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

Risk Assessment Report

Psicose Epimerase

(Food Additives and genetically modified foods)

Food Safety Commission of Japan (FSCJ)
March 2019

ABSTRACT

FSCJ conducted a risk assessment of an enzyme used as an additive, Psicose epimerase, which was produced by genetically modified *Escherichia coli* K-12 W3110 (pWKLP) strain, based on Guidelines for the Risk Assessment of Additives (Enzymes) in Foods (Food Safety Commission Decision of July 18, 2017) (hereinafter referred to as Guidelines for Enzymes) and "Standards for Safety Assessments of Food Additives produced Using Genetically Modified Microorganisms" (Food Safety Commission Decision of March 25, 2004) (hereinafter referred to as Standards for Assessment) using results from various studies.

The data used in the assessment include the pathogenicity and toxigenicity of *E. coli* K-12 *and Arthrobacter globiformis* strain, and the genotoxicity, repeated dose toxicity and allergenicity of psicose epimerase (hereinafter referred to as item) produced by genetically modified *Escherichia coli* K-12 W3110 (pWKLP) strain.

FSCJ assessed the risk of the item produced using recombinant DNA technologies, based on the Standards for Assessment, and concluded that the item does not impair human health.

FSCJ also assessed the risk of the item in relation to designation as an additive and establishment of specifications and standards, based on the Guidelines for Enzymes, and considered as follows:
The production strain, which is properly controlled for the production of the assessed item, has no safety concern relevant to consumption of the item used as a food additive;
FSCJ examined the safety of the item, following "Points relevant to degradability in the gastro-intestinal tract" described in the Guidelines for Enzymes, and decided to evaluate toxicity of the item based on data on its genotoxicity, repeated dose toxicity, and findings on the allergenicity according to the Guidelines for Enzymes;
FSCJ concluded from the examination that the assessed item has no concern for genotoxicity and repeated dose toxicity relevant to human health, and its concern for allergenicity is very low;
There is a sufficient safety margin between the NOAEL: 2.0% (equivalent to 1.02g TOS/kg bw/day for male, 1.12g TOS/kg bw/day for female) obtained at the highest dose in 13-week repeated oral dose toxicity studies in rats and the estimated daily intake (0.332 mg TOS/kg bw/day for total population, and 0.918 mg TOS/kg bw/day for children).

On the basis of the above assessment results, FSCJ concluded that the assessed item has no concern for food safety as long as used appropriately as a food additive, and therefore it is not necessary to specify ADI.