## CODEX ALIMENTARIUS COMMISSION







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Agenda Item 6

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

Twenty-third Session

Houston, Texas, United States of America, 17 - 21 October 2016

## INFORMATION DOCUMENT FOR SUPPORT OF THE DISCUSSION ON THE MAXIMUM RESIDUES LIMITS AND RISK MANAGEMENT RECOMMENDATIONS 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 23<sup>rd</sup> 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 38<sup>th</sup> Session (July 2015); and
- Part 2 Draft and proposed draft MRLs and RMRs.

#### Part 1

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

Updated as at the 38th Session of the Codex Alimentarius Commission (July 2015)

**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.

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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: 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	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: 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  $\mu$ g/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: 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).

Tissue	MRL (μg/kg)	CAC	Notes		
Muscle	200	32 <sup>nd</sup> (2009)			
Liver	300	32 <sup>nd</sup> (2009)			
Kidney	200	32 <sup>nd</sup> (2009)			
Fat/Skin	200	32 <sup>nd</sup> (2009)			
Muscle	200	32 <sup>nd</sup> (2009)			
Liver	300	32 <sup>nd</sup> (2009)			
Kidney	200	32 <sup>nd</sup> (2009)			
Fat/Skin	200	32 <sup>nd</sup> (2009)			
Muscle	200	32 <sup>nd</sup> (2009)			
Liver	300	32 <sup>nd</sup> (2009)			
Kidney	200	32 <sup>nd</sup> (2009)			
Fat/Skin	200	32 <sup>nd</sup> (2009)			
Muscle	200	32 <sup>nd</sup> (2009)			
Liver	300	32 <sup>nd</sup> (2009)			
Kidney	200	32 <sup>nd</sup> (2009)			
Fat/Skin	200	32 <sup>nd</sup> (2009)			
	Muscle Liver Kidney Fat/Skin	(µg/kg)         Muscle       200         Liver       300         Kidney       200         Fat/Skin       200         Liver       300         Kidney       200         Fat/Skin       200         Liver       300         Kidney       200         Fat/Skin       200         Muscle       200         Liver       300         Kidney       200         Liver       300         Kidney       200	(μg/kg)         Muscle       200       32nd (2009)         Liver       300       32nd (2009)         Kidney       200       32nd (2009)         Fat/Skin       200       32nd (2009)         Muscle       200       32nd (2009)         Liver       300       32nd (2009)         Kidney       200       32nd (2009)         Fat/Skin       200       32nd (2009)         Liver       300       32nd (2009)         Kidney       200       32nd (2009)         Fat/Skin       200       32nd (2009)         Muscle       200       32nd (2009)         Liver       300       32nd (2009)         Liver       300       32nd (2009)         Kidney       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 (50<sup>th</sup> JECFA, 1998).

**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: 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	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: 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	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	26th (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: 0-50 µg/kg body weight (45th 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: 0-30  $\mu$ g/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	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	26th (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	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	26 <sup>th</sup> (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	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:0-30 μg/kg body weight (40<sup>th</sup> 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	20 <sup>th</sup> (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	26 <sup>th</sup> (2003)	
Cattle	Liver	20	26 <sup>th</sup> (2003)	
Cattle	Kidney	20	26 <sup>th</sup> (2003)	
Cattle	Fat	200	26th (2003)	
Cattle	Milk (µg/l)	40	26 <sup>th</sup> (2003)	

## **CYHALOTHRIN** (insecticide)

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

Acceptable Daily Intake: 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	28th (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	28th (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	28th (2005)	
Sheep	Kidney	20	28th (2005)	
Sheep	Fat	400	28 <sup>th</sup> (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 (62<sup>nd</sup> 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	29 <sup>th</sup> (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.

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

#### **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 (75<sup>th</sup> 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 (78<sup>th</sup> JECFA,

2013).

Residue Definition: Derquantel.

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

## **DEXAMETHASONE** (glucocorticosteroid)

JECFA Evaluation: 70 (2008)

Acceptable Daily Intake: 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: 0-30 µg/kg body weight (50th 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: 0-7 µg/kg body weigh (54th JECFA, 2000).

Residue Definition: Dicyclanil.

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:0-50  $\mu g/kg$  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	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: 0-100  $\mu$ g/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:**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)	

#### **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	38 <sup>th</sup> (2015)	
Salmon	Fillet	100	38 <sup>th</sup> (2015)	Muscle plus skin in natural proportion
Trout	Muscle	100	38 <sup>th</sup> (2015)	
Trout	Fillet	100	38 <sup>th</sup> (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	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)

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	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.

## $\textbf{FEBANTEL/FENBENDAZOLE/OXFENDAZOLE} \ (anthelmintic \ agent)$

**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.

	1		
Tissue	MRL (µg/kg)	CAC	Notes
Muscle	100	23 <sup>rd</sup> (1999)	
Liver	500	23 <sup>rd</sup> (1999)	
Kidney	100	23 <sup>rd</sup> (1999)	
Fat	100	23 <sup>rd</sup> (1999)	
Milk (µg/l)	100	23 <sup>rd</sup> (1999)	
Muscle	100	23 <sup>rd</sup> (1999)	
Liver	500	23 <sup>rd</sup> (1999)	
Kidney	100	23 <sup>rd</sup> (1999)	
Fat	100	23 <sup>rd</sup> (1999)	
Muscle	100	23 <sup>rd</sup> (1999)	
Liver	500	23 <sup>rd</sup> (1999)	
Kidney	100	23 <sup>rd</sup> (1999)	
Fat	100	23 <sup>rd</sup> (1999)	
Muscle	100	23 <sup>rd</sup> (1999)	
Liver	500	23 <sup>rd</sup> (1999)	
Kidney	100	23 <sup>rd</sup> (1999)	
Fat	100	23 <sup>rd</sup> (1999)	
Muscle	100	23 <sup>rd</sup> (1999)	
Liver	500	23 <sup>rd</sup> (1999)	
Kidney	100	23 <sup>rd</sup> (1999)	
Fat	100	23 <sup>rd</sup> (1999)	
Milk (µg/l)	100	23 <sup>rd</sup> (1999)	
	Muscle Liver Kidney Fat Milk (µg/l) Muscle Liver Kidney Fat Kidney Fat Kidney Fat Kidney Fat	(μg/kg)         Muscle       100         Liver       500         Kidney       100         Fat       100         Milk (μg/l)       100         Muscle       100         Liver       500         Kidney       100         Liver       500         Kidney       100         Fat       100         Muscle       100         Liver       500         Kidney       100         Fat       100         Liver       500         Kidney       100         Liver       500         Kidney       100         Fat       100         Fat       100	(μg/kg)         Muscle       100       23rd (1999)         Liver       500       23rd (1999)         Kidney       100       23rd (1999)         Fat       100       23rd (1999)         Milk (μg/l)       100       23rd (1999)         Muscle       100       23rd (1999)         Liver       500       23rd (1999)         Kidney       100       23rd (1999)         Fat       100       23rd (1999)         Liver       500       23rd (1999)         Kidney       100       23rd (1999)         Fat       100       23rd (1999)         Liver       500       23rd (1999)         Kidney       100       23rd (1999)         Fat       100       23rd (1999)         Muscle       100       23rd (1999)         Liver       500       23rd (1999)         Kidney       100       23rd (1999)         Kidney       100       23rd (1999)         Kidney       100       23rd (1999)         Fat       100       23rd (1999)         Kidney       100       23rd (1999)         Kidney       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	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: 0-12  $\mu g/kg$  body weight (40th 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:**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	28th (2005)	
Chicken	Fat	1000	28th (2005)	
Pig	Muscle	500	28th (2005)	
Pig	Liver	500	28th (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	28th (2005)	
Sheep	Fat	1000	28th (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: 0-20 µg/kg body weight (50th 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: 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	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)

 $\begin{tabular}{lll} \textbf{JECFA Evaluation:} & 36 \ (1990); \ 40 \ (1992); \ 54 \ (2000); \ 58 \ (2002) \\ \textbf{Acceptable Daily Intake:} 0-1 \ \mu g/kg \ body \ weight \ (40^{th} \ JECFA, \ 1992). \\ \textbf{Residue Definition:} & 22,23-Dihydroavermectin B1a \ (H2B1a). \\ \end{tabular}$ 

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: 0-6 µg/kg body weight (42nd 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: 0-30  $\mu g/kg$  body weight (54th JECFA, 2000).

Residue Definition: Lincomycin.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Milk	150	26th (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	26th (2003)	
Pig	Liver	500	26th (2003)	
Pig	Kidney	1500	26th (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); 58 (2002); 62 (2004); 66 (2006) 70 (2008)

Acceptable Daily Intake:0-0.03  $\mu g/kg$  body weight (54th JECFA, 2000).

**Residue Definition:** Melengestrol acetate.

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

Nesidue	Definition:	wonensir	I.	1
Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Muscle	10	32 <sup>nd</sup> (2009)	
Cattle	Liver	100	35 <sup>th</sup> (2012)	
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)	

#### **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 (75 $^{\rm th}$  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  $\mu$ g/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	38 <sup>th</sup> (2015)	
Sheep	Liver	7000	38 <sup>th</sup> (2015)	
Sheep	Kidney	1700	38 <sup>th</sup> (2015)	
Sheep	Fat	13000	38 <sup>th</sup> (2015)	

#### **MOXIDECTIN** (anthelmintic agent)

JECFA Evaluation: 45 (1995); 47 (1996); 48 (1998); 50 (1998) Acceptable Daily Intake: 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:  $0-5 \mu g/kg$  body weight on the basis of a NOAEL of 0.5 mg/kg body weight per day and a safety factor of  $100 (70^{th} \ JECFA, 2008)$ .

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

Residue Definition: Neomycin.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Muscle	500	23 <sup>rd</sup> (1999)	
Cattle	Liver	500	28th (2005)	
Cattle	Kidney	10000	28th (2005)	
Cattle	Fat	500	23 <sup>rd</sup> (1999)	
Cattle	Milk	1500	28th (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: 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	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: 0-4  $\mu$ g/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: 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	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: 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:**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	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	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: 0-1 µg/kg body weight (66th JECFA, 2006).

**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)	
Pig	Muscle	10	35 <sup>th</sup> (2012)	
Pig	Liver	40	35 <sup>th</sup> (2012)	
Pig	Kidney	90	35 <sup>th</sup> (2012)	
Pig	Fat	10	35 <sup>th</sup> (2012)	The MRL includes skin + fat

## **SARAFLOXACIN** (antimicrobial agent)

JECFA Evaluation: 50 (1998)

**Acceptable Daily Intake:**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)	

## **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	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:** 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: 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	21st (1995)	

## **TESTOSTERONE** (production aid)

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

Acceptable Daily Intake: 0-2 µg/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:**0-100 μg/kg body weight (40<sup>th</sup> 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	21st (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	21st (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	21st (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	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	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:** 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	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: 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	29 <sup>th</sup> (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	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: 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	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)

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

Residue Definition: Zeranol.

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

#### CODEX RISK MANAGEMENT RECOMMENDATIONS FOR VETERINARY DRUGS IN FOODS

Updated as at the 38th Session of the Codex Alimentarius Commission (July 2015)

**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:** 12<sup>th</sup> (1968), 32<sup>nd</sup> (1987), 42<sup>nd</sup> (1994) and 62<sup>nd</sup> (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<sup>1</sup> 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.

**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.

<sup>&</sup>lt;sup>1</sup> Semicarbazide is not a unique indicator of nitrofural use and low levels can be associated with other legitimate sources.

**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

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

#### A) Currently under consideration by CCRVDF

### LASALOCID SODIUM (antiparasitic agent)

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 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.

Species	Tissue	MRLs (µg/kg)	Step	JECFA
Chicken	Muscle	400	4	78
Chicken	Liver	1200	4	78
Chicken	Kidney	600	4	78
Chicken	Skin + Fat	600	4	78
Turkey	Muscle	400	4	78
Turkey	Liver	1200	4	78
Turkey	Kidney	600	4	78
Turkey	Skin + Fat	600	4	78
Quail	Muscle	400	4	78
Quail	Liver	1200	4	78
Quail	Kidney	600	4	78
Quail	Skin + Fat	600	4	78
Pheasant	Muscle	400	4	78
Pheasant	Liver	1200	4	78
Pheasant	Kidney	600	4	78
Pheasant	Skin + Fat	600	4	78

NOTE: The 78<sup>th</sup> 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

Step: (r), revised MRL; (a), amended MRL; T, temporary MRL.

JECFA: Meeting number of the Joint FAO/WHO Expert Committee on Food Additives where the MRL was

recommended/considered.

CCRVDF: Session number of the CCRVDF where the MRL was considered and Appendix number of its report where

the MRL is contained.

Keys for List of MRLs for Veterinary Drugs

#### **IVERMECTIN** (antiparasitic agent)

Acceptable Daily Intake (ADI):

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 The GECDE for children is 1.5 µg/kg body weight per day, which represents 15% bound the ADI. of the upper of 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<sub>1a</sub>.

Species	Tissue	MRLs(μg/kg) recommended by the 78 <sup>th</sup> JECFA	Step	JECFA	MRLs (μg/kg) recommended by the 81 <sup>st</sup> JECFA	Step	JECFA
Cattle	Fat				400	3	81
Cattle	Kidney				100	3	81
Cattle	Liver				800	3	81
Cattle	Muscle	4	7	78	30	3	81

In shaded font are the MRLs held at Step 4 by CCRVDF22.

### **TEFLUBENZURON** (insectide)

Acceptable Daily Intake (ADI):

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 bound upper 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	MRLs (μg/kg) recommended by the 81 <sup>st</sup> JECFA	Step	JECFA
Salmon	Fillet <sup>a</sup>	400	3	81
Salmon	Muscle	400	3	81

<sup>&</sup>lt;sup>a</sup> Muscle plus skin in natural proportion.

#### 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  $\mu\text{g}/\text{day}$  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 81 <sup>st</sup> JECFA	Step	JECFA
Cattle	Kidney	3.3	3	81
Cattle	Liver	3.5	3	81
Cattle	Muscle	0.5	3	81

## 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.

#### PROPOSED DRAFT RISK MANAGEMENT RECOMMENDATIONS FOR VETERINARY DRUGS IN FOODS

(at step 3)

GENTIAN VIOLET (antibacterial, antifungal and anthelminthic agent)

JECFA evaluation: 78th (2013) JECFA

#### Recommended risk management measures

#### **OPTION 1**

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.

#### **OPTION 2**

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.