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

Safety Assessment Report

Protease produced using Raα3114 strain

(Genetically Modified Food)

Food Safety Commission of Japan (FSCJ)
January 2024

ABSTRACT

The FSCJ conducted a safety assessment of "Protease produced using the Raα3114 strain."

This additive is a protease produced using the Raα3114 strain, which was developed using the *Bacillus subtilis* Marburg 168 strain as a host, and introducing the protease transgene derived from *Thermus aquaticus* YT1 strain. This resulting additive is an enzyme that hydrolyzes gluten, thereby utilized to enhance the quality of dough for baking bread and confectionery.

Referring to the "Standards for Safety Assessments of Food Additives Produced Using Genetically Modified Microorganisms,[1]" the safety of the inserted gene and the toxicity and allergenicity of the protein produced from the inserted gene were evaluated. From these results, there were no additional factors found that could impair safety compared to conventional additives.

Therefore, it has been concluded that "Protease produced using Raα3114 strain" is unlikely to pose safety concerns relevant to human health.

[1] Decision of the FSCJ dated March 25, 2004