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

Risk Assessment Report

Phenmedipham

(Pesticides)

Food Safety Commission of Japan (FSCJ)
March 2015

ABSTRACT

FSCJ conducted a risk assessment of phenmedipham (CAS No. 13684-63-4), a carbamate herbicide, based on the summary reports made by applicants and documents (from Government of the US, EU, Canada and Australia).

The studies include the fate in animals (rats, cattle and chicken), fate in plants (sugar beets, and strawberries), residues in crops, subacute toxicity (rats, mice and dogs), chronic toxicity (rats and dogs), combined chronic toxicity/carcinogenicity (rats), carcinogenicity (rats and mice), two-generation reproductive toxicity (rats), carcinogenicity (rats and mice), two-generation and three-generation reproductive toxicity (rats), developmental toxicity (rats and rabbits) and genotoxicity.

Major adverse effects of phenmedipham observed are decreased body weight gain, effects on blood such as hemolytic anemia and methemoglobinemia, pigmentation in the liver, pigmentation and epithelial hyperplasia in the kidney, pigmentation and extramedullar hematopoiesis in the spleen.
No carcinogenicity, developmental neurotoxicity, immunotoxicity or genotoxicity relevant to human health was observed.

Based on the above results, only phenmedipham (parent compound) was identified as the residue definition for dietary risk assessment in agricultural products

The lowest no-observed-adverse-effect level (NOAEL) obtained in all tests was 4.60 mg/kg bw/day in a two-year combined chronic toxicity/carcinogenicity study in rats. Applying a safety factor of 100 to the NOAEL, FSCJ specified an acceptable daily intake (ADI) of 0.046 mg/kg bw/day.

Although hemolytic anemia was observed in a repeated dose toxicity study, it is unlikely that phenmedipham exerts toxic effects such as anemia after a single oral dose administration. Therefore, FSCJ considered it unnecessary to specify an acute reference dose (ARfD) for this herbicide.