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

Risk Assessment Report

Fluensulfone

(Pesticides)

Food Safety Commission of Japan (FSCJ)
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ABSTRACT

FSCJ conducted a risk assessment of fluensulfone (CAS No.318290-98-1), a nematicide of the fluoroalkenyl thioether group, based on results from various studies.

The data used in the assessment include fate in animals (rats, goats and chickens), fate in plants (tomatoes, potatoes and lettuce), residues in crops, subacute toxicity (rats, mice and dogs), subacute neurotoxicity (rats), chronic toxicity (rats and dogs), carcinogenicity (rats and mice), 2-generation reproductive toxicity (rats), developmental toxicity (rats and rabbits), immunotoxicity and genotoxicity.

Major adverse effects of fluensulfone identified were reduced gain of body weight, anemia, hepatocellular hypertrophy, bronchiolization and increased kidney weight. Fluensulfone has no reproductive toxicity, teratogenicity, immunotoxicity or genotoxicity.

Increased incidence of alveolar/bronchial adenoma was idenfied in female mice in the carcinogenicity study, however genotoxic mechanism was unlikely involved in the tumor development. Therefore, FSCJ concluded that it was possible to establish a threshold dose in the assessment.

Based on all the results evaluated, fluensulfone (parent compound only) was identified as the relevant substance for the residue definition for dietary risk assessment in agricultural and livestock products.

The lowest no-observed-adverse-effect level (NOAEL) was 1.4 mg/kg bw/day in a 2-year combined chronic/carcinogenicity study in rats. FSCJ specified an acceptable daily intake (ADI) of 0.014 mg/kg bw/day by applying a safety factor of 100 to the NOAEL.

The lowest value of NOAEL or the lowest-observed-adverse-effect level (LOAEL) for potential adverse effects of a single oral administration of fluensulfone was the LOAEL of 100 mg/kg bw/day in an acute neurotoxicity study of rats. FSCJ specified an acute reference dose (ARfD) of 0.33 mg/kg bw by applying a safety factor of 300 (10 for species difference, 10 for individual difference, and an additional factor of 3 to account for the use of a LOAEL instead of a NOAEL.).