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

# Risk Assessment Report

# Chlorpropham

(Pesticides)

Food Safety Commission of Japan (FSCJ)
June 2015

## ABSTRACT

FSCJ conducted a risk assessment of chlorpropham (CAS No. 101-21-3), a herbicide and a plant growth regulator, based on summary reports made by applicants.

The data used in the assessment include fate in animals (rats, goats and chicken), fate in plants (spring wheat and onions among others), residues in crops, subacute toxicity (rats and dogs), acute 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 chlorpropham observed are effects on blood such as hemolytic anemia and methemogulobinemia, and diffuse hyperplasia of follicular epithelial cells of the thyloid (dogs). Chlorpropham showed no neurotoxicity, reproductive toxicity, teratogenicity and genotoxicity relevant to human health.

Although a two-year combined chronic toxicity/carcinogenicity study in rats showed an increased incidence of testicular interstitial cell tumors, a genotoxic mechanism was unlikely to be involved in the tumor induction, and it was considered possible to establish a threshold dose in the assessment.

From these results, FSCJ identified chlorpropham (parent compound only) as the residue definition for this dietary risk assessment in agricultural products and livestock products.

The lowest no-observed-adverse-effect level (NOAEL) obtained was 5 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 0.05 mg/kg bw/day.

The lowest NOAEL for potential adverse effects of a single oral administration of chlorpropham was 50 mg/kg bw/day in a single oral dose toxicity study in dogs. Applying a safety factor of 100 to the NOAEL, FSCJ specified an accute reference dose (ARfD) of 0.5 mg/kg bw.