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

Risk Assessment Report

Tetraniliprole

(Pesticides)

Food Safety Commission of Japan (FSCJ)
September 2018

ABSTRACT

FSCJ established health based guidance vaues of tetraniliprole, an anthranilamide insecticide based on results from various studies in the risk assessment.

The data used in the assessment include fate in animals (rats, goats and chickens), fate in plants (paddy rice, potatoes and others), residue in crops, subacute toxicity (rats, mice and dogs), chronic toxicity (dogs), combined chronic toxicity/carcinogenicity (rats), carcinogenicity (mice), two-generation reproductive toxicity (rats), developmental toxicity (rats and rabbits) and genotoxcity.

Major adverse effects of tetraniliprole were suppressed body weight, squamous epithelial hyperplasia in the uterus and vagina in rats, and decreased number of corpora lutea in aged rats. No carcinogenicity, reproductive toxicity, teratogenicity and genotoxicity was observed.

On the basis of various studies, tetraniliprole (parent compound only) was identified as a relevant substance for residue definition for dietary risk assessment in agricultural, livestock and fishery products.

The lowest no-observed-adverse-effect level (NOAEL) obtained in all studies was 88.4 mg/kg bw/day in a one-year chronic toxicity study in dogs. FSCJ specified an acceptable daily intake (ADI) of 0.88 mg/kg bw/day by applying a safety factor of 100 to the NOAEL.

FSCJ judged it unnecessary to specify an acute reference dose (ARfD), since no adverse effects would be likely to be elicited by a single oral administration of tetraniliprole.

Table 1. *Levels relevant to toxicological evaluation of tetraniliprole*

Species	Study	Dose (mg/kg bw/day)	NOAEL (mg/kg bw/day)	LOAEL (mg/kg bw/day)	Critical endpoints[a)]
Rat	90-day subacute toxicity study	0, 900, 3 000, 10 000 ppm M : 0, 55.0, 178, 608 F : 0, 65.7, 213, 723	M : 608 F : 723	M : — F : —	FM : No toxicological effects
	Two-year combined chronic toxicity/carcinogenicity study	0, 900, 4 000, 18 000 ppm M : 0, 35.3, 159, 741 F : 0, 51.2, 221, 1 050	M : 159 F : 221	M : 741 F : 1 050	FM : Suppressed body weight and others (Not carcinogenic)
	Two-generation reproductive toxicity study	0, 300, 600, 2 700, 12 000 ppm PM : 0, 22, 44, 196, 896 PF : 0, 25, 51, 224, 1 030 F_1M : 0, 28, 57, 253, 1 140 F_1F : 0, 30, 63, 266, 1 220 F_2M : 0, 34, 69, 307, 1 360 F_2F : 0, 34, 68, 312, 1 390	Parent and offspring PM : 196 PF : 224 F_1M : 253 F_1F : 266 F_2M : 307 F_2F : 312	Parent and offspring PM : 896 PF : 1 030 F_1M : 1 140 F_1F : 1 220 F_2M : 1 360 F_2F : 1 390	Parent and offspring : Suppressed body weight and others (No effect on reproduction)
	Developmental toxicity study	0, 62.5, 250, 1 000	Maternal : 1 000 Embryo/fetus : 250	Maternal : — Embryo/fetus : 1 000	Maternal : No toxicological effects Embryo/fetus: Low body weight (Not teratogenic)
Mouse	90-day subacute toxicity study	0, 900, 2 700, 6 000 ppm M : 0, 145, 426, 973 F : 0, 180, 544, 1 220	M : 973 F : 1 220	M : — F : —	FM : No toxicological effects
	18-month carcinogenicity study	0, 260, 1 300, 6 500 ppm M : 0, 32.9, 166, 825 F : 0, 43.1, 215, 1 070	M : 825 F : 1 070	M : — F : —	FM : No toxicological effects (Not carcinogenic)
Rabbit	Developmental toxicity study	0, 62.5, 250, 1 000	Maternal : 1 000 Embryo/fetus: 1 000	Maternal : — Embryo/fetus : —	Maternal and embryo/fetus: No toxicological effects (Not teratogenic)

Species	Study	Dose (mg/kg bw/day)	NOAEL (mg/kg bw/day)	LOAEL (mg/kg bw/day)	Critical endpoints[a)]
Dog	90-day subacute toxicity study	0, 800, 3 200, 12 800 ppm M : 0, 25.6, 126, 440 F : 0, 29.9, 138, 485	M : 126 F : 138	M : 440 F : 485	FM : Suppressed body weight, increase in ALP and others
	One-year chronic toxicity study	0, 650, 2 900, 12 800 ppm M : 0, 19.8, 91.2, 440 F : 0, 18.3, 88.4, 408	M : 91.2 F : 88.4	M : 440 F : 408	FM : Suppressed body weight and others
ADI			NOAEL : 88.4 SF : 100 ADI : 0.88		
The critical study for setting the ADI			One-year chronic toxicity study in dogs		

ADI, Acceptable daily intake; NOAEL, No-observed-adverse-effect level; SF, Safety factor;
－, Lowest-observed-effect level (LOAEL) was not derived; [a)], Adverse effect observed at LOAEL