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

Risk Assessment Report

Cyanazine
(Pesticides)

Food Safety Commission of Japan (FSCJ)
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ABSTRACT

FSCJ conducted a risk assessment of cyanazine (CAS No.21725-46-2), a triazine herbicide, based on results from various studies.

The data used in the assessment include fate in animals (rats), fate in plants (spring wheat, green onions and others), residues in crops, subacute toxicity (rats, mice and dogs), subacute neurotoxicity (rats), chronic toxicity (rats and dogs), combined chronic toxicity/carcinogenicity (rats), carcinogenicity (mice), three-generation reproductive toxicity (rats), developmental toxicity (rats and rabbits), genotoxicity, and also on their mechanisms.

Major adverse effect of cyanazine was observed as depression of body weight. Cyanazine is considered to have no neurotoxicity, reproductive toxicity and genotoxicity relevant to human health.

Increased incidences of mammary gland tumor were observed in female rats in a combined two-year chronic toxicity/carcinogenicity study, however, a genotoxic mechanism was unlikely to be involved in the tumor induction. It was thus considered reasonable to set a threshold dose in the assessment.

Increased incidences of external, visceral or skeletal malformations were identified in rats at a dose level in which maternal toxicity was observed. No teratogenicity was observed in rabbits.

Based on various studies, cyanazine (parent compound only) was identified as the relevant substance for the residue definition for dietary risk assessment in agricultural products.

The lowest no-observed-adverse-effect level (NOAEL) obtained in all studies was 0.053 mg/kg bw/day in a two-year combined chronic toxicity/carcinogenicity study in rats. FSCJ specified an acceptable (ADI) of 0.00053 mg/kg bw/day, applying a safety factor of 100 to the NOAEL.

A NOAEL for adverse effects possibly caused by a single oral administration of cyanazine was not obtained in one of developmental toxicity studies (Study No.4) in rats. , However, the lower NOAEL of 4.5 mg/kg bw was derived in other developmental toxicity study (Sutyd No.1) in rats conducted at

lower doses. Consequently, FSCJ specified an acute reference dose (ARfD) of 0.045 mg/kg bw, applying a safety factor of 100 to the NOAEL.