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

Risk Assessment Report

Aminoethoxyvinylglycine

(Pesticides)

Food Safety Commission of Japan (FSCJ)
January 2014

ABSTRACT

FSCJ conducted a risk assessment of “aminoethoxyvinylglycine” (CAS No. 79540-50-4), a plant growth regulator, based on documents of US and Australia with data on chronic toxicity and carcinogenicity.

Although the US and Australia used only one animal species for chronic toxicity and carcinogenicity studies, which do not meet the requirements for pesticide registration in Japan, FSCJ concluded that it is possible to conduct the safety assessment based on the documents, since data on subacute toxicity (rats, mice and dogs) were available.

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

Major adverse effects of aminoethoxyvinylglycine hydrochloride observed are: periportal hepatocellular vacuolation and others in the liver and atrophy and others in the testis. This chemical had no genotoxicity.

Significant increases in testicular interstitial cell adenomas in male rats and adrenal phechromocytomas in female rats were observed in a carcinogenicity study. However, genotoxic mechanism was not likely to be involved in the tumor induction and therefore FSCJ concluded that it is possible to establish a threshold dose.

Decreased sperm motility in parental males was observed in a two-year reproduction test in rats. Developmental malformation (lobular agenesis of right lung) was observed in a developmental toxicity test in rabbits. No teratogenicity was observed in rats.

Based on the various study results, only aminoethoxyvinylglycine (parent compound) was included in a residue definition for dietary risk assessment in agricultural and fishery products.

The minimum value of the no-observed adverse effect levels (NOAEL) was 0.2 mg/kg bw per day in a developmental toxicity study in rabbits.

Based on this NOAEL and combined chronic/carcinogenicity study, using one animal species each, FSCJ specified an acceptable daily intake (ADI) of 0.0002 mg/kg bw/day by dividing the NOAEL by the safety factor of 1,000 (10 for species difference, 10 for individual difference, and 10 for uncertainty factor due to insufficient number of animal species in chronic toxicity and carcinogenicity studies).