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

Risk Assessment Report

Quizalofop-ethyl and quizalofop-p-tefuryl

(Pesticides)

Food Safety Commission of Japan (FSCJ)

April 2014

Comprehensive assessment

Quizalofop-ethyl and quizalohop-p-tefuryl have different chemical structures in their ester moiety and their toxicity has been studied independently, indicating that the food safety risk from respective substances can not be evaluated in one assessment procedure because these two substances are distinct from each other. FSCJ therefore conducted risk assessment of each substance first, then evaluated the food safety risk from both substances comprehensively considering that metabolic pathway of the two substances in animals and plants are similar. Risk assessment individualy performed on each substance was reported as part 1 and part 2.

(1) Abstract of risk assessment of quizalofop-ethyl

FSCJ conducted a risk assessment of a phenoxypropionic acid herbicide, quizalofop-ethyl (CAS No. 76578-14-8), based on summary reports made by applicants and other documents from the Governments of US, Australia and others. Data on residues in crops (Japanese white radish) and others were newly presented in this assessement.
The data used in the assessment are on: fate in animals (rats, mice and dogs), fate in plants (soybeans, sugar beet and others), residues in crops, subacute toxicity (rats, mice and dogs), chronic toxicity (dogs), combined chronic toxicity/carcinogenicity (rats), carcinogenicity (mice), two-generation reproductive toxicity (rats), developmental toxicity (rats and rabbits), genotoxicity and others.

Major adverse effects of quizalofop-ethyl observed are: hepatocellular hypertrophy in the liver and atrophy in the testis. No carcinogenicity, effects on reproductive ability, teratogenicity or genotoxicity were observed.

Based on the results from various studies, FSCJ specified the residue definition for this dietary risk assessment in agricultural and fishery products to be quizalofop-ethyl and its metabolite B.

The lowest no-observed-adverse-effect level (NOAEL) obtained in all tests was 0.9 mg/kg body weight/day in a two-year combined chronic toxicity/carcinogenicity study in rats. FSCJ specified an acceptable daily intake (ADI) of 0.009 mg/kg body weight/day by applying a safety factor of 100 to the NOAEL.

(2) Abstract of risk assessment of quizalofop-p-tefuryl

FSCJ conducted a risk assessment of a phenoxypropionic acid herbicide, quizalofop-p-tefuryl (CAS No. 119738-06-6) based on evaluation reports from the Australian Government (2010) and EU (2008).
The data used in the assessment are on: fate in animals (rats, goats and chickens), fate in plants (soybeans, potatoes and others), residues in crops, subacute toxicity (rats, mice and dogs), chronic toxicity (dogs), combined chronic toxicity/carcinogenicity (rats), carcinogenicity (mice), two-generation reproductive toxicity (rats), developmental toxicity (rats and rabbits), genotoxicity and others.

Major adverse effects of quizalofop-p-tefuryl observed are: hepatocellular hypertrophy and others in the liver, decreased weights and others in the testis and effects on blood such as anemia. No neurotoxicity and genotoxicity was observed.
Increases in the incidence of squamous cell carcinomas of the kidney, Leydig cell tumors and hepatocellular adenomas/carcinomas were identified in a carcinogenicity test in rats. However, a genotoxic mechanism was unlikely to be involved in the tumor development, and it was considered possible to establish a threshold dose in the assessment.
In a two-generation reproduction test of quizalofop-p-tefuryl in rats, decreased conception rate, decreased number of living infants and others were identified.
Developmental toxicity tests in rats showed that quizalofop-p-tefuryl at the dose with mataernal toxicity caused cleft palate and anomaly of the tail in fetuses. No teratogenicity was observed in rabbits.

Based on the results from various studies, FSCJ specified the residue definition for this dietary risk assessment in agricultural products to be quizalofop-p-tefuryl and its metabolite B.

The lowest no-observed-adverse-effect level (NOAEL) obtained in all tests was 1.3 mg/kg body weight/day in a two-year combined chronic toxicity/carcinogenicity study in rats. FSCJ specified an ADI of 0.013 mg/kg body weight/day by applying a safety factor of 100 to the NOAEL.

(3) Comprehensive assessment

On the basis of the comprehensive assessment of risk to human health from quizalofop-ethyl and quizalofop-p-tefuryl, FSCJ specified a group acceptable daily intake (ADI) for both substances to be 0.009 mg/kg body weight/day which is the lower value of ADI for quizalofop-ethyl and quizalofop-p-tefuryl.

FSCJ specified the residue definition for this dietary risk assessment in agricultural products to be quizalofop-ethyl, quizalofop-p-tefuryl and the metabolite B, and in fishery products to be quizalofop-ethyl and its metabolite B.