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

25th Session

San Diego, California, United States of America, 25 – 29 May 2020

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

(Prepared by the Codex Secretariat)

INTRODUCTION

This working document is in support to the discussion on the residues of veterinary drugs in foods of the 25th Session of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF25). 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 41st Session (July 2018); and
- Part 2 Draft and proposed draft MRLs and RMRs arising from the 88th Meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA88).

ACRONYMS

ADI	Acceptable Daily Intake
ARfD	Acute Reference Dose
BMDL10	Benchmark Dose for a 10% Response
CCRVDF	Codex Committee on Residues of Veterinary Drugs in Foods
EDI	Estimated Dietary Exposure
GEADE	Global Estimate of Acute Dietary Exposure
GECDE	Global Estimate of Chronic Dietary Exposure
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOAEL	Lowest-Observed-Adverse-Effect Level
mADI	Microbiological ADI
MRL	Maximum Residue Limit
NOAEL	No-Observed-Adverse-Effect Level
TMDI	Theoretical Maximum Daily Intake
TRR	Total Radioactive Residue

3 Part 1

A) MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS IN FOODS

ABAMECTIN (anthelmintic agent)						
JECFA Evaluati	on:	45 (1995); 4	7 (1996)			
ADI:		0-2 μg/kg body weight (1997). Established for the sum of abamectin and (Z)-8,9 isomer by JMPR (1997)				
Residue Defini	Residue Definition:		Avermectin B1a			
Species	Tissue	MRL (μg/kg)	CAC	Notes		
Cattle	Liver	100	26 th (2003)			
Cattle	Kidney	50	26 th (2003)			
Cattle	Fat	100	26 th (2003)			

ALBENDAZOLE (anthelmintic agent)						
JECFA Evaluation:		34 (1989)				
ADI:		0-50 μg/kg bo	0-50 μg/kg body weight (JECFA34, 1989)			
Residue Definition:		Except milk, 2	2-aminosulfone m	etabolite; Milk, not yet identified.		
Species	Tissue	MRL (μg/kg)	CAC	Notes		
Not specified	Muscle	100	20 th (1993)			
Not specified	Liver	5000	20 th (1993)			
Not specified	Kidney	5000	20 th (1993)			
Not specified	Fat	100	20 th (1993)			
Not specified	Milk (µg/l)	100	20 th (1993)			

JECFA Evaluation:		75 (2011); 8	5 (2017)		
ADI:		0-0.07 μg/kg (JECFA75, 20		the basis of microbiological effects	
mADI:		_	/kg body weight (icrobiota (JECFA8!	ow) based on the effects of amoxicillin on the 5, 2017)	
ARfD:		0.005 mg/kg (JECFA85, 20		robiological effects on the intestinal microbiota	
EDI:		JECFA75 (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 TMDI is 31 μ g/person, which represents 74% of the upper bound of the ADI.			
GECDE:				e general population), oper bound of the mADI (JECFA85, 2017).	
GEADE:		1.4 μg/kg bw (for the general population), which represents 28% of the microbiological ARfD. (JECFA85, 2017). 1.6 μg/kg bw (for children), which represents 31% of the microbiological ARfD (JECFA85, 2017)			
Residue Definition	າ:	Amoxicillin			
Species	Tissue	MRL (μg/kg)	CAC	Notes	
Cattle	Muscle	50	35 th (2012)		
Cattle	Liver	50	35 th (2012)		
Cattle	Kidney	50	35 th (2012)		
Cattle	Fat	50	35 th (2012)		
Cattle	Milk	4	35 th (2012)		
Sheep	Muscle	50	35 th (2012)		
Sheep	Liver	50	35 th (2012)		
Sheep	Kidney	50	35 th (2012)		
Sheep	Fat	50	35 th (2012)		
Sheep	Milk	4	35 th (2012)		
•	Muscle	50	35 th (2012)		
		1	a=th (aa4a)		
Pigs	Liver	50	35 th (2012)		
Pigs Pigs	Liver Kidney	50 50	35 th (2012)		
Pigs Pigs Pigs Pigs			-		
Pigs Pigs Pigs	Kidney	50	35 th (2012)		

^aThe term "finfish" includes all fish species.

 $^{^{\}mbox{\scriptsize b}}$ Muscle plus skin in natural proportion.

AMPICILLIN (ant	imicrobial agent)				
JECFA Evaluatio	n:	85 (2017				
mADI:		0–0.003 mg/kg bw based on a NOAEL equivalent to 0.025 mg/kg bw per day for increase in population(s) of ampicillin-resistant bacteria in the gastrointestinal tract in humans, and using a safety factor of 10 (for the variability in the composition of the intestinal microbiota within and between individuals) (JECFA85, 2017).				
ARfD:		0.012 mg/	kg bw based on t	the microbiological end-point (JECFA85, 2017)		
GECDE:			0.29 μg/kg bw per day (for the general population), which represents 10% of the upper bound of the ADI (JECFA85, 2017)			
GEADE:		1.9 μg/kg bw per day (for the general population), which represents 16% of the ARfD (JECFA85, 2017) 1.7 μg/kg bw per day (for children), which represents 14% of the ARfD (JECFA85, 2017)				
Residue Definiti	on:	Ampicillin				
Species	Tissue	MRL (μg/kg)	CAC	Notes		
Finfisha	Fillet ^b	50	41 st (2018)	JECFA85 recommended an MRL of 50 μg/kg for		
Finfish ^a Muscle		50	41 st (2018)	ampicillin in finfish muscle and in finfish muscle plus skin in natural proportion, the same as that recommended for amoxicillin, because the modes of action, the physicochemical properties and the toxicological and pharmacokinetic profiles of amoxicillin and ampicillin are very similar.		

^aThe term "finfish" includes all fish species.

 $^{^{\}mbox{\scriptsize b}}$ Muscle plus skin in natural proportion.

AVILAMYCIN (antimicro	AVILAMYCIN (antimicrobial agent)					
JECFA Evaluation:	70 (2008)					
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 (JECFA70, 2008)					
Residue Definition:	Dichloroisoeverninic acid (DIA)					

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

AZAPERONE (tranquilizing agent)						
JECFA Evaluation:		38 (1991); 43 (1994); 50 (1998); 52 (1999)				
ADI:		0-6 μg/kg body weight (JECFA50, 1998)				
Residue Definition:		Sum of azaperone and azaperol				
Species	Tissue	MRL (μg/kg)	CAC	Notes		
Pig	Muscle	60	23 rd (1999)			
Pig	Liver	100	23 rd (1999)			
Pig	Kidney	100	23 rd (1999)			
Pig	Fat	60	23 rd (1999)			

BENZYLPENICILLIN/PROCAINE BENZYLPENICILLIN (antimicrobial agent)							
JECFA Evaluation:		36 (1990); 50	36 (1990); 50 (1998)				
ADI:			30 μg-penicillin/person/day (JECFA50, 1998). Residues of benzylpenicillin and procaine benzylpenicillin should be kept below this level.				
Residue Defin	ition:	Benzylpenici	llin				
Species	Tissue	MRL (μg/kg) CAC Notes					
Cattle	Muscle	50	23 rd (1999)				
Cattle	Liver	50	23 rd (1999)				
Cattle	Kidney	50	23 rd (1999)				
Cattle	Milk (μg/l)	4	23 rd (1999)				
Chicken	Muscle	50	23 rd (1999)	Applies to procaine benzylpenicillin only			
Chicken	Liver	50	23 rd (1999)	Applies to procaine benzylpenicillin only			
Chicken	Kidney	50	23 rd (1999)	Applies to procaine benzylpenicillin only			
Pig	Muscle	50	23 rd (1999)				
Pig	Liver	50	23 rd (1999)				
Pig	Kidney	50	23 rd (1999)				

CARAZOLOL (beta-adreniceptor-blocking agent)							
JECFA Evaluation:		38 (1991); 4	38 (1991); 43 (1994); 52 (1999)				
ADI:	ADI:		0-0.1 μg/kg body weight (JECFA43, 1994). ADI based on the acute pharmacological effects of carazolol.				
Residue Defin	ition:	Carazolol					
Species	Tissue	MRL (μg/kg)	CAC	Notes			
Pig	Muscle	5	26 th (2003)	The concentration at the injection site two hours after treatment may result in an intake that exceeds the ARfD and therefore, an appropriate withdrawal period should be applied.			
Pig	Liver	25	26 th (2003)				
Pig	Kidney	25	26 th (2003)				
Pig	Fat/Skin	5	26 th (2003)	The concentration at the injection site two hours after treatment may result in an intake that exceeds the ARfD and therefore, an appropriate withdrawal period should be applied.			

CEFTIOFUR (antimicrobial agent)						
JECFA Evaluation:		45 (1995); 48 (1997)				
ADI:		0-50 μg/kg b	ody weight (JECF	A45, 1995)		
Residue Definit	tion:	Desfuroylceft	tiofur			
Species	Tissue	MRL (μg/kg) CAC Notes				
Cattle	Muscle	1000	23 rd (1999)			
Cattle	Liver	2000	23 rd (1999)			
Cattle	Kidney	6000	23 rd (1999)			
Cattle	Fat	2000	23 rd (1999)			
Cattle	Milk (μg/l)	100	23 rd (1999)			
Pig	Muscle	1000	23 rd (1999)			
Pig	Liver	2000	23 rd (1999)			
Pig	Kidney	6000	23 rd (1999)			
Pig	Fat	2000	23 rd (1999)			

CHLORTETRACYCLINE/OXYTETRACYCLINE/TETRACYCLINE (antimicrobial agent)						
JECFA Evaluation:		45 (1995); 47 (1996); 50 (1998); 58 (2002)				
ADI:			0-30 μg/kg body weight (JECFA50, 1998). Group ADI for chlortetracycline, oxytetracycline and tetracycline.			
Residue Definition:		Parent drug	s, singly or in cor	nbination		
Species	Tissue	MRL (μg/kg)	CAC	Notes		
Cattle	Muscle	200	26 th (2003)			
Cattle	Liver	600	26 th (2003)			
Cattle	Kidney	1200	26 th (2003)			
Cattle	Milk (μg/l)	100	26 th (2003)			
Fish	Muscle	200	26 th (2003)	Applies only to oxytetracycline		
Giant prawn (Paeneus monodon)	Muscle	200	26 th (2003)	Applies only to oxytetracycline		
Pig	Muscle	200	26 th (2003)			
Pig	Liver	600	26 th (2003)			
Pig	Kidney	1200	26 th (2003)			
Poultry	Muscle	200	26 th (2003)			
Poultry	Liver	600	26 th (2003)			
Poultry	Kidney	1200	26 th (2003)			
Poultry	Eggs	400	26 th (2003)			
Sheep	Muscle	200	26 th (2003)			
Sheep	Liver	600	26 th (2003)			
Sheep	Kidney	1200	26 th (2003)			
Sheep	Milk (μg/l)	100	26 th (2003)			

CLENBUTEROI	(adrenoceptor a	gonist)					
JECFA Evaluat	tion:	47 (1996)					
ADI:		0-0.004 μg/kg body weight (JECFA47, 1996)					
Residue Definition:		Clenbuterol					
Species	Tissue	MRL (μg/kg)	CAC	Notes			
Cattle	Muscle	0.2	26 th (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 th (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 th (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 th (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 th (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 th (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 th (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 th (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 th (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 (ar	nthelmintic agent)					
JECFA Evaluat	ion:	36 (1990); 40 (1992)				
ADI:		0-30 μg/kg b	ody weight (JECF	A40, 1992)		
Residue Defin	ition:	Closantel				
Species	Tissue	MRL (μg/kg)	CAC	Notes		
Cattle	Muscle	1000	20 th (1993)			
Cattle	Liver	1000	20 th (1993)			
Cattle	Kidney	3000	20 th (1993)			
Cattle	Fat	3000	20 th (1993)			
Sheep	Muscle	1500	20 th (1993)			
Sheep	Liver	1500	20 th (1993)			
Sheep	Kidney	5000	20 th (1993)			
Sheep	Fat	2000	20 th (1993)			

COLISTIN (anti	microbial agent)						
JECFA Evaluat	tion:	66 (2006)	66 (2006)				
ADI:	ADI:		0-7 μg/kg body weight (JECFA66, 2006)				
Residue Defin	nition:	Sum of colis	tin A and colistin	n B			
Species	Tissue	MRL (μg/kg)	CAC	Notes			
Cattle	Muscle	150	31 st (2008)				
Cattle	Liver	150	31 st (2008)				
Cattle	Kidney	200	31 st (2008)				
Cattle	Fat	150	31 st (2008)				
Cattle	Milk	50	31 st (2008)				
Sheep	Muscle	150	31 st (2008)				
Sheep	Liver	150	31 st (2008)				
Sheep	Kidney	200	31 st (2008)				
Sheep	Fat	150	31 st (2008)				
Sheep	Milk	50	31 st (2008)				
Goat	Muscle	150	31 st (2008)				
Goat	Liver	150	31 st (2008)				
Goat	Kidney	200	31 st (2008)				
Goat	Fat	150	31 st (2008)				
Pig	Muscle	150	31 st (2008)				
Pig	Liver	150	31 st (2008)				
Pig	Kidney	200	31 st (2008)				
Pig	Fat	150	31 st (2008)	The MRL includes skin + fat			
Chicken	Muscle	150	31 st (2008)				
Chicken	Liver	150	31 st (2008)				
Chicken	Kidney	200	31 st (2008)				
Chicken	Fat	150	31 st (2008)	The MRL includes skin + fat			
Chicken	Eggs	300	31 st (2008)				
Turkey	Muscle	150	31 st (2008)				
Turkey	Liver	150	31 st (2008)				
Turkey	Kidney	200	31 st (2008)				
Turkey	Fat	150	31 st (2008)	The MRL includes skin + fat			
Rabbit	Muscle	150	31 st (2008)				
Rabbit	Liver	150	31 st (2008)				
Rabbit	Kidney	200	31 st (2008)				
Rabbit	Fat	150	31 st (2008)				

CYFLUTHRIN (insecticide)					
JECFA Evaluati	on:	48 (1997)			
ADI:		0-20 μg/kg b	ody weight (JECF	A48, 1997)	
Residue Defini	tion:	Cyfluthrin			
Species	Tissue	MRL (μg/kg)	CAC	Notes	
Cattle	Muscle	20	26 th (2003)		
Cattle	Liver	20	26 th (2003)		
Cattle	Kidney	20	26 th (2003)		
Cattle	Fat	200	26 th (2003)		
Cattle	Milk (μg/l)	40	26 th (2003)		

CYHALOTHRIN	(insecticide)						
JECFA Evaluation:		54 (2000); 5	54 (2000); 58 (2002); 62 (2004)				
ADI:		0-5 μg/kg bo	ody weight (JECFA6	2, 2004)			
Residue Defir	nition:	Cyhalothrin					
Species	Tissue	MRL (μg/kg)	CAC	Notes			
Cattle	Muscle	20	28 th (2005)				
Cattle	Liver	20	28 th (2005)				
Cattle	Kidney	20	28 th (2005)				
Cattle	Fat	400	28 th (2005)				
Cattle	Milk	30	28 th (2005)				
Pig	Muscle	20	28 th (2005)				
Pig	Liver	20	28 th (2005)				
Pig	Kidney	20	28 th (2005)				
Pig	Fat	400	28 th (2005)				
Sheep	Muscle	20	28 th (2005)				
Sheep	Liver	50	28 th (2005)				
Sheep	Kidney	20	28 th (2005)				
Sheep	Fat	400	28 th (2005)				

CYPERMETHRI	N AND ALPHA-CYP	ERMETHRIN (in	secticide)	
JECFA Evaluat	tion:	62 (2004)		
ADI:			ished a common A methrin (JECFA62,	DI of 0-20 μg/kg bw for both cypermethrin and 2004)
Residue Definition: Total of cypermethrin residues (resulting from the use of cypermethrin as veterinary drugs)				
Species	Tissue	MRL (μg/kg) CAC Note		
Cattle	Muscle	50	29 th (2006)	
Cattle	Liver	50	29 th (2006)	
Cattle	Kidney	50	29 th (2006)	
Cattle	Fat	1000	29 th (2006)	
Cattle	Milk	100	29 th (2006)	
Sheep	Muscle	50	29 th (2006)	
Sheep	Liver	50	29 th (2006)	
Sheep	Kidney	50	29 th (2006)	
Sheep	Fat	1000	29 th (2006)	

DANOFLOXAC	CIN (antimicrobial	agent)					
JECFA Evaluation:		48 (1997)	48 (1997)				
ADI:		0-20 μg/kg k	ody weight (JECI	FA48, 1997)			
Residue Defir	nition:	Danofloxaci	n				
Species	Tissue	MRL (μg/kg)	CAC	Notes			
Cattle	Muscle	200	24 th (2001)				
Cattle	Liver	400	24 th (2001)				
Cattle	Kidney	400	24 th (2001)				
Cattle	Fat	100	24 th (2001)				
Chicken	Muscle	200	24 th (2001)				
Chicken	Liver	400	24 th (2001)				
Chicken	Kidney	400	24 th (2001)				
Chicken	Fat	100	24 th (2001)	Fat/skin in normal proportion			
Pig	Muscle	100	24 th (2001)				
Pig	Liver	50	24 th (2001)				
Pig	Kidney	200	24 th (2001)				
Pig	Fat	100	24 th (2001)				

DELTAMETHRIN (insecticide)							
JECFA Evaluat	JECFA Evaluation:		52 (1999); 60 (2003)				
ADI:		0-10 μg/kg l	oody weight (1982)	. Established by JMPR (1982)			
Residue Defin	nition:	Deltamethri	n				
Species	Tissue	MRL (μg/kg)	CAC	Notes			
Cattle	Muscle	30	26 th (2003)				
Cattle	Liver	50	26 th (2003)				
Cattle	Kidney	50	26 th (2003)				
Cattle	Fat	500	26 th (2003)				
Cattle	Milk	30	26 th (2003)				
Chicken	Muscle	30	26 th (2003)				
Chicken	Liver	50	26 th (2003)				
Chicken	Kidney	50	26 th (2003)				
Chicken	Fat	500	26 th (2003)				
Chicken	Eggs	30	26 th (2003)				
Salmon	Muscle	30	26 th (2003)				
Sheep	Muscle	30	26 th (2003)				
Sheep	Liver	50	26 th (2003)				
Sheep	Kidney	50	26 th (2003)				
Sheep	Fat	500	26 th (2003)				

DERQUANTEL	(anthelmintic age	nt)			
JECFA Evaluat	ion:	75 (2011); 78	3 (2013)		
ADI:		0-0.3 μg/kg body weight on the basis of a 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 (JECFA75, 2011).			
EDI:		There were insufficient data to calculate an EDI, and the TMDI approach w used. Using the model diet and the MT:TR approach, these MRLs result in estimated dietary exposure of 6.8 µg/person, which represents approxima 38% of the upper bound of the ADI (JECFA78, 2013).			
Residue Defin	ition:	Derquantel			
Species	Tissue	MRL (μg/kg)	CAC	Notes	
Sheep	Muscle	0.3	38 th (2015)		
Sheep	Liver	0.8 38 th (2015)			
Sheep	Kidney	0.4 38 th (2015)			
Sheep	Fat	7.0	38 th (2015)		

DEXAMETHASONE (glucocorticosteroid)							
JECFA Evaluat	JECFA Evaluation:		70 (2008)				
ADI:		0-0.015 μg/l	kg body weight (JEC	CFA42, 1995)			
Residue Defin	nition:	Dexamethas	sone				
Species	Tissue	MRL (μg/kg)	CAC Notes				
Cattle	Muscle	1.0	32 nd (2009)				
Cattle	Liver	2.0	32 nd (2009)				
Cattle	Kidney	1.0	32 nd (2009)				
Cattle	Milk (μg/l)	0.3	32 nd (2009)				
Pig	Muscle	1.0	32 nd (2009)				
Pig	Liver	2.0	32 nd (2009)				
Pig	Kidney	1.0	32 nd (2009)				
Horses	Muscle	1.0	32 nd (2009)				
Horses	Liver	2.0	32 nd (2009)				
Horses	Kidney	1.0	32 nd (2009)				

DICLAZURIL (antiprotozoal agent)						
JECFA Evaluation:		45 (1995); 50 (1998)				
ADI:		0-30 μg/kg b	ody weight (JECFA	50, 1998)		
Residue Definit	tion:	Diclazuril				
Species	Tissue	MRL (μg/kg)	CAC	Notes		
Poultry	Muscle	500	23 rd (1999)			
Poultry	Liver	3000	23 rd (1999)			
Poultry	Kidney	2000	23 rd (1999)			
Poultry	Fat/Skin	1000	23 rd (1999)			
Rabbit	Muscle	500	23 rd (1999)			
Rabbit	Liver	3000	23 rd (1999)			
Rabbit	Kidney	2000	23 rd (1999)			
Rabbit	Fat	1000	23 rd (1999)			
Sheep	Muscle	500	23 rd (1999)			
Sheep	Liver	3000	23 rd (1999)			
Sheep	Kidney	2000	23 rd (1999)			
Sheep	Fat	1000	23 rd (1999)			

DICYCLANIL (insecticide)					
JECFA Evaluation	on:	54 (2000); 60	0 (2003)		
ADI:		0-7 μg/kg bo	dy weight (JECFA54, 2000)		
Residue Definit	tion:	Dicyclanil			
Species	Tissue	MRL (μg/kg)	CAC	Notes	
Sheep	Muscle	150	28 th (2005)		
Sheep	Liver	125	28 th (2005)		
Sheep	Kidney	125	28 th (2005)		
Sheep	Fat	200	28 th (2005)		

DIHYDROSTRI	EPTOMYCIN/STRE	PTOMYCIN (an	timicrobial agent)			
JECFA Evaluation:		43 (1994); 4	43 (1994); 48 (1997); 52 (1999); 58 (2002) 0-50 μg/kg body weight (JECFA48, 1997). Group ADI for combined residues of dihydrostreptomycin and streptomycin.			
ADI:	ADI:					
Residue Defir	nition:	Sum of dihy	drostreptomycin a	and streptomycin		
Species	Tissue	MRL (μg/kg)	CAC	Notes		
Cattle	Muscle	600	24 th (2001)			
Cattle	Liver	600	24 th (2001)			
Cattle	Kidney	1000	24 th (2001)			
Cattle	Fat	600	24 th (2001)			
Cattle	Milk	200	26 th (2003)			
Chicken	Muscle	600	24 th (2001)			
Chicken	Liver	600	24 th (2001)			
Chicken	Kidney	1000	24 th (2001)			
Chicken	Fat	600	24 th (2001)			
Pig	Muscle	600	24 th (2001)			
Pig	Liver	600	24 th (2001)			
Pig	Kidney	1000	24 th (2001)			
Pig	Fat	600	24 th (2001)			
Sheep	Muscle	600	24 th (2001)			
Sheep	Liver	600	24 th (2001)			
Sheep	Kidney	1000	24 th (2001)			
Sheep	Fat	600	24 th (2001)			
Sheep	Milk	200	26 th (2003)			

DIMINAZENE (trypanocide)				
JECFA Evaluation	on:	34 (1989); 42 (1994)	
ADI:		0-100 μg/kg bo	ody weight (JECFA	42, 1994)
Residue Definit	tion:	Diminazene		
Species	Tissue	MRL (μg/kg)	CAC	Notes
Cattle	Muscle	500	22 nd (1997)	
Cattle	Liver	12000	22 nd (1997)	
Cattle	Kidney	6000	22 nd (1997)	
Cattle	Milk (μg/l)	150	22 nd (1997)	Limit of quantitation of the analytical method

DORAMECTIN (anthelmintic agent)						
JECFA Evaluat	tion:	45 (1995); 5	45 (1995); 52 (1999); 58 (2002); 62 (2004)			
ADI:		0-1 μg/kg b	ody weight (JECF	A58, 2002)		
Residue Defir	nition:	Doramectin				
Species	Tissue	MRL (μg/kg)	CAC	Notes		
Cattle	Muscle	10	22 nd (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 nd (1997)			
Cattle	Kidney	30	22 nd (1997)			
Cattle	Fat	150	22 nd (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 th (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 th (2001)			
Pig	Liver	100	24 th (2001)			
Pig	Kidney	30	24 th (2001)			
Pig	Fat	150	24 th (2001)			

EMAMECTIN BENZOATE (antiparasitic agent)					
JECFA Evaluation: 78 (2013)					
ADI:		ADI of 0–0.5 µg/kg body weight established by JMPR (2011), based on an overall 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 LOAEL in dogs, as used by JMPR and confirmed by the current Committee (JECFA78, 2013).			
EDI:		$11 \mu g/person$ per day, which represents approximately 37% of the upper bound of the ADI (JECFA78, 2013).			
Residue Defir	nition:	Emamectin B1a.			
Species	Tissue	MRL (μg/kg)	CAC	Notes	
Salmon	Muscle	100 38 th (2015)			
Salmon	Fillet	100	38 th (2015)	Muscle plus skin in natural proportion	
Trout	Muscle	100	38 th (2015)		
Trout	Fillet	100	38 th (2015)	Muscle plus skin in natural proportion	

EPRINOMECTIN (anthelmintic agent)					
JECFA Evaluation	on:	50 (1998)			
ADI:		0-10 μg/kg body weight (JECFA50, 1998).			
Residue Definit	tion:	Eprinomectin B1a.			
Species	Tissue	MRL (μg/kg)	CAC	Notes	
Cattle	Muscle	100	26 th (2003)		
Cattle	Liver	2000	26 th (2003)		
Cattle	Kidney	300	26 th (2003)		
Cattle	Fat	250	26 th (2003)		
Cattle	Milk (µg/l)	20	26 th (2003)		

ERYTHROMYCIN (antimicrobial agent)						
JECFA Evaluation:		66 (2006)				
ADI:		0-0.7 μg/kg b	ody weight (JECF	A66, 2006)		
Residue Definit	ion:	Erythromycin	Α			
Species	Tissue	MRL (μg/kg)	CAC	Notes		
Chicken	Muscle	100	31 st (2008)			
Chicken	Liver	100	31 st (2008)			
Chicken	Kidney	100	31 st (2008)			
Chicken	Fat	100	31 st (2008)	The MRL includes skin + fat		
Chicken	Eggs	50	31 st (2008)			
Turkey	Muscle	100	31 st (2008)			
Turkey	Liver	100	31 st (2008)			
Turkey	Kidney	100	31 st (2008)			
Turkey	Fat	100	31 st (2008)	The MRL includes skin + fat		

ESTRADIOL-17BETA (production aid)						
JECFA Evaluation:		25 (1981); 32 (1987); 52 (1999)				
ADI:	ADI:		CFA32, 1987); 0-	0.05 μg/kg body weight (JECFA52, 1999).		
Residue Defin	ition:	Estradiol-17beta	1			
Species	Tissue	MRL (μg/kg)	CAC	Notes		
Cattle	Muscle	Unnecessary	21 st (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 st (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 st (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 st (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 Evaluati	on:	38 (1991); 45 (1995); 50 (1998)				
ADI:		0-7 μg/kg body weight (JECFA50, 1998). Group ADI.				
Residue Defini	tion:		endazole, oxfendaz s oxfendazole sulph	ole and oxfendazole sulphone, one equivalents.		
Species	Tissue	MRL (μg/kg)	I CΔC I Notes			
Cattle	Muscle	100	23 rd (1999)			
Cattle	Liver	500	23 rd (1999)			
Cattle	Kidney	100	23 rd (1999)			
Cattle	Fat	100	23 rd (1999)			
Cattle	Milk (µg/l)	100	23 rd (1999)			
Goat	Muscle	100	23 rd (1999)			
Goat	Liver	500	23 rd (1999)			
Goat	Kidney	100	23 rd (1999)			
Goat	Fat	100	23 rd (1999)			
Horse	Muscle	100	23 rd (1999)			
Horse	Liver	500	23 rd (1999)			
Horse	Kidney	100	23 rd (1999)			
Horse	Fat	100	23 rd (1999)			
Pig	Muscle	100	23 rd (1999)			
Pig	Liver	500	23 rd (1999)			
Pig	Kidney	100	23 rd (1999)			
Pig	Fat	100	23 rd (1999)			
Sheep	Muscle	100	23 rd (1999)			
Sheep	Liver	500	23 rd (1999)			
Sheep	Kidney	100	23 rd (1999)			
Sheep	Fat	100	23 rd (1999)			
Sheep	Milk (μg/l)	100	23 rd (1999)			

FLUAZURON (insecticide)						
JECFA Evaluation	on:	48 (1997)				
ADI:		0-40 μg/kg bo	0-40 μg/kg body weight (JECFA48, 1997)			
Residue Definit	tion:	Fluazuron.				
Species	Tissue	MRL (μg/kg)	CAC	Notes		
Cattle	Muscle	200	23 rd (1999)			
Cattle	Liver	500	23 rd (1999)			
Cattle	Kidney	500	23 rd (1999)			
Cattle	Fat	7000	23 rd (1999)			

FLUBENDAZOLE (anthelmintic agent)						
JECFA Evaluat	ion:	40 (1992)				
ADI:		0-12 μg/kg b	ıg/kg body weight (JECFA40, 1992)			
Residue Defin	ition:	Flubendazole				
Species	Tissue	MRL (μg/kg)	CAC	Notes		
Pig	Muscle	10	21 st (1995)			
Pig	Liver	10	21 st (1995)			
Poultry	Muscle	200	21 st (1995)			
Poultry	Liver	500	21 st (1995)			
Poultry	Eggs	400	21 st (1995)			

FLUMEQUINE	(antimicrobial ag	ent)					
JECFA Evaluation:		42 (1994); 4	42 (1994); 48 (1997); 54 (2000); 60 (2002); 62 (2004); 66 (2006				
ADI:		0-30 μg/kg b	oody weight (JECF	462, 2004)			
Residue Defir	nition:	Flumequine					
Species	Tissue	MRL (μg/kg)	CAC	Notes			
Cattle	Muscle	500	28 th (2005)				
Cattle	Liver	500	28 th (2005)				
Cattle	Kidney	3000	28 th (2005)				
Cattle	Fat	1000	28 th (2005)				
Chicken	Muscle	500	28 th (2005)				
Chicken	Liver	500	28 th (2005)				
Chicken	Kidney	3000	28 th (2005)				
Chicken	Fat	1000	28 th (2005)				
Pig	Muscle	500	28 th (2005)				
Pig	Liver	500	28 th (2005)				
Pig	Kidney	3000	28 th (2005)				
Pig	Fat	1000	28 th (2005)				
Sheep	Muscle	500	28 th (2005)				
Sheep	Liver	500	28 th (2005)				
Sheep	Kidney	3000	28 th (2005)				
Sheep	Fat	1000	28 th (2005)				
Trout	Muscle	500	28 th (2005)	Muscle including normal proportion of skin			

GENTAMICIN (antimicrobial agent)						
JECFA Evaluation:		43 (1994); 48	43 (1994); 48 (1997); 50 (1998)			
ADI:		0-20 μg/kg b	ody weight (JECFA	50, 1998)		
Residue Defin	ition:	Gentamicin				
Species	Tissue	MRL (μg/kg)	CAC	Notes		
Cattle	Muscle	100	24 th (2001)			
Cattle	Liver	2000	24 th (2001)			
Cattle	Kidney	5000	24 th (2001)			
Cattle	Fat	100	24 th (2001)			
Cattle	Milk (μg/l)	200	24 th (2001)			
Pig	Muscle	100	24 th (2001)			
Pig	Liver	2000	24 th (2001)			
Pig	Kidney	5000	24 th (2001)			
Pig	Fat	100	24 th (2001)			

IMIDOCARB (antiprotozoal agent)					
JECFA Evaluation	on:	50 (1998); 60 (2003)			
ADI:		0-10 μg/kg body weight (JECFA50, 1998)			
Residue Definit	tion:	Imidocarb			
Species	Tissue	MRL (μg/kg)	CAC	Notes	
Cattle	Muscle	300	28 th (2005)		
Cattle	Liver	1500	28 th (2005)		
Cattle	Kidney	2000	28 th (2005)		
Cattle	Fat	50	28 th (2005)		
Cattle	Milk	50	28 th (2005)		

ISOMETAMIDIUM (trypanocide)					
JECFA Evaluati	on:	34 (1989); 40 (1992)			
ADI:		0-100 μg/kg body weight (JECFA40, 1992)			
Residue Defini	tion:	Isometamidiu	ım		
Species	Tissue	MRL (μg/kg)	CAC	Notes	
Cattle	Muscle	100	21 st (1995)		
Cattle	Liver	500	21 st (1995)		
Cattle	Kidney	1000	21 st (1995)		
Cattle	Fat	100	21 st (1995)		
Cattle	Milk (μg/l)	100	21 st (1995)		

IVERMECTIN ((anthelmintic ager	nt)				
JECFA Evaluat	tion:	36 (1990); 40	36 (1990); 40 (1992); 54 (2000); 58 (2002); 81 (2015)			
ADI:		day for neurol week dog stud interspecies d and 10 for interspecies	0-10 μ g/kg body weight on the basis of a 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 μ g/kg body weight was withdrawn. (JECFA81, 2015).			
ARfD:		highest dose t healthy huma	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 (JECFA81, 2015).			
GECDE:		-	ug/person per day, er bound of the AD	based on a 60 kg individual, which represents I.		
		The GECDE for the general population is $0.9 \mu g/kg$ body weight per day, which represents 9% of the upper bound of the ADI. The GECDE for children is $1.5 \mu g/kg$ body weight per day, which represents 15% of the upper bound of the ADI. The GECDE for infants is $1.3 \mu g/kg$ body weight per day, which represents 13% of the upper bound of the ADI. (JECFA81, 2015)				
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 GEADE of 52 μ g/kg bw for the general population and 87 μ g/kg bw for children, corresponding, respectively, to 27% and 43% of the ARfD. (JECFA81, 2015)				
Residue Defin	nition:	Ivermectin B _{1a}				
Species	Tissue	MRL (μg/kg)	CAC	Notes		
Cattle	Muscle	30	40 th (2017)			
Cattle	Liver	800	40 th (2017)			
Cattle	Kidney	100	40 th (2017)			
Cattle	Fat	400	40 th (2017)			
Cattle	Milk	10	26 th (2003)			
Pig	Liver	15	15 20 th (1993)			
Pig	Fat	20	20 th (1993)			
Sheep	Liver	15	20 th (1993)			
Sheep	Fat	20	20 th (1993)			

LASALOCID SC	DDIUM (antiparasit	ic agent)			
JECFA Evaluation:		78 (2013)			
ADI:.		$0-5~\mu g/kg$ 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 (JECFA78, 2013).			
EDI:				ated, which represents approximately ADI (JECFA78, 2013).	
Residue Defin	ition:	Lasalocid A			
Note	:	JECFA78 extended the MRLs in chicken to turkey and quail and extrapolated the MRLs in chicken to pheasant. No information was available for duck, including on approved uses. As the compound is not registered for use in laying hens, according to the sponsor, it is not appropriate to recommend MRLs for egg.			
Species	Tissue	MRL (μg/kg)	CAC	Notes	
Chicken	Muscle	400	40 th (2017)		
Chicken	Liver	1200	40 th (2017)		
Chicken	Kidney	600	40 th (2017)		
Chicken	Skin + Fat	600	40 th (2017)		
Turkey	Muscle	400	40 th (2017)		
Turkey	Liver	1200	40 th (2017)		
Turkey	Kidney	600	40 th (2017)		
Turkey	Skin + Fat	600	40 th (2017)		
Quail	Muscle	400	40 th (2017)		
Quail	Liver	1200	40 th (2017)		
Quail	Kidney	600	40 th (2017)		
Quail	Skin + Fat	600	40 th (2017)		
Pheasant	Muscle	400	40 th (2017)		
Pheasant	Liver	1200	40 th (2017)		
Pheasant	Kidney	600	40 th (2017)		
Pheasant	Skin + Fat	600	40 th (2017)		

LEVAMISOLE (anthelmintic ager	it)					
JECFA Evaluat	tion:	36 (1990); 4	36 (1990); 42 (1994)				
ADI:		0-6 μg/kg bo	0-6 μg/kg body weight (JECFA42, 1994)				
Residue Defin	nition:	Levamisole					
Species	Tissue	MRL (μg/kg)	CAC	Notes			
Cattle	Muscle	10	22 nd (1997)				
Cattle	Liver	100	22 nd (1997)				
Cattle	Kidney	10	22 nd (1997)				
Cattle	Fat	10	22 nd (1997)				
Pig	Muscle	10	22 nd (1997)				
Pig	Liver	100	22 nd (1997)				
Pig	Kidney	10	22 nd (1997)				
Pig	Fat	10	22 nd (1997)				
Poultry	Muscle	10	22 nd (1997)				
Poultry	Liver	100	22 nd (1997)				
Poultry	Kidney	10	22 nd (1997)				
Poultry	Fat	10	22 nd (1997)				
Sheep	Muscle	10	22 nd (1997)				
Sheep	Liver	100	22 nd (1997)				
Sheep	Kidney	10	22 nd (1997)				
Sheep	Fat	10	22 nd (1997)				

LINCOMYCIN (antimicrobial age	nt)			
JECFA Evaluation:		54 (2000); 58 (2002); 62 (2004)			
ADI:		0-30 μg/kg b	ody weight (JECF	A54, 2000)	
Residue Defin	ition:	Lincomycin			
Species	Tissue	MRL (μg/kg) CAC Notes			
Cattle	Milk	150	26 th (2003)		
Chicken	Muscle	200	26 th (2003)		
Chicken	Liver	500	26 th (2003)		
Chicken	Kidney	500	26 th (2003)		
Chicken	Fat	100	26 th (2003)	Additional MRL for skin with adhering fat of 300 $\mu g/kg$	
Pig	Muscle	200	26 th (2003)		
Pig	Liver	500	26 th (2003)		
Pig	Kidney	1500	26 th (2003)		
Pig	Fat	100	26 th (2003)	Additional MRL for skin with adhering fat of 300 μ g/kg	

LUNEFURON (insecticide)					
JECFA Evaluation	on:	85 (2017)			
ADI:		0–0.02 mg/kg bw based on the NOAEL of 1.93 mg/kg bw per day for tonic-clonic seizures and findings in lungs, gastrointestinal tract, liver and urinary tract in a 2-year dietary study in rats, and using a safety factor of 100 (10 for interspecies variability and 10 for intraspecies variability) (JECFA85, 2017).			
ARfD: Unnecessary, in view of lufenuron low acute oral toxicity and the absence developmental toxicity and other toxicological effects likely to be elicite single dose (JECFA85, 2017)			•		
upper bound of the ADI. As lufenuron is also used as pesticide the overall estimated. The assumptions and detailed results			general population), which represents 5.5% of the esticide the overall dietary exposure was and detailed results will be displayed in the JECFA85 for use as veterinary drug (JECFA85, 2017).		
Residue Defini	tion:	Lunefuron			
Species	Tissue	MRL (μg/kg) CAC Notes			
Salmon	Fillet ^a	1350	41 st (2018)		
Trout	Fillet ^a	1350	41 st (2018)		

^a Muscle plus skin in natural proportion.

MELENGESTROL ACETATE (production aid)						
JECFA Evaluation	on:	54 (2000); 58	3 (2002); 62 (2004);	66 (2006) 70 (2008)		
ADI:		0-0.03 μg/kg	body weight (JECF	body weight (JECFA54, 2000)		
Residue Definit	ion:	Melengestro	l acetate			
Species	Tissue	MRL (μg/kg)	CAC	Notes		
Cattle	Muscle	1	32 nd (2009)			
Cattle	Liver	10	32 nd (2009)			
Cattle	Kidney	2	32 nd (2009)			
Cattle	Fat	18	32 nd (2009)			

ADI: Estimated Dietary Exposure:		 70 (2008); 75 (2011) 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 (JECFA70, 2008). 				
						value of 481
		Residue Defin	nition:	Monensin		
Species	Tissue	MRL (μg/kg)	CAC	Notes		
Cattle	Muscle	10	32 nd (2009)			
Cattle	Liver	100	35 th (2012)			
Cattle	Kidney	10	32 nd (2009)			
Cattle	Fat	100	32 nd (2009)			
Cattle	Milk	2	32 nd (2009)			
Sheep	Muscle	10	32 nd (2009)			
Sheep	Liver	20	32 nd (2009)			
Sheep	Kidney	10	32 nd (2009)			
Sheep	Fat	100	32 nd (2009)			
Goats	Muscle	10	32 nd (2009)			
Goats	Liver	20	32 nd (2009)			
Goats	Kidney	10	32 nd (2009)			
Goats	Fat	100	32 nd (2009)			
Chicken	Muscle	10	32 nd (2009)			
Chicken	Liver	10	32 nd (2009)			
Chicken	Kidney	10	32 nd (2009)			
Chicken	Fat	100	32 nd (2009)			
Turkey	Muscle	10	32 nd (2009)			
Turkey	Liver	10	32 nd (2009)			
Turkey	Kidney	10	32 nd (2009)			
Turkey	Fat	100	32 nd (2009)			
Quail	Muscle	10	32 nd (2009)			
Quail	Liver	10	32 nd (2009)			
Quail	Kidney	10	32 nd (2009)			
Quail	Fat	100	32 nd (2009)			

MONEPANTEI	L (anthelmintic age	ent)				
JECFA Evaluation:		75 (2011); 78	75 (2011); 78 (2013); 85 th (2017)			
ADI:		seizures and f	0–0.02 mg/kg bw based on the NOAEL of 1.93 mg/kg bw per day for tonic-clonic seizures and findings in lungs, gastrointestinal tract, liver and urinary tract in a 2-year dietary study in rats, and using a safety factor of 100 (10 for interspecies variability and 10 for intraspecies variability) (JECFA85, 2017).			
ARfD:		Unnecessary				
Estimated Die	etary Exposure:	Using the model diet and marker residue to total residue ratios of 1.00 for muscle and 0.66 for fat, liver and kidney, and applying a correction factor of 0.94 to account for the mass difference between monepantel sulfone (the marker residue) and monepantel, the EDI is 446 µg/person per day, which represents approximately 37% of the upper bound of the ADI (JECFA78, 2013).				
GECDE:		 13.7 μg per kg bw per day (for the general population), which represents 68% of the upper bound of the ADI (JECFA85, 2017). 5.0 μg per kg bw per day (for children), which represents 22% of the upper bound of the ADI (JECFA85, 2017). 4.4 μg per kg bw per day (for infants), which represents 25% of the upper bound 				
		of the ADI (JECFA85, 2017).				
Residue Defir	nition:	Monepantel sulfone, expressed as monepantel.				
Species	Tissue	MRL (μg/kg)	CAC	Notes		
Cattle	Muscle	300	41 st (2018)			
Cattle	Liver	2000	41 st (2018)			
Cattle	Kidney	1000	41 st (2018)			
Cattle	Fat	7000	41 st (2018)			
Sheep	Muscle	500 38 th (2015)				
Sheep	Liver	7000 38 th (2015)				
Sheep	Kidney	1700	38 th (2015)			
Sheep	Fat	13000	38 th (2015)			

MOXIDECTIN	(anthelmintic age	nt)				
JECFA Evalua	tion:	45 (1995); 4	45 (1995); 47 (1996); 48 (1998); 50 (1998)			
ADI:		0-2 μg/kg bo	ody weight (JECF	A45, 1995)		
Residue Defir	nition:	Moxidectin				
Species	Tissue	MRL (μg/kg)	CAC	Notes		
Cattle	Muscle	20	22 nd (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 nd (1997)			
Cattle	Kidney	50	22 nd (1997)			
Cattle	Fat	500	22 nd (1997)			
Deer	Muscle	20	23 rd (1999)			
Deer	Liver	100	23 rd (1999)			
Deer	Kidney	50	23 rd (1999)			
Deer	Fat	500	23 rd (1999)			
Sheep	Muscle	50	22 nd (1997)			
Sheep	Liver	100	22 nd (1997)			
Sheep	Kidney	50	22 nd (1997)			
Sheep	Fat	500	22 nd (1997)			

NARASIN (ant	imicrobial agent)				
JECFA Evaluation:		70 (2008); 75 (2011)			
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 (JECFA70, 2008)			
Residue Defin	nition:	Narasin A			
Species	Tissue	MRL (μg/kg)	CAC	Notes	
Cattle	Muscle	15	35 th (2012)		
Cattle	Liver	50	35 th (2012)		
Cattle	Kidney	15	35 th (2012)		
Cattle	Fat	50	35 th (2012)		
Chicken	Muscle	15	32 nd (2009)		
Chicken	Liver	50	32 nd (2009)		
Chicken	Kidney	15	32 nd (2009)		
Chicken	Fat	50	32 nd (2009)		
Pig	Muscle	15	34 th (2011)		
Pig	Liver	50	34 th (2011)		
Pig	Kidney	15	34 th (2011)		
Pig	Fat	50	34 th (2011)		

NEOMYCIN (ar	ntimicrobial ager	it)				
JECFA Evaluat	ion:	43 (1994); 47 (1996); 52 (1999); 58 (2002); 60 (2003)				
ADI:		0-60 μg/kg body weight (JECFA47, 1996)				
Residue Defin	ition:	Neomycin				
Species	Tissue	MRL (μg/kg) CAC Notes				
Cattle	Muscle	500	23 rd (1999)			
Cattle	Liver	500	28 th (2005)			
Cattle	Kidney	10000	28 th (2005)			
Cattle	Fat	500	23 rd (1999)			
Cattle	Milk	1500	28 th (2005)			
Chicken	Muscle	500	23 rd (1999)			
Chicken	Liver	500	23 rd (1999)			
Chicken	Kidney	10000	23 rd (1999)			
Chicken	Fat	500	23 rd (1999)			
Chicken	Eggs	500	23 rd (1999)			
Duck	Muscle	500	23 rd (1999)			
Duck	Liver	500	23 rd (1999)			
Duck	Kidney	10000	23 rd (1999)			
Duck	Fat	500	23 rd (1999)			
Goat	Muscle	500	23 rd (1999)			
Goat	Liver	500	23 rd (1999)			
Goat	Kidney	10000	23 rd (1999)			
Goat	Fat	500	23 rd (1999)			
Pig	Muscle	500	23 rd (1999)			
Pig	Liver	500	23 rd (1999)			
Pig	Kidney	10000	23 rd (1999)			
Pig	Fat	500	23 rd (1999)			
Sheep	Muscle	500	23 rd (1999)			
Sheep	Liver	500	23 rd (1999)			
Sheep	Kidney	10000	23 rd (1999)			
Sheep	Fat	500	23 rd (1999)			
Turkey	Muscle	500	23 rd (1999)			
Turkey	Liver	500	23 rd (1999)			
Turkey	Kidney	10000	23 rd (1999)			
Turkey	Fat	500	23 rd (1999)			

NICARBAZIN (antiprotozoal agent)						
JECFA Evaluation	on:	50 (1998)				
ADI:		0-400 μg/kg b	0-400 μg/kg body weight (JECFA50, 1998)			
Residue Definit	tion:	N,N'-bis(4-nitropheyl)urea				
Species	Tissue	MRL (μg/kg)	CAC	Notes		
Chicken	Muscle	200	23 rd (1999)	Broilers		
Chicken	Liver	200 23 rd (1999) Broilers				
Chicken	Kidney	200	23 rd (1999)	Broilers		
Chicken	Fat/Skin	200	23 rd (1999)	Broilers		

PHOXIM (inse	cticide)						
JECFA Evaluation:		52 (1999); 62	52 (1999); 62 (2004)				
ADI:		0-4 μg/kg bo	dy weight (JECFA5	52, 1999)			
Residue Defir	nition:	Phoxim					
Species	Tissue	MRL (μg/kg)	CAC	Notes			
Goat	Muscle	50	26 th (2003)				
Goat	Liver	50	26 th (2003)				
Goat	Kidney	50	26 th (2003)				
Goat	Fat	400	26 th (2003)				
Pig	Muscle	50	26 th (2003)				
Pig	Liver	50	26 th (2003)				
Pig	Kidney	50	26 th (2003)				
Pig	Fat	400	26 th (2003)				
Sheep	Muscle	50	26 th (2003)				
Sheep	Liver	50	26 th (2003)				
Sheep	Kidney	50	26 th (2003)				
Sheep	Fat	400	26 th (2003)				

PIRLIMYCIN (antimicrobial agent)						
JECFA Evaluation:		62 (2004)	62 (2004)			
ADI:		0-8 μg/kg bv	v (JECFA62, 2004)		
Residue Defin	ition:	Pirlimycin				
Species	Tissue	MRLs (μg/kg)	CAC	Note		
Cattle	Muscle	100	29 th (2006)			
Cattle	Liver	1000	29 th (2006)			
Cattle	Kidney	400	29 th (2006)			
Cattle	Fat	100	29 th (2006)			
Cattle	Milk	100	29 th (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	on:	52 (1999)			
ADI:		Not Specified	(JECFA52, 1999)		
Residue Definit	tion:	Not applicable			
Species	Tissue	MRL (μg/kg)	CAC	Notes	
Pig	Muscle	not specified	26 th (2003)		
Pig	Liver	not specified	26 th (2003)		
Pig	Kidney	not specified	26 th (2003)		
Pig	Fat	not specified	26 th (2003)		

PROGESTERONE (production aid)						
JECFA Evaluation:		25 (1981); 32 (25 (1981); 32 (1987); 52 (1999)			
ADI:		0-30 μg/kg bo	dy weight (JECF	A52, 1999)		
Residue Defi	nition:	Progesterone				
Species	Tissue	MRL (μg/kg)	CAC	Notes		
Cattle	Muscle	Unnecessary	21 st (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 st (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 st (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 st (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	JECFA Evaluation:		(2004); 66 (2006	5)	
ADI:		0-1 μg/kg boo	dy weight (JECFA	56, 2006)	
Residue Defini	tion:	Ractopamine			
Species	Tissue	MRL (μg/kg)	CAC	Notes	
Cattle	Muscle	10	35 th (2012)		
Cattle	Liver	40	35 th (2012)		
Cattle	Kidney	90	35 th (2012)		
Cattle	Fat	10	35 th (2012)		
Pig	Muscle	10	35 th (2012)		
Pig	Liver	40	35 th (2012)		
Pig	Kidney	90	35 th (2012)		
Pig	Fat	10	35 th (2012)	The MRL includes skin + fat	

SARAFLOXACIN	V (antimicrobial ag	ent)					
JECFA Evaluati	JECFA Evaluation:		50 (1998)				
ADI:		0-0.3 μg/kg b	oody weight (JECI	FA50, 1998)			
Residue Defini	ition:	Sarafloxacin					
Species	Tissue	MRL (μg/kg)	CAC	Notes			
Chicken	Muscle	10	24 th (2001)				
Chicken	Liver	80	24 th (2001)				
Chicken	Kidney	80	24 th (2001)				
Chicken	Fat	20	24 th (2001)				
Turkey	Muscle	10	24 th (2001)				
Turkey	Liver	80	24 th (2001)				
Turkey	Kidney	80	24 th (2001)				
Turkey	Fat	20	24 th (2001)				

SPECTINOMY	CIN (antimicrobial	agent)					
JECFA Evaluat	tion:	42 (1994); 5	42 (1994); 50 (1998)				
ADI:	ADI:		0-40 μg/kg body weight (JECFA42, 1994)				
Residue Defin	nition:	Spectinomy	cin				
Species	Tissue	MRL (μg/kg)	CAC	Notes			
Cattle	Muscle	500	23 rd (1999)				
Cattle	Liver	2000	23 rd (1999)				
Cattle	Kidney	5000	23 rd (1999)				
Cattle	Fat	2000	23 rd (1999)				
Cattle	Milk (µg/l)	200	23 rd (1999)				
Chicken	Muscle	500	23 rd (1999)				
Chicken	Liver	2000	23 rd (1999)				
Chicken	Kidney	5000	23 rd (1999)				
Chicken	Fat	2000	23 rd (1999)				
Chicken	Eggs	2000	23 rd (1999)				
Pig	Muscle	500	23 rd (1999)				
Pig	Liver	2000	23 rd (1999)				
Pig	Kidney	5000	23 rd (1999)				
Pig	Fat	2000	23 rd (1999)				
Sheep	Muscle	500	23 rd (1999)				
Sheep	Liver	2000	23 rd (1999)				
Sheep	Kidney	5000	23 rd (1999)				
Sheep	Fat	2000	23 rd (1999)				

SPIRAMYCIN (antimicrobial agent)						
JECFA Evaluation:		38 (1991); 43	38 (1991); 43 (1994); 47 (1996); 48 (1997)			
ADI:		0-50 μg/kg bo	ody weight (JECFA	43, 1994)		
Residue Defin	ition:		ickens, sum of spi antimicrobially ac	ramycin and neospiramycin; Pigs, spiramycin tive residues).		
Species	Tissue	MRL (μg/kg)	CAC	Notes		
Cattle	Muscle	200	22 nd (1997)			
Cattle	Liver	600	22 nd (1997)			
Cattle	Kidney	300	22 nd (1997)			
Cattle	Fat	300	22 nd (1997)			
Cattle	Milk (μg/l)	200	22 nd (1997)			
Chicken	Muscle	200	22 nd (1997)			
Chicken	Liver	600	22 nd (1997)			
Chicken	Kidney	800	22 nd (1997)			
Chicken	Fat	300	22 nd (1997)			
Pig	Muscle	200	22 nd (1997)			
Pig	Liver	600	22 nd (1997)			
Pig	Kidney	300	22 nd (1997)			
Pig	Fat	300	22 nd (1997)			

SULFADIMIDINE (antimicrobial agent)							
JECFA Evaluation	on:	34 (1989); 38	34 (1989); 38 (1991); 42 (1994)				
ADI:		0-50 μg/kg bo	0-50 μg/kg body weight (JECFA42, 1994)				
Residue Definit	tion:	Sulfadimidine					
Species	Tissue	MRL (μg/kg)	CAC	Notes			
Cattle	Milk (μg/l)	25	21 st (1995)				
Not specified	Muscle	100	21 st (1995)				
Not specified	Liver	100	21 st (1995)				
Not specified	Kidney	100	21 st (1995)				
Not specified	Fat	100	21 st (1995)				

TEFLUBENZURO	TEFLUBENZURON (insecticide)				
JECFA Evaluation	on:	81 (2015)			
ADI:		0-5 µg/kg body weight on the basis of a lower 95% confidence limit on the 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 (JECFA81, 2015).			
GECDE: The EDI is 42.9 μg/person per day represents approximately 14% of the general population is 1.6 μg/l of the upper bound of the ADI. The per day, which represents 43% of the upper second sec			lay, on the basis of a 60 kg individual, which of the upper bound of the ADI. The GECDE for g/kg body weight per day, which represents 31% The GECDE for children is 2.1 µg/kg body weight of the upper bound of the ADI. The GECDE for t per day, which represents 18% of the upper 15)		
Residue Definit	ion:	Teflubenzuron			
Species	Tissue	MRL (μg/kg) CAC Notes			
Salmon	Muscle	400	40 th (2017)		
Salmon	Fillet	400	40 th (2017)	Muscle plus skin in natural proportion	

TESTOSTERONE (production aid)					
JECFA Evaluation: ADI: Residue Definition:		25 (1981); 32 (1987); 52 (1999)			
		0-2 μg/kg body weight (JECFA52, 1999)			
		Testosterone			
Species	Tissue	MRL (μg/kg)	CAC	Notes	
Cattle	Muscle	Unnecessary	21 st (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 st (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 st (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 st (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.	

JECFA Evaluat	tion:	40 (1992): 4	40 (1992); 48 (1997); 58 (2002)				
ADI:		, ,	g body weight (JE	•			
Residue Defin	nition:		Sum of thiabendazole and 5-hydroxythiabendazole				
Species	Tissue	MRL (µg/kg)	CAC	Notes			
Cattle	Muscle	100	21 st (1995)	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.			
Cattle	Liver	100	21 st (1995)	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.			
Cattle	Kidney	100	21 st (1995)	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.			
Cattle	Fat	100	21 st (1995)	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.			
Cattle	Milk (μg/l)	100	21 st (1995)	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.			
Goat	Muscle	100	21 st (1995)	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.			
Goat	Liver	100	21 st (1995)	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.			
Goat	Kidney	100	21 st (1995)	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.			
Goat	Fat	100	21 st (1995)	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.			
Goat	Milk (μg/l)	100	21 st (1995)	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.			
Pig	Muscle	100	21 st (1995)	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.			
Pig	Liver	100	21 st (1995)	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.			
Pig	Kidney	100	21 st (1995)	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.			
Pig	Fat	100	21 st (1995)	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.			
Sheep	Muscle	100	21 st (1995)	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.			

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

TILMICOSIN (a	intimicrobial agent)						
JECFA Evaluat	JECFA Evaluation:		47 (1996); 54 (2000); 70 (2008) 0-40 μg/kg body weight (JECFA47, 1996)				
ADI: Residue Definition:		0-40 μg/kg b					
		Tilmicosin					
Species	Tissue	MRL (μg/kg)	CAC	Notes			
Cattle	Muscle	100	23 rd (1999)				
Cattle	Liver	1000	23 rd (1999)				
Cattle	Kidney	300	23 rd (1999)				
Cattle	Fat	100	23 rd (1999)				
Chicken	Muscle	150	34 th (2011)				
Chicken	Liver	2400	34 th (2011)				
Chicken	Kidney	600	34 th (2011)				
Chicken	Skin/Fat	250	34 th (2011)				
Pig	Muscle	100	23 rd (1999)				
Pig	Liver	1500	23 rd (1999)				
Pig	Kidney	1000	23 rd (1999)				
Pig	Fat	100	23 rd (1999)				
Sheep	Muscle	100	23 rd (1999)				
Sheep	Liver	1000	23 rd (1999)				
Sheep	Kidney	300	23 rd (1999)				
Sheep	Fat	100	23 rd (1999)				
Turkey	Muscle	100	34 th (2011)				
Turkey	Kidney	1200	34 th (2011)				
Turkey	Liver	1400	34 th (2011)				
Turkey	Skin/Fat	250	34 th (2011)				

TRENBOLONE ACETATE (growth promoter)					
JECFA Evaluation:		26 (1982); 27 (1983); 32 (1987); 34 (1989)			
ADI:		0-0.02 μg/kg body weight (JECFA34, 1989)			
Residue Definition: Cattle muscle, beta-Trenbolone; Cattle liver, alpha-Trenbolone.			e; Cattle liver, alpha-Trenbolone.		
Species	Tissue	MRL (μg/kg)	CAC	Notes	
Cattle	Muscle	2	21 st (1995)		
Cattle	Liver	10	21 st (1995)		

TRICHLORFON (Metrifonate) (insecticide)					
JECFA Evaluation: 54 (2000); 60 (2003); 66 (2006)					
ADI:		0-2 μg/kg bw (JECFA60, 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 54 th meeting (WHO TRS 900, 2001)			
Species	Tissue	MRLs (μg/kg)	CAC	Notes	
Cattle	Milk	50	29 th (2006)		

TRICLABENDAZOLE (anthelmintic agent)					
JECFA Evaluation	on:	40 (1992); 66	(2006); 70 (2008)		
ADI:		0-3 μg/kg bod	ly weight (JECFA4	0, 1993).	
Residue Definit	tion:	Ketotriclabne	dazole		
Species	Tissue	MRL (μg/kg)	CAC	Notes	
Cattle	Muscle	250	32 nd (2009)		
Cattle	Liver	850	32 nd (2009)		
Cattle	Kidney	400	32 nd (2009)		
Cattle	Fat	100	32 nd (2009)		
Sheep	Muscle	200	32 nd (2009)		
Sheep	Liver	300	32 nd (2009)		
Sheep	Kidney	200	32 nd (2009)		
Sheep	Fat	100	32 nd (2009)		

TYLOSIN (antin	nicrobial agent)						
JECFA Evaluat	JECFA Evaluation:		70 (2008)				
ADI:		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) (JECFA70, 2008).					
Residue Defir	nition:	Tylosin A					
Species Tissue		MRLs (μg/kg)	CAC	Notes			
Cattle	Muscle	100	32 nd (2009)				
Cattle	Liver	100	32 nd (2009)				
Cattle	Kidney	100	32 nd (2009)				
Cattle	Fat	100	32 nd (2009)				
Cattle	Milk	100	32 nd (2009)				
Pig	Muscle	100	32 nd (2009)				
Pig	Liver	100	32 nd (2009)				
Pig	Kidney	100	32 nd (2009)				
Pig	Fat	100	32 nd (2009)				
Chicken	Muscle	100	32 nd (2009)				
Chicken	Liver	100	32 nd (2009)				
Chicken	Kidney	100	32 nd (2009)				
Chicken	Fat/Skin	100	32 nd (2009)				
Chicken	Eggs	300	32 nd (2009)				

ZERANOL (growth promoter)						
JECFA Evaluation:		26 (1982); 27 (1983); 32 (1987)				
ADI:		0-0.5 μg/kg body weight (JECFA32, 1987)		32, 1987)		
Residue Definit	Residue Definition:		Zeranol			
Species	Tissue	MRL (μg/kg)	CAC	Notes		
Cattle	Muscle	2	21 st (1995)			
Cattle	Liver	10	21 st (1995)			

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

CARBADOX (growth promoter)

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

CAC37 (2014)

Recommended risk management measures

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

CHLORAMPHENICOL (antimicrobial agent)

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

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)

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)

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)

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.

GENTIAN VIOLET (antibacterial, antifungal and anthelminthic agent)

JECFA evaluation: 78th (2013)

CAC41 (2018)

Recommended risk management measures

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

IPRONIDAZOLE (antiprotozoal agent)

JECFA evaluation: 34th (1989)

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)

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)

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)

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 metabolites¹ in food representing an acceptable risk to consumers, significant health concerns were identified. For this reason, competent authorities should prevent residues of nitrofural in food. This can be accomplished by not using nitrofural in food producing animals.

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

OLAQUINDOX (antibacterial agent)

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

CAC37 (2014)

Recommended risk management measures

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

RONIDAZOLE (antiprotozoal agent)

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

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)

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.

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

DIFLUBENZURON (inse	ecticide)					
ADI		0–0.02 mg/kg body weight (bw) – based on a NOAEL of 2 mg/kg bw per day for increased methaemoglobin and sulfhaemoglobin levels in a 2-year study of toxicity and carcinogenicity in rats; and increased methaemoglobin and sulfhaemoglobin levels, platelet counts and hepatic pigmentation in a 1-year study of toxicity in dogs – applying a safety factor of 100 (10 for interspecies variability and 10 for intraspecies variability) (JECFA88, 2019).				
ARfD:		Unnecessary (JECFA85 reiterated the conclusion of JECFA81 that it was not necessary to establish an ARfD, in view of the low acute oral toxicity and the absence of developmental toxicity, and any other toxicological effects likely to be elicited by a single dose (JECFA88, 2019).				
GECDE:		0.84 μg/kg bw per day (for the general population), which represents 4% of the upper bound of the ADI (JECFA88, 2019).				
		2.85 μ g/kg bw per day (for children), which represents 14% of the upper bound of the ADI. (JECFA88, 2019).				
GEADE:		Not estimated because JECFA88 concluded that it was not necessary to establish an ARfD.				
Residue Definition:	Residue Definition:		Diflubenzuron and the ratio of the MR to the TRR of 0.9 established at its 81st meeting (JECFA88, 2019).			
Species	Tissue	MRLs (μg/kg) recommended by JECFA85	Step	JECFA		
Salmon	Muscle plus skin in natural proportions	10	3	88		

FLUMETHRIN (insectic	ide)						
ADI:		0–0.004 mg/kg bw based on the NOAEL of 0.37 mg/kg bw per day for skin lesions in parental animals and reduced survival and body-weight gain in pups in a two-generation toxicity study in rats, and using a safety factor of 100 (10 for interspecies variability and 10 for intraspecies variability).					
ARfD:		0.005 mg/kg bw based on the NOAEL of 0.5 mg/kg bw for salivation in dams in a developmental toxicity study in rats, and using a safety factor of 100 (10 for interspecies variability and 10 for intraspecies variability).					
GECDE:		0.008 μg/kg bw per day (for th 0.2% of the upper bound of th		, which represents			
		0.006 μg/kg bw per day (for children), which represents 0.2% of the upper bound of the ADI.					
		Note: As flumethrin is also used as pesticide the overall dietary exposure was estimated. The assumptions and detailed results will be displayed in the JECFA85 report. Results below are only for use as veterinary drug.					
GEADE:		0.1 μg/kg bw per day (for the 2.2% of the ARfD.	general population), w	hich represents			
		$0.1\ \mu\text{g/kg}$ bw per day (for children), which represents 2.2% of the ARfD.					
Residue Definition:		Flumethrin (trans-Z1 and trans Z2 diastereomers at a ratio of approximately 60:40)					
Species	Tissue	MRLs (µg/kg) recommended by JECFA85	Step	JECFA			
	Honey	6	5	85			

Note: JECFA85 set an MRL for honey of 6 μ g/kg, which is twice the limit of quantification (LOQ; 3 μ g/kg) of the most reliable analytical method (liquid chromatography coupled with tandem mass spectrometry; LC-MS/MS) used in the residues studies

HALQUINOL (broad-	-spectrum antimicrobi	al)					
ADI:		accompanied by increases in a year chronic toxicity study in r	0–0.2 mg/kg bw, based on histopathological changes in the kidney, accompanied by increases in absolute and relative renal weight in a 1-year chronic toxicity study in rats, applying a safety factor of 100 (10 for interspecies variability and 10 for intraspecies variability) (JECFA88, 2019).				
ARfD:		dams observed in a developm application of a safety factor of	0.3 mg/kg bw, based on a NOAEL of 30 mg/kg bw for clinical signs in dams observed in a developmental toxicity study in mice, with application of a safety factor of 100 (10 for interspecies variability and 10 for intraspecies variability) (JECFA88, 2019).				
GECDE:		5.9 μg/kg bw per day (for generate upper bound of the ADI (J	• •	n represents 3% of			
		6.9 μg/kg bw per day (for children), which represents 3.4% of the upper bound of the ADI (JECFA88, 2019).					
GEADE:		2–224 μg/kg bw per day, which represents 0.5–75% of the ARfD (comparable for children and adults) (JECFA88, 2019).					
Residue Definition:		The sum of 5-chloroquinolin-8-ol (5-CL), 5,7-dichloroquinolin-8-ol 5,7-DCL (5,7-DCL) and their glucuronide metabolites: 5-CLG (expressed as 5-CL equivalents) and 5,7-DCLG (expressed as 5,7-DCL equivalents) (JECFA88, 2019).					
Species	Tissue	MRLs (μg/kg) recommended by JECFA85	Step	JECFA			
Swine	Muscle	40	3	88			
Swine	Liver	500	3	88			
Swine	Kidney	900	3	88			
Swine	Skin plus fat	350	3	88			

IVERMECTIN (broad	d-spectrum antiparasitic	agent)				
ADI:		0–10 μg/kg bw. (JECFA81, 2015)				
ARfD:		0.2 mg/kg bw. (JECFA81, 20	015)			
GECDE:		0.41 μg/kg bw per day (for 4% of the upper bound of t		•		
		0.59 μg/kg bw per day (for upper bound of the ADI. (JE		esents 5.9% of the		
GEADE: 87 μg/kg bw per day (for general population), which re 43% of the ARfD, from consumption of cattle muscle, a 1.1 μg/kg bw, which represents 0.6% of the ARfD (JECF 82 μg/kg bw per day (for children), which represents 4 ARfD, from consumption of cattle muscle and of 1.0 μg which represents 0.5% of the ARfD, from consumption muscle (JECFA88, 2019).			uscle, and of O (JECFA88, 2019). ents 41% of the 1.0 µg/kg bw,			
Residue Definition:		Ivermectin B_{1a} (H_2B_{1a} , or 22,23-dihydroavermectin B_{1a}) in sheep and goat (JECFA88, 2019).				
Species	Tissue	MRLs (µg/kg) recommended by JECFA85	Step	JECFA		
Pig	Muscle	10	3	88		
Pig	Liver	15	3	88		
Pig	Kidney	15	3	88		
Pig	Fat	20	3	88		
Sheep	Muscle	10	3	88		
Sheep	Liver	15	3	88		
Sheep	Kidney	15	3	88		
Sheep	Fat	20	3	88		
Goat	Muscle	10	3	88		
Goat	Liver	15	3	88		
<u> </u>	Kidney	15	3	88		
Goat	Ridiley	13	3	00		

ZILPATEROL HYDROCHLORIDE (β2-adrenoceptor agonist)								
ADI:		0-0.04 μ g/kg body weight established at JECFA78 (WHO TRS No. 988, 2014) and reaffirmed at JECFA81 (JECFA81, 2015).						
ARfD:		$0.04~\mu g/kg$ body weight based on a lowest-observed-adverse-effect level (LOAEL) of $0.76~\mu g/kg$ 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 (JECFA81, 2015).						
GEADE:		1.9 µg/day for the general population, which represents approximately 80% of the ARfD. The GEADE is 0.57 µg/day for children, which represents approximately 94% of the ARfD. (JECFA81, 2015).						
Residue Definition:		Zilpaterol (free base) in muscle, liver and kidney.						
Species	Tissue	MRLs (μg/kg) recommended by JECFA81	Step	JECFA				
Cattle	Kidney	3.3	4	81				
	Liver	3.5	4	81				
	Muscle	0.5 4		81				

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

BOVINE SOMATOTROPINS (production aid)								
JECFA Evaluation:		40 (1992); 50 (1998)						
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, 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, 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.