



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

Risk Assessment Report

Toku-gyu sarashia premium

(Food for specified health uses)

Food Safety Commission of Japan (FSCJ)
September 2020

ABSTRACT

FSCJ conducted a risk assessment of a frozen food for specified health uses, Toku-gyu sarashia premium which contains salacia-derived salacinol as a relevant ingredient, based on the documents submitted by the applicant. The food is aimed for specified use suitable for easing the postprandial elevation of blood glucose levels by slowing down the speed of sugar absorption from food into the blood.

A recommended daily intake of this food, 135 g, contains 0.5 mg of salacia-derived salacinol as an ingredient relevant to its specified use.

The data used in the assessment include experiences of consumption, genotoxicity studies, a single oral gavage test in rats, 13-week repeated oral gavage tests in rats, and tests in humans. As for tests in humans, 12-week of single and continuous intake test and 4-week continuous consumption of a three-fold excess level test were conducted in groups of people with normal fasting blood-glucose range and boundary range. FSCJ concluded, from these test results, that Toku-gyu sarashia premium has no obvious risk to human health.

Since the assessed food is expected to alter blood-glucose level, special care must be taken based on the policy prescribed in the Approach to the Safety Assessment of Each Product of Foods for Specified Health Use¹. Hence, persons carrying on the food business need to make efforts to collect and provide information on the health effects of their products. In addition, caution label indicating that patients should consult physicians or medical personnel for their ingestion of the food should be required.

¹ The policy prescribed in (2) of 2 of the Approach to the Safety Assessment of Each Product of Foods for Specified Health Use (Decision of the Commission dated 10 May 2007).