



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

## Safety Assessment Report

### Phytase produced using Morph $\Delta$ E8 BP17 4c strain

(Genetically Modified Foods and Feeds)

Food Safety Commission of Japan (FSCJ)

December 2018

#### ABSTRACT

FSCJ conducted a safety assessment of a feed additive, phytase produced using Morph $\Delta$ E8 BP17 4c strain, based on the documents submitted by the applicant.

The Morph $\Delta$ E8 BP17 4c strain was generated through the introduction of the phytase gene derived from the *Buttiauxella* P1-29 strain into the *Trichoderma reesei* RL-P37 strain as the host. This feed additive is an enzyme that decomposes phytic acid liberating inorganic phosphate. Since this enzyme is heat resistant due to the gene introduction, the enzyme activity is protected from the inhibition by heat and thus it is used as a feed additive for improving the utilization of phosphorus in feeds for poultry chicken and for pigs.

As none of harmful substance is newly produced in this additive, a transfer of any newly produced harmful substance into meat, milk, eggs, or other livestock products is unlikely. 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 a newly production of a harmful substance.

As a result of evaluation of 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 reevaluation 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 evaluated to be negative.

Relating to this feed additive, amendment of standards and specification of feed additives based on the Act on Safety Assurance and Quality Improvement of Feeds (Act No. 35 of 1953) has been demanded, and the MAFF has requested FSCJ to conduct a risk assessment related to such amendment separately from this assessment. Thus, the results of the risk assessment as a feed additive are also required on the safety decision of this additive by the MAFF.