

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

Risk Assessment Report

ガセリ菌SP株ヨーグルト

*Gaseri-kin SP kabu youguruto*¹

(Yogurt containing *Lactobacillus gasseri* SBT2055)

(Food for specified health uses)

Food Safety Commission of Japan (FSCJ)

June 2017

ABSTRACT

FSCJ conducted a risk assessment of a food for specified health uses (FOSHU), *Gaseri-kin SP kabu youguruto* based on the documents submitted by the applicant. *Gaseri-kin SP kabu youguruto* is a fermented dairy product containing *gasseri* SP strain (*Lactobacillus gasseri* SBT2055) as the ingredient relevant to its specified health use, “to improve diet for those who are concerned about visceral fat or tend to be over weight”.

In a 100 gram of this product, corresponding to the recommended daily intake, a billion (10^9 cfu) of *gasseri* SP strain is contained.

The data used in the assessment include experiences of consumption; reverse mutation tests using microorganisms; a single oral gavage test in rats; 4-week repeated oral gavage tests and 13-week repeated oral gavage tests/4-week reversibility tests in rats; human trials of 12-week continuous consumption with groups of people with BMI of 25.0 to <30 and visceral fat area ≥ 80 cm²; and human trials of 4-week continuous 3 fold excessive consumption with groups of people with BMI of 18.5 to <30.

Based on the above results and the presented documents, FSCJ concluded that *Gaseri-kin SP kabu youguruto* has no concern relevant to human health as long as the presented documents concern.

¹ “*Gaseri-kin SP kabu youguruto*” is a name romanized the product name in Japanese using Hepburn's method for this provisional English translation.