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

Risk Assessment Report

Chlofentezine

(Pesticides)

Food Safety Commission of Japan (FSCJ)
June 2015

ABSTRACT

FSCJ conducted a risk assessment of chlofentezine (CAS No. 74115-24-5), an acaricide, based on the summary reports made by applicants.

The studies include the fate in animals (rats and mouse), fate in plants (apples and peaches), residues in crops, subacute toxicity (rats, mice and dogs), acute neurotoxicity (rats), chronic toxicity (rats and dogs), combined chronic toxicity/carcinogenicity (rats), carcinogenicity (mice), two-generation reproductive toxicity (rats), reproductive toxicity (rats), developmental toxicity (rats and rabbits) and genotoxicity.

Major adverse effects of chlofentezine observed are decreased body weight gain, increased organ weights and centrilobular hypertrophy of hepatocytes in the liver, and follicular cell hypertrophy. No neurotoxicity, reproductive toxicity, teratogenicity or genotoxicity relevant to human health were observed.

Although an increased incidence of follicular cell tumors in the thyroid was observed in a two-year chronic toxicity/carcinogenicity study in rats, a genotoxic mechanism was unlikely to be involved in the tumor induction.

Based on the above results, chlofentezine (parent compound only) 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 1.70 mg/kg bw/day in a one-year chronic toxicity study in dogs. Applying a safety factor of 100 to the NOAEL, FSCJ specified an acceptable daily intake (ADI) of 0.017 mg/kg bw/day.

It is unlikely that chlofentezine exerts toxic effects after a single oral dose administration. Therefore, FSCJ considered it unnecessary to specify an acute reference dose (ARfD) for this acaricide.