

Risk Assessment Report

6-Phytase from *Escherichia coli* B expressed in *K. pastoris* P-132 (Feed Additives)

Food Safety Commission of Japan (FSCJ)
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SUMMARY

FSCJ conducted a risk assessment of 6-Phytase from *Escherichia coli* B expressed in *K. pastoris* P-132, 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 *Escherichia coli* B expressed in *K. pastoris* P-132 (Phytase P-132) as the active substance. The recommended additive amount of this feed additive is 125~1,000 FTU per kg of feed for pigs, chicken, quails and aquatic animals.

Pharmacokinetic study and residue study of this additive have not been conducted.

FSCJ considered that phytase P-132 has no genotoxicity relevant to human health since the results of genotoxicity studies both *in vitro* and *in vivo* were negative.

Toxic effect of phytase P-132 interim technical products was not observed in 90-day subacute toxicity study in rats, so FSCJ considered the NOAEL in this test is 1,000 mg/kg bw (27,000 FTU/ kg bw), which was the highest dose.

The feeding trial of phytase P-132 formulation in chicken, turkeys, pigs and aquatic animals showed that the oral administration with the dose even 50 to 100 times higher than the recommended addition (50,000 FTU/kg of feed) did not cause a toxic effect.

Regarding substances other than phytase P-132 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 P-132 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.