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

Risk Assessment Report

Pyriproxyfen (4th Edition)

(Pesticides)

Food Safety Commission of Japan (FSCJ)
2019

ABSTRACT

FSCJ established health based guidance values of pyriproxyfen (CAS No.95737-68-1), an insecticide having 4-phenoxyphenyl structure based on results from various studies in the risk assessment. Data including acute neurotoxicity study (rats), 90-day subacute neurotoxicity study (rats), four-week immunotoxicity study (mice), and residues in crops (Japanese wild parsley, citrus and coffee beans) were newly submitted for application of new use and import tolerance.

The data used in the assessment include fate in animals (rats), fate in plants (cucumbers, oranges and others), residue in crops, acute toxicity (mice and rats), subacute toxicity (rats, mice and dogs), subacute neurotoxicity (rats), chronic toxicity (dogs), combined chronic toxicity/carcinogenicity (rats), carcinogenicity (mice), two-generation reproductive toxicity (rats), developmental toxicity (rats and rabbits) , genotoxcity, immunotoxicity (mice) and screening assays for endocrine disruptors, which have already been submitted.

Major adverse effects of pyriproxyfen were effects on hematopoietic system such as anemia, hepatocellular hypertrophy, liver fibrosis in dogs and chronic progressive nephropathy in mice.
No neurotoxicity, carcinogenicity, reproductive toxicity, teratogenicity, genotoxicity or immunotoxicity was observed.

On the basis of various studies, pyriproxyfen (parent compound only) was identified as a relevant substance for residue definition for dietary risk assessment in agricultural products.

The lowest no-observed-adverse-effect level (NOAEL) obtained in all tests was 10 mg/kg bw/day in a one-year chronic toxicity study in dogs. FSCJ specified an acceptable daily intake (ADI) of 0.1 mg/kg bw/day, which was the same as previous one, by applying a safety factor of 100 to the NOAEL.

The lowest value of NOAEL for adverse effects of eliciting a single oral administration of pyriproxyfen was NOAEL of 300 mg/kg bw/day obtained in the developmental toxicity study in rats and the administration study in rats during the perinatal and lactation period. FSCJ specified an acute reference dose (ARfD) to be 3 mg/kg bw/day by applying a safety factor of 100 to the NOAEL.