

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

## Risk Assessment Report

### Nitenpyram (Pesticides)

Food Safety Commission of Japan (FSCJ)  
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#### ABSTRACT

FSCJ conducted a risk assessment of nitenpyram (CAS No. 150824-47-8), an insecticide, based on results from various studies.

The data used in the assessment include fate in animals (rats), fate in plants (eggplants and paddy rice), 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 effect of nitenpyram observed was the reduction of body weight gain.

Nitenpyram had no carcinogenicity, teratogenicity and genotoxicity.

Decreases in number of implantations and of offspring were observed in a reproduction study in rats.

Nitenpyram (parent compound) was identified as the relevant substance for a residue definition for dietary risk assessment in agricultural products

The lowest no-observed-adverse-effect level (NOAEL) obtained from all toxicity studies was 53.7 mg/kg bw/day in a two-year combined chronic toxicity/carcinogenicity study in rats. FSCJ specified an acceptable daily intake (ADI) of 0.53 mg/kg bw/day by applying a safety factor of 100 to the NOAEL.

The lowest NOAEL for potential adverse effects of single oral administration of nitenpyram was overall NOAEL of 60 mg/kg bw obtained from NOAELs in a 28-day subacute toxicity study and a one-year chronic toxicity study in dogs. FSCJ specified an acute reference dose (ARfD) of 0.6 mg/kg bw by applying a safety factor of 100 to the NOAELs.