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

Risk Assessment Report

Quinomethionate

(Pesticides)

Food Safety Commission of Japan (FSCJ)
November 2015

ABSTRACT

FSCJ conducted a risk assessment of quinomethionate (CAS No. 2439-01-2), a quinoxaline acaricide and fungicide, based on results from various studies.

The data used in the assessment include fate in animals (rats), fate in plants (apples, eggplants and mandarin oranges), residues in crops, subacute toxicity (rats and dogs), chronic toxicity (rats and dogs), combind chronic toxicity/carcinogenicity (mice), carcinogenicity (rats), one and multi-generation reproductive toxicity (rats), developmental toxicity (rats and rabbits), and genotoxicity.

Major adverse effects of quinomethionate identified were anemia including extramedullary hematopoiesis in the spleen, hepatogoxicity including hepatocellular degeneration and kupffer cell aggregation, and decreased spermatogenesis and reduced sperm counts in the epididymides in rats. Quinomethionate had no neurotoxicity, carcinogenicity, teratogenicity or genotoxicity relevant to human health. Male infertility, which was observed at the high dose of quinomethionate in the reproduction study in rats, was considered the damage to sperm maturation in the epididymides resulting in oligospermia.

Based on all results evaluated, quinomethionate (parent compound only) was identified as the relevant substance for the residue definition for dietary risk assessment in agricultural products.

The lowest no-observed-adverse-effect level (NOAEL) obtained in all the studies was 0.644 mg/kg bw/day in a 1-year chronic toxicity study in dogs. FSCJ specified an acceptable daily intake (ADI) of 0.0064 mg/kg bw/day applying a safety factor of 100 to the NOAEL.
The lowest NOAEL for potential adverse effects of single oral administration of quinomethionate was no-observed-effect level (NOEL) of 150 mg/kg bw based on adverse clinical signs in a pharmacological study in mice and rabbits. The FSCJ specified an acute reference dose (ARfD) of 1.5 mg/kg bw by applying a safety factor of 100 to the NOEL.