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

Risk Assessment Report

Triafamone

(Pesticides)

Food Safety Commission of Japan (FSCJ)
May 2015

ABSTRACT

FSCJ conducted a risk assessment of a sulphonanilide herbicide for paddy field, triafamone (CAS No. 874195-61-6), based on results from various studies.

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

Major adverse effects of triafamone observed are decreased body weight gain, increased organ weights and hepatocellular hypertrophy in the liver, hypertrophy of follicular cells and colloid changes in the rat thyroid. Triafamone showed no teratogenicity and genotoxicity relevant to human health.

Although increased incidences of hepatocellular tumors were observed in rats in a two-year combined chronic toxicity/carcinogenicity study, genotoxic mechanisms were unlikely involved in the tumor induction. It was thus considered possible to establish a threshold dose in the assessment. In a two-generation reproduction test of triafamone in rats, prolonged gestational period was observed.

From these results, FSCJ identified triafamone (parent compound only) as the residue definition for this dietary risk assessment in agricultural products.

The lowest no-observed-adverse-effectlevel (NOAEL) obtained was 1.96 mg/kg bw/day in a combined two-year chronic toxicity/carcinogenicity study in rats. Applying a safety factor of 100 to the NOAEL, FSCJ specified an acceptable daily intake (ADI) of 0.019 mg/kg bw/day.
There was no appropriate end-point in potential adverse effects from a single oral administration of tralomethron. Hence, FSCJ considered it unnecessary to specify an acuter reference dose (ARfD).