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

# Risk Assessment Report

## Gamithromycin
(Veterinary Medicinal Products)

Food Safety Commission of Japan (FSCJ)
July 2014

## ABSTRACT

FSCJ conducted a risk assessment of gamithromycin (CAS No.113617-63-3), a family of antimicrobial agents of macrolides, based on a written application for the marketing approval of new veterinary medicinal products and its attached documents.

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

Data of i*n vitro* reverse mutation and *in vivo* genotoxicity studies were negative in amithromysin, although the results of *in vitro* chromosomal aberration tests were weakly positive. Therefore, FSCJ concluded that gamithromycin has no genotoxicity relevant to human health.
No carcinogenicity was observed in carcinogenicity studies, suggesting that gamithromycin is not a genotoxic carcinogen. Hence, FSCJ concludes that an acceptable daily intake (ADI) can be specified.

From the results of toxicity studies, FSCJ judged it appropriate to use a no-observed–adverse-effect level (NOAEL) of 1 mg/kg bw/day observed in a 13-week subacute toxicity study and 52-weak chronic toxicity study in dogs, and to specify a toxicological ADI as 0.01 mg/kg bw/day, applying a safety factor of 100 to this NOAEL. This safety factor of 100 was composed of 10 for species difference and 10 for individual difference,

Microbiological ADI was estimated to be 0.045 mg/kg bw/day based on the VICH[1] guideline 36.
FSCJ specified the ADI of gamithromycin as 0.01 mg/kg bw/day as the toxicological ADI is smaller than the microbiological ADI.

[1] The International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products.