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

Risk Assessment Report

Isoxathion

(Pesticides)

Food Safety Commission of Japan (FSCJ)
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ABSTRACT

FSCJ conducted a risk assessment of an organophospholus insecticide, isoxathion (CAS No. 18854-01-8), based on results from various studies.

The data used in the assessment include fate in animals (rats), fate in plants (kidney beans and apples), residues in crops, subacute toxicity (rats and mice), acute/subacute neurotoxicity (rats), chronic toxicity (dogs), combind chronic toxicity/carcinogenicity (rats), carcinogenicity (mice), three-generation reproductive toxicity (rats), developmental toxicity (rats and rabbits), and genotoxicity, and on the studies on inhibitory effects on ChE in rats or humans.
Major adverse effect of isoxathion observed was inhibition of brain- and RBC-ChE activity. Isoxathion showed no carcinogenicity, adverse effects on reproductivity, teratogenicity, delayed neurotoxicity and genotoxicity relevant to human health

Based on the results of fate of animals and plants and redisues in crops, isoxanthion (parent compound only) was identified as the relevant substance for the residue definition for dietary risk assessment in agricultural products and fishery products.

The lowest value of no-observed-adverse-effect level (NOAEL) was 0.2 mg/kg bw per day based on RBC ChE inhibition (>20%) in a 2-year chronic toxicity study in dogs at 0.6 mg/kg bw per day, and body weight depression at 1.0 mg/kg bw/day in a developmental toxicity study in rabbits. FSCJ specified an acceptable daily intake (ADI) of 0.002 mg/kg bw per day by applying a safety factor of 100 to the NOAEL.
The lowest NOAEL for potential adverse effects of single oral administration of isoxathion was 0.03 mg/kg bw the highest dose tested based on no inihibitory effect on RBC ChE activity in human. FSCJ specified an acute reference dose (ARfD) of 0.003 mg/kg bw by applying a safety factor of 10 (1 for species difference and 10 for individual difference because of human study) to the NOAEL.