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

Risk Assessment Report

Pirimicarb

(Pesticides)

Food Safety Commission of Japan (FSCJ)

March 2014

ABSTRACT

FSCJ conducted a risk assessment of a carbamate insecticide, pirimicarb (CAS No. 23103-98-2), based on evaluation reports from Joint FAO/WHO Meeting on Pesticides Residue (JMPR) (2004 and 2006), EU (2005) and Australia (1997).

FSCJ considered it possible to conduct the assessment based on the relevant reports since the reports provided the data from examinations which fulfill the requirement for safety assessments.

The data used in the assessment are on: fate in animals (rats, goats and chickens), fate in plants (apples, lettuce and others), residues in crops, subacute toxicity (rats and dogs), subacute neurotoxicity (rats), chronic toxicity (dogs), combined chronic toxicity/carcinogenicity (rats), carcinogenicity (rats), two-generation reproductive toxicity (rats), developmental toxicity (rats and rabbits), genotoxicity and others.

Major adverse effects of pirimicarb observed are: decreased body weight gain, inhibition of ChE activity and effects on blood such as anemia and others in dogs.

No adverse effects on reproductive ability, teratogenicity and genotoxicity relevant to human health were observed.

Although the incidence of lung adenomas increased in a carcinogenicity study in mice, mechanisms for the carcinogenicity are considered unlikely to be genotoxic mechanisms, and FSCJ concluded that the threshold could be specified for pirimicarb. Moreover, JMPR concluded that the incidence of liver tumors was not related to the administration of pirimicarb since increased incidence of liver tumors was observed in a 96 weeks carcinogenicity test, but not in an 80 week carcinogenicity test in mice. FSCJ supported this conclusion of JMPR.

Based on the results of various studies, pirimcarb (parent compound only) was considered as a residue definition for dietary risk assessment in agricultural products and livestock products.

The lowest no-observed-adverse-effect level (NOAEL) in all tests was 1.8 mg/kg body weight/day obtained in a two-year chronic toxicity study and in a 90-day subacute toxicity study in dogs. Applying a safety factor of 100 to the NOAEL, FSCJ specified an acceptable daily intake (ADI) of 0.018 mg/kg body weight/day.