ANNEX 1

RECOMMENDATIONS ON COMPOUNDS ON THE AGENDA AND FURTHER INFORMATION REQUIRED

Avilamycin (antimicrobial agent)

Acceptable daily intake: The Committee established an ADI of 0–2 mg/kg bw on the basis of a NOAEL of 150 mg avilamycin activity/kg bw per day and a safety factor of 100 and rounding to one significant figure.

Residue definition: Dichloroisoeverninic acid (DIA)

Recommended maximum residue limits (MRLs)

Species	Skin/fat (µg/kg)	Kidney (µg/kg)	Liver (µg/kg)	Muscle (µg/kg)
Pigs	200	200	300	200
Chickens	200	200	300	200
Turkeys	200	200	300	200
Rabbits	200	200	300	200

Dexamethasone (glucocorticosteroid)

Acceptable daily intake: The Committee established an ADI of 0–0.015 µg/kg bw at the 42nd meeting of the Committee (WHO TRS No. 851, 1995, reference 9).

Residue definition: Dexamethasone

Recommended maximum residue limits (MRLs)

Species	Kidney (µg/kg)	Liver (µg/kg)	Muscle (µg/kg)	Milk (µg/l)
Cattle	1.0	2.0	1.0	0.3
Pigs	1.0	2.0	1.0	
Horses	1.0	2.0	1.0	

Malachite green (antimicrobial agent and contaminant)

Acceptable daily intake: The Committee considered it inappropriate to establish an ADI for malachite green and did not support the use of malachite green for food-producing animals.

Residues: The Committee did not recommend MRLs for malachite green and leucomalachite green, as it did not support the use of malachite green for food-producing animals.

Melengestrol acetate (production aid)

Acceptable daily intake: The Committee established an ADI of 0–0.03 µg/kg bw at its 54th meeting (WHO TRS No. 900, 2001, reference 18). It did not consider it necessary to reconsider the ADI at the current meeting on the basis of new data provided.

Residues: The MRLs that were recommended by the 66th meeting of the Committee (WHO TRS No. 939, 2006, reference 22) were not reconsidered and were maintained.

Monensin (antimicrobial agent and production aid)

Acceptable daily intake: The Committee established an ADI of 0–10 µg/kg bw on the basis of a NOAEL of 1.14 mg/kg bw per day and a safety factor of 100 and rounding to one significant figure.

Residue definition: Monensin

Recommended maximum residue limits (MRLs)

Species	Fat (µg/kg)	Kidney (µg/kg)	Liver (µg/kg)	Muscle (µg/kg)	Milk (µg/kg)
Cattle	100	10	20	10	2
Sheep	100	10	20	10	
Goats	100	10	20	10	
Chickens	100	10	10	10	
Turkeys	100	10	10	10	
Quail	100	10	10	10	

Narasin (antimicrobial agent and production aid)

Acceptable daily intake: The Committee established an ADI of 0–5 µg/kg bw on the basis of a NOAEL of 0.5 mg/kg bw per day and a safety factor of 100.

Residues: Narasin A

Recommended maximum residue limits (MRLs)

Species	Fat (µg/kg)	Kidney (µg/kg)	Liver (µg/kg)	Muscle (µg/kg)
Cattle	50[a]	15[a]	50[a]	15[a]
Chickens	50	15	50	15
Pigs	50	15	50	15

[a] The MRL is temporary.

Before a re-evaluation of narasin with the aim of recommending MRLs in tissues of cattle, the Committee would require a detailed description of a regulatory method, including its performance characteristics and validation data. This information is required by the end of 2010.

Tilmicosin (antimicrobial agent)

Acceptable daily intake: The Committee established an ADI of 0–40 µg/kg bw at its 47th meeting (WHO TRS No. 876, 1998, reference 12).

Residue definition: Tilmicosin

Recommended maximum residue limits (MRLs)

Species	Skin/fat (µg/kg)	Kidney (µg/kg)	Liver (µg/kg)	Muscle (µg/kg)
Chickens	250	600	2400	150
Turkeys	250	1200	1400	100

The Committee was not able to recommend a MRL for sheep milk.

Before a re-evaluation of tilmicosin with the aim of recommending MRLs in tissues of rabbits, the Committee would require adequately designed residue studies with doses and routes of administration under authorized conditions of use and using a validated method suitable for the purpose.

Triclabendazole (anthelminthic)

Acceptable daily intake: The Committee established an ADI of 0–3 µg/kg bw at its 40th meeting (WHO TRS No. 832, 1993, reference 8).

Residue definition: Ketotriclabendazole

Recommended maximum residue limits (MRLs)

Species	Fat (µg/kg)	Kidney (µg/kg)	Liver (µg/kg)	Muscle (µg/kg)
Cattle	100	400	850	250
Sheep	100	200	300	200

Tylosin (antimicrobial agent)

Acceptable daily intake: The Committee established an ADI of 0–30 µg/kg bw based on a microbiological end-point derived from in vitro MIC susceptibility testing and faecal binding data (MIC_{calc} = 1.698).

Residue definition: Tylosin A

Recommended maximum residue limits (MRLs)

Species	Fat (µg/kg)	Kidney (µg/kg)	Liver (µg/kg)	Muscle (µg/kg)	Skin/fat (µg/kg)	Milk (µg/kg)	Eggs (µg/kg)
Cattle	100	100	100	100		100	
Pigs	100	100	100	100			
Chickens		100	100	100	100		300

ANNEX 2

SUMMARY OF JECFA EVALUATIONS OF VETERINARY DRUG RESIDUES FROM THE 32ND MEETING TO THE PRESENT

The following table summarises the veterinary drug evaluations conduced by JECFA at the 32nd (1987), 34th (1989), 36th (1990), 38th (1991), 40th (1992), 42nd (1994), 43rd (1994), 45th (1995), 48th (1997), 50th (1998), 52nd (1999), 54th (2000), 58th (2002), 60th (2003), 62nd (2004), 66th (2006) and 70th (2008) meetings. These meetings were devoted exclusively to the evaluation of veterinary drug residues in food. **This table must be considered in context with the full reports of these meetings, published as WHO Technical Report Series.**

Some notes regarding the table:
-The "ADI Status" column refers to the ADI and indicates whether an ADI was established; If a full ADI was given, or if the ADI is temporary (T).

-Where an MRL is temporary, it is indicated by "T".

-Where a compound has been evaluated more than once, the data given are for the most recent evaluation, including the 70th meeting of the Committee.

Substance	ADI (µg/kg bw)	ADI Status	JECFA[1]	MRL (µg/kg)	Tissue	Species	Marker residue and other remarks
Abamectin	0-1 (JMPR 1995)	Full	47 (1996)	100 50	Liver, Fat Kidney	Cattle	Avermectin B_{1a}
Albendazole	0-50	Full	34 (1989)	100 5000	Muscle, Fat, Milk Liver, Kidney	Cattle, Sheep	MRLs analyzed as 2-amino-benzimidazole, expressed as albendazole equivalents
Avilamycin	0-2000 (as avilamycin activity)	Full	70 (2008)	200 300	Muscle, Kidney, Skin/Fat Liver	Pig, Chicken, Turkey, Rabbit Pig, Chicken, Turkey, Rabbit	Dichloroisoeverninic acid (DIA), expressed as avilamycin equivalents
Azaperone	0-6	Full	50 (1998)	60 100	Muscle, Fat Liver, Kidney	Pig	Sum of azaperone and azaperol
Benzylpenicillin	<30µg/person/ day of the penicillin moiety	Full	36 (1990)	50 4	Muscle, Liver, Kidney Milk	All species	Benzylpenicillin
Bovine Somatotropins	Not specified	Full	50 (1998)	Not specified	Muscle, Liver, Kidney, Fat, Milk	Cattle	
Carazolol	0-0.1	Full	43 (1994)	5 25	Muscle, Fat/Skin Liver, Kidney	Pig	Carazolol. The Committee noted that the concentration of carazolol at the injection site may exceed the ADI that is based on the acute pharmacological effect of carazolol
Carbadox	No ADI		60 (2003)	No MRL			The Committee decided that quinoxaline-2-carboxylic acid is not an appropriate marker residue
Ceftiofur	0-50	Full	48 (1997)	1000 2000 6000 2000 100	Muscle Liver Kidney Fat Milk	Cattle, Pig Cattle	Desfuroylceftiofur
Cefuroxime	No ADI		62 (2004)	No MRL			
Chloramphenicol	No ADI		62 (2004)	No MRL			
Chlorpromazine	No ADI		38 (1991)	No MRL			

[1] Only the last meeting of the Committee where the substance was on the agenda; earlier evaluations are referred to in the respective reports of the meetings

Substance	ADI (µg/kg bw)	ADI Status	JECFA[1]	MRL (µg/kg)	Tissue	Species	Marker residue and other remarks
Chlortetracycline Oxytetracycline Tetracycline	0-30 (Group ADI)	Full	58 (2002)	200 600 1200 400 100 200 200	Muscle Liver Kidney Eggs Milk Muscle Muscle	Cattle, Pig, Sheep, Poultry Poultry Cattle, Sheep Fish Giant prawn	Parent drugs, either singly or in combination Oxytetracycline only
Clenbuterol	0-0.004	Full	47 (1996)	0.2 0.6 0.05	Muscle, Fat Liver, Kidney Milk	Cattle, Horse Cattle	Clenbuterol
Closantel	0-30	Full	40 (1992)	1000 3000 1500 5000 2000	Muscle, Liver Kidney, Fat Muscle, Liver, Kidney Fat	Cattle Sheep	Closantel
Colistin	0-7	Full	66 (2006)	150 200 50 300	Muscle, Liver, Fat Kidney Milk Eggs	Cattle, Sheep, Goat, Chicken, Turkey, Pig, Rabbit Cattle, Sheep Chicken	Residue definition is the sum of Colistin A and colistin B. The MRL includes skin + fat where appropriate (chicken, turkey, pigs).
Cyfluthrin	0-20	Full	48 (1997)	20 200 40	Muscle, Liver, Kidney Fat Milk	Cattle	Cyfluthrin
Cyhalothrin	0-5	Full	62 (2004)	20 400 20 50 30	Muscle, Kidney Fat Liver Liver Milk	Cattle, Sheep, Pig Cattle, Pig Sheep Cattle, Sheep	Cyhalothrin
Cypermethrin α-Cypermethrin	0-20 (Group ADI)	Full	62 (2004)	50 1000 100	Muscle, Liver, Kidney Fat Milk	Cattle, Sheep Cattle, Sheep	Total of cypermethrin residues (resulting from the use of cypermethrin or α-cypermethrin as veterinary drugs)

Substance	ADI (µg/kg bw)	ADI Status	JECFA[1]	MRL (µg/kg)	Tissue	Species	Marker residue and other remarks
Danofloxacin	0-20	Full	48 (1997)	200 400 100 100 50 200 100	Muscle Liver, Kidney Fat Muscle Liver Kidney Fat	Cattle, Chicken Pig	Danofloxacin For chicken fat/skin
Deltamethrin	0-10 (1982 JMPR)	Full	60 (2003)	30 50 500 30 30	Muscle Liver, Kidney Fat Milk Eggs	Cattle, Chicken, Sheep, Salmon Cattle, Sheep, Chicken Cattle Chicken	Deltamethrin
Dexamethasone	0-0.015	Full	70 (2008)	1 2 0.3	Muscle, Kidney Liver Milk	Cattle, Pig, Horse Cattle, Pig, Horse Cattle	Dexamethasone
Diclazuril	0-30	Full	50 (1998)	500 3000 2000 1000	Muscle Liver Kidney Fat	Sheep, Rabbit, Poultry	Diclazuril Poultry skin + fat
Dicyclanil	0-7	Full	60 (2003)	150 125 200	Muscle Liver, Kidney Fat	Sheep	Dicyclanil
Dihydro-streptomycin Streptomycin	0-50 (Group ADI)	Full	58 (2002)	600 1000 200	Muscle, Liver, Fat Kidney Milk	Cattle, Pig, Chicken, Sheep Cattle, Sheep	Sum of dihydrostreptomycin and streptomycin
Dimetridazole	No ADI		34 (1989)	No MRL			
Diminazene	0-100	Full	42 (1994)	500 12000 6000 150	Muscle Liver, Kidney Milk	Cattle	Diminazene
Enrofloxacin	0-2	Full	48 (1997)	No MRL			

Substance	ADI (µg/kg bw)	ADI Status	JECFA[1]	MRL (µg/kg)	Tissue	Species	Marker residue and other remarks
Eprinomectin	0-10	Full	50 (1998)	100 2000 300 250 20	Muscle Liver Kidney Fat Milk	Cattle	Eprinomectin B_{1a}
Erythromycin	0-0.7	Full	66 (2006)	100 50	Muscle, Liver, Kidney, Fat/Skin Eggs	Chicken, Turkey Chicken	Erythromycin A
Estradiol-17β	0-0.05	Full	52 (1999)	Not specified	Muscle, Liver, Kidney, Fat	Cattle	
Febantel Fenbendazole Oxfendazole	0-7 (group ADI)	Full	50 (1998)	100 500 100	Muscle, Kidney, Fat Liver Milk	Cattle, Goat, Horses, Pig, Sheep Cattle, Sheep	Sum of febantel, fenbendazole and oxfendazole, expressed as oxfendazole sulfone equivalents
Fenbendazole (see Febantel)							
Fluazuron	0-40	Full	48 (1997)	200 500 7000	Muscle Liver, Kidney Fat	Cattle	Fluazuron
Flubendazole	0-12	Full	40 (1992)	10 200 500 400	Muscle, Liver Muscle Liver Eggs	Pig Poultry	Flubendazole
Flumequine	0-30	Full	66 (2006)	500 1000 500 3000 500 500T 500T	Muscle Fat Liver Kidney Muscle Muscle Muscle	Cattle, Sheep, Pig, Chicken Trout Black Tiger Shrimp Shrimp	Flumequine. The MRLs are temporary for Black Tiger Shrimp and Shrimp. The MRLs for shrimp applies to all fresh water and marine shrimp.
Furazolidone	No ADI		40 (1992)	No MRL			
Gentamicin	0-20	Full	50 (1998)	100 2000 5000 200	Muscle, Fat Liver Kidney Milk	Cattle, Pig Cattle	Gentamicin

Substance	ADI (µg/kg bw)	ADI Status	JECFA[1]	MRL (µg/kg)	Tissue	Species	Marker residue and other remarks
Imidocarb	0-10	Full	60 (2003)	300 1500 2000 50	Muscle Liver Kidney Fat, Milk	Cattle	Imidocarb, free base
Ipronidazole	No ADI		34 (1989)	No MRL			
Isometamidium	0-100	Full	40 (1992)	100 500 1000	Muscle, Fat, Milk Liver Kidney	Cattle	Isometamidium
Ivermectin	0-1	Full	58 (2002)	100 40 15 20 10	Liver Fat Liver Fat Milk	Cattle Cattle Pig, Sheep Pig, Sheep Cattle	Ivermectin B_{1a}
Levamisole	0-6	Full	42 (1994)	10 100	Muscle, Kidney, Fat Liver	Cattle, Sheep, Pig, Poultry Cattle, Sheep, Pig, Poultry	Levamisole
Lincomycin	0-30	Full	58 (2002)	200 500 1500 500 100 150	Muscle Liver Kidney Kidney Fat Milk	Chicken, Pig Chicken, Pig Pig Chicken Chicken, Pig Cattle	Lincomycin A separate MRL of 300 µg/kg for skin with adhering fat for pigs was recommended in order to reflect the concentrations found in skin of pigs and this MRL was also extended skin/fat for chicken.
Melengestrol Acetate	0-0.03	Full	66 (2006)	1 10 2 18	Muscle Liver Kidney Fat	Cattle	Melengestrol acetate
Metronidazole	No ADI		34 (1989)	No MRL			
Monensin	0-10	Full	70 (2008)	10 10 20 100 2	Muscle, Liver, Kidney Muscle, Kidney Liver Fat Milk	Chicken, Turkey, Quail Cattle, Sheep, Goat Cattle, Sheep, Goat Cattle, Sheep, Goat, Chicken, Turkey, Quail Cattle	Monensin

Substance	ADI (µg/kg bw)	ADI Status	JECFA[1]	MRL (µg/kg)	Tissue	Species	Marker residue and other remarks
Moxidectin	0-2	Full	50 (1998)	20 50 100 50 500	Muscle Muscle Liver Kidney Fat	Cattle, Deer Sheep Cattle, Deer, Sheep Cattle, Deer, Sheep Cattle, Deer, Sheep	Moxidectin The Committee noted very high concentrations and great variation in the residue levels at the injection site in cattle over a 49-day period after dosing.
Narasin	0-5	Full	70 (2008)	15 50 15T 50T	Muscle, Kidney Liver, Fat Muscle, Kidney Liver, Fat	Chicken, Pig Chicken, Pig Cattle Cattle	Narasin A Temporary MRLs for cattle, until end 2010
Neomycin	0-60	Full	60 (2003)	500 10000 500 1500	Muscle, Fat, Liver Kidney Eggs Milk	Cattle, Chicken, Sheep, Turkey Goat, Pig, Duck Cattle, Chicken, Sheep, Turkey Goat, Pig, Duck Chicken Cattle	Neomycin
Nicarbazin	0-400	Full	50 (1998)	200	Muscle, Liver, Kidney, Fat/Skin	Chicken (broilers)	N,N'-bis(4-nitrophenyl)urea
Nitrofurazone/ Nitrofural	No ADI		40 (1992)	No MRL			
Olaquindox	No ADI		42 (1994)	No MRL			The Committee recommended no MRLs but noted that 4µg/kg in muscle of pigs of the metabolite MQCA (3-Methylquinoxaline-2-carboxylic acid) is consistent with Good Veterinary Practice.
Oxfendazole (See Febantel)							
Oxolinic acid	No ADI		43 (1994)	No MRL			
Oxytetracycline (See chlortetracycline)							
Permethrin	No ADI		54 (2000)	No MRL			
Phoxim	0-4	Full	62 (2004)	50 400	Muscle, Liver, Kidney Fat	Goat, Pig, Sheep	Phoxim

Substance	ADI (µg/kg bw)	ADI Status	JECFA[1]	MRL (µg/kg)	Tissue	Species	Marker residue and other remarks
Pirlimycin	0-8	Full	62 (2004)	100 1000 400 100	Muscle, Fat Liver Kidney Milk	Cattle	Pirlimycin
Porcine Somatotropin	Not Specified		52 (1999)	Not Specified	Muscle, Liver, Kidney, Fat	Pig	
Procaine benzylpenicillin	< 30µg/person/ day of the penicillin moiety	Full	50 (1998)	50 4	Muscle, Liver, Kidney Milk	All species	Benzylpenicillin
Progesterone	0-30	Full	52 (1999)	Not Specified	Muscle, Liver, Kidney, Fat	Cattle	
Propionyl-promazine	No ADI		38 (1991)	No MRL			
Ractopamine	0-1	Full	66 (2006)	10 40 90	Muscle, Fat Liver Kidney	Cattle, Pig	Ractopamine
Ronidazole	No ADI		42 (1994)	No MRL			
Sarafloxacin	0-0.3	Full	50 (1998)	10 80 20	Muscle Liver, Kidney Fat/skin	Chicken, Turkey	Sarafloxacin
Spectinomycin	0-40	Full	50 (1998)	500 2000 5000 2000 200	Muscle Liver, Fat Kidney Eggs Milk	Cattle, Chicken, Pig, Sheep Chicken Cattle	Spectinomycin
Spiramycin	0-50	Full	48 (1997)	200 600 300 800 300 200	Muscle Liver Kidney Kidney Fat Milk	Cattle, Chicken, Pig Cattle, Chicken Pig Cattle, Chicken, Pig Cattle	For cattle and chicken, MRLs are expressed as the sum of spiramycin and neospiramycin. For pigs, the MRLs are expressed as spiramycin equivalents (antimicrobial active residues).
Streptomycin (See dihydro-streptomycin)							

Substance	ADI (µg/kg bw)	ADI Status	JECFA[1]	MRL (µg/kg)	Tissue	Species	Marker residue and other remarks
Sulfadimidine (Sulfamethazine)	0-50	Full	42 (1994)	100 25	Muscle, Liver, Kidney, Fat Milk	Cattle, Sheep, Pig, Poultry Cattle	Sulfadimidine
Sulfathiazole	No ADI		34 (1989)	No MRL			
Testosterone	0-2	Full	52 (1999)	Not specified	Muscle, Liver, Kidney, Fat	Cattle	
Tetracycline (See chlortetracycline)							
Thiamphenicol	0-5	Full	58 (2002)	No MRL			
Tiabendazole (Thiabendazole)	0-100	Full	58 (2002)	100 100	Muscle, Liver, Kidney, Fat	Cattle, Pig, Goat, Sheep Cattle, Goat	Sum of tiabendazole + 5-hydroxy tiabendazole
Tilmicosin	0-40	Full	70 (2008)	100 1000 1500 300 1000 150 100 2400 1400 600 1200 250	Muscle, Fat Liver Liver Kidney Kidney Muscle Muscle Liver Liver Kidney Kidney Skin/Fat	Cattle, Pig, Sheep Cattle Sheep Pig Cattle, Sheep Pig Chicken Turkey Chicken Turkey Chicken Turkey Chicken, Turkey	Tilmicosin
Trenbolone acetate	0-0.02	Full	34 (1989)	2 10	Muscle Liver	Cattle	β Trenbolone for muscle α-Trenbolone for liver
Trichlorfon (Metrifonate)	0-2	Full	66(2006)	50 50	Milk Muscle, Liver, Kidney, Fat	Cattle	Trichlorfon Guidance MRLs at the limit of quantitation of the analytical method for monitoring purposes. No residues should be present in tissues when used with Good Veterinary Practice.

Substance	ADI (µg/kg bw)	ADI Status	JECFA[1]	MRL (µg/kg)	Tissue	Species	Marker residue and other remarks
Triclabendazole	0-3	Full	70 (2008)	250 850 400 200 300 200 100	Muscle Liver Kidney Muscle Liver Kidney Fat	Cattle Sheep Cattle, Sheep	Keto-triclabendazole
Tylosin	0-30	Full	70 (2008)	100 100 100 100 300	Muscle, Liver, Kidney Fat Skin/Fat Milk Eggs	Cattle, Pig, Chicken Cattle, Pig Chicken Cattle Chicken	Tylosin A
Xylazine	No ADI		47 (996)	No MRL			
Zeranol	0-0.5	Full	32 (1987)	2 10	Muscle Liver	Cattle	Zeranol

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RESIDUE EVALUATION OF CERTAIN VETERINARY DRUGS

Joint FAO/WHO Expert Committee on Food Additives

70th meeting 2008

This document contains monographs on residue evaluations of certain veterinary drugs, prepared at the seventieh meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA), which was held in Geneva, Switzerland from 21 to 29 October 2008. Three substances were evaluated for the first time for the animal species concerned, avilamycin, monensin and narasin. Four substances were reassessed, dexamethasone, tilmicosin, triclabendazole and tylosin. The residue monographs provide information on chemical identity and properties of the compounds, pharmacokinetics and metabolism, residue depletion studies and analytical methods validated and used for the detection and quantification of the compounds. In addition to these monographs, this document includes the considerations and recommendations developed by the Committee for residues of veterinary drugs in honey and possible approaches to derive MRLs for this commodity; and a monograph on residues in aquatic species of and an estimatation of human dietary exposure to malachite green (an antimicrobial agent and contamimant). This publication and other documents produced by JECFA contain information that is useful to those who work with or are involved with recommending or controlling maximum residue limits for veterinary drugs in foods.

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