

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

Risk Assessment Report

Deltamethrin and Tralomethrin (Pesticides)

Food Safety Commission of Japan (FSCJ)
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OVERALL ASSESSMENT

Deltamethrin, a pyrethroid herbicide, is a metabolite of tralomethrin. Since toxicity studies and others on these two compounds have been conducted independently, the risk of these two compounds cannot be evaluated together as one compound. Therefore, FSCJ conducted a risk assessment on each of the compounds independently first, then conducted an overall assessment taking into account the fact that tralomethrin is easily metabolized into deltamethrin in animals and plants. The individual assessments of deltamethrin and tralomethrin are reported in the abstract-1 and abstract-2, respectively.

(1) Abstract-1. Assessment of deltamethrin

FSCJ conducted a risk assessment of deltamethrin (CAS No.52918-63-5), a pyrethroid herbicide, based on results from various studies.

The data used in the assessment include fate in animals (rats, mice, cattle, horses, chickens and salmon), fate in plants (cotton and apples), residues in crops, subacute toxicity (rats, mice and dogs), subacute neurotoxicity (rats), chronic toxicity (dogs), combined chronic toxicity/carcinogenicity (rats), carcinogenicity (mice), three-generation reproductive toxicity (rats), two-generation reproductive toxicity (rats), developmental toxicity (rats, mice and rabbits), developmental neurotoxicity (rats) and genotoxicity.

Major adverse effects of deltamethrin observed are decreased body weight gain and effects on the nervous system such as convulsion. Deltamethrin showed no carcinogenicity, reproductive toxicity, teratogenicity, developmental neurotoxicity and genotoxicity relevant to human health.

Based on the above results, deltamethrin (total amount of the isomers) was identified as the residue definition for dietary risk assessment in agricultural products and livestock products.

The lowest no-observed-adverse-effect level (NOAEL) obtained in all tests was 1 mg/kg bw/day in a 2-year combined chronic toxicity/carcinogenicity study in rats, and in one- and two-year chronic toxicity studies in dogs. FSCJ specified an acceptable daily intake (ADI) of 0.01 mg/kg bw/day by applying a safety factor of 100 to the NOAEL.

The lowest NOAEL for potential adverse effects of a single oral administration of deltamethrin was 1 mg/kg bw/day in a subacute toxicity study in dogs. FSCJ specified an acute reference dose (ARfD) as 0.01 mg/kg/bw applying a safety factor of 100 to the NOAEL.

(2) Abstract-2. Assessment of tralomethrin

FSCJ conducted a risk assessment of tralomethrin (CAS No.66841-25-6), a pyrethroid herbicide, based on results from various studies.

The data used in the assessment include fate in animals (rats), fate in plants (cotton and tomatoes), residues in crops, subacute toxicity (rats and dogs), subacute neurotoxicity (rats), chronic toxicity (dogs), combined chronic toxicity/carcinogenicity (rats and mice), two-generation reproductive toxicity (rats), developmental toxicity (rats and rabbits) and genotoxicity.

Major adverse effects of tralomethrin observed are decreased body weight gain, dermatitis and effects on the nervous system such as convulsion. Tralomethrin showed no carcinogenicity, reproductive toxicity, teratogenicity and genotoxicity.

Based on the above results, tralomethrin and its metabolite C were identified as the residue definition for dietary risk assessment in agricultural products.

The lowest NOAEL obtained in all tests was 0.75 mg/kg bw/day in a two-year combined chronic toxicity/carcinogenicity study in rats and a two-year combined chronic toxicity/carcinogenicity study in mice. FSCJ specified an ADI of 0.0075 mg/kg bw/day by applying a safety factor of 100 to the NOAEL. While, there was no appropriate end point in potential adverse effects due to a single oral administration of tralomethrin. Hence, FSCJ considered it difficult to specify ARfD.

(3) Overall Assessment

As for the overall assessment of both compounds, FSCJ considered it appropriate to specify the ADI based on the assessment of tralomethrin that the toxicity was higher than that of deltamethrin. Accordingly, FSCJ specified a group ADI for both deltamethrin and tralomethrin to be 0.0075 mg/kg bw/day which was specified for tralomethrin. Regarding an ARfD, no appropriate end point was found in potential adverse effects due to a single oral administration of tralomethrin. Even if an additional safety factor of 10 is applied to the LOAEL in acute toxicity study in mice, i.e. 27.4 mg/kg bw, taking into account the severity of clonic convulsion, the ARfD value will never become lower than that of deltamethrin. Therefore, FSCJ considered it appropriate to apply the ARfD obtained from the result of a subacute toxicity study of deltamethrin in dogs and specified a group ARfD for both compounds to be 0.01 mg/kg bw.

In addition, deltamethrin (total amount of the isomers) and tralomethrin were identified as the residue definition for exposure risk assessment in agricultural products and livestock products.