



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

Safety Assessment Report

Phytase produced using LU17257 strain

(Genetically Modified Foods and Feeds)

Food Safety Commission of Japan (FSCJ)

May 2019

ABSTRACT

FSCJ conducted a safety assessment of a feed additive, phytase produced using LU17257 strain, based on the documents submitted by the applicant.

The LU17257 strain was generated through the introduction of the phytase gene derived from a fusion gene into the *Aspergillus niger* ISO-502 strain as the host. The fusion gene was artificially produced from the phytase genes of *Hafnia* sp. LU11047 strain, *Yersinia mollaretii* ATCC43969 and from *Buttiauxella gaviniae* DSM 18930. This feed additive is an enzyme that decomposes phytic acid liberating inorganic phosphate. Since this enzyme becomes heat resistant due to the gene introduction, the enzyme activity is protected from the heat inactivation and thus it is used as a feed additive for improving the utilization of phosphorus in feeds for livestock animals.

As none of harmful substance is newly produced in this additive, any newly produced harmful substance is unlikely to be transferred into meat, milk, eggs, or other livestock products. In addition, it is also unlikely that an ingredient originated from the gene recombination is changed to a harmful substance then accumulated in the livestock products, or it is unlikely that an ingredient originated from the gene recombination affects metabolism in the livestock animals resulting in a newly production of a harmful substance.

As a result of assessing this additive based on “Stance on Safety Assessments of Genetically Modified Feed and Feed Additives” (Food Safety Commission Decision of May 6, 2004), FSCJ considered that reassessment based on “Standards for Safety Assessments of Food Additives produced Using Genetically Modified Microorganisms” (Food Safety Commission Decision of March 25, 2004) was unnecessary. Hence, FSCJ concluded that the food safety risk from the assessed item through livestock products was negative.

As amendment of standards and specification of this feed additive based on the Act on Safety Assurance and Quality Improvement of Feeds (Act No. 35 of 1953) has been also demanded, the MAFF has requested



FSCJ to conduct a risk assessment related to such amendment separately from this assessment. Thus, the risk assessment as a feed additive is also required on the safety decision of this additive by the MAFF.