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

Risk Assessment Report

Pyflubumide

(Pesticides)

Food Safety Commission of Japan (FSCJ)
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ABSTRACT

FSCJ conducted a risk assessment of “pyflubumide” (CAS No. 926914), a miticide, based on results from various studies.

The data used in the assessment are on: fate in animals (rats), fate in plants (eggplants and apples), residues in crops, subacute toxicity (rats, mice, and dogs), carcinogenicity (rats and mice), two-generation reproductive toxicity (rats), developmental toxicity (rats and rabbits), and genotoxicity.

Major adverse effects of pyflubumide observed are: effects on blood such as anemia, hypertrophy of follicular epithelial cells and others in the thyroid, hepatocellular hypertrophy, alveolar ectasia (rat off-spring) and myocardial fibrosis. No effects on the reproductive ability or genotoxicity were observed.

Significant increases in the incidence of hepatocellular adenomas in male rats were identified in carcinogenicity tests. However, genotoxicity tests gave negative results indicating that genotoxic mechanism was not likely to be involved in the tumorinduction, and therefore FSCJ concluded that it is possible to establish a threshold dose.

In a reproduction test in rats, prolonged gestational period in parental generation and increased stillborns were observed.

Based on the various study results, only pyflubumide (parent compound) was included in a residue definition for dietary risk assessment in agricultural products.

The minimum value of the no-observed adverse effect level (NOAEL) was 0.735 mg/kg bw/day in a two year carcinogenicity study in rats. FSCJ specified an acceptable daily intake (ADI) of 0.0073 mg/kg bw/day by applying a safety factor of 100 to the NOAEL.