



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

Risk Assessment Report

Propyzamide

(Pesticides)

Food Safety Commission of Japan (FSCJ)

January 2014

ABSTRACT

FSCJ conducted a risk assessment of propyzamide (CAS No. 23950-58-5), an amide herbicide, based on the summary reports made by applicants, data related to the request for setting the import-tolerance and other documents of US, EU and Australia.

The data used in the assessment are on: fate in animals (rats), fate in plants (alfalfa, lettuce and others), residues in crops, subacute toxicity (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 propyzamide observed are: decreased body weight gain, increased liver weights, centrilobular hypertrophy of hepatocytes and others in the liver, increased thyroid weights, enlargement of follicular epithelial cells and others in the thyroid.

No effects on reproductive ability, teratogenicity or genotoxicity were observed.

Administration of propyzamide resulted in increased incidences of follicular adenomas of the thyroid and interstitial cell tumors of the testis in rats. Tendency to increase incidence of hepatocellular adenomas and carcinomas was also observed in rats. Increased incidences of hepatocellular adenomas and carcinomas by the treatment of propyzamide were observed in mice. However, the carcinogenicity was unlikely attributable to the genotoxicity, thus FSCJ concluded that the threshold could be specified for propyzamide.

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

Among the NOAELs obtained in various studies, the lowest value was 1.95 mg/kg bw per day obtained in a two-year carcinogenicity study in mice. Dividing the NOAEL by the safety factor of 100, FSCJ specified the acceptable daily intake (ADI) to be 0.019 mg/kg body weight per day.