

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

Risk Assessment Report

Tricyclazole (Pesticides)

Food Safety Commission of Japan (FSCJ)
January 2014

ABSTRACT

The FSCJ conducted a risk assessment of tricyclazole (CAS No. 41814-78-2), a fungicide, based on summary reports made by applicants.

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

Major adverse effects of tricyclazole observed were: decreased body weight gain and increased organ weights and others in the liver.

Tricyclazole had no concern for carcinogenicity, did not affect reproductive capacity, and had no developmental toxicity or genotoxicity relevant to human health.

Based on the various study results, only tricyclazole (parent compound) was included in a residue definition for dietary risk assessment in agricultural and fishery products. Moreover, only tricyclazole (parent compound) and metabolite D was considered for residue definition for dietary risk assessment in livestock products.

The minimum value of the no-observed-adverse-effect level (NOAEL) was 5 mg/kg bw per day in a developmental study in rats. FSCJ specified an acceptable daily intake (ADI) of 0.05 mg/kg bw per day by applying a safety factor of 100 to the NOAEL.