

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

Risk Assessment Report

朝食プロバイオティクスヨーグルト **BifiX**

*Choshoku Purobaioteikusu Yoguruto BifiX*¹

(A cultured milk product containing *Bifidobacterium animalis* subsp. *lactis*
GCL2505)

(Food for Specified Health Uses)

Food Safety Commission of Japan (FSCJ)

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ABSTRACT

FSCJ conducted a risk assessment of *Choshoku Purobaioteikusu Yoguruto BifiX* as a food for specified health uses, which aim to improve enteral environment and to maintain the digestive function. This product contains *Bifidobacterium animalis* subsp. *lactis* GCL2505 as relevant ingredients. The assessment was conducted based on the documents submitted by the applicant.

In a 100 gram of this product, corresponding to the recommended daily intake, more than a billion of *B. lactis* GCL2505 is contained.

The assessed data include history of safe use as the food, reverse mutation tests using microorganisms, a single oral gavage test in rats, 28-day repeated dietary administration tests in rats, and human trials of 12-week continuous consumption and of 4-week continuous 4.5 fold excessive consumption.

Based on the above results and the presented documents, FSCJ concluded that *Choshoku Purobaioteikusu Yoguruto BifiX* has no concern relevant to human health as long as the presented documents concern.

¹ “*Choshoku Purobaioteikusu Yoguruto BifiX*” is a name romanized the product name in Japanese using Hepburn's method for this provisional English translation.