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

Safety Assessment Report

Phytase produced using JPAo012 strain

(Genetically Modified Feed)

Food Safety Commission of Japan (FSCJ)
March 2024

ABSTRACT

The FSCJ conducted a safety assessment of a feed additive "Phytase produced using the JPAo012 strain."

This feed additive is a phytase (modified CbPhyt) produced using the JPAo012 strain, which was developed by introducing a modified phytase transgene derived from the *Citrobacter braakii* ATCC51113 strain into the *Aspergillus oryzae* IFO4177 strain as a host. This phytase is an enzyme that degrades phytic acid to release inorganic phosphoric acid, and is a 6-phytase used to improve phosphorus availability in feed for poultry, swine and cultured aquatic animals.

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

In particular, the FSCJ confirmed that no safety issues were reported regarding *Citrobactor braakii,* 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, the FSCJ evaluated the toxicity or the induction of allergenicity of proteins produced by insertion of the modified CbPhyt transgene, and the open reading frames (ORFs) in the junction region 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 or translation products of ORFs being transferred into livestock and fishery products.

Considering the above evaluations, 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 or fishery products. It is also 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, it was deemed unnecessary to re-conduct a safety assessment by applying mutatis mutandis to the "Standards 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.

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