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

Risk Assessment Report

Diethofencarb

(Pesticides)

Food Safety Commission of Japan (FSCJ)
May 2015

ABSTRACT

FSCJ conducted a risk assessment of N-phenylcarbamate fungicide, diethofencarb (CAS No. 87130-20-9), based on results from various studies.

The data used in the assessment include fate in animals (rats), fate in plants (cucumbers and grapes), residues in crops, subacute toxicity (rats 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), immunotoxicity (rats) and genotoxicity.

Major adverse effects of diethofencarb observed are decreased body weight gain, and increased organ weights and centrilobular hepatocellular hypertrophy in the liver. Diethofencarb showed no neurotoxicity, reproductive toxicity, teratogenicity, immunotoxicity and genotoxicity relevant to human health.

Two-year combined chronic toxicity/carcinogenicity studies of diethofencarb in rats exhibited significant increases in the incidence of thyroid follicular carcinomas in males, incidence of thyroid follicular adenomas in females, total incidence of thyroid follicular carcinomas and adenomas in both sexes. However, mechanisms of the carcinogenicity were unlikely attributable to the genotoxicity, and FSCJ concluded that the threshold could be specified for diethofencarb.

From these results, FSCJ identified diethofencarb (parent compound only) as the residue definition for this dietary risk assessment in agricultural products.

The lowest no-observed-adverse-effect level (NOAEL) obtained was 42.7 mg/kg bw/day in a 2-year combined chronic toxicity/carcinogenicity study in rats. Applying a safety factor of 100 to the NOAEL, FSCJ specified an acceptable daily intake (ADI) of 0.42 mg/kg bw/day.

The lowest NOAEL for potential adverse effects of a single oral administration of diethofencarb was 200 mg/kg bw in acute neurotoxicity tests in rats. Applying a safety factor of 100 to the NOAEL, FSCJ specified an accute reference dose (ARfD) of 2 mg/kg bw.