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

Risk Assessment Report

Lasalocid

(Veterinary medicinal products)

Food Safety Commission of Japan (FSCJ)
August 2014

ABSTRACT

FSCJ conducted a risk assessment of lasalocid (CAS No. 25999-20-6), a polyether antibiotic, based on documents including assessment reports from the European Medicines Agency (EMEA) and documents prepared by an applicant for designation of a new feed additive.

The data used in the assessment include: pharmacokinetics (mice, rats, cattle, pigs, chickens and turkeys), residues (cattle, chicken, turkeys, pheasants and quails), genotoxicity, acute toxicity (mice, rats, rabbits, cattle, houses and chickens), subacute toxicity (rats and dogs), chronic toxicity and carcinogenicity (mice, rats and dogs), reproductive and developmental toxicity (rats and rabbits), microbiological effects and others.

Results of genotoxicity studies indicated that lasalocid is unlikely to show its effect by direct covalent binding to DNA, and suggested that it was possible to establish a threshold dose.
Moreover, since no carcinogenicity was identified, FSCJ suggested that an acceptable daily intake (ADI) can be specified.

The minimum value of the no-observed-adverse-effect level (NOAEL) obtained in various toxicological studies was 0.5 mg/kg bw/day in a 130-week combined chronic toxicity/carcinogenicity study in rats and a developmental study in rabbits.
Hence, FSCJ specified the toxicological ADI of 0.005 mg/kg body weight/day, by applying a safety factor of 100 (10 for species differences, 10 for individual differences) to the NOAEL.

Microbiological ADI was calculated to be 0.0317 mg/kg bw/day based on the VICH (the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products) guideline 36.
FSCJ specified the ADI of lacalocid as 0.005 mg/kg bw/day because the toxicological ADI is smaller than the microbiological ADI.