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

Risk Assessment Report

6-Phytase from *Buttiauxella P1-29* expressed in *Trichoderma reesei* Morph ΔE8 BP17 4c

(Feed Additives)

Food Safety Commission of Japan (FSCJ)
December 2018

SUMMARY

FSCJ conducted a risk assessment a phytase produced by *Trichoderma reesei* Morph ΔE8 BP17 4c, based on the documents prepared by an applicant for designation of a new feed additive.

There are liquid type and solid type in the formulations of feed additives that contain 6-Phytase from *Trichoderma reesei* Morph ΔE8 BP17 4c (phytase BP-17) as the active substance. The recommended additive amount of this feed additive is 250~2,000 FTU per kg of feed for pigs and quails.

Pharmacokinetic study and residue study of this additive have not been conducted.
Although in vivo genotoxicity study of this additive was not conducted, results of in vitro reverse mutation test and chromosomal aberration tests using human peripheral blood lymphocytes were negative. In addition, phytase BP-17 is a protein and it is used as a feed additive. Taking these facts into consideration, FSCJ concluded that exposure to his additive through livestock products has no genotoxicity relevant to human health.

Toxic effects of phytase BP-17 interim technical products was not observed in 90-day sub-acute toxicity study in rats, so FSCJ considered the NOAEL in this tests as 144 mg total protein/kg bw/day (151.35 mg total organic solids (TOS)/kg bw/day which is equivalent to 52,500 FTU/kg bw/day) which was the highest dose.

The feeding trial of phytase BP-17 formulation in chicken and pigs showed that the oral administration with the dose even 100 times higher than the recommended addition (200,000 FTU/kg of feed) did not cause a toxic effect.
Regarding substances other than phytase BP-17 contained in this formulation, FSCJ concludes that considering the usage, existing toxicity data, and the dosage and administration, the risk to human health from the intake of these additives as a component of this product is negligible.

Consequently, FSCJ concluded that risks of feed additives that contain phytase BP-17 as the active substance to human health through foods are negligible as long as normally used as feed additives.

A safety assessment of genetically modified feed additives concerning this feed additive is expected to be requested from the MAFF based on the provision of 2 of Appendix 2 of Ordinance of Ministry of Agriculture and Forestry (1976, No.35) regarding the standards for feed and feed additives. Therefore, the results of the present risk assessment should be taken into consideration in the handling of this feed additive by the MAFF.