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

Safety Assessment Report

Phytase produced using the *Trichoderma reesei* RF8694 strain

(Genetically Modified Feed)

Food Safety Commission of Japan (FSCJ)
September 2025

ABSTRACT

The FSCJ conducted a safety assessment of a feed additive "Phytase produced using the *Trichoderma reesei* RF8694 strain."

This feed additive is a phytase produced using the RF8694 strain which was developed by introducing a modified phytase transgene derived from the *Escherichia coli* B strain into the *Trichoderma reesei* RF5307 strain as a host. This feed additive is an enzyme, 6-phytase, that releases inorganic phosphoric acid from phytic acid, and is used to improve phosphorus availability in feed for swine, poultry, coturnix japonica and cultured aquatic animals.

The safety assessment was conducted with reference to the "Stance on Safety Assessments of Genetically Modified Feed and Feed Additive.[1]"

In particular, FSCJ confirmed that no safety issues were reported regarding *E. coli B* strain which is the donor of the inserted gene, and that the base sequence of the inserted gene was identified. Furthermore, considering that this feed additive is used in feed for cultured aquatic animals, FSCJ evaluated the toxicity or the induction of allergenicity of proteins produced by insertion of the *qpt2* transgene *etc.*, and the open reading frames produced by the introduction of the gene expression cassette into the host by verification through database and literature search. As a result, it was considered unlikely that this feed additive contains harmful substances or has allergenic properties. Additionally, a literature search did not yield any reports of proteins produced by gene insertion being transferred into livestock and fishery products.

Considering the above evaluations, there is no possibility that additional harmful substances derived from the recombinant organism will be generated and be transferred into meat, milk, eggs, and other livestock or fishery products. FSCJ also considered it unlikely that components derived from the genetic modification will be converted into harmful substances or accumulated in livestock and fishery products, or that these components will interact with the metabolic system of livestock and others to produce additional harmful substances. Therefore, FSCJ deemed it unnecessary to conduct a safety assessment by

[1] Decision of the FSCJ dated May 6, 2004
[2] Decision of the FSCJ dated March 25, 2004

applying mutatis mutandis to the “Guidelines for Safety Assessments of Food Additives Produced Using Genetically Modified Microorganisms,[2]” and it was also considered that products derived from livestock and cultured aquatic animals fed this feed additive are unlikely to pose safety concerns relevant to human health.