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

Risk Assessment Report

Fipronil

(Pesticides and Veterinary medicinal products)

Food Safety Commission of Japan (FSCJ)
January 2014

ABSTRACT

FSCJ conducted a risk assessment of "fipronil" (CAS No.120068-37-3), a phenylpirazole insecticide, based on results from various studies.

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

Major adverse effects of fipronil observed are: effect on the central nervous system such as convulsions, increased organ weights and others in the liver, and increased organ weights and others in the thyroid of rats.

No teratogenicity and genotoxicity relevant to human health were observed.

Two-year combined chronic toxicity/carcinogenicity studies of fipronil in rats exhibited a significant increase in the incidence of thyroid follicular cell tumors in the dose of 300 ppm (12.7 mg/kg bw per day for male, 16.8 mg/kg bw per day for female). This increase was likely a consequence of the following chain of events: fipronil activated the biliary clearance of T4. As a result, the T4 level decreased while the TSH level increased leading to stimulation of thyroid follicular cells. Therefore, mechanisms for the carcinogenicity are unlikely attributable to the genotoxicity, and FSCJ concluded that the threshold could be specified for fipronil.

A reproduction study in rats demonstrated a decrease in the survival rate of postimplantation embryo and other effects.

Based on the results from various studies, FSCJ specified the residue definition to be fipronil (parent compound only) for this dietary risk assessment in agricultural products, and fipronil (parent compound) and its metabolite/catabolite F for the risk assessment in livestock products.

The minimum value of NOAEL obtained in all tests referred to was NOAEL of 0.019 mg/kg body weight per day in a two-year combined chronic toxicity/carcinogenicity study in rats. Dividing the NOAEL by the safety factor of 100, FSCJ specified the acceptable daily intake (ADI) to be 0.00019 mg/kg body weight per day.