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

Risk Assessment Report

Fluthiacet-methyl

(Pesticides)

Food Safety Commission of Japan (FSCJ)

December 2014

ABSTRACT

FSCJ conducted a risk assessment of fluthiacet-methyl (CAS No. 117337-19-6), an isourazole herbicide, based on results from various studies.

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

Major adverse effects of fluthiacet-methyl observed are decreased body weight gain, effects on blood such as anemia, and degeneration/necrosis of the liver. Fluthiacet-methyl showed no neurotoxicity, reproductive toxicity, teratogenicity and genotoxicity relevant to human health.

Increases in the incidence of hepatocellular adenomas in male mice, exocrine pancreas cell adenomas and islet cell adenomas in male rats were observed in carcinogenicity tests. However, a genotoxic mechanism was unlikely to be involved in the tumor induction. It was thus considered possible to establish a threshold in the assessment.

Based on the results from various studies, only fluthiacet-methyl (parent compound) was identified as the residue definition for dietary risk assessment in agricultural products.

The lowest no-observed-adverse-effect level (NOAEL) in all tests was 0.1 mg/kg bw/day in an 18-month carcinogenicity study in mice. By applying a safety factor of 100 to the NOAEL, FSCJ specified an acceptable daily intake (ADI) to be 0.001 mg/kg bw/day.
Since no potential adverse effect of a single oral administration of fluthiacet-methyl was observed, FSCJ considered it unnecessary to specify an acute reference dose (ARfD).