



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

Risk Assessment Report

Teflubenzuron

(Pesticides and Veterinary medicinal products)

Food Safety Commission of Japan (FSCJ)

January 2014

ABSTRACT

FSCJ conducted a risk assessment of teflubenzuron (CAS No. 83121-18-0), a benzoylphenylurea insecticide, based on the summary reports made by applicants and other data of JMPR and EU.

The data used in the assessment are on: fate in animals (rats and others), fate in plants (soybean, spinach and others), residues in crops, subacute toxicity (rats, mice, dogs), 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 teflubenzuron observed are: hepatocellular hypertrophy, hepatocellular necrosis, amphophilic altered cell foci and others in the liver. No effects on reproductive ability, teratogenicity or genotoxicity were observed.

In a carcinogenicity study in rats, an increased incidence of hepatocellular adenoma was observed in males. However, studies on the mechanism suggested that the carcinogenicity was unlikely to be attributable to genotoxic mechanism. Therefore FSCJ considered it possible to establish a threshold dose in the assessment.

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

The minimum value of NOAEL or lowest observed adverse effect level (LOAEL) in the toxicological studies was LOAEL of 2.1 mg/kg body weight per day in a 78 weeks carcinogenicity study in mice. Dividing the LOAEL by the safety factor of 200 (10 for species difference, 10 for individual difference and 2 for the adopted LOAEL value), FSCJ specified the acceptable daily intake (ADI) to be 0.01 mg/kg body weight per day.