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

Risk Assessment Report

Semduramicin

(Veterinary Medicinal Products and Feed Additives)

Food Safety Commission of Japan (FSCJ)
November 2017

ABSTRACT

FSCJ conducted a risk assessment of semduramicin, an antibiotic and a pesticide, by use of various documents on semduramicin sodium (CAS No. 119068-77-8) including the assessment report from FDA and documents used when it was designated as a feed additive.

Data used in the assessment include pharmacokinetics (rats, dogs and chicken), residues (chicken), genotoxicity, acute toxicity (mice and rats), subacute toxicity (mice, rats and dogs), chronic toxicity and carcinogenicity (mice, rats and dogs), reproductive developmental toxicity (rats and rabbits), cardiovascular toxicity (dogs) and microbiological effects.

FSCJ recognized that the ADI for semduramicin could be specified since semduramicin was judged to have no genotoxicity based on the results of genotoxicity studies.
Data of various toxicity studies except the genotoxicity study indicated that the major adverse effects of semduramicin observed were suppressed body weight, retinal lesions and abnormal values of blood biochemical tests. No carcinogenicity was observed.
Major adverse effects on fetuses observed in the reproductive developmental toxicity study were decreased body weight and delayed ossification. No teratogenicity was observed.

FSCJ specified toxicological ADI of semduramicin to be 0.003 mg/kg bw/day applying a safety factor of 100 to the NOAEL of 0.3 mg/kg bw/day that was obtained in one-year chronic toxicity study in dogs.
Microbiological ADI was estimated to be 0.024 mg/kg bw/day.
FSCJ specified the ADI of semduramicin as 0.003 mg/kg bw/day as the toxicological ADI is smaller than the microbiological ADI.