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FOOD SAFETY

Quinoclamine

Summary

Food Safety Commission of Japan

The Food Safety Commission of Japan (FSCJ) conducted a risk assessment of quinoclamine (CAS No. 2797–51-5), a herbicide having the structural feature of naphthoquinone, based on summary reports submitted by the applicant. Major adverse effects of quinoclamine observed are decreased body weight gain and epithelial hyperplasia of the urinary tract. Quinoclamine did not show any clear reproductive toxicity, developmental toxicity, and genotoxicity relevant to human health. Although increased incidences of transitional cell papillomas were observed in the urinary bladder of both sexes at 676 ppm in a chronic toxicity study and a carcinogenicity study in rats, a genotoxic mechanism was not likely to participate in the tumor development. It was thus considered possible to establish a threshold in the assessment. Based on the above results, only quinoclamine (parent compound) was identified as a residue definition for dietary risk assessment in agricultural products and fishery products. The lowest no-observed-adverse-effect level (NOAEL) obtained in all the tests was 0.21 mg/kg bw/day in a two-year carcinogenicity study in rats. FSCJ specified an acceptable daily intake (ADI) of 0.0021 mg/kg bw/day by applying a safety factor of 100 to the NOAEL.

Conclusion in Brief

FSCJ conducted a risk assessment of quinoclamine (CAS No. 2797–51-5), a herbicide having the structural feature of naphthoquinone, based on summary reports submitted by the applicant.

The data used in the assessment include fate in animals (rats), fate in plants (rice and lotus root), residues in crops, subacute toxicity (rats, dogs, etc.), chronic toxicity (rats and dogs), carcinogenicity (rats and mice), two-generation reproductive toxicity (rats), developmental toxicity (rats and rabbits) and genotoxicity.

Major adverse effects of quinoclamine observed are decreased body weight gain and epithelial hyperplasia of the urinary tract. Quinoclamine did not show any clear reproductive toxicity, developmental toxicity, and genotoxicity relevant to human health.

Although increased incidences of transitional cell papillomas were observed in the urinary bladder of both sexes at 676 ppm in a chronic toxicity study and a carcinogenicity study in rats, a genotoxic mechanism was not likely to participate in the tumor development. It was thus considered possible to establish a threshold in the assessment.

Based on the above results, only quinoclamine (parent compound) was identified as a residue definition for dietary risk assessment in agricultural products and fishery products.

The lowest no-observed-adverse-effect level (NOAEL) obtained in all the tests was 0.21 mg/kg bw/day in a two-year carcinogenicity study in rats. FSCJ specified an acceptable daily intake (ADI) of 0.0021 mg/kg bw/day by applying a safety factor of 100 to the NOAEL.

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