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

Risk Assessment Report

Fenothiocarb

(Pesticides)

Food Safety Commission of Japan (FSCJ)

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ABSTRACT

FSCJ conducted a risk assessment of fenothiocarb (CAS No. 6285032-2), an acaricide, based on the summary reports made by applicants and others.

The studies include fate in animals (rats), fate in plants (chinese citron and mandarin orange), residues in crops, subacute toxicity (rats and mice), chronic toxicity (dogs), combined chronic toxicity/carcinogenicity (rats and mice), two-generation reproductive toxicity (rats), developmental toxicity (rats and rabbits) and genotoxicity.

Major adverse effects of fenothiocarb observed are intimal thickening of intrahepatic portal vein branches and effects on blood such as anemia and others. No carcinogenicity was observed.

A reproduction study in rats showed decreases in mean number of corpora lutea and mean number of implantations. Fenothiocarb, at the dose with maternal toxicity caused an external malformation such as an encephalocele and others in rat fetuses.

Among genotoxicity studies, DNA repair test, reverse mutation test and host-mediated assay gave negative results. An *in vitro* chromosomal aberration test with metabolic activation and a bone marrow micronucleus test in mice sunbjected to oral administration gave positive results. However, since this micronucleus formation may be attributable to hypothermia, and fenothiocarb did not show any carcinogenicity, these positive responses in genotoxicity studies are considered to be phenomena unrelated to the carcinogenicity. It was thus considered possible to establish an acceptable daily intake (ADI) and acute reference dose (ARfD) in the assessment.

Based on the above results, only fenothiocarb (parent compound) was identified as the residue definition for dietary risk assessment in agricultural products.

The lowest no-observed-adverse-effect level (NOAEL) in the toxicological studies was 1.5 mg/kg bw/day in a one-year chronic toxicity study in dogs. Applying a safety factor of 100 to the NOAEL, FSCJ specified the ADI to be 0.015 mg/kg bw/day.

The lowest NOAEL for potential adverse effects of single oral administration of fenothiocarb was 13 mg/kg bw/day in a two-generation reproductive toxicity study in rats. Applying a safety factor of 100 to the NOAEL, FSCJ specified the ARfD to be 0.13 mg/kg bw/day.