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

Risk Assessment Report

Sulfoxaflor

(Pesticides)

Food Safety Commission of Japan (FSCJ)
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ABSTRACT

FSCJ conducted a risk assessment of sulfoxaflor (CAS No.946578-00-3), an insecticide, based on results from various studies.

The data used in the assessment include fate in animals (rats, goats and others), fate in plants (paddy rice, lettuce and others), residues in crops, subacute toxicity (rats, mice and dogs), chronic toxicity (dogs), combined chronic toxicity/carcinogenicity (rats), carcinogenicity (mice), two-generation reproductive toxicity (rats), developmental toxicity (rats and rabbits), developmental neurotoxicity (rats), immunotoxicity (rats), and genotoxicity.

Major adverse effects of sulfoxaflor observed are hepatocellular hypertrophy and increased liver weights, and increased testis weights. Sulfoxaflor did not show any clear developmental neurotoxicity, immunotoxicity or genotoxicity.

Although increased incidences of hepatocellular adenomas and testicular interstitial cell adenomas in male rats and hepatocellular adenomas and carcinomas in both male and female rats were observed in carcinogenicity tests, a genotoxic mechanism was unlikely to participate in the tumor development. It was thus considered possible to establish a threshold in the assessment.

Neonatal death in a reproduction test of sulfoxaflor in rats, and anomaly of the extremity and others in rat fetuses in a developmental toxicity test were observed at the dose with maternal toxicity. However, such maldevelopments were likely attributed to mechanisms through nicotinic receptors that are specifically expressed during the fetal stage in rats. It was thus concluded that sulfoxaflor unlikely causes these maldevelopments in human.

Based on the above results, only sulfoxaflor (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 4.25 mg/kg bw/day in a combined two-year chronic toxicity/carcinogenicity study in rats. FSCJ specified an acceptable daily intake (ADI) of 0.042 mg/kg bw/day by applying a safety factor of 100 to the NOAEL.