

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

Risk Assessment Report

Thifensulfuron-methyl

(Pesticides)

Food Safety Commission of Japan (FSCJ)
December 2015

ABSTRACT

FSCJ conducted a risk assessment of thifensulfuron-metyl (CAS No.79277-27-3), a sulfonylurea herbicide, based on results from various studies.

The data used in the assessment include fate in animals (rats), fate in plants (wheat and soy beans), residues in crops, subacute toxicity (rats, mice and dogs), chronic toxicity (dogs), combined chronic/carcinogenicity (rats), carcinogenicity (mice), 2-generation reproductive toxicity (rats), developmental toxicity (rats and rabbits) and genotoxicity.

Major adverse effects of thifensulfuron-metyl were reduced gain of body weight. Thifensulfuron-metyl had no carcinogenicity, reproductive toxicity, teratogenicity, or genotoxicity.

Based on all results evaluated, thifensulfuron-metyl (parent compound only) was identified as the relevant substance for the residue definition for dietary risk assessment in agricultural products.

The lowest no-observed-adverse-effect level (NOAEL) was 0.96 mg/kg bw/day in a 2-year combined chronic/carcinogenicity study in rats. FSCJ specified an acceptable daily intake (ADI) of 0.0096 mg/kg bw/day by applying a safety factor of 100 to the NOAEL.

The lowest NOAELs for potential adverse effects of a single oral administration of thifensulfuron-metyl were 200 mg/kg bw/day in developmental toxicity studies in rats and rabbits. FSCJ specified an acute reference dose (ARfD) of 2 mg/kg bw by applying a safety factor of 100 to the NOAELs.