

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

Risk Assessment Report

Benzofenap

(Pesticides)

Food Safety Commission of Japan (FSCJ) August 2015

ABSTRACT

FSCJ conducted a risk assessment of benzofenap (CAS No. 82692-44-2), a pyrazole herbicide, based on results from various studies.

The data used in the assessment include the fate in animals (rats and goats), fate in plant (rice paddy), 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 benzofenap include decreased body weight gain, increased liver weight, and anemia. No carcinogenicity, teratogenicity or genotoxicity were observed.

In a two-generation reproductive toxicity study in rats, fertility rate was decreased.

Based on the data of the fate in animals and plants, benzofenap (only parent compound) was identified as the residue definition for dietary risk assessment in agricultural products.

The lowest no-observed-adverse-effect level (NOAEL) obtained in all studies was 0.203 mg/kg bw/day in a combined chronic toxicity/carcinogenicity study in rats. FSCJ specified an acceptable daily intake (ADI) of 0.002 mg/kg bw/day by applying a safety factor of 100 to the NOAEL.

FSCJ considered it unnecessary to specify an acute reference dose (ARfD), because benzofenap does not exerts potential adverse effects of a single dose administration.