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

Risk Assessment Report

Diflubenzuron

(Pesticides and Veterinary medicinal products)

Food Safety Commission of Japan (FSCJ)
July 2015

ABSTRACT

FSCJ conducted a risk assessment of diflubenzuron (CAS No. 35367-38-5), a benzoylphenyl urea type insecticide, using various documents.

The data used in the assessment include fate in animals (rats and lactating cows), fate in plants (soybeans and rice plants), residues in crops, subacute toxicity (rats, mice and dogs), subacute neurotoxicity (rats), chronic toxicity (dogs), combined chronic toxicity/carcinogenicity (rats and mice), carcinogenicity (rats), three-, two-, and one-generation repeoductive toxicity (rats), developmental toxicity (rats and rabbits), genotoxicity and others.

Hemolytic anemia was observed as the major adverse effect of diflubenzuron, and related changes were observed in red blood cells such as an increased MetHb.
Diflubenzuron showed no carcinogenicity, reproductive toxicity, teratogenicity and genotoxicity relevant to human health.

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

The minimum value of the no-observed-adverse-effect level (NOAEL) obtained was 2 mg/kg bw/day in a one-year chronic toxicity study in dogs. Applying a safety factor of 100 to the NOAEL, FSCJ specified an acceptable daily intake (ADI) of 0.02 mg/kg bw/day.

As a side note, para-chloroaniline which is a metabolite G/impurity has genotoxicity and is carcinogenic in rodents. The risk management agencies, therefore, should continue to collect further information and take appropriate measures to reduce contamination with the impurity.

In addition, FSCJ judged that methemoglobinemia induced by the treatment of diflubenzuron is hardly evoked by a single aministration of it from various studies in rats and dogs. Because of no potential adverse effects due to a single oral administration of diflubenzuron, FSCJ considered it unnecessary to specify an acuter reference dose (ARfD).