

SPIRAMYCIN

First draft prepared by

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ADDENDUM

to the Spiramycin residue monograph prepared by the 47th meeting of the Committee
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Background

The Forty-seventh Session of the Committee recommended the following MRLs for spiramycin in cattle, chickens and pigs.

Muscle	(cattle, pigs, chicken)	200 µg/kg
Liver	(cattle, pigs, chicken)	600 µg/kg
Kidney	(cattle, pigs)	300 µg/kg
	(chickens)	800 µg/kg
Fat	(cattle, pigs, chicken)	300 µg/kg
Milk	(cattle)	100 µg/l

For cattle and chickens MRLs are expressed as the sum of spiramycin and neospiramycin, for pigs as spiramycin equivalents (antimicrobially active residues).

The 10th Session of the Codex Committee on Residues of Veterinary Drugs in Foods advanced the recommended MRLs for muscle, liver, kidney and fat (cattle and chickens) and muscle (pigs) to Step 8. The Codex Committee advanced the proposed draft MRLs for pigs (liver, kidney, fat) to Step 5/8, by omitting Steps 6 and 7, as these were modifications of previous assessments which presented no additional toxicological concerns. The Codex Committee also advanced the MRL of 100 µg/l for cattle milk to step 8. It noted proposals to increase this MRL to 200 µg/l and requested that the Expert Committee re-evaluates the MRL for cattle milk at its 48th meeting to determine, if it could be raised to 200 µg/l. The Codex Committee requested the Expert Committee to advise the Codex Alimentarius Commission of its opinion on raising the MRL from 100 µg/l to 200 µg/l, and indicated that it would support such an increase on the basis of that opinion.

Using the MRLs for chickens (which results in the largest theoretical maximum daily intake) and a standard daily intake of 300 g muscle, 100 g liver, 50 g kidney, 50 g fat and 1.5 litres of milk, the theoretical maximum daily intake of antimicrobially active spiramycin residues is 440 µg. Using an ADI of 0-50 µg/kg of body weight, a 60-kg person would therefore be permitted to consume 3000 µg/kg of antimicrobially active spiramycin residues. Therefore, the maximum daily intake of spiramycin residues of concern would use 14.7% of the ADI. If the MRL for cattle milk were increased to 200 µg/l, the theoretical maximum daily intake would increase to 590 µg or 19.7% of the ADI.

Table. Theoretical maximum daily intake (TMDI) of antimicrobially active spiramycin residues

Tissue	MRL (µg/kg)	Daily Intake of Tissue (g)	Ratio TR/MR	TMDI (µg)
Muscle	200	300	1	60
Liver	600	100	2	120
Kidney	800	50	2	80
Fat	300	50	2	30
Milk	200 µg/l	1.5 litres	1	300
Total				590

TR=Total antimicrobially active residues; MR=Marker residues

Maximum Residue Limits

The Committee recommended that the MRL for milk be increased from 100 to 200 µg/l.