

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

Risk Assessment Report

Fluoxastrobin

(Pesticides)

Food Safety Commission of Japan (FSCJ)

March 2015

ABSTRACT

FSCJ conducted a risk assessment of fluoxastrobin (CAS No. 361377-29-9), a strobilurin fungicide, based on results of various studies.

The data used in the assessment include fate in animals (rats), fate in plants (spring wheat and peanuts), residues in crops, subacute toxicity (rats, mice 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 fluoxastrobin observed are decreased body weight gain, hepatocellular hypertrophy, increased organ weights in the liver, uropathy such as pyelolithiasis and urethral calculus.

No neurotoxicity, carcinogenicity, developmental toxicity, teratogenicity or genotoxicity was observed.

Based on the above results, only fluoxastrobin (including Z body) 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 1.5 mg/kg bw/day in a one-year combined chronic toxicity/carcinogenicity study in dogs. Applying a safety factor of 100 to the NOAEL, FSCJ specified an acceptable daily intake (ADI) of 0.015 mg/kg bw/day.

It is unlikely that fluoxastrobin exerts toxic effects of a single oral administration.

Therefore, FSCJ concluded that it is not necessary to specify the acute reference dose (ARfD).