

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

Risk Assessment Report

Asulam (Pesticides)

Food Safety Commission of Japan (FSCJ)
October 2014

ABSTRACT

FSCJ conducted a risk assessment of asulam (CAS No. 3337-71-1), a carbamate/sulfonamide herbicide, based on the summary reports made by applicants and documents from the Governments of the United States of America and the European Union.

Data used in the assessment include fate in animals (rats and goats), fate in plants (sugarcane and alfalfa), residues in crops, subacute toxicity (rats), chronic toxicity (dogs), combined chronic toxicity/carcinogenicity (rats and mice), two-generation reproductive toxicity (rats), developmental toxicity (rats and rabbits) and genotoxicity.

Major adverse effects of asulam observed are decreased body weight gain and hypertrophy of follicular epithelial cells of the thyroid. Asulam did not show teratogenicity and genotoxicity.

Number of newborn was decreased in a two-generation reproductive toxicity study in rats.

In a combined chronic toxicity/carcinogenicity study, increased incidences of adrenal pheochromocytomas and Leydig cell tumors of the testis were observed in male rats and male mice, respectively. However, a genotoxic mechanism was unlikely to be involved in the tumor development. It was thus considered possible to establish a threshold in the assessment.

Based on the above results, only asulam (parent compound) was identified as the residue definition for dietary risk assessment in agricultural and livestock products.

The lowest no-observed-adverse-effect level (NOAEL) obtained in all tests was 36 mg/kg bw/day in a combined two-year chronic toxicity/carcinogenicity study in rats. FSCJ specified an acceptable daily intake (ADI) of 0.36 mg/kg bw/day by applying a safety factor of 100 to the NOAEL.

The lowest NOAEL for potential adverse effects of a single oral administration of asulam was 300 mg/kg bw/day obtained in 6-month and 1-year chronic toxicity studies in dogs. FSCJ specified an acute reference dose (ARfD) to be 3 mg/kg bw by applying a safety factor of 100 to the NOAEL.