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

Risk Assessment Report

Clethodim

(Pesticides)

Food Safety Commission of Japan (FSCJ)
March 2016

ABSTRACT

FSCJ conducted a risk assessment of clethodim (CAS No. 99129-21-2), a cyclohexanedione herbicide, based on results from various studies.

The data used in the assessment include fate in animals (rats, goats and chicken), fate in plants (soybean and carrots), residues in crops, subacute toxicity (rats, mice and dogs), subacute neurotoxicity (rats), chronic toxicity (dogs), combind chronic toxicity/carcinogenicity (rats), carcinogenicity (mice), two-generation reproductive toxicity (rats), developmental toxicity (rats and rabbits), immunotoxicity (mice) , genotoxicity and mechanisms of toxicities.

Major adverse effects of clethodim are suppression of body weight gain, anemia, liver hypertrophy and aggregation of alveolar macrophage (mice only). Clehtodim had no carcinigenicity, reproductivity, immunotoxicity and genotoxicity relevant to human health.

Incidences of external malformation was increased by clethodim treatment with the dose with maternal toxicity in a developmental toxicity study in rats, but no teratogenicity was observed in rabbits.
Clethodim and its metabolite B and C were identified as the relevant substances for a residue definition for dietary risk assessment in agricultural products, and clethodim (parent compound only) for livestock products.

The lowest no-observed-adverse-effect level (NOAEL) in various toxicological studies was 1 mg/kg bw /day in one-year chronic toxicity study in dogs. Applying a safety factor of 100 to the lowest NOAEL, FSCJ specified an acceptable daily intake (ADI) of 0.01 mg/kg bw/day.

The lowest NOAEL for potential adverse effects of single oral administration of clethodim was 100 mg/kg bw/day obtained from an acute neurotoxicyt study in rats. FSCJ specified an acute reference dose (ARfD) of 1 mg/kg bw/day applying a safety factor of 100 to the NOAEL.