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

Risk Assessment Report

Spectinomycin

(Veterinary Medicinal Products)

Food Safety Commission of Japan (FSCJ)
July 2017

ABSTRACT

FSCJ conducted a risk assessment of an aminoglycoside antibiotic, spectinomycin (CAS No.1695-77-8), by use of various documents on spectinomycin including the assessment report from JECFA and EMEA, and documents regarding the revision of residue standards.

Data used in the assessment include ADME (absorption, distribution, metabolism and excretion) (rats, dogs, cattle, sheep, pigs and humans), residues (cattle, sheep, pigs and chicken), genotoxicity, acute toxicity (mice, rats, rabbits, cats, dogs, monkeys and chicken), subacute toxicity (rats and dogs), reproductive developmental toxicity (rats, mice and rabbits), and microbiological effects.

Data of all genotoxicity either in vitro or in vivo studies were negative suggesting that spectinomycin has no genotoxicity. Therefore, FSCJ considered that an ADI could be specified for spectinomycin.

In addition, spectinomycin has no structural similarity with any known carcinogen and no findings on carcinogenicity of spectionomycin was available for the moment, although assessable data from chronic toxicity study and carcinogenicity study were not available. Accordingly, FSCJ considered that carcinogenic concern of spectinomycin was unlikely.

Orally administered spectinomycin is hardly absorbed, and remarkable toxicity was not observed in the toxicity studies. FSCJ, therefore, considered it appropriate to specify the ADI based on the microbiological effects rather than the toxicological effects.
Microbiological ADI was estimated to be 0.053 mg/kg bw/day based on the VICH[1] guideline 36, and FSCJ thus specified the ADI of spectinomycin as 0.053 mg/kg bw/day.

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