

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

Risk Assessment Report

Pyrazosulfuron-ethyl

(Pesticides)

Food Safety Commission of Japan (FSCJ)

May 2014

ABSTRACT

FSCJ conducted a risk assessment of a pyrimidinylsulfonylurea herbicide, pyrazosulfuron-ethyl (CAS No. 93697-74-6), based on summary reports made by applicants.

The data used in the assessment are on: fate in animals (rats, mice and goat), fate in plants (paddy rice, Japanese millet and others), residues in crops, subacute toxicity (rats, mice and 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 pyrazosulfuron-ethyl observed are: centrilobular hypertrophy of hepatocytes, vacuolar degeneration and others in the liver, effects on blood such as anemia and decreased serum Chol. None of neurotoxicity, carcinogenicity, effects on reproductive ability, teratogenicity and genotoxicity were observed.

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

The minimum value of the no observed adverse effect level (NOAEL) obtained in all tests referred was 1 mg/kg bw/day obtained in a one-year chronic toxicity study in dogs. FSCJ specified an acceptable daily intake (ADI) of 0.01 mg/kg bw/day by applying a safety factor of 100 to the NOAEL.