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

Risk Assessment Report

Cycloprothrin

(Pesticides)

Food Safety Commission of Japan (FSCJ)

February 2015

ABSTRACT

FSCJ conducted a risk assessment of cycloprothrin (CAS No. 63935-38-6), a pyrethroid insecticide, based on results from various studies.

The data used in the assessment include fate in animals (rats), fate in plants (paddy rice and oranges), residues in crops, subacute toxicity (rats), subacute neurotoxicity (rats), chronic toxicity (dogs), combind chronic toxicity/carcinogenicity (rats and mice), two-generation reproductive toxicity (rats), developmental toxicity (rats and rabbits), and genotoxicity.

Major adverse effects of cycloprothrin observed are decreased body weight gain, increased organ weights and hepatocellular hypertrophy in the liver. Cycloprothrin showed no reproductive toxicity, teratogenicity and genotoxicity.
Increases in the incidence of hepatocellular adenomas and carcinomas in male mice, and an incease in the combind incidence of hepatocellular adenomas and carcinomas in both male and female mice were observed in carcinogenicity tests. However, a genotoxic mechanism was unlikely to be involved in the tumor development. It was thus considered possible to establish a threshold in the assessment.

Based on the above results, only cycloprothrin (parent compound) was identified as the residue definition for dietary risk assessment in agricultural and fishery products.

The lowest no-observed-adverse-effect level (NOAEL) obtained in all tests was 8.57 mg/kg bw/day in a two-year combind chronic toxicity/carcinogenicity study in mice. FSCJ specified an acceptable daily intake (ADI) of 0.085 mg/kg bw/day by applying a safety factor of 100 to the NOAEL.

The lowest NOAEL for potential adverse effects of a single oral administration of cycloprothrin was 1,000 mg/kg bw obtained in a general pharmacological study in mice. FSCJ considered it unnecessary to specify an acute reference dose (ARfD), since the NOAEL was above the cut off level (500 mg/kg bw).