



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

Safety Assessment Report

Phytase produced using CRC2836-13885 LVS ETD MB#2 strain (Genetically Modified Feed)

Food Safety Commission of Japan (FSCJ)
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ABSTRACT

The FSCJ conducted a safety assessment of a feed additive “Phytase produced using the CRC2836-13885 LVS ETD MB#2 strain.”

This feed additive is a phytase (CRC2836 phytase) produced using the CRC2836-13885 LVS ETD MB#2 strain, which was developed by using the *Trichoderma reesei* RL-P37 strain as a host, and introducing the *CRC2836-13885* transgene, a chemically synthesized gene encoding phytase designed based on the consensus sequence of phytase from various bacteria, including enterobacterium *Buttiauxella*. It is a 6-phytase that degrades phytic acid to release inorganic phosphoric acid, and is used to improve phosphorus availability in feed for swine, chicken, and quails.

The safety assessment was conducted referring to the “Stance on Safety Assessments of Genetically Modified Feed and Feed Additive.”¹

In particular, the FSCJ confirmed that the base sequence of the inserted gene was identified. Furthermore, as for the inserted DNA and the open reading frame in the junction region, structural homology with known toxic proteins was examined, all of which lead to the conclusion that the feed additive is unlikely to contain harmful substances. Moreover, a literature search on CRC2836 phytase yielded no reports on its transfer into livestock 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 products. It is also unlikely that components derived from the genetic modification will be converted into harmful substances or accumulated in livestock 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 referring to the “Standards for Safety Assessments of Food Additives Produced Using Genetically Modified Microorganisms²,” and it was also considered that products derived from livestock 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