



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

Safety Assessment Report

Phytases produced using ASP595-1 strain (Genetically Modified Foods and Feeds)

Food Safety Commission of Japan (FSCJ)
March 2016

ABSTRACT

FSCJ conducted a safety assessment of a feed additive, phytases, produced using ASP595-1 strain based on the applicant documents submitted.

ASP595-1 strain was derived from *Schizosaccharomyces pombe* ATCC 38399, which was generated through the introduction of a gene for phytase originated from *Escherichia coli* B to enhance the productivity of phytases. This additive is a 6-phytase liberating enzymatically inorganic phosphate from phytic acid and thus used for a purpose to enhance the availability of inorganic phosphate in feeds for livestock.

From this additive, none of newly generated safety concerns are thus yielded in livestock products such as meat, milk and eggs through the feeds containing this additive. It is also unlikely that a component derived from relevant genetic modification is transformed to a harmful substance and/or accumulated in the livestock products.

FSCJ considered it unnecessary to evaluate safety of this additive following the “Standards for Safety Assessments of Food Additives produced Using Genetically Modified Microorganisms” based on the “Stance on Safety Assessments of Genetically Modified Feed and Feed Additives”¹. Consequently, FSCJ concluded that the food safety risk from the assessed item through livestock products was unlikely. Besides, an amendment of the standards for feed additives based on the “Act on Safety Assurance and Quality Improvement of Feeds”² is necessary for this phytases and a risk assessment of relevant amendment has been requested from the Ministry of Agriculture, Forestry and Fisheries (MAFF). Thus, the results of the safety assessment as a food additive are also required on the safety decision of this additive by the MAFF.

¹ Food Safety Commission Decision of May 6, 2004

² Act No. 35 of 1953