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## Risk Assessment Report

### Flumioxazin

(Pesticides)

Food Safety Commission of Japan (FSCJ)

May 2014

#### ABSTRACT

The Food Safety Commission of Japan (FSCJ) conducted a risk assessment of flumioxazin (CAS No. 103361-09-7), an *N*-phenylphthalimide herbicide, based on summary reports submitted by the applicants and documents from the governments of the US and Australia.

The data used in the assessment include fate in animals (rats, rabbits, goats and chicken), fate in plants (mandarin oranges, soybeans and others), residues in crops, subacute toxicity (rats, mice, 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), genotoxicity and immunotoxicity.

Major adverse effects of flumioxazin observed are on blood (anemia), and liver (hepatocellular hypertrophy and increased organ weight). None of neurotoxicity, immunotoxicity and carcinogenicity, as well as genotoxicity relevant to human health were observed.

In a two-generation reproduction study of flumioxazin in rats, decreased copulation index and birth rate, and decreased viability index on day 4 of the offsprings were observed.

In developmental toxicity tests in rats, cardiovascular malformations including ventricular septal defect, and skeletal malformations such as curvature of the scapula were identified in fetuses.

Based on the results from various studies, FSCJ specified the residue definition for dietary risk assessment in agricultural and livestock products to be flumioxazin (parent compound only).

The lowest no-observed-adverse-effect level (NOAEL) obtained in all studies was 1.8 mg/kg bw/day in a combined two-year chronic toxicity/carcinogenicity study in rats. FSCJ specified an acceptable daily intake (ADI) of 0.018 mg/kg bw/day by applying a safety factor of 100 to the NOAEL.