

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

## Safety Assessment Report

### Phytase produced using *Komagataella pastoris* 132 strain (Genetically Modified Feed)

Food Safety Commission of Japan (FSCJ)  
March 2021

#### ABSTRACT

The FSCJ conducted a safety assessment of a feed additive, phytase produced using *Komagataella pastoris* 132 strain, based on the documents submitted by the applicant.

This feed additive is phytase produced using 132 strain which was generated through the introduction of the phytase gene derived from *Escherichia coli* B strain into *Komagataella pastoris* GS115 strain as a host. This is an enzyme that hydrolyzes phytic acid and isolates inorganic phosphoric acid. It is a 6-phytase used to improve the application rate of phosphorus in the livestock feed.

In accordance with “Stance on Safety Assessments of Genetically Modified Feed and Feed Additives”<sup>1</sup>, the following possibilities were considered:

- i. new harmful substances derived from recombinants are generated in said genetically modified feed and transferred to meat, milk, eggs and other livestock products;
- ii. components in said genetically modified feed which are derived from genetic modification are transformed into harmful substances and accumulate in livestock products; and
- iii. components in said genetically modified feed which are the result of genetic modification interact with the metabolic system of livestock animals and produce new harmful substances.

As a result of assessing this additive, none of these possibilities could be putative. Accordingly, the FSCJ determined that it is unnecessary to assess this additive based on “Standards for Safety Assessments of Food Additives produced Using Genetically Modified Microorganisms”<sup>2</sup>.

The FSCJ concluded that there is no concern about human consumption of products derived from livestock fed this additive.

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<sup>1</sup> Decision of the FSCJ dated May 6, 2004

<sup>2</sup> Decision of the FSCJ dated March 25, 2004