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

Risk Assessment Report

Diflufenican

(Pesticides)

Food Safety Commission of Japan (FSCJ)

May 2014

ABSTRACT

FSCJ conducted a risk assessment of a phenoxynicotine anilide herbicide, diflufenican (CAS No. 83164-33-4), based on summary reports made by applicants and other documents from EU and the Australian Government.

The data used in the assessment are on: fate in animals (rats, cattle and chicken), fate in plants (wheat, cabbage and others), residues in crops, subacute toxicity (rats, mice, and dogs), chronic toxicity (dogs), combined chronic toxicity/carcinogenicity (rats and mice), two-generation reproductive toxicity (rats), developmental toxicity (rats and rabbits), genotoxicity and others.

Major adverse effects of diflufenican observed are: decreased body weight gain, increased organ weights in the liver and decreased feed consumption.
No carcinogenicity, effects on reproductive ability, teratogenicity and genotoxicity relevant to human health were observed.

Based on these results, FSCJ specified the residue definition for this dietary risk assessment in agricultural products to be diflufenican (parent compound only).

The minimum value of the no observed adverse effect level (NOAEL) obtained in all tests referred were 18.5 mg/kg bw/day obtained in a 90-day subacute toxicity test that was performed thirdly in rats. However, the NOAEL in a test for longer period, 2-year combined chronic toxicity/carcinogenicity study in rats, was 23.3 mg/kg bw/day. The discrepancy in the NOAELs was due to the difference in dose settings, and considering the toxicological data obtained, FSCJ concluded that the value, 23.3 mg/kg bw/day, was appropriate as the NOAEL in rats.
Applying a safety factor of 100 to this NOAEL, FSCJ specified an acceptable daily intake (ADI) to be 0.23 mg/kg bw/day.