

PHILIPPINE NATIONAL STANDARD

**PNS/BAFS 48:2022
ICS 65.020.30**

Veterinary Drug Residues in Food — Product Standard — Maximum Residue Limit (MRL)



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PNS/BAFS 48:2022
ICS 65.120.30

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Foreword

Republic Act No. 10611, also known as the Food Safety Act of 2013, mandates the Bureau of Agriculture and Fisheries Standards-Department of Agriculture (BAFS-DA) to develop science-based food safety standards for primary and postharvest foods and adopt Codex standards. Consistent with these mandates, BAFS initiated the amendment of the PNS/BAFS 48:2016 (Veterinary Drug Residues in Food: Maximum Residue Limits [MRL]) to harmonize it with the Codex MRL and Risk Management Recommendations (RMR) for Residues of Veterinary Drugs in Foods (CX/MRL 2-2018).

A Technical Working Group (TWG) was established through Special Order No. 103, series of 2022 (Creation of TWG for the development of PNS for agriculture and fishery products, machineries, and infrastructures). The TWG was composed of representatives from relevant government agencies, academe, and Civil Society Organization (CSO). The draft PNS underwent a series of TWG meetings and stakeholder consultations conducted physically and via online platforms before its endorsement to the DA Secretary for approval.

This Standard includes the following significant changes compared to the PNS/BAFS 48:2016:

- a) Addition of the following MRL: ampicillin in finfish; derquantel in sheep; diflubenzuron in salmon; flumethrin in honey, halquinol in swine; lasalocid sodium in chicken, turkey, quail, and pheasant; lufenuron in salmon and trout; and teflubenzuron in salmon; and
- b) Amendment of the following MRL: ivermectin in cattle; amoxicillin in finfish; and monepantel in cattle.

This Standard is drafted in accordance with the BAFS-Standards Development Division (SDD) Standardization Guide No. 1: Writing the PNS.

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1 Scope

This Standard covers the Maximum Residue Limits (MRL) of veterinary drugs established for livestock and poultry including their products such as egg and raw milk, honey, and fish and fishery products.

This Standard is adopted from the Codex MRL and Risk Management Recommendations (RMR) for Residues of Veterinary Drugs in Foods (CX/MRL 2-2018). It also provides additional information on banned veterinary drugs in the Philippines, as supported by regulations from the competent authority.

2 Normative References

The following documents are referred to in the text in such a way that some or all their contents constitute the requirements of this document. The latest edition of the referenced documents (including any amendments) applies.

Codex Alimentarius Commission (CAC). (2018). Maximum Residue Limits (MRL) and Risk Management Recommendations (RMR) for residues of veterinary drugs in foods (CX/MRL 2-2018). <https://www.fao.org/fao-who-codexalimentarius/sh-proxy/es/?Ink=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXM%2B2%252FMRL2e.pdf>

3 Terms and Definitions

For the purpose of this document, the following terms and definitions apply:

3.1

adrenoceptor agonist

used to increase the rate of weight gain without additional feed intake, making feed efficiency greater (Pennsylvania State University [PSU], 2017)

3.2

anthelmintic agent

used to treat flat (trematodes), tape (cestodes) and round (nematodes) worm infections (Moreno & Lanusse, 2017, *modified*)

3.3

antimicrobial agent

any substance of natural, semi-synthetic, or synthetic origin that at *in vivo* concentrations kills or inhibits the growth of microorganisms by interacting with a specific target (CAC, 2021)

3.4

antiparasitic agent

used to treat ectoparasitic (e.g., sea lice) and endoparasitic infestations caused by a diverse and complex group of organisms encompassing the unicellular protozoa, which have intricate life cycles often involving more than one host, as well as the helminths, which have highly developed organ systems (Kuhlmann & Fleckenstein, 2017, *modified*)

3.5**antiprotozoal agent**

used in treatment of protozoan infection (Kayarohanam, 2015)

3.6**beta-adrenoceptor-blocking agent**

family of agents widely used to treat hypertension, angina pectoris and cardiac arrhythmias, also known as beta-adrenergic receptor antagonist (National Center for Biotechnology Information [NCBI], 2018)

3.7**competent authority**

official government organization/agency(ies) having jurisdiction (CAC, 2013)

3.8**egg**

egg-in-shell other than broken, incubated, or thermally processed egg that is produced by domesticated chicken and duck and are fit for direct human consumption or for the preparation of egg products (Bureau of Agriculture and Fisheries Standards [BAFS]-Department of Agriculture [DA], 2021)

3.9**glucocorticosteroid**

commonly used as anti-inflammatory drugs (Edwards, 2021)

3.10**growth promoter**

used in farm animals with the purpose to promote growth, to improve the distribution of fat and protein, and to increase the feed-to-muscle conversion rate (Toldra & Reig, 2016)

3.11**insecticide**

chemical used to control insects by killing them or preventing them from engaging in undesirable or destructive behaviors (Environmental Protection Agency [EPA], 2022)

3.12**maximum residue limit for veterinary drugs (MRLVD)**

maximum concentration of residue resulting from the use of a veterinary drug (expressed in mg/kg or µg/kg on a fresh weight basis) that is recommended by

the CAC to be legally permitted or recognized as acceptable in or on a food (CAC,1993)

3.13

production aid

any substance or material, not including apparatus or utensils, and consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foods or its ingredients, to fulfill a certain technological purpose during treatment or processing and which may result in the non-intentional but unavoidable presence of residues or derivatives in the final product (CAC, 2022)

4 MRL for Veterinary Drugs in Food

The following are the MRL for veterinary drugs in food. A list of acronyms is provided in Annex A for reference.

4.1 Abamectin (anthelmintic agent)

The MRL for abamectin are shown in Table 1.

Table 1. MRL of abamectin in cattle

Joint FAO/WHO Expert Committee of Food Additives (JECFA) Evaluation		45 (1995); 47 (1996)		
Allowable Daily Intake (ADI)		0-2 µg/kg body weight (bw) (1997) established for the sum of abamectin and (Z)-8,9 isomer by Joint Food and Agriculture/World Health Organization (FAO/WHO) Expert Meeting on Pesticide Residues (JMPR) (1997)		
Residue Definition		Avermectin B1a		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Cattle	Liver	100	26 (2003)	
	Kidney	50		
	Fat	100		

4.2 Albendazole (anthelmintic agent)

The MRL for albendazole are shown in Table 2.

Table 2. MRL for albendazole

JECFA Evaluation		34 (1989)		
ADI		0-50 µg/kg bw (JECFA 34)		
Residue Definition		Except raw milk, 2-aminosulfone metabolite; raw milk, not yet identified		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Not specified	Muscle	100	20 (1993)	
	Liver	5000		
	Kidney	5000		
	Fat	100		
	Raw milk (µg/l)	100		

4.3 Amoxicillin (antimicrobial agent)

The MRL for amoxicillin are shown in Table 3.

Table 3. MRL of amoxicillin in different species of food animals

JECFA Evaluation		75 (2011); 85 (2017)		
Microbiological Acceptable Daily Intake (mADI)		0-0.002 mg/kg bw based on the effects of amoxicillin on the intestinal microbiota		
Acute Reference Dose (ARfD)		0.005 mg/kg bw based on microbiological effects on the intestinal microbiota		
Estimated Chronic Dietary Exposure		0.14 µg/kg bw per day (for the general population), which represents 7% of the upper bound of the Microbiological Acceptable Daily Intake (mADI)		
Estimated Acute Dietary Exposure		1.4 µg/kg bw (for the general population), which represents 28% of the microbiological ARfD 1.6 µg/kg bw (for children), which represents 31% of the microbiological ARfD		
Residue Definition		Amoxicillin		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Cattle, Sheep, Pig	Muscle	50	35 (2012)	
	Liver	50		
	Kidney	50		
	Fat	50		

Cattle, Sheep	Raw milk	4		
Finfish	Fillet	50	41 (2018)	The term “finfish” includes all fish species. Muscle plus skin in natural proportion.
	Muscle	50		The term “finfish” includes all fish species.

4.4 Ampicillin (antimicrobial agent)

The MRL for ampicillin are shown in Table 4.

Table 4. MRL of ampicillin for finfish

JECFA Evaluation		85 (2017)		
mADI		0–0.003 mg/kg bw based on a No-Observed-Adversed-Effect-Level (NOAEL) equivalent to 0.025 mg/kg bw per day for increase in population(s) of ampicillin-resistant bacteria in the gastrointestinal tract in humans, and using a safety factor of 10 (for the variability in the composition of the intestinal microbiota within and between individuals)		
ARfD		0.012 mg/kg bw based on the microbiological end-point		
Estimated Chronic Dietary Exposure		0.29 µg/kg bw per day (for the general population), which represents 10% of the upper bound of the ADI		
Estimated Acute Dietary Exposure		1.9 µg/kg bw per day (for the general population), which represents 16% of the ARfD 1.7 µg/kg bw per day (for children), which represents 14% of the ARfD		
Residue Definition		Ampicillin		
Note		JECFA85 recommended an MRL of 50 µg/kg for ampicillin in finfish muscle and in finfish muscle plus skin in natural proportion, the same as that recommended for amoxicillin, because the modes of action, the physicochemical properties and the toxicological and pharmacokinetic profiles of amoxicillin and ampicillin are very similar.		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks

Finfish	Fillet	50	41 (2018)	The term “finfish” includes all fish species. Muscle plus skin in natural proportion.
	Muscle	50		The term “finfish” includes all fish species.

4.5 Avilamycin (antimicrobial agent)

The MRL for avilamycin are shown in Table 5.

Table 5. MRL of avilamycin in different species of food animals

JECFA Evaluation		70 (2008)		
ADI		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 (JECFA70)		
Residue Definition		Dichloroisoevernic acid (DIA)		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Pig, Chicken, Turkey, Rabbits	Muscle	200	32 (2009)	
	Liver	300		
	Kidney	200		
	Fat/Skin	200		

4.6 Azaperone (tranquilizing agent)

The MRL for azaperone are shown in Table 6.

Table 6. MRL of azaperone in pig

JECFA Evaluation		38 (1991); 43 (1994); 50 (1998); 52 (1999)		
ADI		0-6 µg/kg bw (JECFA50)		
Residue Definition		Sum of azaperone and azaperol		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Pig	Muscle	60	23 (1999)	
	Liver	100		
	Kidney	100		
	Fat	60		

4.7 Benzylpenicillin/Procaine benzylpenicillin (antimicrobial agent)

The MRL for benzylpenicillin/procaine benzylpenicillin are shown in Table 7.

Table 7. MRL of benzylpenicillin/procaine benzylpenicillin in different species of food animals

JECFA Evaluation		36 (1990); 50 (1998)		
ADI		30 µg-penicillin/person/day (JECFA50). Residues of benzylpenicillin and procaine benzylpenicillin should be kept below this level.		
Residue Definition		Benzylpenicillin		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Cattle, Chicken, Pig	Muscle	50	23 (1999)	Chicken: applies to procaine benzylpenicillin only
	Liver	50		
	Kidney	50		
Cattle	Raw milk (µg/l)	4		

4.8 Carazolol (beta-adrenoceptor-blocking agent)

The MRL for carazolol are shown in Table 8.

Table 8. MRL of carazolol in pig

JECFA Evaluation		38 (1991); 43 (1994); 52 (1999)		
ADI		0-0.1 µg/kg bw (JECFA43). ADI based on the acute pharmacological effects of carazolol		
Residue Definition		Carazolol		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Pig	Muscle	5	26 (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

	Liver	25		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
	Kidney	25		
	Fat/Skin	5		

4.9 Ceftiofur (antimicrobial agent)

The MRL for ceftiofur are shown in Table 9.

Table 9. MRL of ceftiofur in cattle and pig

JECFA Evaluation		45 (1995); 48 (1997)		
ADI		0-50 µg/kg bw (JECFA45)		
Residue Definition		Desfuroylceftiofur		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Cattle, Pig	Muscle	1000	23 (1999)	
	Liver	2000		
	Kidney	6000		
	Fat	2000		
Cattle	Raw milk (µg/l)	100		

4.10 Chlortetracycline/oxytetracycline/tetracycline (antimicrobial agent)

The MRL for chlortetracycline/oxytetracycline/tetracycline are shown in Table 10.

Table 10. MRL of chlortetracycline/oxytetracycline/tetracycline in different species of food animals

JECFA Evaluation	45 (1995); 47 (1996); 50 (1998); 58 (2002)
ADI	Group ADI for chlortetracycline, oxytetracycline and tetracycline: 0-30 µg/kg bw (JECFA50). Group ADI for chlortetracycline, oxytetracycline, and tetracycline.
Residue Definition	Parent drugs, singly or in combination

Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Cattle, Pig, Poultry, Sheep	Muscle	200	26 (2003)	
	Liver	600		
	Kidney	1200		
Cattle, Sheep	Raw milk (µg/l)	100		
Poultry	Eggs	400		
Fish	Muscle	200		
Giant prawn (<i>Paeneus monodon</i>)	Muscle	200		Applies only to oxytetracycline

4.11 Clenbuterol (adrenoceptor agonist)

The MRL for clenbuterol are shown in Table 11.

Table 11. MRL of clenbuterol in cattle and horse

JECFA Evaluation		47 (1996)		
ADI		0-0.004 µg/kg bw (JECFA47)		
Residue Definition		Clenbuterol		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Cattle, Horse	Muscle	0.2	26 (2003)	Due to the potential abuse of this drug, the MRL are recommended only when associated with a nationally approved therapeutic use, such as tocolysis or as an adjunct therapy in respiratory diseases
	Liver	0.6		
	Kidney	0.6		
	Fat	0.2		
Cattle	Raw milk (µg/l)	0.05		

4.12 Closantel (anthelmintic agent)

The MRL for closantel are shown in Table 12.

Table 12. MRL of closantel in cattle and sheep

JECFA Evaluation		36 (1990); 40 (1992)		
ADI		0-30 µg/kg bw (JECFA40)		
Residue Definition		Closantel		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Cattle	Muscle	1000	20 (1993)	
	Liver	1000		
	Kidney	3000		
	Fat	3000		
Sheep	Muscle	1500		
	Liver	1500		
	Kidney	2000		
	Fat	2000		

4.13 Colistin (antimicrobial agent)

The MRL for colistin are shown in Table 13.

Table 13. MRL of colistin in different species of food animals

JECFA Evaluation		66 (2006)		
ADI		0-7 µg/kg bw (JECFA66)		
Residue Definition		Sum of colistin A and colistin B		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Cattle, Sheep, Goat, Pig, Chicken, Turkey, Rabbit	Muscle	150	31 (2008)	Pig, Chicken, Turkey: The MRL for fat includes skin + fat.
	Liver	150		
	Kidney	200		
	Fat	150		
Cattle, Sheep	Raw milk	50		
Chicken	Eggs	300		

4.14 Cyfluthrin (insecticide)

The MRL for cyfluthrin are shown in Table 14.

Table 14. MRL of cyfluthrin in cattle

JECFA Evaluation		48 (1997)		
ADI		0-20 µg/kg bw (JECFA48)		
Residue Definition		Cyfluthrin		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Cattle	Muscle	20	26 (2003)	
	Liver	20		
	Kidney	20		
	Fat	200		
	Raw milk (µg/l)	40		

4.15 Cyhalothrin (insecticide)

The MRL for cyhalothrin are shown in Table 15.

Table 15. MRL of cyhalothrin in different species of food animals

JECFA Evaluation		48 (1997)		
ADI		0-20 µg/kg bw (JECFA48)		
Residue Definition		Cyfluthrin		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Cattle, Pig	Muscle	20	28 (2005)	
	Liver	20		
	Kidney	20		
	Fat	400		
Cattle	Raw milk	30		
Sheep	Muscle	20		
	Liver	50		
	Kidney	20		
	Fat	400		

4.16 Cypermethrin and alpha-cypermethrin (insecticide)

The MRL for cypermethrin are shown in Table 16.

Table 16. MRL of cypermethrin in cattle and sheep

JECFA Evaluation		62 (2004)		
ADI		JECFA62 established a common ADI of 0-20 µg/kg bw for both cypermethrin and alpha-cypermethrin		
Residue Definition		Total of cypermethrin residues (resulting from the use of cypermethrin or alpha-cypermethrin as veterinary drugs)		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Cattle, Sheep	Muscle	50	29 (2006)	
	Liver	50		
	Kidney	50		
	Fat	1000		
Cattle	Raw milk	100		

4.17 Danofloxacin (antimicrobial agent)

The MRL for danofloxacin are shown in Table 17.

Table 17. MRL of danofloxacin in different species of food animals

JECFA Evaluation		48 (1997)		
ADI		0-20 µg/kg bw (JECFA48)		
Residue Definition		Danofloxacin		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Cattle, Chicken	Muscle	200	24 (2001)	
	Liver	400		
	Kidney	400		
	Fat	100		Chicken: Fat/skin in normal proportion
Pig	Muscle	100		
	Liver	50		
	Kidney	200		
	Fat	100		

4.18 Deltamethrin (insecticide)

The MRL for deltamethrin are shown in Table 18.

Table 18. MRL of deltamethrin in different species of food animals

JECFA Evaluation		52 (1999); 60 (2003)		
ADI		0-10 µg/kg bw (1982). Established by JMPR (1982)		
Residue Definition		Deltamethrin		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Cattle, Chicken, Sheep	Muscle	30	26 (2003)	
	Liver	50		
	Kidney	50		
	Fat	500		
Cattle	Raw milk	30		
Chicken	Eggs	30		
Salmon	Muscle	30		

4.19 Derquantel (anthelmintic agent)

The MRL for derquantel are shown in Table 19.

Table 19. MRL of derquantel in sheep

JECFA Evaluation		75 (2011); 78 (2013)
ADI		0-0.3 µg/kg bw on the basis of a Lowest-Observed-Adverse-Effect-Level (LOAEL) of 0.1 mg/kg bw 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)
Estimated Dietary Exposure		There were insufficient data to calculate an Estimated Daily Intake (EDI), and the Theoretical Maximum Daily Intake (TMDI) approach was used. Using the model diet and the MT:TR approach, these MRL result in an estimated dietary exposure of 6.8 µg/person, which represents approximately 38% of the upper bound of the ADI. (JECFA78)
Residue Definition		Derquantel

Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Sheep	Muscle	0.3	38 (2015)	
	Liver	0.8		
	Kidney	0.4		
	Fat	7.0		

4.20 Dexamethasone (glucocorticosteroid)

The MRL for dexamethasone are shown in Table 20.

Table 20. MRL of dexamethasone in different species of food animals

JECFA Evaluation		70 (2008)		
ADI		0-0.015 µg/kg bw (JECFA42)		
Residue Definition		Dexamethasone		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Cattle, Pig, Horses	Muscle	1.0	32 (2009)	
	Liver	2.0		
	Kidney	1.0		
Cattle	Raw milk (µg/l)	0.3		

4.21 Diclazuril (antiprotozoal agent)

The MRL for diclazuril are shown in Table 21.

Table 21. MRL of diclazuril in different species of food animals

JECFA Evaluation		45 (1995); 50 (1998)		
ADI		0-30 µg/kg bw (JECFA50)		
Residue Definition		Diclazuril		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
	Muscle	500	23 (1999)	Poultry: fat/skin

Poultry, Rabbit, Sheep	Liver	3000		
	Kidney	2000		
	Fat	1000		

4.22 Dicyclanil (insecticide)

The MRL for dicyclanil are shown in Table 22.

Table 22. MRL of dicyclanil in sheep

JECFA Evaluation		54 (2000); 60 (2003)		
ADI		0-7 µg/kg bw (JECFA54)		
Residue Definition		Dicyclanil		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Sheep	Muscle	150	28 (2005)	
	Liver	125		
	Kidney	125		
	Fat	200		

4.23 Diflubenzuron (insecticide)

The MRL for diflubenzuron is shown in Table 23.

Table 23. MRL of diflubenzuron in salmon

JECFA Evaluation	88 (2019)
ADI	0–0.02 mg/kg 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).
Estimated chronic dietary exposure	The Global Estimated Chronic Dietary Exposure (GECDE) for the general population is 0.84 µg/kg bw per day, which represents 4% of the upper bound of the ADI. The GECDE for children is 2.85 µg/kg bw per day, which represents 14% of the upper bound of the ADI.

Residue Definition		Diflubenzuron		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Salmon	Muscle + skin	10	44 (2021)	In natural proportions

4.24 Dihydrostreptomycin/streptomycin (antimicrobial agent)

The MRL for dihydrostreptomycin/streptomycin are shown in Table 24.

Table 24. MRL of dihydrostreptomycin/streptomycin in different species of food animals

JECFA Evaluation		43 (1994); 48 (1997); 52 (1999); 58 (2002)		
ADI		0-50 µg/kg bw (JECFA48). Group ADI for combined residues of dihydrostreptomycin and streptomycin.		
Residue Definition		Sum of dihydrostreptomycin and streptomycin		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Cattle, Chicken, Pig, Sheep	Muscle	600	24 (2001)	
	Liver	600		
	Kidney	1000		
	Fat	600		
Cattle, Sheep	Raw milk	200	26 (2003)	

4.25 Diminazene (trypanocide)

The MRL for diminazene are shown in Table 25.

Table 25. MRL of diminazene in cattle

JECFA Evaluation		34 (1989); 42 (1994)		
ADI		0-100 µg/kg bw (JECFA42)		
Residue Definition		Diminazene		
Species	Tissue	MRL (µg/kg)	Session and Year	Remarks

			Adopted by Codex	
Cattle	Muscle	500	22 (1997)	
	Liver	12000		
	Kidney	6000		
	Raw milk (µg/l)	150		Limit of Quantification (LOQ) of the analytical method

4.26 Doramectin (anthelmintic agent)

The MRL for doramectin are shown in Table 26.

Table 26. MRL of doramectin in cattle and pig

JECFA Evaluation		45 (1995); 52 (1999); 58 (2002); 62 (2004)		
ADI		0-1 µg/kg bw (JECFA58)		
Residue Definition		Doramectin		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Cattle	Muscle	10	22 (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
	Liver	100		
	Kidney	30		
	Fat	150		
	Raw milk	15	29 (2006)	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
Pig	Muscle	5	24 (2001)	
	Liver	100		
	Kidney	30		
	Fat	150		

4.27 Emamectin benzoate (antiparasitic agent)

The MRL for emamectin benzoate are shown in Table 27.

Table 27. MRL of emamectin benzoate in salmon and trout

JECFA Evaluation		78 (2013)		
ADI		ADI of 0–0.5 µg/kg bw established by JMPR (2011), based on an overall NOAEL of 0.25 mg/kg bw per day for neurotoxicity from 14- and 53-week studies in dogs, supported by an overall NOAEL of 0.25 mg/kg bw 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 JECFA78.		
Estimated Dietary Exposure		11 µg/person per day, which represents approximately 37% of the upper bound of the ADI (JECFA78)		
Residue Definition		Emamectin B1a		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Salmon, Trout	Muscle	100	38 (2015)	
	Fillet	100		Muscle + skin in natural proportion

4.28 Eprinomectin (anthelmintic agent)

The MRL for eprinomectin are shown in Table 28.

Table 28. MRL of eprinomectin in cattle

JECFA Evaluation		50 (1998)		
ADI		0-10 µg/kg bw (JECFA50)		
Residue Definition		Eprinomectin B1a		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Cattle	Muscle	100	26 (2003)	
	Liver	2000		
	Kidney	300		
	Fat	250		

	Raw milk (µg/l)	20		
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4.29 Erythromycin (antimicrobial agent)

The MRL for erythromycin are shown in Table 29.

Table 29. MRL of erythromycin in cattle

JECFA Evaluation		50 (1998)		
ADI		0-10 µg/kg bw (JECFA50)		
Residue Definition		Eprinomectin B1a		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Cattle	Muscle	100	26 (2003)	
	Liver	2000		
	Kidney	300		
	Fat	250		
	Raw milk (µg/l)	20		

4.30 Febantel/fenbendazole/oxfendazole (anthelmintic agent)

The MRL for febantel/fenbendazole/oxfendazole are shown in Table 30.

Table 30. MRL of febantel/fenbendazole/oxfendazole in different species of food animals

JECFA Evaluation		38 (1991); 45 (1995); 50 (1998)		
ADI		Group ADI of 0-7 µg/kg bw (JECFA50)		
Residue Definition		Sum of fenbendazole, oxfendazole and oxfendazole sulphone, expressed as oxfendazole sulphone equivalents		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Cattle, Goat, Horse,	Muscle	100	23 (1999)	
	Liver	500		
	Kidney	100		

Pig, Sheep	Fat	100		
Cattle, Sheep	Raw milk (µg/l)	100		

4.31 Fluazuron (insecticide)

The MRL for fluazuron are shown in Table 31.

Table 31. MRL of fluazuron in cattle

JECFA Evaluation		48 (1997)		
ADI		0-40 µg/kg bw (JECFA48)		
Residue Definition		Fluazuron		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Cattle	Muscle	200	23 (1999)	
	Liver	500		
	Kidney	500		
	Fat	7000		

4.32 Flubendazole (anthelmintic agent)

The MRL for flubendazole are shown in Table 32.

Table 32. MRL of flubendazole in pig and poultry

JECFA Evaluation		40 (1992)		
ADI		0-12 µg/kg bw (JECFA40)		
Residue Definition		Flubendazole		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Pig	Muscle	10	21 (1995)	
	Liver	10		
Poultry	Muscle	200		
	Liver	500		
	Eggs	400		

4.33 Flumequine (antimicrobial agent)

The MRL for flumequine are shown in Table 33.

Table 33. MRL of flumequine in different species of food animals

JECFA Evaluation		42 (1994); 48 (1997); 54 (2000); 60 (2002); 62 (2004); 66 (2006)		
ADI		0-30 µg/kg bw (JECFA62)		
Residue Definition		Flumequine		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Cattle, Chicken, Pig, Sheep	Muscle	500	28 (2005)	
	Liver	500		
	Kidney	3000		
	Fat	1000		
Trout	Muscle	500		Muscle including normal proportion of skin

4.34 Gentamicin (antimicrobial agent)

The MRL for gentamicin are shown in Table 34.

Table 34. MRL of gentamicin in cattle and pig

JECFA Evaluation		43 (1994); 48 (1997); 50 (1998)		
ADI		0-20 µg/kg bw (JECFA50)		
Residue Definition		Gentamicin		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Cattle, Pig	Muscle	100	24 (2001)	
	Liver	2000		
	Kidney	5000		
	Fat	100		
Cattle	Raw milk (µg/l)	200		

4.35 Halquinol (broad-spectrum antimicrobial)

The MRL for halquinol are shown in Table 35.

Table 35. MRL of halquinol in pig

JECFA Evaluation		88 (2019)		
ADI		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).		
ARfD		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).		
Estimated Chronic Dietary Exposure		The GECDE for the general population is 5.9 µg/kg bw per day, which represents 3% of the upper bound of the ADI. The GECDE for children is 6.9 µg/kg bw per day, which represents 3.4% of the upper bound of the ADI.		
Estimated Acute Dietary Exposure		The Global Estimated Acute Dietary Exposure (GEADE) was comparable for children and adults, being 2–224 µg/kg bw per day, which represents 0.5–75% of the ARfD.		
Residue Definition		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)		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Pig	Muscle	40	44 (2021)	
	Liver	500		
	Kidney	9000		
	Skin+Fat	350		

4.36 Imidocarb (antiprotozoal agent)

The MRL for imidocarb are shown in Table 36.

Table 36. MRL of imidocarb in cattle

JECFA Evaluation	50 (1998); 60 (2003)
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ADI		0-10 µg/kg bw (JECFA50)		
Residue Definition		Imidocarb		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Cattle	Muscle	300	28 (2005)	
	Liver	1500		
	Kidney	2000		
	Fat	50		
	Raw milk	50		

4.37 Isometamidium (trypanocide)

The MRL for isometamidium are shown in Table 37.

Table 37. MRL of isometamidium in cattle

JECFA Evaluation		34 (1989); 40 (1992)		
ADI		0-100 µg/kg bw (JECFA40)		
Residue Definition		Isometamidium		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Cattle	Muscle	100	21 (1995)	
	Liver	500		
	Kidney	1000		
	Fat	100		
	Raw milk (µg/l)	100		

4.38 Ivermectin (anthelmintic agent)

The MRL for ivermectin are shown in Table 38.

Table 38. MRL of ivermectin in different species of food animals

JECFA Evaluation		36 (1990); 40 (1992); 54 (2000); 58 (2002); 81 (2015)
ADI		0-10 µg/kg bw on the basis of a NOAEL of 0.5 mg/kg bw 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 bw was withdrawn. (JECFA81)			
Estimated Chronic Dietary Exposure	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 GECDE for the general population is 0.9 µg/kg bw per day, which represents 9% of the upper bound of the ADI. The GECDE for children is 1.5 µg/kg body weight per day, which represents 15% of the upper bound of the ADI. The GECDE for infants is 1.3 µg/kg bw per day, which represents 13% of the upper bound of the ADI. (JECFA81)			
ARfD	0.2 mg/kg bw, based on a NOAEL of 1.5 mg/kg bw, 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)			
Estimated Acute Dietary Exposure	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 µg/kg bw for the general population and 87 µg/kg bw for children, corresponding, respectively, to 27% and 43% of the ARfD. (JECFA81)			
Residue Definition	Ivermectin B _{1a}			
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Cattle	Muscle	30	40 (2017)	
	Liver	800		
	Kidney	100		
	Fat	400		
	Raw milk	10	26 (2003)	
Pig, Sheep	Liver	15	20 (1993)	
	Fat	20		

4.39 Lasalocid sodium (antiparasitic agent)

The MRL for lasalocid are shown in Table 39.

Table 39. MRL of lasalocid in different species of food animals

JECFA Evaluation		78 (2013)		
ADI		0-5 µg/kg bw on the basis of a NOAEL of 0.5 mg/kg bw 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)		
Estimated Dietary Exposure		80 µg/person per day was calculated, which represents approximately 27% of the upper bound of the ADI (JECFA78)		
Residue Definition		Lasalocid A		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Chicken, Turkey, Quail, Pheasant	Muscle	400	40 (2017)	JECFA78 extended the MRL in chicken to turkey and quail and extrapolated the MRL 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 MRL for egg.
	Liver	1200		
	Kidney	600		
	Skin+Fat	600		

4.40 Levamisole (anthelmintic agent)

The MRL for levamisole are shown in Table 40.

Table 40. MRL of levamisole in different species of food animals

JECFA Evaluation		36 (1990); 42 (1994)		
ADI		0-6 µg/kg bw (JECFA42)		
Residue Definition		Levamisole		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Cattle, Pig, Poultry, Sheep	Muscle	10	22 (1997)	
	Liver	100		
	Kidney	10		
	Fat	10		

4.41 Lincomycin (antimicrobial agent)

The MRL for lincomycin are shown in Table 41.

Table 41. MRL of lincomycin in different species of food animals

JECFA Evaluation		54 (2000); 58 (2002); 62 (2004)		
ADI		0-30 µg/kg bw (JECFA54)		
Residue Definition		Lincomycin		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Cattle	Raw milk	150	26 (2003)	
Chicken	Muscle	200		
	Liver	500		
	Kidney	500		
	Fat	100		Additional MRL for skin with adhering fat of 300 µg/kg
Pig	Muscle	200		
	Liver	500		
	Kidney	1500		
	Fat	100		Additional MRL for skin with adhering fat of 300 µg/kg

4.42 Lufenuron (insecticide)

The MRL for lufenuron is shown in Table 42.

Table 42. MRL of lufenuron in salmon and trout

JECFA Evaluation	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)
Estimated Chronic Dietary Exposure	1.1 µg/kg bw per day (for the general population), which represents 5.5% of the upper bound of the ADI. As lufenuron is also used as pesticide, the overall dietary exposure was estimated. The assumptions and detailed results will be displayed in the JECFA85 report. Results below are only for use as veterinary drug.

Residue Definition		Lufenuron		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Salmon, Trout	Fillet	1350	41 (2018)	Muscle plus skin in natural proportion

4.43 Melengestrol acetate (production aid)

The MRL for melengestrol acetate are shown in Table 43.

Table 43. MRL of melengestrol acetate in cattle

JECFA Evaluation		54 (2000); 58 (2002); 62 (2004); 66 (2006) 70 (2008)		
ADI		0-0.03 µg/kg bw (JECFA54)		
Residue Definition		Melengestrol acetate		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Cattle	Muscle	1	32 (2009)	
	Liver	10		
	Kidney	2		
	Fat	18		

4.44 Monensin (antimicrobial agent)

The MRL for monensin are shown in Table 44.

Table 44. MRL of monensin in different species of food animals

JECFA Evaluation		70 (2008); 75 (2011)		
ADI		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 (JECFA70)		
Estimated Dietary Exposure		Using the revised MRL, the TMDI from JECFA70 was recalculated, resulting in a value of 481 µg/person, which represents 80% of the upper bound of the ADI (JECFA75)		
Residue Definition		Monensin		
Species	Tissue	MRL (µg/kg)	Session and Year	Remarks

			Adopted by Codex	
Cattle	Muscle	10	32 (2009)	
	Liver	100	35 (2012)	
	Kidney	10	32 (2009)	
	Fat	100		
	Raw milk	2		
Sheep, Goats	Muscle	10		
	Liver	20		
	Kidney	10		
	Fat	100		
Chicken, Turkey, Quail	Muscle	10		
	Liver	10		
	Kidney	10		
	Fat	100		

4.45 Monepantel (anthelmintic agent)

The MRL for monepantel are shown in Table 45.

Table 45. MRL of monepantel in cattle and sheep

JECFA Evaluation		75 (2011); 78 (2013), 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)		
Estimated Chronic Dietary Exposure		13.7 µg per kg bw per day (for the general population), which represents 68% of the upper bound of the ADI 5.0 µg per kg bw per day (for children), which represents 22% of the upper bound of the ADI 4.4 µg per kg bw per day (for infants), which represents 25% of the upper bound of the ADI		
Residue Definition		Monepantel sulfone, expressed as monepantel		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Cattle	Muscle	300	41 (2018)	
	Liver	2000		
	Kidney	1000		
	Fat	7000		

Sheep	Muscle	500	38 (2015)	
	Liver	7000		
	Kidney	1700		
	Fat	13000		

4.46 Moxidectin (anthelmintic agent)

The MRL for moxidectin are shown in Table 46.

Table 46. MRL of moxidectin in different species of food animals

JECFA Evaluation		45 (1995); 47 (1996); 48 (1998); 50 (1998)		
ADI		0-2 µg/kg bw (JECFA45)		
Residue Definition		Moxidectin		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Cattle	Muscle	20	22 (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
	Liver	100		
	Kidney	50		
	Fat	500		
Deer	Muscle	20	23 (1999)	
	Liver	100		
	Kidney	50		
	Fat	500		
Sheep	Muscle	50	22 (1997)	
	Liver	100		
	Kidney	50		
	Fat	500		

4.47 Narasin (antimicrobial agent)

The MRL for narasin are shown in Table 47.

Table 47. MRL of narasin in different species of food animals

JECFA Evaluation		70 (2008); 75 (2011)
ADI		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 (JECFA70)

Residue Definition		Narasin A		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Cattle	Muscle	15	35 (2012)	
	Liver	50		
	Kidney	15		
	Fat	50		
Chicken	Muscle	15	32 (2009)	
	Liver	50		
	Kidney	15		
	Fat	50		
Pig	Muscle	15	34 (2011)	
	Liver	50		
	Kidney	15		
	Fat	50		

4.48 Neomycin (antimicrobial agent)

The MRL for neomycin are shown in Table 48.

Table 48. MRL of neomycin in different species of food animals

JECFA Evaluation		43 (1994); 47 (1996); 52 (1999); 58 (2002); 60 (2003)		
ADI		0-60 µg/kg bw (JECFA47)		
Residue Definition		Neomycin		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Cattle	Muscle	500	23 (1999)	
	Liver	500	28 (2005)	
	Kidney	10000		
	Fat	500	23 (1999)	
	Raw milk	1500	28 (2005)	
Chicken, Duck, Goat, Pig, Sheep, Turkey	Muscle	500	23 (1999)	
	Liver	500		
	Kidney	10000		
	Fat	500		
Chicken	Eggs	500		

4.49 Nicarbazin (antiprotozoal agent)

The MRL for nicarbazin are shown in Table 49.

Table 49. MRL of nicarbazin in chicken

JECFA Evaluation		50 (1998)		
ADI		0-400 µg/kg bw (JECFA50)		
Residue Definition		N,N'-bis(4-nitrophenyl)urea		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Chicken	Muscle	200	23 (1999)	Broilers only
	Liver	200		
	Kidney	200		
	Fat/Skin	200		

4.50 Phoxim (insecticide)

The MRL for phoxim are shown in Table 50.

Table 50. MRL of phoxim in different species of food animals

JECFA Evaluation		52 (1999); 62 (2004)		
ADI		0-4 µg/kg bw (JECFA52)		
Residue Definition		Phoxim		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Goat, Pig, Sheep	Muscle	50	26 (2003)	
	Liver	50		
	Kidney	50		
	Fat	400		

4.51 Pirlimycin (antimicrobial agent)

The MRL for pirlimycin are shown in Table 51.

Table 51. MRL of pirlimycin in cattle

JECFA Evaluation		62 (2004)		
ADI		0-8 µg/kg bw (JECFA62)		
Residue Definition		Pirlimycin		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Cattle	Muscle	100	29 (2006)	
	Liver	1000		
	Kidney	400		
	Fat	100		
	Raw milk	100		JECFA evaluated the effect of pirlimycin residues on starter cultures and for this reason recommended an MRL of 100 µg/kg of raw milk. Codex Members may therefore adapt national/regional MRL in order to address this technological aspect for trade of fresh liquid raw milk intended for processing using starter culture

4.52 Ractopamine (production aid)

The MRL for ractopamine are shown in Table 52.

Table 52. MRL of ractopamine in cattle and pig

JECFA Evaluation		40 (1992); 62 (2004); 66 (2006)		
ADI		0-1 µg/kg bw (JECFA66)		
Residue Definition		Ractopamine		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Cattle, Pig	Muscle	10	35 (2012)	
	Liver	40		
	Kidney	90		
	Fat	10		Pig: The MRL includes skin + fat

4.53 Sarafloxacin (antimicrobial agent)

The MRL for sarafloxacin are shown in Table 53.

Table 53. MRL of sarafloxacin in chicken and turkey

JECFA Evaluation		50 (1998)		
ADI		0-0.3 µg/kg bw (JECFA50)		
Residue Definition		Sarafloxacin		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Chicken, Turkey	Muscle	10	24 (2001)	
	Liver	80		
	Kidney	80		
	Fat	20		

4.54 Spectinomycin (antimicrobial agent)

The MRL for spectinomycin are shown in Table 54.

Table 54. MRL of spectinomycin in different species of food animals

JECFA Evaluation		50 (1998)		
ADI		0-0.3 µg/kg bw (JECFA50)		
Residue Definition		Sarafloxacin		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Cattle, Chicken, Pig, Sheep	Muscle	500	23 (1999)	
	Liver	2000		
	Kidney	5000		
	Fat	2000		
Cattle	Raw milk (µg/l)	200		
Chicken	Eggs	2000		

4.55 Spiramycin (antimicrobial agent)

The MRL for spiramycin are shown in Table 55.

Table 55. MRL of spiramycin in different species of food animals

JECFA Evaluation		38 (1991); 43 (1994); 47 (1996); 48 (1997)		
ADI		0-50 µg/kg bw (JECFA43)		
Residue Definition		Cattle and chickens, sum of spiramycin and neospiramycin; Pigs, spiramycin equivalents (antimicrobially active residues)		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Cattle, Pig	Muscle	200	22 (1997)	
	Liver	600		
	Kidney	300		
	Fat	300		
Cattle	Raw milk (µg/l)	200		
Chicken	Muscle	200		
	Liver	600		
	Kidney	800		
	Fat	300		

4.56 Sulfadimidine (antimicrobial agent)

The MRL for sulfadimidine are shown in Table 56.

Table 56. MRL for sulfadimidine

JECFA Evaluation		34 (1989); 38 (1991); 42 (1994)		
ADI		0-50 µg/kg bw (JECFA42)		
Residue Definition		Sulfadimidine		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Cattle	Raw milk (µg/l)	25	21 (1995)	
Not specified	Muscle	100		
	Liver	100		
	Kidney	100		
	Fat	100		

4.57 Teflubenzuron (insecticide)

The MRL for teflubenzuron are shown in Table 57.

Table 57. MRL of teflubenzuron in salmon

JECFA Evaluation		81 (2015)		
ADI		0-5 µg/kg bw on the basis of a lower 95% BMDL for a 10% response (BMDL10) of 0.54 mg/kg bw 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)		
Estimated Chronic Dietary Exposure		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 bw per day, which represents 31% of the upper bound of the ADI. The GECDE for children is 2.1 µg/kg bw per day, which represents 43% of the upper bound of the ADI. The GECDE for infants is 0.9 µg/kg bw per day, which represents 18% of the upper bound of the ADI. (JECFA81)		
Residue Definition		Teflubenzuron		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Salmon	Muscle	400	40 (2017)	Muscle + skin in natural proportion
	Fillet	400		

4.58 Thiabendazole (anthelmintic agent)

The MRL for thiabendazole are shown in Table 58.

Table 58. MRL of thiabendazole in different species of food animals

JECFA Evaluation		40 (1992); 48 (1997); 58 (2002)		
ADI		0-100 µg/kg bw (JECFA40)		
Residue Definition		Sum of thiabendazole and 5-hydroxythiabendazole		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks

Cattle, Goat, Pig, Sheep	Muscle	100	21 (1995)	The MRL also covers residues derived from feed containing the residues resulted from agricultural use.
	Liver	100		
	Kidney	100		
	Fat	100		
Cattle, Goat	Raw milk (µg/l)	100		

4.59 Tilmicosin (antimicrobial agent)

The MRL for tilmicosin are shown in Table 59.

Table 59. MRL of tilmicosin in different species of food animals

JECFA Evaluation		47 (1996); 54 (2000); 70 (2008)		
ADI		0-40 µg/kg bw (JECFA47)		
Residue Definition		Tilmicosin		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Cattle, Sheep	Muscle	100	23 (1999)	
	Liver	1000		
	Kidney	300		
	Fat	100		
Chicken	Muscle	150	34 (2011)	
	Liver	2400		
	Kidney	600		
	Fat/Skin	250		
Pig	Muscle	100	23 (1999)	
	Liver	1500		
	Kidney	1000		
	Fat	100		
Turkey	Muscle	100	34 (2011)	
	Liver	1200		
	Kidney	1400		
	Fat/Skin	250		

4.60 Trenbolone acetate (growth promoter)

The MRL for trenbolone are shown in Table 60.

Table 60. MRL of trenbolone in cattle

JECFA Evaluation		26 (1982); 27 (1983); 32 (1987); 34 (1989)		
ADI		0-0.02 µg/kg bw (JECFA34)		
Residue Definition		Cattle muscle, beta-Trenbolone; Cattle liver, alpha-Trenbolone		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Cattle	Muscle	2	21 (1995)	
	Liver	10		

4.61 Trichlorfon (metrifonate) (insecticide)

The MRL for trichlorfon is shown in Table 61.

Table 61. MRL of trichlorfon in cattle

JECFA Evaluation		54 (2000); 60 (2003); 66 (2006)		
ADI		0-2 µg/kg bw (JECFA60)		
Residue Definition		JECFA54 confirmed the MRL for cows' raw milk and the guidance levels for muscle, liver, kidney and fat of cattle recommended (WHO TRS 900, 2001)		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Cattle	Raw milk	50	29 (2006)	

4.62 Triclabendazole (anthelmintic agent)

The MRL for triclabendazole are shown in Table 62.

Table 62. MRL of triclabendazole in cattle and sheep

JECFA Evaluation		40 (1992); 66 (2006); 70 (2008)		
ADI		0-3 µg/kg bw (JECFA40)		
Residue Definition		Ketotriclabendazole		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Cattle	Muscle	250	32 (2009)	

Sheep	Liver	850		
	Kidney	400		
	Fat	100		
	Muscle	200		
	Liver	300		
	Kidney	200		
	Fat	100		

4.63 Tylosin (antimicrobial agent)

The MRL for tylosin are shown in Table 63.

Table 63. MRL of tylosin in different species of food animals

JECFA Evaluation		70 (2008)		
ADI		0-30 µg/kg bw based on a microbiological end-point derived from in vitro MIC susceptibility testing and fecal binding data (MIC _{calc} = 1.698) (JECFA70)		
Residue Definition		Tylosin A		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Cattle, Pig	Muscle	100	32 (2009)	
	Liver	100		
	Kidney	100		
	Fat	100		
Cattle	Raw milk	100		
Chicken	Muscle	100		
	Liver	100		
	Kidney	100		
	Fat/Skin	100		
	Eggs	300		

4.64 Zeranol (growth promoter)

The MRL for zeranol are shown in Table 64.

Table 64. MRL of zeranol in cattle

JECFA Evaluation	26 (1982); 27 (1983); 32 (1987)
ADI	0-0.5 µg/kg bw (JECFA32)

Residue Definition		Zeranol		
Species	Tissue	MRL (µg/kg)	Session and Year Adopted by Codex	Remarks
Cattle	Muscle	2	21 (1995)	
	Liver	10		

5 Risk Management Recommendations (RMR) for Residues of Veterinary Drug

In Table 65, the following are the RMR for residues of veterinary drugs:

Table 65. RMR for veterinary drugs residues

Veterinary Drugs	JECFA Evaluation	CAC Adoption	RMR Measures
Carbadox (growth promoter)	36 (1990); 60 (2003)	37 (2014)	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)	12 (1968); 32 (1987); 42 (1994); 62 (2004)	37 (2014)	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.

Veterinary Drugs	JECFA Evaluation	CAC Adoption	RMR Measures
Chlorpromazine (tranquilliser agent)	38 (1991)	37 (2014)	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)	34 (1989)	38 (2015)	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)	40 (1992)	37 (2014)	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

Veterinary Drugs	JECFA Evaluation	CAC Adoption	RMR Measures
			not using furazolidone in food producing animals.
Gentian Violet (antibacterial, antifungal and anthelmintic agent)	78 (2013)	41 (2018)	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)	34 (1989)	38 (2015)	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)	70 (2008)	37 (2014)	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.

Veterinary Drugs	JECFA Evaluation	CAC Adoption	RMR Measures
Metronidazole (antiprotozoal agent)	34 (1989)	38 (2015)	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.
Nitrofurantoin (antimicrobial agent)	40 (1992)	37 (2014)	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 nitrofurantoin or its metabolites ¹ in food representing an acceptable risk to consumers, significant health concerns were identified. For this reason, competent authorities should prevent residues of nitrofurantoin in food. This can be accomplished by not using nitrofurantoin in food producing animals. ¹ Semicarbazide is not a unique indicator of nitrofurantoin use and low levels can be associated with other legitimate sources.
Olaquinox (antibacterial agent)	36 (1990); 42 (1994)	37 (2014)	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 olaquinox or its metabolites in food representing an acceptable risk to

Veterinary Drugs	JECFA Evaluation	CAC Adoption	RMR Measures
			consumers, significant health concerns were identified. For this reason, competent authorities should prevent residues of olaquinox in food. This can be accomplished by not using olaquinox in food producing animals.
Ronidazole (antiprotozoal agent)	34 (1989); 42 (1994)	38 (2015)	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: 5 (1960); IARC: monograph 100A (2012)	37 (2014)	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.

6 Veterinary Drugs without MRL

In Table 66, the following are the veterinary drugs that has no MRL.

Table 66. List of veterinary drugs without MRL set by Codex

Veterinary Drug	Species/ Tissue	JECFA Evaluation	Session and Year Adopted by Codex	Remarks
Estradiol-17beta (production aid)	Cattle	25 (1981); 32 (1987); 52 (1999)	21 (1995)	Residues resulting from the use of this substance as a growth promoter in accordance with good animal husbandry practices are unlikely to pose a hazard to human health
Flumethrin (insecticide)	Honey	85 (2018)	25 (2021)	Residues resulting from the use of this substances as an insecticide in accordance with good practice for veterinary drug is unlikely to pose a hazard to human health.
Porcine Somatotropin (production aid)	Pig	52 (1999)	26 (2003)	Not specified
Testosterone (production aid)	Cattle	25 (1981); 32 (1987); 52 (1999)	21 (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.

7 Banned Veterinary Drugs in the Philippines

Table 67 shows the banned veterinary drugs in the Philippines as supported by regulations from the competent authority.

Table 67. List of banned veterinary drugs

Drug	Administrative Order (AO)/Administrative Circular (AC)	Title
1. Beta-Agonist a) Clenbuterol b) Salbutamol c) Terbutalin d) Pirbuterol	Department of Agriculture (DA) AO No. 14, series of 2003	Ban on the Use in Food Animals of Beta-Agonist Drugs Used in Human as Bronchodilators and Tocolytic Agents
2. Nitrofurans a) Furaltadone b) Furazolidone c) Nitrofurazone	DA-Department of Health (DOH) AO No. 2, series of 2000	Declaring a Ban/Phase Out of the Use of Nitrofurans in Food Producing Animals
3. Carbadox and Olaquinox	DA AO No. 60, series of 2000 DOH AO No.4-A, series of 2000	Ban and Withdrawal of Olaquinox and Carbadox in the Market
4. Chloramphenicol	DA AO No. 60, series of 1990 DOH AO No. 91, series of 1990	Declaring a Ban on the Use of Chloramphenicol in Food Producing Animals
5. Diethylstilbestrol (DES)	DOH AO 194, series of 1973	Ban on the use of diethylstilbestrol (DES)
6. Malachite green and Gentian Violet	Bureau of Fisheries and Aquatic Resources (BFAR) - AC No. 256, series of 2015	Declaring malachite green and gentian violet as health hazards and prohibiting their use in food fish production and trade
7. Chloroform (Trichloromethane)	DOH AO No. 341. series of 1978	Ban on the use of chloroform (trichloromethane)

ANNEX A
(Informative)**List of acronyms**

ADI	Acceptable Daily Intake
ARfD	Acute Reference Dose
BFAR	Bureau of Fisheries and Aquatic Resources
BMD	Benchmark Dose
BMDL	Confidence Limit for BMD
bw	Body Weight
CAC	Codex Alimentarius Commission
DA	Department of Agriculture
DOH	Department of Health
EDI	Estimated Daily Intake
FAO	Food and Agriculture Organization
GEADE	Global Estimated Acute Dietary Exposure
GECDE	Global Estimated Chronic Dietary Exposure
JECFA	Joint FAO/WHO Expert Committee of Food Additives
JMPR	Joint FAO/WHO Expert Meeting on Pesticide Residues
LOAEL	Lowest-Observed-Adverse-Effect-Level
NOAEL	No-Observed-Adverse-Effect-Level
LOQ	Limit of Quantification
mADI	Microbiological Acceptable Daily Intake
MRL	Maximum Residue Limit
RMR	Risk Management Recommendation
TMDI	Theoretical Maximum Daily Intake
WHO	World Health Organization

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**Department of Agriculture (DA)
Bureau of Agriculture and Fisheries Standards (BAFS)**

**Technical Working Group (TWG) for the Philippine National Standard (PNS) on
Veterinary Drug Residues in Food — Product Standard — Maximum Residue
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