FOOD SAFETY

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Tolprocarb

Summary

Food Safety Commission of Japan

The Food Safety Commission of Japan (FSCJ) conducted a risk assessment of tolprocarb (CAS No. 911499-62-2), a fungicide, based on results from various studies. Major adverse effects of tolprocarb observed are decreased body weight gain, hepatocellular hypertrophy and increased liver weights, and increased organ weights and colloid degeneration of the thyroid. Tolprocarb showed no carcinogenicity, reproductive toxicity, teratogenicity and genotoxicity. Based on the results from various studies, only tolprocarb (parent compound) was identified as the residue definition for dietary risk assessment in agricultural and marine products. The lowest no-observed-adverse-effect level (NOAEL) obtained in all tests was 20.5 mg/kg bw/day in a two-year carcinogenicity study in rats. FSCJ specified an acceptable daily intake (ADI) of 0.2 mg/kg bw/day, applying a safety factor of 100 to the NOAEL. The lowest NOAEL for potential adverse effects of a single oral administration of tolprocarb was 600 mg/kg bw obtained in a general pharmacological study in rats. FSCJ considered it unnecessary to specify an acute reference dose (ARfD), since the NOAEL was above the cut off level (500 mg/kg bw).

Conclusion in Brief

The Food Safety Commission of Japan (FSCJ) conducted a risk assessment of tolprocarb (CAS No. 911499-62-2), a fungicide, based on results from various studies.

The studies include the fate in animals (rats), fate in plants (paddy rice), residues in crops, subacute neurotoxicity (rats and dogs), chronic toxicity (rats and dogs), carcinogenicity (rats and mice), two-generation reproductive toxicity (rats), developmental toxicity (rats and rabbits), and genotoxicity.

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Tolprocarb showed no carcinogenicity, reproductive toxicity, teratogenicity and genotoxicity.

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The lowest NOAEL for adverse effects of a single oral administration of tolprocarb was 600 mg/kg bw observed in a general pharmacological study in rats. FSCJ considered it unnecessary to specify an acute reference dose (ARfD), since the NOAEL was above the cut off level (500 mg/kg bw).

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