FOOD SAFETY

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Propiconazole

Summary

Food Safety Commission of Japan

The Food Safety Commission of Japan (FSCJ) conducted a risk assessment of propiconazole (CAS No. 60207–90-1), one of triazole-type fungicides, based on results from various studies. Major adverse effects of propiconazole observed are on hepatocellular hypertrophy, vacuolation and necrosis in the liver of rats and mice, and on congested duodenal mucosa and others in the gastrointestinal tract of dogs. Neither reproductive toxicity nor genotoxicity was observed. Although increases in the incidence of hepatocellular adenomas and carcinomas in male rats were observed in carcinogenicity tests, a genotoxic mechanism is unlikely to participate in the tumor development. It was thus considered possible to establish a threshold dose. Developmental toxicity tests in rats and rabbits showed cleft palate in the fetuses at the dose with maternal toxicity. Based on the results from various studies, FSCJ specified the residue definition for this dietary risk assessment in agricultural and livestock products to be propiconazole (parent compound only). The lowest no-observed-adverse-effect level (NOAEL) obtained in all studies referred was 1.9 mg/kg bw/day obtained in a one-year chronic toxicity study in dogs. FSCJ specified an acceptable daily intake (ADI) of 0.019 mg/kg bw/day by applying a safety factor of 100 to the NOAEL.

Conclusion in Brief

The Food Safety Commission of Japan (FSCJ) conducted a risk assessment of propiconazole (CAS No. 60207–90-1), one of triazole-type fungicides, based on results from various studies.

The data used in the assessment include fate in animals (rats, goats and chicken), fate in plants (wheat, peanut and others), residues 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 genotoxicity.

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Based on the results from various studies, FSCJ specified the residue definition for dietary risk assessment in agricultural and livestock products to be propiconazole (parent compound only).

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