

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

## Risk Assessment Report

### Phosalone

(Pesticides)

Food Safety Commission of Japan (FSCJ)

March 2014

### ABSTRACT

FSCJ conducted a risk assessment of an organophosphorus pesticide, phosalone (CAS No. 2310-17-0), based on summary reports made by applicants, data of JMPR and documents from the US government.

The data used in the assessment are on: fate in animals (rats and dairy cows), fate in plants (sorghums and apples), residues in crops, subacute toxicity (rats and dogs), subacute neurotoxicity (rats), subacute delayed neurotoxicity (chickens), chronic toxicity (dogs), combined chronic toxicity/carcinogenicity (rats), carcinogenicity (mice), two-generation reproductive toxicity (rats), developmental toxicity (rats and rabbits), and genotoxicity and others.

Major adverse effect of phosalone observed is ChE inhibition. No effects on reproductive ability, carcinogenicity, teratogenicity or genotoxicity relevant to human health were observed.

Based on the results of various studies, phosalone (parent compound only) was included in a residue definition for dietary risk assessment in agricultural products.

The minimum value of the no-observed-adverse-effect level (NOAEL) obtained in all tests was 0.2 mg/kg bw/day obtained in a 2-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 0.002 mg/kg bw/day.