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

# Risk Assessment Report

## Benzovindiflupyr

(Pesticides)

Food Safety Commission of Japan (FSCJ)
September 2015

## ABSTRACT

FSCJ conducted a risk assessment of benzovindiflupyr (CAS No. 1072957-71-1), a pyrazole carboxamide fungicide, based on results from various studies.

The data used in the assessment include fate in animals (rats), fate in plants (spring wheat and tomatoes), residues in crops, subacute toxicity (rats, mice 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), immunotoxicity (mice) and genotoxicity.

Major adverse effects of benzovindiflupyr were reduced gain of body weight, centrilobular hypertrophy of hepatocytes in rats, and mucosal hyperplasia in the large intestine in mice. Benzovindiflupyr showed no adverse effect on reproductivity, teratogenicity, immunotoxicity and genotoxicity relevant to human health.

Increased incidence of follicular adenomas in the thyroid gland in male rats was observed in combined chronic toxicity/carcinogenicity study. However, a genotoxic mechanism was unlikely to be involved in the tumor development. It was thus considered possible to establish a threshold for specifying an acceptable daily intake (ADI) or an acute reference dose (ARfD).

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

The lowest no-observed-adverse-effect level (NOAEL) was 1.21 mg/kg bw/day in a two-year combined chronic toxicity/carcinogenicity study in rats. FSCJ specified the ADI of 0.012 mg/kg bw/day, applying a safety factor of 100 to the NOAEL.

The lowest NOAEL for potential adverse effect of a single oral administration of benzovindiflupyr was 10 mg/kg bw obtained in an acute neurotoxicity study in rats. FSCJ specified the ARfD of 0.1 mg/kg bw, applying a safety factor of 100 to the NOAEL.