

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

Safety Assessment Report

Pullulanase produced using LDN487 strain

(Genetically Modified Food)

Food Safety Commission of Japan (FSCJ)
March 2025

ABSTRACT

The FSCJ conducted a safety assessment of "Pullulanase produced using the LDN487 strain".

This additive is a pullulanase produced using the *Bacillus licheniformis* LDN487 strain, which was developed by introducing a modified pullulanase transgene derived from the *Bacillus deramificans* T89.117D strain into the *Bacillus licheniformis* BRA7 strain as a host. This additive is an enzyme that hydrolyzes the α -1,6 glucoside bonds of amylopectin, *etc.* Added during the manufacturing process of beer and isomerized sugar, the enzyme is used in combination with other enzymes for the purpose of efficiently producing monosaccharides and disaccharides.

Referring to the "Standards for Safety Assessments of Food Additives Produced Using Genetically Modified Microorganisms, 1" evaluations were made on the donor of the inserted gene, the safety of the inserted gene such as the identification of its base sequence of the inserted gene, and the toxicity and allergenicity of the protein produced from the inserted gene. Results of these evaluations indicated that no additional factors were found in this additive that could impair safety compared to conventional ones.

Considering the above, it has been concluded that "Pullulanase using the LDN487 strain" is unlikely to pose safety concerns relevant to human health.

¹ Decision of the FSCJ dated March 25, 2004