

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

## Risk Assessment Report

### Kasugamycin

(Pesticides)

Food Safety Commission of Japan (FSCJ)

March 2014

#### ABSTRACT

FSCJ conducted a risk assessment of kasugamycin (CAS No.19408-46-9), an aminoglycoside antibiotic, based on the summary reports made by applicants and evaluation reports from the Governments of US and Canada.

The data used in the assessment are on: fate in animals (rats and goats), fate in plants (paddy rice, tomatoes and others), residues in crops, subacute toxicity (rats, mice, dogs), subacute neurotoxicity (rats), chronic toxicity (dogs), combined chronic toxicity/carcinogenicity (rats), carcinogenicity (mice), two-generation reproductive toxicity (rats), developmental toxicity (rats and rabbits), genotoxicity and others.

Major adverse effects of kasugamycin observed are: decreased body weight gain, ulcer and others in the rectum and anus, effects on the lingua (disappearance of the papillary epithelial cells in dogs), brown pigmentation in proximal tubular epithelial cells and others in the kidney, and tubular atrophy and others in the testes. No neurotoxicity, carcinogenicity, teratogenicity or genotoxicity was observed.

In a two-generation reproductive toxicity study in rats, the incidence of testicular abnormalities such as tubular atrophy increased in F1 parental animals, and decrease in conception rate and others were observed.

Based on the results from various studies, FSCJ specified the residue definition for this dietary risk assessment in agricultural products to be kasugamycin (parent compound only).

The lowest no-observed-adverse-effect level (NOAEL) in the toxicological studies was 9.43 mg/kg body weight/day in a two-generation reproductive toxicity study in rats. Applying the safety factor of 100 to the lowest NOAEL, FSCJ specified the acceptable daily intake (ADI) to be 0.094 mg/kg body weight/day.