## CODEX ALIMENTARIUS COMMISSION R





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Agenda Item 5

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# JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

**Twenty-first Session** 

Minneapolis, Minnesota, United States of America, 26 – 30 August 2013

## INFORMATION DOCUMENT IN SUPPORT TO THE DISCUSSION ON THE MAXIMUM RESIDUES LIMITS FOR 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 21<sup>st</sup> Session of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF). The document includes:

- Part 1 Codex Maximum Residue Limits (MRLs) for Veterinary Drugs as adopted by the Codex Alimentarius Commission as its 35<sup>th</sup> Session (July 2012); and
- Part 2 Draft and proposed draft MRLs.

Part 1

#### **CODEX MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS IN FOODS**

Updated as at the 35<sup>th</sup> Session of the Codex Alimentarius Commission (July 2012)

**ABAMECTIN** (anthelmintic agent)

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

Acceptable Daily Intake (ADI): 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	26 <sup>th</sup> (2003)	
Cattle	Kidney	50	26 <sup>th</sup> (2003)	
Cattle	Fat	100	26 <sup>th</sup> (2003)	

**ALBENDAZOLE** (anthelmintic agent)

JECFA Evaluation: 34 (1989)

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

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

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

**AMOXICILLIN** (antimicrobial agent)

JECFA Evaluation: 75 (2011)

Acceptable Daily Intake (ADI): 0-0.7 µg/kg body weight on the basis of microbiological effects (75<sup>th</sup> JECFA,

2011).

Estimated Dietary Exposure (EDI): The 75<sup>th</sup> 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	35 <sup>th</sup> (2012)	
Cattle	Liver	50	35 <sup>th</sup> (2012)	
Cattle	Kidney	50	35 <sup>th</sup> (2012)	
Cattle	Fat	50	35 <sup>th</sup> (2012)	
Cattle	Milk	4	35 <sup>th</sup> (2012)	
Sheep	Muscle	50	35 <sup>th</sup> (2012)	
Sheep	Liver	50	35 <sup>th</sup> (2012)	
Sheep	Kidney	50	35 <sup>th</sup> (2012)	
Sheep	Fat	50	35 <sup>th</sup> (2012)	
Sheep	Milk	4	35 <sup>th</sup> (2012)	
Pigs	Muscle	50	35 <sup>th</sup> (2012)	
Pigs	Liver	50	35 <sup>th</sup> (2012)	
Pigs	Kidney	50	35 <sup>th</sup> (2012)	
Pigs	Fat/Skin	50	35 <sup>th</sup> (2012)	

**AVILAMYCIN** (antimicrobial agent)

**JECFA Evaluation:** 70 (2008)

Acceptable Daily Intake (ADI): 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 (70<sup>th</sup> JECFA, 2008).

**Residue Definition:** Dichloroisoeverninic acid (DIA).

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

**AZAPERONE** (tranquilizing agent)

38 (1991); 43 (1994); 50 (1998); 52 (1999) **JECFA Evaluation:** 0-6 μg/kg body weight (50<sup>th</sup> JECFA, 1998). Acceptable Daily Intake (ADI):

**Residue Definition:** Sum of azaperone and azaperol.

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

BENZYLPENICILLIN/PROCAINE BENZYLPENICILLIN (antimicrobial agent)

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

Acceptable Daily Intake (ADI): 30 µg-penicillin/person/day (50<sup>th</sup> 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	23 <sup>rd</sup> (1999)	
Cattle	Liver	50	23 <sup>rd</sup> (1999)	
Cattle	Kidney	50	23 <sup>rd</sup> (1999)	
Cattle	Milk (µg/l)	4	23 <sup>rd</sup> (1999)	
Chicken	Muscle	50	23 <sup>rd</sup> (1999)	Applies to procaine benzylpenicillin only.
Chicken	Liver	50	23 <sup>rd</sup> (1999)	Applies to procaine benzylpenicillin only.
Chicken	Kidney	50	23 <sup>rd</sup> (1999)	Applies to procaine benzylpenicillin only.
Pig	Muscle	50	23 <sup>rd</sup> (1999)	
Pig	Liver	50	23 <sup>rd</sup> (1999)	
Pig	Kidney	50	23 <sup>rd</sup> (1999)	

**CARAZOLOL** (beta-adreniceptor-blocking agent)

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

Acceptable Daily Intake (ADI): 0-0.1 µg/kg body weight (43<sup>rd</sup> JECFA, 1994). ADI based on the acute

pharmacological effects of carazolol.

Residue Definition: Carazolol.

Species	Tissue	MRL (µg/kg)	CAC	Notes	
Pig	Muscle	5	26 <sup>th</sup> (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	26 <sup>th</sup> (2003)		
Pig	Kidney	25	26 <sup>th</sup> (2003)		
Pig	Fat/Skin	5	26 <sup>th</sup> (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 (ADI):** 0-50 μg/kg body weight (45<sup>th</sup> JECFA, 1995).

Residue Definition: Desfuroylceftiofur.

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

CHLORTETRACYCLINE/OXYTETRACYCLINE/TETRACYCLINE (antimicrobial agent)

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

**Acceptable Daily Intake (ADI):** 0-30 μg/kg body weight (50<sup>th</sup> 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	26 <sup>th</sup> (2003)	
Cattle	Liver	600	26 <sup>th</sup> (2003)	
Cattle	Kidney	1200	26 <sup>th</sup> (2003)	
Cattle	Milk (µg/l)	100	26 <sup>th</sup> (2003)	
Fish	Muscle	200	26 <sup>th</sup> (2003)	Applies only to oxytetracycline.
Giant prawn (Paeneus monodon)	Muscle	200	26 <sup>th</sup> (2003)	Applies only to oxytetracycline.
Pig	Muscle	200	26 <sup>th</sup> (2003)	
Pig	Liver	600	26 <sup>th</sup> (2003)	
Pig	Kidney	1200	26 <sup>th</sup> (2003)	
Poultry	Muscle	200	26 <sup>th</sup> (2003)	
Poultry	Liver	600	26 <sup>th</sup> (2003)	
Poultry	Kidney	1200	26 <sup>th</sup> (2003)	
Poultry	Eggs	400	26 <sup>th</sup> (2003)	
Sheep	Muscle	200	26 <sup>th</sup> (2003)	
Sheep	Liver	600	26 <sup>th</sup> (2003)	
Sheep	Kidney	1200	26 <sup>th</sup> (2003)	
Sheep	Milk (µg/l)	100	26 <sup>th</sup> (2003)	

**CLENBUTEROL** (adrenoceptor agonist)

JECFA Evaluation: 47 (1996)

Acceptable Daily Intake (ADI): 0-0.004  $\mu g/kg$  body weight (47<sup>th</sup> JECFA, 1996).

Residue Definition: Clenbuterol.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Muscle	0.2	26 <sup>th</sup> (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	26 <sup>th</sup> (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	26 <sup>th</sup> (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	26 <sup>th</sup> (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	26 <sup>th</sup> (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	26 <sup>th</sup> (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	26 <sup>th</sup> (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	26 <sup>th</sup> (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	26 <sup>th</sup> (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 (ADI):  $0-30 \mu g/kg$  body weight ( $40^{th}$  JECFA, 1992).

Residue Definition: Closantel.

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

**COLISTIN** (antimicrobial agent)

JECFA Evaluation: 66 (2006)

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

**Residue Definition:** Sum of colistin A and colistin B.

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

**CYFLUTHRIN** (insecticide)

JECFA Evaluation: 48 (1997)

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

Residue Definition: Cyfluthrin.

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

**CYHALOTHRIN** (insecticide)

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

**Acceptable Daily Intake (ADI):** 0-5 μg/kg body weight (62<sup>nd</sup> JECFA, 2004).

Residue Definition: Cyhalothrin.

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

### CYPERMETHRIN AND ALPHA-CYPERMETHRIN (insecticide)

JECFA Evaluation: 62 (2004)

Acceptable Daily Intake (ADI): JECFA 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	MRLs(µg/kg)	CAC	Note
Cattle	Muscle	50	29 <sup>th</sup> (2006)	
Cattle	Liver	50	29 <sup>th</sup> (2006)	
Cattle	Kidney	50	29 <sup>th</sup> (2006)	
Cattle	Fat	1000	29 <sup>th</sup> (2006)	
Cattle	Milk	100	29 <sup>th</sup> (2006)	
Sheep	Muscle	50	29 <sup>th</sup> (2006)	
Sheep	Liver	50	29 <sup>th</sup> (2006)	
Sheep	Kidney	50	29 <sup>th</sup> (2006)	
Sheep	Fat	1000	29 <sup>th</sup> (2006)	

**DANOFLOXACIN** (antimicrobial agent)

JECFA Evaluation: 48 (1997)

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

Residue Definition: Danofloxacin.

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

**DELTAMETHRIN** (insecticide)

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

Acceptable Daily Intake (ADI): 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	26 <sup>th</sup> (2003)	
Cattle	Liver	50	26 <sup>th</sup> (2003)	
Cattle	Kidney	50	26 <sup>th</sup> (2003)	
Cattle	Fat	500	26 <sup>th</sup> (2003)	
Cattle	Milk	30	26 <sup>th</sup> (2003)	
Chicken	Muscle	30	26 <sup>th</sup> (2003)	
Chicken	Liver	50	26 <sup>th</sup> (2003)	
Chicken	Kidney	50	26 <sup>th</sup> (2003)	
Chicken	Fat	500	26 <sup>th</sup> (2003)	
Chicken	Eggs	30	26 <sup>th</sup> (2003)	
Salmon	Muscle	30	26 <sup>th</sup> (2003)	
Sheep	Muscle	30	26 <sup>th</sup> (2003)	
Sheep	Liver	50	26 <sup>th</sup> (2003)	
Sheep	Kidney	50	26 <sup>th</sup> (2003)	
Sheep	Fat	500	26 <sup>th</sup> (2003)	

**DEXAMETHASONE** (glucocorticosteroid)

JECFA Evaluation: 70 (2008)

Acceptable Daily Intake (ADI): 0-0.015 µg/kg body weight (42<sup>nd</sup> JECFA, 1995).

**Residue Definition:** Dexamethasone.

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

**DICLAZURIL** (antiprotozoal agent)

**JECFA Evaluation:** 45 (1995); 50 (1998)

**Acceptable Daily Intake (ADI):** 0-30 μg/kg body weight (50<sup>th</sup> JECFA, 1998).

Residue Definition: Diclazuril.

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

**DICYCLANIL** (insecticide)

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

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

Residue Definition: Dicyclanil.

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

**DIHYDROSTREPTOMYCIN/STREPTOMYCIN** (antimicrobial agent)

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

Acceptable Daily Intake (ADI): 0-50 µg/kg body weight (48<sup>th</sup> 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	24 <sup>th</sup> (2001)	
Cattle	Liver	600	24 <sup>th</sup> (2001)	
Cattle	Kidney	1000	24 <sup>th</sup> (2001)	
Cattle	Fat	600	24 <sup>th</sup> (2001)	
Cattle	Milk	200	26 <sup>th</sup> (2003)	
Chicken	Muscle	600	24 <sup>th</sup> (2001)	
Chicken	Liver	600	24 <sup>th</sup> (2001)	
Chicken	Kidney	1000	24 <sup>th</sup> (2001)	
Chicken	Fat	600	24 <sup>th</sup> (2001)	
Pig	Muscle	600	24 <sup>th</sup> (2001)	
Pig	Liver	600	24 <sup>th</sup> (2001)	
Pig	Kidney	1000	24 <sup>th</sup> (2001)	
Pig	Fat	600	24 <sup>th</sup> (2001)	
Sheep	Muscle	600	24 <sup>th</sup> (2001)	
Sheep	Liver	600	24 <sup>th</sup> (2001)	
Sheep	Kidney	1000	24 <sup>th</sup> (2001)	
Sheep	Fat	600	24 <sup>th</sup> (2001)	
Sheep	Milk	200	26 <sup>th</sup> (2003)	

**DIMINAZENE** (trypanocide)

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

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

Residue Definition: Diminazene.

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

**DORAMECTIN** (anthelmintic agent)

JECFA Evaluation: 45 (1995); 52 (1999); 58 (2002); 62 (2004)
Acceptable Daily Intake (ADI): 0-1 µg/kg body weight (58<sup>th</sup> JECFA, 2002).

Residue Definition: Doramectin.

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

**EPRINOMECTIN** (anthelmintic agent)

JECFA Evaluation: 50 (1998)

Acceptable Daily Intake (ADI): 0-10  $\mu$ g/kg body weight (50<sup>th</sup> JECFA, 1998).

**Residue Definition:** Eprinomectin B1a.

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

**ERYTHROMYCIN** (antimicrobial agent)

**JECFA Evaluation:** 66 (2006)

 $0\text{-}0.7 \mu g/kg$  body weight (66<sup>th</sup> JECFA, 2006). Acceptable Daily Intake (ADI):

**Residue Definition:** Erythromycin A

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

ESTRADIOL-17BETA (production aid)

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

unnecessary (32<sup>nd</sup> JECFA, 1987); 0-0.05 μg/kg body weight (52<sup>nd</sup> JECFA, Acceptable Daily Intake (ADI):

1999).

Residue D	Residue Definition:		liol-17beta.		
Species	Tissue	MRL (µg/kg)	CAC	Notes	
Cattle	Muscle	unnecessary	21 <sup>st</sup> (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	21 <sup>st</sup> (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	21 <sup>st</sup> (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	21 <sup>st</sup> (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 (ADI):** 0-7 μg/kg body weight (50<sup>th</sup> 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	23 <sup>rd</sup> (1999)	
Cattle	Liver	500	23 <sup>rd</sup> (1999)	
Cattle	Kidney	100	23 <sup>rd</sup> (1999)	
Cattle	Fat	100	23 <sup>rd</sup> (1999)	
Cattle	Milk (µg/l)	100	23 <sup>rd</sup> (1999)	
Goat	Muscle	100	23 <sup>rd</sup> (1999)	
Goat	Liver	500	23 <sup>rd</sup> (1999)	
Goat	Kidney	100	23 <sup>rd</sup> (1999)	
Goat	Fat	100	23 <sup>rd</sup> (1999)	
Horse	Muscle	100	23 <sup>rd</sup> (1999)	
Horse	Liver	500	23 <sup>rd</sup> (1999)	
Horse	Kidney	100	23 <sup>rd</sup> (1999)	
Horse	Fat	100	23 <sup>rd</sup> (1999)	
Pig	Muscle	100	23 <sup>rd</sup> (1999)	
Pig	Liver	500	23 <sup>rd</sup> (1999)	
Pig	Kidney	100	23 <sup>rd</sup> (1999)	
Pig	Fat	100	23 <sup>rd</sup> (1999)	
Sheep	Muscle	100	23 <sup>rd</sup> (1999)	
Sheep	Liver	500	23 <sup>rd</sup> (1999)	
Sheep	Kidney	100	23 <sup>rd</sup> (1999)	
Sheep	Fat	100	23 <sup>rd</sup> (1999)	
Sheep	Milk (µg/l)	100	23 <sup>rd</sup> (1999)	

**FLUAZURON** (insecticide)

JECFA Evaluation: 48 (1997)

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

Residue Definition: Fluazuron.

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

FLUBENDAZOLE (anthelmintic agent)

JECFA Evaluation: 40 (1992)

**Acceptable Daily Intake (ADI):** 0-12 μg/kg body weight (40<sup>th</sup> JECFA, 1992).

Residue Definition: Flubendazole.

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

**FLUMEQUINE** (antimicrobial agent)

**JECFA Evaluation:** 42 (1994); 48 (1997); 54 (2000); 60 (2002); 62 (2004); 66 (2006)

Acceptable Daily Intake (ADI): 0-30 μg/kg body weight (62<sup>nd</sup> JECFA, 2004).

**Residue Definition:** Flumequine.

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

**GENTAMICIN** (antimicrobial agent)

**JECFA Evaluation:** 43 (1994); 48 (1997); 50 (1998)

**Acceptable Daily Intake (ADI):** 0-20 μg/kg body weight (50<sup>th</sup> JECFA, 1998).

Residue Definition: Gentamicin.

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

**IMIDOCARB** (antiprotozoal agent)

**JECFA Evaluation:** 50 (1998), 60 (2003)

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

Residue Definition: Imidocarb.

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

**ISOMETAMIDIUM** (trypanocide)

**JECFA Evaluation:** 34 (1989); 40 (1992)

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

Residue Definition: Isometamidium.

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

**IVERMECTIN** (anthelmintic agent)

JECFA Evaluation:36 (1990); 40 (1992); 54 (2000); 58 (2002)Acceptable Daily Intake (ADI):0-1 μg/kg body weight (40th JECFA, 1992).Residue Definition:22,23-Dihydroavermectin B1a (H2B1a).

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Liver	100	20 <sup>th</sup> (1993)	
Cattle	Fat	40	20 <sup>th</sup> (1993)	
Cattle	Milk	10	26 <sup>th</sup> (2003)	
Pig	Liver	15	20 <sup>th</sup> (1993)	
Pig	Fat	20	20 <sup>th</sup> (1993)	
Sheep	Liver	15	20 <sup>th</sup> (1993)	
Sheep	Fat	20	20 <sup>th</sup> (1993)	

**LEVAMISOLE** (anthelmintic agent)

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

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

Residue Definition: Levamisole.

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

**LINCOMYCIN** (antimicrobial agent)

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

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

Residue Definition: Lincomycin.

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

**MELENGESTROL ACETATE** (production aid)

JECFA Evaluation: 54 (2000); 66 (2006)
Acceptable Daily Intake (ADI): 0-0.03 µg/kg body weight.
Residue Definition: Melengestrol acetate.

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

**MONENSIN** (antimicrobial agent)

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

Acceptable Daily Intake (ADI): 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

(70<sup>th</sup> JÉCFA, 2008).

Estimated Dietary Exposure (EDI) 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 (75<sup>th</sup> JECFA, 2011).

Residue Definition: Monensin.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Muscle	10	32 <sup>nd</sup> (2009)	
Cattle	Liver	100	35 <sup>th</sup> (2012) <sup>1</sup>	
Cattle	Kidney	10	32 <sup>nd</sup> (2009)	
Cattle	Fat	100	32 <sup>nd</sup> (2009)	
Cattle	Milk	2	32 <sup>nd</sup> (2009)	
Sheep	Muscle	10	32 <sup>nd</sup> (2009)	
Sheep	Liver	20	32 <sup>nd</sup> (2009)	
Sheep	Kidney	10	32 <sup>nd</sup> (2009)	
Sheep	Fat	100	32 <sup>nd</sup> (2009)	
Goats	Muscle	10	32 <sup>nd</sup> (2009)	
Goats	Liver	20	32 <sup>nd</sup> (2009)	
Goats	Kidney	10	32 <sup>nd</sup> (2009)	
Goats	Fat	100	32 <sup>nd</sup> (2009)	
Chicken	Muscle	10	32 <sup>nd</sup> (2009)	
Chicken	Liver	10	32 <sup>nd</sup> (2009)	
Chicken	Kidney	10	32 <sup>nd</sup> (2009)	
Chicken	Fat	100	32 <sup>nd</sup> (2009)	
Turkey	Muscle	10	32 <sup>nd</sup> (2009)	
Turkey	Liver	10	32 <sup>nd</sup> (2009)	
Turkey	Kidney	10	32 <sup>nd</sup> (2009)	
Turkey	Fat	100	32 <sup>nd</sup> (2009)	
Quail	Muscle	10	32 <sup>nd</sup> (2009)	
Quail	Liver	10	32 <sup>nd</sup> (2009)	
Quail	Kidney	10	32 <sup>nd</sup> (2009)	
Quail	Fat	100	32 <sup>nd</sup> (2009)	

<sup>1</sup> The 75<sup>th</sup> JECFA was unable to revise the current MRLs for goats and sheep, as no additional residue data were provided.

**MOXIDECTIN** (anthelmintic agent)

JECFA Evaluation: 45 (1995); 47 (1996); 48 (1998); 50 (1998) Acceptable Daily Intake (ADI): 0-2 µg/kg body weight (45<sup>th</sup> JECFA, 1995).

Residue Definition: Moxidectin.

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

NARASIN (antimicrobial agent)

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

Acceptable Daily Intake (ADI): 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 (70<sup>th</sup> JECFA, 2008).

Residue Definition: Narasin A.

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

**NEOMYCIN** (antimicrobial agent)

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

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

Residue Definition: Neomycin.

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

**NICARBAZIN** (antiprotozoal agent)

JECFA Evaluation: 50 (1998)

**Acceptable Daily Intake (ADI):** 0-400 μg/kg body weight (50<sup>th</sup> JECFA, 1998).

**Residue Definition:** N,N'-bis(4-nitropheyl)urea.

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

**PHOXIM** (insecticide)

**JECFA Evaluation:** 52 (1999); 62 (2004)

Acceptable Daily Intake (ADI): 0-4 µg/kg body weight (52<sup>nd</sup> JECFA, 1999).

Residue Definition: Phoxim

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

### PIRLIMYCIN (antimicrobial agent)

JECFA Evaluation: 62 (2004)

Acceptable Daily Intake (ADI): 0-8  $\mu$ g/kg bw (62<sup>nd</sup> JECFA, 2004).

Residue Definition: Pirlimycin.

Species	Tissue	MRLs(µg/kg)	CAC	Note
Cattle	Muscle	100	29 <sup>th</sup> (2006)	
Cattle	Liver	1000	29 <sup>th</sup> (2006)	
Cattle	Kidney	400	29 <sup>th</sup> (2006)	
Cattle	Fat	100	29 <sup>th</sup> (2006)	
Cattle	Milk	100	29 <sup>th</sup> (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 (ADI): Not Specified (52<sup>nd</sup> JECFA, 1999).

Residue Definition: Not applicable.

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

**PROGESTERONE** (production aid)

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

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

**Residue Definition:** Progesterone.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Muscle	unnecessary	21 <sup>st</sup> (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	21 <sup>st</sup> (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	21 <sup>st</sup> (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	21 <sup>st</sup> (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 (ADI): 0-1  $\mu$ g/kg body weight (62<sup>nd</sup> JECFA, 2004)

Residue Definition: Ractopamine.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Muscle	10	35 <sup>th</sup> (2012)	
Cattle	Liver	40	35 <sup>th</sup> (2012)	
Cattle	Kidney	90	35 <sup>th</sup> (2012)	
Cattle	Fat	10	35 <sup>th</sup> (2012)	
Pigs	Muscle	10	35 <sup>th</sup> (2012)	
Pigs	Liver	40	35 <sup>th</sup> (2012)	
Pigs	Kidney	90	35 <sup>th</sup> (2012)	
Pigs	Fat/skin	10	35 <sup>th</sup> (2012)	

**SARAFLOXACIN** (antimicrobial agent)

JECFA Evaluation: 50 (1998)

**Acceptable Daily Intake (ADI):** 0-0.3 μg/kg body weight (50<sup>th</sup> JECFA, 1998).

Residue Definition: Sarafloxacin.

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

**SPECTINOMYCIN** (antimicrobial agent)

**JECFA Evaluation:** 42 (1994); 50 (1998)

Acceptable Daily Intake (ADI): 0-40 µg/kg body weight (42<sup>nd</sup> JECFA, 1994).

Residue Definition: Spectinomycin.

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

**SPIRAMYCIN** (antimicrobial agent)

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

Acceptable Daily Intake (ADI): 0-50 μg/kg body weight (43<sup>rd</sup> 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	22 <sup>nd</sup> (1997)	
Cattle	Liver	600	22 <sup>nd</sup> (1997)	
Cattle	Kidney	300	22 <sup>nd</sup> (1997)	
Cattle	Fat	300	22 <sup>nd</sup> (1997)	
Cattle	Milk (µg/l)	200	22 <sup>nd</sup> (1997)	
Chicken	Muscle	200	22 <sup>nd</sup> (1997)	
Chicken	Liver	600	22 <sup>nd</sup> (1997)	
Chicken	Kidney	800	22 <sup>nd</sup> (1997)	
Chicken	Fat	300	22 <sup>nd</sup> (1997)	
Pig	Muscle	200	22 <sup>nd</sup> (1997)	
Pig	Liver	600	22 <sup>nd</sup> (1997)	
Pig	Kidney	300	22 <sup>nd</sup> (1997)	
Pig	Fat	300	22 <sup>nd</sup> (1997)	

**SULFADIMIDINE** (antimicrobial agent)

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

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

Residue Definition: Sulfadimidine.

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

**TESTOSTERONE** (production aid)

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

Acceptable Daily Intake (ADI): 0-2  $\mu$ g/kg body weight (52<sup>nd</sup> JECFA, 1999).

**Residue Definition:** Testosterone.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Muscle	unnecessary	21 <sup>st</sup> (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	21 <sup>st</sup> (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	21 <sup>st</sup> (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	21 <sup>st</sup> (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 (ADI):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	21 <sup>st</sup> (1995)	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.
Cattle	Liver	100	21 <sup>st</sup> (1995)	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.
Cattle	Kidney	100	21 <sup>st</sup> (1995)	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.
Cattle	Fat	100	21 <sup>st</sup> (1995)	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.
Cattle	Milk (µg/l)	100	21 <sup>st</sup> (1995)	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.
Goat	Muscle	100	21 <sup>st</sup> (1995)	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.
Goat	Liver	100	21 <sup>st</sup> (1995)	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.
Goat	Kidney	100	21 <sup>st</sup> (1995)	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.
Goat	Fat	100	21 <sup>st</sup> (1995)	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.
Goat	Milk (µg/l)	100	21 <sup>st</sup> (1995)	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.
Pig	Muscle	100	21 <sup>st</sup> (1995)	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.
Pig	Liver	100	21 <sup>st</sup> (1995)	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.
Pig	Kidney	100	21 <sup>st</sup> (1995)	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.
Pig	Fat	100	21 <sup>st</sup> (1995)	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.
Sheep	Muscle	100	21 <sup>st</sup> (1995)	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.
Sheep	Liver	100	21 <sup>st</sup> (1995)	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.
Sheep	Kidney	100	21 <sup>st</sup> (1995)	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.
Sheep	Fat	100	21 <sup>st</sup> (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 (ADI): 0-40 µg/kg body weight (47<sup>th</sup> JECFA, 1996).

Residue Definition: Tilmicosin.

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

TRENBOLONE ACETATE (growth promoter)

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

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

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

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

### TRICHLORFON (METRIFONATE) (insecticide)

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

Acceptable Daily Intake (ADI): 0-2 μg/kg bw (60<sup>th</sup> JECFA, 2003).

Residue Definition: JECFA confirmed the MRL for cows' 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	29 <sup>th</sup> (2006)	

**TRICLABENDAZOLE** (anthelmintic agent)

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

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

Residue Definition: Ketotriclabnedazole

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

TYLOSIN (antimicrobial agent)

**JECFA Evaluation:** 70 (2008)

Acceptable Daily Intake (ADI):  $0\text{-}30~\mu\text{g/kg}$  body weight based on a microbiological end-point derived from in

vitro MIC susceptibility testing and faecal binding data (MICcalc = 1.698) (70<sup>th</sup> JECFA, 2008).

**Residue Definition:** Tylosin A.

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

**ZERANOL** (growth promoter)

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

 $0\text{-}0.5 \mu g/kg$  body weight (32<sup>nd</sup> JECFA, 1987). **Acceptable Daily Intake:** 

**Residue Definition:** Zeranol.

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

Part 2

#### DRAFT AND PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS IN FOOD

#### A) Currently under consideration by CCRVDF

**APRAMYCIN** (antimicrobial agent)

Acceptable Daily Intake (ADI): 0-30 µg/kg body weight on the basis of microbiological effects (75<sup>th</sup> JECFA,

2011).

Estimated Dietary Exposure (EDI): Using the limits of quantification (LOQs) of the analytical methods as calculated

by the 75<sup>th</sup> JECFA as residue levels for muscle, fat and liver, together with the proposed MRLs for kidney, the theoretical intake in the worst-case scenario would be around 1400 µg/day and would not exceed the upper bound of the

ADI (75<sup>th</sup> JECFA, 2011).

Residue Definition: Apramycin.

Species	Tissue	MRLs (µg/kg)	Step	JECFA
Cattle	Kidney	5000 T <sup>a</sup>	4	75
Chickens	Kidney	5000 T <sup>a</sup>	4	75

<sup>&</sup>lt;sup>(a)</sup> The MRLs are temporary. The sponsor is requested to provide improved analytical methods with better performance and lower limits of quantification (LOQs) and residue depletion studies with appropriate sampling points close to the zero withdrawal periods for all tissues and species. The validated analytical methods and residue depletion studies are requested by the end of 2014.

Because of data limitations, the 75<sup>th</sup> JECFA was unable to recommend MRLs in tissues and species other than cattle kidney and chicken kidney.

**DERQUANTEL** (antiparasitic agent)

(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 (75<sup>th</sup> JECFA, 2011).

Estimated Dietary Exposure (EDI): As the ADI was based on an acute effect, the 75<sup>th</sup> JECFA (2011) did not

calculate an EDI. 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 8 µg/person, which represents 45% of the

upper bound of the ADI.

Residue Definition: Derquantel.

Species	Tissue	MRLs (µg/kg)	Step	JECFA	
Sheep	Muscle	0.2	4	75	
Sheep	Liver	2.0	4	75	
Sheep	Kidney	0.2	4	75	
Sheep	Fat	0.7	4	75	

The 75<sup>th</sup> JECFA was not able to recommend a MRL for sheep milk, as no residue data were provided.

**MONEPANTEL** (anthelminthic)

Acceptable Daily Intake (ADI): 0-20 µg/kg body weight on the basis of a lowest-observed-adverse-effect level

(LOAEL) 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 ( $75^{th}$  JECFA,

2011).

Estimated Dietary Exposure (EDI): Using the model diet and a ration of marker residue to total residue of 100% for

muscle and 66% for fat, liver and kidney, and applying a correction factor of 0.94 to account for the mass difference between the marker residue and

monepantel, the EDI is 201  $\mu g/person,$  which represents 17% of the upper bound of the ADI (75  $^{th}$  JECFA, 2011).

**Residue Definition:** 

Monepantel sulfone.

Species	Tissue	MRLs (µg/kg)	Step	JECFA
Sheep	Muscle	300	6	75
Sheep	Liver	3000	6	75
Sheep	Kidney	700	6	75
Sheep	Fat	5500	6	75

The 75<sup>th</sup> JECFA was unable to propose an MRL for sheep milk, as no data were provided.

#### B) 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.