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

Risk Assessment Report

Acibenzolar-S-methyl

(Pesticides)

Food Safety Commission of Japan (FSCJ)
March 2015

ABSTRACT

FSCJ conducted a risk assessment of a fungicide, acibenzolar-S-methyl (CAS No. 135158-54-2), based on results from various studies.

The studies include the fate in animals (rats), fate in plants (spring wheat and tabacco plant), 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), developmental neurotoxicity, immunotoxicity and genotoxicity.

Major adverse effects of acibenzolar-S-methyl observed are decreased body weight gain, effects on blood such as hemolytic anemia, hemosiderosis in Kupffer cells, hemosiderosis and extramedullary hematopoiesis in the spleen. No carcinogenicity, reproductive toxicity or genotoxicity was observed.

In the developmental toxicity study, external-, internal- and skeletal anomaly such as gastric rupture and hernia of the umbilical cord were observed in rats at the dose with maternal toxicity. Also at the dose with maternal toxicity, malformation of the caudal vertebral body was observed in rabbits.
High amplitude of the auditory startle response was observed in rat offsprings in a developmental neurotoxicity test.

Based on the above results, only acibenzolar-S-methyl (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 tests was 7.77 mg/kg bw/day in a two-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 0.077 mg/kg bw/day.

The lowest NOAEL for potential adverse effects of a single oral administration of acibenzolar-S-methyl was 50 mg/kg bw/day in a developmental toxicity study in rats. FSCJ specified an acute reference dose (ARfD) of 0.5 mg/kg bw applying a safety factor of 100 to the NOAEL.