

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

## **Risk Assessment Report**

### **Ethoxysulfuron (Pesticides)**

Food Safety Commission of Japan (FSCJ)

October 2013

#### **ABSTRACT**

FSCJ conducted a risk assessment of “ethoxysulfuron” (CAS No. 126801-58-9), a sulfonylurea herbicide, based on summary reports made by applicants and documents from the Australian Government.

The data used in the assessment are on; fate in animals (rats), fate in plants (paddy rice and sugarcane), 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), and genotoxicity.

Major adverse effects of ethoxysulfuron observed were: decreased body weight gain, chronic septal hepatitis etc. in hepato-biliary system of dogs and decreased serum T3 and T4 in thyroid. No effects on the reproductive ability, developmental toxicity or genotoxicity were observed.

Two-year combined chronic toxicity/carcinogenicity studies of ethoxysulfuron in rats exhibited an increased incidence of uterine adenocarcinomas. However, a genotoxic mechanism was unlikely to be involved in the tumor development, and FSCJ concluded that it was possible to establish a threshold dose in the assessment.

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

The minimum value of the no-observed adverse effect level (NOAEL) in all tests was 5.60 mg/kg bw/day in a 90-day subacute toxicity study in dogs. FSCJ specified an acceptable daily intake (ADI) of 0.056 mg/kg bw/day by applying a safety factor of 100 to the NOAEL.