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Risk Assessment Report

Phytase produced using *Komagataella phaffii* BSY-0007 strain (Feed Additive)

Food Safety Commission of Japan (FSCJ) June 2023

ABSTRACT

The FSCJ conducted a risk assessment of a feed additive, phytase produced using *Komagataella phaffii* BSY-0007 strain (hereinafter referred to as "A2P phytase"), based on the evaluation documents for feed additive designation.

There are two kinds of formulations in a feed additive containing A2P phytase: liquid and powder. The recommended additive amount is 250 phytic acid decomposition power (phytase units: FTU) per kg of feed for pigs, chickens and quails.

The FSCJ conducted a safety assessment of genetically modified feed additives for A2P phytase¹ and concluded that there is no concern about adverse effects on human health for the products derived from livestock which consumed this feed additive.

In the genotoxicity study, an *in vitro* reverse mutation test using bacteria and an *in vivo* micronucleus test using mouse bone marrow cells were implemented. The results were negative for both. Consequently, the FSCJ determined that there is no genotoxicity on A2P phytase.

In a 90-day subacute toxicity study in rats, no toxicity was observed due to the administration. Accordingly, the FSCJ determined that the no-observed-adverse-effect level (NOAEL) should be the highest dose of 1,000 mg/kg bw per day (300,000 FTU/kg bw per day for phytase).

The FSCJ presumed that the diluting agent, etc. included in this feed additive would have negligible effects on health when consuming this substance, considering its usage, existing toxicity assessments, directions and dosage.

From the results of safety and feeding tests for the target animals applying this feed additive, the dosage of 200 times of the recommended additive amount was tolerated in the diet, and no abnormalities were observed in the case of dosage of the recommended additive amount.

Given the above, the FSCJ concluded that the probability of this feed additive affecting human health through food would be negligible as long as it is used appropriately.

¹ Safety assessment of the FSCJ in May, 2022