consumers. For this reason, competent authorities should prevent residues of gentian violet in food. This can be accomplished by not using gentian violet in food producing animals.

C) MRLS HELD AT STEP 8 BY THE CODEX ALIMENTARIUS COMMISSION

BOVINE SOMATOTROPINS (production aid)

JECFA Evaluation: 40 (1992); 50 (1998)

Acceptable Daily Intake (ADI): Not specified (1992) The ADI applies to somagrebove, sometribove, somavubove, somidobove

Residue Definition: Not applicable

Species	Tissue	MRL (µg/kg)		Step	JECFA	CCRVDF
Cattle	Muscle	Not specified	1/	8	40, 50	7IV, 8II
Cattle	Liver	Not specified	1/	8	40	7IV, 8II
Cattle	Kidney	Not specified	1/	8	40	7IV. 8II
Cattle	Fat	Not specified	1/	8	40	7IV. 8II
Cattle	Milk	Not specified	1/	8	40	7IV, 8II

ADI "not specified" means that available data on the toxicity and intake of the veterinary drug indicate a large margin of safety for consumption of residues in food when the drug is used according to good practice in the use of veterinary drugs. For that reason, and for the reasons stated in the individual evaluation, the JECFA concluded that use of the veterinary drugs does not represent a hazard to human and that there is no need to specify a numerical ADI.

1/ MRL "not specified" means that available data on the identity and concentration of residues of the veterinary drug in animal tissues indicate a wide margin of safety for consumption of residues in food when the drug is used according to good practice in the use of veterinary drugs. For that reason, and for the reasons stated in the individual evaluation, the JECFA concluded that the presence of drug residues in the named animal product does not present a health concern and that there is no need to specify a numerical MRL.