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

Risk Assessment Report

Metamifop
(Pesticides)

Food Safety Commission of Japan (FSCJ)
October 2016

ABSTRACT

FSCJ conducted a risk assessment of metamifop (CAS No. 256412-89-2), an aryloxyphenoxy propionate herbicide, based on results from various studies.

The data used in the assessment include the fate in animals (rats), fate in plants (paddy rice), 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 results of mechanism studies related to liver tumor in mice.

Major interspecies adverse effects of metamifop were body weight depression, anemia, hepatocellular hypertrophy, or follicular epithelial cell hypertrophy in the thyroid. The renal toxicity such as urothelial hyperplasia and mineralization of the renal pelvis were observed in rats. None of teratogenicity and genotoxicity were observed.

The incidence of benign ovarian granulosa cell tumor and hepatocellular adenomas and carcinomas were increased in rats in the combined chronic/carcinogenicity study and in both sexes of male and female mice in the carcinogenicity study, respectively. However, genotoxic mechanisms were unlikely involved in their increases. Therefore it was considered possible to establish a threshold in the assessment.

Decreases in number of primordial follicle, and mean numbers of implantation and birth were observed in a two-generation reproductive toxicity study in rats.

Based on the above results, only parent metamifop was identified as the relevant substance to the residue definition in agricultural products.

The lowest no-observed-adverse-effect level (NOAEL) obtained in all the toxicity studies was 0.42 mg/kg bw/day in the two-year combined chronic toxicity/carcinogenicity study in rats. Applying a safety factor of 100 to the NOAEL, FSCJ has established an acceptable daily intake (ADI) of 0.0042 mg/kg bw/day.

The lowest NOAEL for adverse effects that would be likely to be elicited by a single oral administration of metamifop was 120 mg/kg bw/day based on the developmental toxicity study ① in rats. FSCJ specified an acute reference dose (ARfD) of 1.2 mg/kg bw/day, applying a safety factor of 100 to the NOAEL.