

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

Safety Assessment Report

Alpha-amylase produced using JPBL011 strain (Genetically Modified Feed)

Food Safety Commission of Japan (FSCJ)
June 2024

ABSTRACT

The FSCJ conducted a safety assessment of a feed additive “ α -amylase produced using the JPBL011 strain.”

This feed additive is an α -amylase (hereinafter “modified amyS”) produced using the JPBL011 strain, which was developed by introducing a modified α -amylase transgene derived from the *Geobacillus stearothermophilus* ATCC7953 strain into the *Bacillus licheniformis* Ca63 strain as a host. This feed additive is an enzyme that hydrolyzes glycosidic bonds in starch to produce oligosaccharides and disaccharides, and is used to improve starch availability in livestock feeds.

The safety assessment was conducted referring to the “Stance on Safety Assessments of Genetically Modified Feed and Feed Additive.”¹

Specifically, the FSCJ confirmed that no reports of safety concerns have been reported regarding *G. stearothermophilus* ATCC7953, which is the donor of the inserted gene, and that the base sequence of the inserted gene was identified. Furthermore, regarding the inserted DNA and the open reading frame in the junction region, the structural homology with known toxic proteins was verified, and it was considered unlikely that this feed additive contained any harmful substances. Additionally, a database search of the modified amyS did not yield any reports of its transfer into livestock products.

Considering the above, it is unlikely that additional harmful substances derived from the recombinant organism will be generated and be transferred into meat, milk, eggs, and other livestock products. It is also unlikely that components derived from the recombinant organism will be converted into harmful substances or accumulated in livestock products, nor that these components will interact with the metabolic system of livestock and produce additional harmful substances. Therefore, it was deemed unnecessary to reconduct a safety assessment in reference to the “Standards for Safety Assessments of Food Additives Produced Using Genetically Modified Microorganisms,”² and it was also considered that livestock products derived from animals fed this feed additive is unlikely to pose safety concerns relevant to human health.

¹ Decision of the FSCJ dated May 6, 2004

² Decision of the FSCJ dated March 25, 2004