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

Risk Assessment Report

Flumethrin
(Veterinary Medicinal Products)

Food Safety Commission of Japan (FSCJ)
September 2015

ABSTRACT

FSCJ conducted a risk assessment of flumethrin (CAS No. 69770-45-2), a parasiticide, based on documents including the assessment reports of the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) and European Medical Agency (EMEA) and documents from the Australian government.

The data used in the assessment include pharmacokinetics (rats, cattle, sheep, and chickens), residues (cattle, sheep and chickens), genotoxicity, acute toxicity (mice, rats and dogs), subacute toxicity (rats and dogs), chronic toxicity/carcinogenicity (rats), carcinogenicity (mice), as well as reproductive and developmental toxicity (rats and rabbits).

Flumethrin has no genototoxicity relevant to human health based on results from various genotoxicity studies, and no carcinogenicity was observed in the combined chronic toxicity/carcinogenicity study in rats and carcinogenicity study in mice. FSCJ concluded that flumethrin is not a genotoxic carcinogen, and considered it possible to establish an acceptable daily intake (ADI) in the assessment.

The lowest no-observed-adverse-effect level (NOAEL) in various toxicological studies was 5 ppm (relevant to 0.36 mg/kg bw/day for males, and 0.40 mg/kg bw/day for females) based on skin lesions and reduced gain of body weight in parental animals as well as a lower survival rate and reduced gain of body weight in offspring at 50 ppm, the lowest-observed-adverse-effect level (LOAEL), in a two-generation reproductive toxicity study in rats. The common ratio was 10 in this study. While NOAEL was 3 ppm (male mice at 0.39 mg/kg bw/day and female mice at 0.52 mg/kg bw/day) based on skin lesions in a 79-week carcinogenicity study in mice. The LOAEL in this study was 15 ppm, and the common ratio was 5. The NOAEL of 3 ppm (0.39 mg/kg bw/day) in the 79-week carcinogenicity study in mice was judged to be appropriate as the basis of ADI, because of the larger common ratio applied in the reproductive study and the long-term duration in carcinogenicity study in mice.

FSCJ specified the ADI of 0.0039 mg/kg bw/day for fulmethrin by applying a safety factor of 100 (10 for species difference, 10 for individual difference) to the NOAEL of 0.39 mg/kg bw/day in the 79-week carcinogenicity study in mice.