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

Risk Assessment Report

Epoxiconazole

(Pesticides)

Food Safety Commission of Japan (FSCJ)
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ABSTRACT

FSCJ conducted a risk assessment of “epoxiconazole” (CAS No. 133855-98-8), a triazole fungicide based on documents describing the data for establishing Import Tolerance and documents from EU and US.

The data used in the assessment are on: fate in animals (rats, goats and chicken), fate in plants (coffee and wheat), residues in crops, subacute toxicity (rats, mice, and dogs), chronic toxicity (rats and dogs), carcinogenicity (rats and mice), two-generation reproductive toxicity (rats), developmental toxicity (rats and rabbits), and genotoxicity.

Major adverse effects of epoxiconazole observed are: hepatocellular hypertrophy, fatty deposition in adrenal gland cortex of rats, and ovarian cysts in rats. Epoxiconazole had no neurotoxicity or genotoxicity.

Increases in the incidence of adrenal gland cortical tumors and ovarian theca-granulosa cell tumors in female rats as well as hepatocellular adenomas and carcinomas in both male and female rats were identified in carcinogenicity tests. However, the results in the genotoxicity studies of epoxiconazole suggest that genotoxic mechanism was not likely to be involved in the tumorinduction, and therefore FSCJ concluded that it is possible to establish a threshold dose.

In the reproduction study in rats, impaired fertility in parental males in the highest dose group, vaginal haemorrhages in parental females, prolonged gestational period and increased stillbirths were observed.

In the developmental study in rats, increased placental weights in dam animals and increased accessory 14th ribs in fetuses were observed.

Based on the various study results, only epoxiconazole (parent compound) was included in a residue definition for dietary risk assessment in agricultural products.

The minimum value of the no-observed adverse effect level (NOAEL) was 0.69 mg/kg bw/day in a 18 months carcinogenicity study in mice. FSCJ specified an acceptable daily intake (ADI) of 0.0069 mg/kg bw/day by applying a safety factor of 100 to the NOAEL.