

This is a provisional English translation of an excerpt from the original full report.

Risk Assessment Report

Spiramycin

(Veterinary Medicinal Products)

Food Safety Commission of Japan (FSCJ)
December 2016

ABSTRACT

FSCJ conducted a risk assessment of spiramycin (CAS No. 8025-81-8), a macrolide antibiotic, based on documents evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and submitted for a new veterinary medicinal product by an applicant.

The data used in the assessment include pharmacokinetics (rats, guinea pigs, cattle, pigs, chickens, yellow tail and humans), residues (cattle, pigs, chickens and yellow tail), genotoxicity, acute toxicity (mice, rats, guinea pigs, rabbits, cats, dogs and turkeys), subacute toxicity (rats and dogs), chronic toxicity (dogs), combined chronic toxicity/carcinogenicity (rats), reproductive toxicity (mice and rabbits) and microbiological effects.

FSCJ considered that spiramycin has no genotoxicity relevant to human health based on negative results in all genotoxicity studies tested. FSCJ concluded it possible to specify a toxicological acceptable daily intake (ADI). No carcinogenicity was observed.

FSCJ evaluated the toxicological ADI based on the results of the toxicity studies as follows. Among various toxicity studies, the lowest no-observed- adverse-effect level (NOAEL) was 60 mg/kg bw/day in a 28-week subacute toxicity study in dogs. FSCJ, however judged that it was appropriate to adopt the NOAEL of 75 mg/kg bw/day in a two-year chronic toxicity study in dogs because of longer period administration than 28 weeks. FSCJ estimated the toxicological ADI of 0.075 mg/kg bw/day if applied a maximum safety factor of 1,000 (100 for species and individual difference as well as 10 for and additional safety factor) to the NOAEL.

FSCJ specified the microbiological ADI to be 0.025 mg/kg bw/day.

FSCJ considered that using the microbiological ADI was appropriate for setting the ADI of spiramycin because the microbiological ADI was lower than the estimated toxicological one. The process for the evaluation was the same as that in JECFA.

FSCJ specified 0.025 mg/kg bw/day as the ADI of spiramycin.