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

Risk Assessment Report

Prohexadione-calcium

(Pesticides)

Food Safety Commission of Japan (FSCJ)

March 2015

ABSTRACT

FSCJ conducted a risk assessment of prohexadione-calcium (CAS No. 127277-53-6), a cyclohexanedione plant growth regulator based on report made by applicants and documents from Govermnet of the EU and the US.

The data used in the assessment include fate in animals (rats, goats and chicken), fate in plants (paddy rice and cabbage), residues in crops, subacute toxicity (rats and dogs), subacute 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 prohexadione-calcium observed are forestomach squamous epithelial hyperplasia and ectopic tissue of glandular stomach submucosa (rats and mice), and cortical tubular dilatation and others in the kidney (dogs).

No neurotoxicity, carcinogenicity, effects on developmental toxicity, teratogenicity or genotoxicity relevant to human health was observed.

Based on the above results, only prohexadione-calcium was identified as the residue definition for dietary risk assessment in agricultural products

The lowest no-observed-adverse-effect level (NOAEL) for potential toxic effects of a single oral administration of prohexadione-calcium was 910 mg/kg bw/day in acute toxicity studies in female rats and was more than the cutoff value (500 mg/kg bw/day).
Therefore, FSCJ concluded that it is not necessary to specify the acute reference dose (ARfD).