

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

Risk Assessment Report

Fluazuron (Veterinary Medicinal Products)

Food Safety Commission of Japan (FSCJ)
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ABSTRACT

FSCJ conducted a risk assessment of fluazuron (CAS No. 86811-58-7), an acaricides, based on documents from the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

The data used in the assessment included pharmacokinetics/metabolism (rats and cattle), residues (cattle), acute toxicity (rats), subacute toxicity (rats and dogs), chronic toxicity and carcinogenicity (mice, rats and dogs), reproductive and developmental toxicity (rats and rabbits), genotoxicity and other toxicities.

Fluazuron had no genotoxicity relevant to human health, because all data in *in vitro* genotoxicity studies are negative, and because diflubenzuron, a substance of a structure analogous with fluazuron, has no genotoxicity. Fluazuron had no carcinogenicity in a carcinogenicity study in mice and in chronic toxicity and carcinogenicity combined study in rats. Therefore, FSCJ concluded that fluazuron is not a genotoxic carcinogen and an acceptable daily intake (ADI) can be specified.

The lowest no-observed-adverse-effect level (NOAEL) in various toxicological studies was 40 ppm (relevant to 4.3 mg/kg bw/day) based on an increased incidence of uterine inflammatory polyp in a 2-year carcinogenicity study in mice. No NOAEL was established in 13-week subacute toxicity study in mice, and the lowest-observed-adverse-effect level (LOAEL) was 100 ppm (relevant to 6.4 mg/kg bw/day) based on increased absolute and relative liver weights and glycogen deposition in the liver. These changes were considered toxicologically less significant because of no reproducibility in a 2-year carcinogenicity study in rats, and the NOAEL in this study was predicted to be close to the LOAEL.

From these results, FSCJ specified the ADI of 0.043 mg/kg bw/day, based on the NOAEL in the carcinogenicity study in mice (4.3 mg/kg bw/day) and applying a safety factor of 100 (10 for species difference and 10 for individual difference) to the NOAEL.