FOOD SAFETY

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Fenoxasulfone

Summary

Food Safety Commission of Japan

The Food Safety Commission of Japan (FSCJ) conducted a risk assessment of an isoxazoline herbicide fenoxasulfone (CAS No. 639826-16-7). Major adverse effects observed are: degeneration in the peripheral nerves of dogs, renal papillary necrosis, chronic progressive nephrosis and others in the kidney, and increased organ weights, centrilobular hypertrophy of hepatocytes and others in the liver. No carcinogenicity, effects on reproductive ability, developmental toxicity or genotoxicity was observed. Nerve fiber degeneration and other effects in the peripheral nerves were observed in a 90-day subacute toxicity study and a one-year chronic toxicity study in dogs, indicating neurotoxicity of fenoxasulfone. Based on the results from various studies, FSCJ specified the residue definition for this dietary risk assessment in agricultural products and seafood to be fenoxasulfone (parent compound only). The lowest no-observed-adverse-effect level (NOAEL) in toxicological studies was 17.6 mg/kg body weight/day in an 18-month carcinogenicity study in mice. Applying the safety factor of 100 to this NOAEL, FSCJ specified the acceptable daily intake (ADI) to be 0.17 mg/kg body weight/day.

Conclusion in Brief

The Food Safety Commission of Japan (FSCJ) conducted a risk assessment of an isoxazoline herbicide fenoxasulfone (CAS No. 639826–16-7) based on results from various studies. The data used in the assessment are on: fate in animals (rats and mice), fate in plants (paddy rice), residues in crops etc., subacute toxicity (rats, mice, and dogs), subacute neurotoxicity (rats), chronic toxicity (dogs), combined chronic toxicity/carcinogenicity (rats), carcinogenicity (mice), two-generation reproductive toxicity (rats), developmental toxicity (rats and rabbits), and genotoxicity. Major adverse effects of fenoxasulfone observed are: degeneration in the peripheral nerves of dogs, renal papillary necrosis, chronic progressive nephrosis and others in the kidney, and increased organ weights, centrilobular hypertrophy of hepatocytes and others in the liver. No carcinogenicity, effects on reproductive ability, developmental toxicity or genotoxicity was observed.

Nerve fiber degeneration and other effects in the peripheral nerves were observed in a 90-day subacute toxicity study and a one-year chronic toxicity study in dogs, indicating neurotoxicity of fenoxasulfone. Based on the results from various studies, FSCJ specified the residue definition for this dietary risk assessment in agricultural products and seafood to be fenoxasulfone (parent compound only). The lowest no-observed-adverse-effect level (NOAEL) in toxicological studies was 17.6 mg/kg body weight/day in an 18-month carcinogenicity study in mice. Applying the safety factor of 100 to the lowest NOAEL, FSCJ specified the acceptable daily intake (ADI) to be 0.17 mg/kg body weight/day.

This is an English translation of excerpts from the original full report (October 2013 − FS/871/2013).
The original full report is available in Japanese at http://www.fsc.go.jp/fsciis/evaluationDocument/show/kya20120718569
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