For background information, please see CL 2023/75/OCS-CAC

Codex Members and Observers are invited to submit comments on MRLs as follows:

MRLs derived through JECFA evaluation:

1. Ivermectin (sheep, pigs, and goats – fat, kidney, liver, and muscle)
2. Nicarbazin (chicken)

MRLs derived through extrapolation:

Ruminants

3. Amoxicillin –muscle, fat, liver, kidney, and milk
4. Benzylpenicillin –muscle, liver, kidney, milk
5. Cyhalothrin –muscle, fat, liver, kidney, milk
6. Cypermethrin –muscle, fat, liver, kidney
7. Deltamethrin –muscle, fat, liver, kidney
8. Levamisole –muscle, fat, liver, kidney
9. Moxidectin –muscle, fat, liver, kidney
10. Spectinomycin –muscle, fat, liver, kidney, milk
11. Tetracyclines –muscle, liver, kidney, milk
12. Tilmicosin –muscle, fat, liver, kidney

Finfish

13. Deltamethrin –muscle
14. Flumequine –muscle

Comments should address **whether the MRLs are ready for adoption or not.** If not, provide the rationale and proposals to facilitate adoption. Comments should be provided in conformity with the *Procedure for the Elaboration of Codex Standards and Related Texts (*Part 3 – *Uniform Procedure for the Elaboration of Codex Standards and Related Texts,* Procedural Manual of the Codex Alimentarius Commission.

MAXIMUM RESIDUE LIMITS (MRLs) FOR VETERINARY DRUGS IN FOODS

IVERMECTIN

(Broad-spectrum antiparasitic agent)

(PIGS, SHEEP AND GOATS – FAT, KIDNEY, LIVER AND MUSCLE)

(For adoption at Step 5/8)

Acceptable daily intake	JECFA established an ADI of 0–10 µg/kg body weight at the eighty-first meeting.
Acute reference dose	JECFA established an ARfD of 200 µg/kg body weight at the eighty-first meeting.
Residue definition	The marker residue in sheep, pigs and goats is ivermectin B_{1a} (H_2B_{1a}, or *22,23*-dihydroavermectin B1a).
Estimated chronic dietary exposure	The GECDE for adults and the elderly is 0.72 µg/kg bw per day, which represents 7.2% of the upper bound of the ADI of 10 µg/kg bw. The GECDE for children and adolescents is 0.93 µg/kg bw per day, which represents 9.3% of the upper bound of the ADI of 10 µg/kg bw. The GECDE for infants and toddlers is 0.48 µg/kg bw per day, which represents 4.8% of the upper bound of the ADI of 10 µg/kg bw.
Estimated acute dietary exposure	The GEADE for cattle muscle, applicable to children and the general population, is 69 µg/kg bw, which represents 35% of the ARfD of 200 µg/kg bw. The GEADE for sheep muscle, applicable to children and the general population, is 73 µg/kg bw, which represents 37% of the ARfD of 200 µg/kg bw. The GEADE for pig muscle, applicable to children and the general population, is 30 µg/kg bw, which represents 15% of the ARfD of 200 µg/kg bw.

Maximum residue limits (MRLs)

Species	Muscle (µg/kg)	Liver (µg/kg)	Kidney (µg/kg)	Fat (µg/kg)
Pigs	15	30	20	50
Sheep and goats	30	60	20	100

NICARBAZIN
(Coccidiostat)
(CHICKEN)
(For adoption at Step 5/8)

Toxicological effects	The NOAEL was 60 mg/kg bw per day (equivalent to 42.5 mg/kg bw per day of DNC) due to prominent liver lobulation, observed in a study of developmental toxicity in the rabbit.
Uncertainty factor	When considering nicarbazin it is DNC that is the toxic component, and its absorption alone or in a mixture with HDP is substantially less (< 5%) than when formed from ingested nicarbazin. As DNC is the residue of concern and there is no nicarbazin in products from treated animals, JECFA concluded that despite limitations in the database, a reduction in the default safety factor of 100 used to account for interspecies and intraspecies variability, would be justified. JECFA was unable to quantify just how much of a reduction would be appropriate, but concluded that 50 could certainly be supported, and would still result in a conservative evaluation.
Toxicological ADI	The tADI for nicarbazin was established at 0–0.9 mg/kg bw (DNC).
Microbiological effects	Nicarbazin and/or its metabolites show no antimicrobial activity towards representative bacteria of the human intestinal microbiota.
Microbiological ADI	JECFA concluded that it was not necessary to establish an mADI for nicarbazin.
Acceptable daily intake	The ADI for nicarbazin was established at 0–0.9mg/kg bw based on toxicological effects.
Acute reference dose	JECFA concluded that it was not necessary to establish an ARfD for nicarbazin.
Residue definition	The marker residue in chickens is DNC.
Estimated dietary exposure	Based on incurred DNC residues in chicken muscle, offal, and skin with fat, at 24 hours withdrawal time and 125 mg/kg feed: The global estimate of chronic dietary exposure (GECDE) for adults and the elderly is 120 µg/kg body weight (bw) per day, which represents 13% of the upper bound of the ADI of 900 µg/kg bw. The GECDE for children and adolescents is 160 µg/kg bw per day, which represents 18% of the upper bound of the ADI of 900 µg/kg bw. The GECDE for infants and toddlers is 210 µg/kg bw per day, which represents 23% of the upper bound of the ADI of 900 µg/kg bw. Based on incurred DNC residues in chicken muscle, offal, and skin with fat, at zero days withdrawal time and 50 mg/kg feed: The GECDE for adults and the elderly is 95 µg/kg bw per day, which represents 11% of the upper bound of the ADI of 900 µg/kg bw. The GECDE for children and adolescents is 120 µg/kg bw per day, which represents 14% of the upper bound of the ADI of 900 µg/kg bw. The GECDE for infants and toddlers is 160 µg/kg bw per day, which represents 18% of the upper bound of the ADI of 900 µg/kg bw.

Maximum residue limits (MRLs)

Species	Muscle (µg/kg)	Liver (µg/kg)	Kidney (µg/kg)	Skin with fat (µg/kg)
Chicken	4000	15 000	8000	4000

IVERMECTIN
(Broad-spectrum antiparasitic agent)
(At Step 7)
(SHEEP, PIGS AND GOATS – FAT, KIDNEY, LIVER AND MUSCLE)
(For discontinuation)

Acceptable daily intake	The ADI of 0–10 µg/kg bw established by JECFA81 (1) remains unchanged.
Acute reference dose	The ARfD of 0.2 mg/kg bw established by JECFA81 remains unchanged.
Estimated chronic dietary exposure	JECFA established a GECDE for the general population of 0.41 µg/kg bw per day, which represents 4% of the upper bound of the ADI. JECFA established a GECDE for children of 0.59 µg/kg bw per day, which represents 5.9% of the upper bound of the ADI.
Estimated acute dietary exposure	JECFA established a GEADE for the general population of 87 µg/kg bw per day, which represents 43% of the ARfD, from consumption of cattle muscle, and of 1.1 µg/kg bw, which represents 0.6% of the ARfD, from consumption of sheep muscle. JECFA established a GEADE for children of 82 µg/kg bw per day, which represents 41% of the ARfD, from consumption of cattle muscle and of 1.0 µg/kg bw, which represents 0.5% of the ARfD, from consumption of sheep muscle.
Residue definition	The marker residue (MR) in sheep, pigs and goats is Ivermectin B_{1a} (H_2B_{1a}, or 22,23-dihydroavermectin B_{1a}).
Maximum residue limits	JECFA established MRLs for sheep, pigs and goats of 20 µg/kg for fat, 15 µg/kg for kidney, 15 µg/kg for liver and 10 µg/kg for muscle.

Maximum residue limits (MRLs)

Species	Fat (µg/kg)	Kidney (µg/kg)	Liver (µg/kg)	Muscle (µg/kg)
Sheep, pigs and goats	20	15	15	10

EXTRAPOLATION OF MRLs
IN ACCORDANCE WITH THE
APPROACH FOR THE EXTRAPOLATION OF MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS TO ONE OR MORE SPECIES
(For adoption at Step 5/8)

1. Amoxicillin – extrapolation to ruminants

Species	Tissue	MRL (µg/kg)	Note
All other ruminants	Muscle	50	MRL extrapolated
All other ruminants	Fat	50	MRL extrapolated
All other ruminants	Liver	50	MRL extrapolated
All other ruminants	Kidney	50	MRL extrapolated
All other ruminants	Milk	4	MRL extrapolated

2. Benzylpenicillin – extrapolation to ruminants

Species	Tissue	MRL (µg/kg)	Note
All other ruminants	Muscle	50	MRL extrapolated
All other ruminants	Liver	50	MRL extrapolated
All other ruminants	Kidney	50	MRL extrapolated
All other ruminants	Milk	4	MRL extrapolated

3. Tetracyclines - extrapolation to ruminants

Species	Tissue	MRL (µg/kg)	Note
All other ruminants	Muscle	200	MRL extrapolated
All other ruminants	Liver	600	MRL extrapolated
All other ruminants	Kidney	1200	MRL extrapolated
All other ruminants	Milk	100	MRL extrapolated

4. Cyhalothrin - extrapolation to ruminants

Species	Tissue	MRL (µg/kg)	Note
All other ruminants	Muscle	20	MRL extrapolated
All other ruminants	Fat	400	MRL extrapolated
All other ruminants	Liver	20	MRL extrapolated
All other ruminants	Kidney	20	MRL extrapolated
All other ruminants	Milk	30	MRL extrapolated

5. Cypermethrin - extrapolation to ruminants

Species	Tissue	MRL (µg/kg)	Note
All other ruminants	Muscle	50	MRL extrapolated
All other ruminants	Fat	1000	MRL extrapolated
All other ruminants	Liver	50	MRL extrapolated
All other ruminants	Kidney	50	MRL extrapolated

6. Deltamethrin - extrapolation to ruminants

Species	Tissue	MRL (µg/kg)	Note
All other ruminants	Muscle	30	MRL extrapolated
All other ruminants	Fat	500	MRL extrapolated
All other ruminants	Liver	50	MRL extrapolated
All other ruminants	Kidney	50	MRL extrapolated

7. Moxidectin - extrapolation to ruminants

Species	Tissue	MRL (µg/kg)	Note
All other ruminants	Muscle	20	MRL extrapolated
All other ruminants	Fat	500	MRL extrapolated
All other ruminants	Liver	100	MRL extrapolated
All other ruminants	Kidney	50	MRL extrapolated

8. Spectinomycin -extrapolation to ruminants

Species	Tissue	MRL (µg/kg)	Note
All other ruminants	Muscle	500	MRL extrapolated
All other ruminants	Fat	2000	MRL extrapolated
All other ruminants	Liver	2000	MRL extrapolated
All other ruminants	Kidney	5000	MRL extrapolated
All other ruminants	Milk	200	MRL extrapolated

9. Levamisole extrapolation to ruminants

Species	Tissue	MRL (µg/kg)	Note
All other ruminants	Muscle	10	MRL extrapolated
All other ruminants	Fat	10	MRL extrapolated
All other ruminants	Liver	100	MRL extrapolated
All other ruminants	Kidney	10	MRL extrapolated

10. Tilmicosin extrapolation to ruminants

Species	Tissue	MRL (µg/kg)	Note
All other ruminants	Muscle	100	MRL extrapolated
All other ruminants	Fat	100	MRL extrapolated
All other ruminants	Liver	1000	MRL extrapolated
All other ruminants	Kidney	300	MRL extrapolated

11. Deltamethrin extrapolation to finfish

Species	Tissue	MRL (µg/kg)	Note
All other finfish	Muscle	30	MRL extrapolated

12. Flumequine extrapolation to finfish

Species	Tissue	MRL (µg/kg)	Note
All other finfish	Muscle	500	MRL extrapolated