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

Risk Assessment Report

Amylase produced using *Bacillus licheniformis* JPBL011 strain

(Feed Additive)

Food Safety Commission of Japan (FSCJ)
December 2024

ABSTRACT

The FSCJ conducted a risk assessment of a feed additive, amylase produced using *Bacillus licheniformis* JPBL011 strain (hereinafter referred to as "modified amyS amylase"), based on the evaluation documents for feed additive designation.

There are two kinds of formulations in a feed additive containing modified amyS amylase: liquid and powder. The recommended additive amount is 300-400 Kilo Novo alpha amylase Unit (KNU) (1,050-1,400 starch saccharification activity unit) per kg of feed for cattle; and 60-120 KNU (210-420 starch saccharification activity unit) per kg of feed for pigs and chicken.

The FSCJ conducted a safety assessment of genetically modified feed additives for modified amyS amylase[1] and concluded that there is no concern about adverse effects on human health for the products derived from livestock that consumed this feed additive.

In the genotoxicity study, an *in vivo* test has not been implemented. In an *in vitro* reverse mutation test using bacteria and a chromosomal aberration test using human peripheral blood lymphocyte [HPBL], the results were negative for both. The FSCJ viewed that a modified amyS amylase would not indicate genotoxicity of particular concern to humans, grounded that the residues of a modified amyS amylase in food are normally negligible.

In a 13-week 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 16,689 KNU/kg bw per day. It was thought that the health effects on humans would be insignificant as long as it is used appropriately as a feed additive since the residues of a modified amyS amylase in food would be normally negligible.

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

[1] Safety assessment of the FSCJ on June 27, 2024

From the results of a safety test for the target animals, the FSCJ assumed that there would be no safety issues for these animals when applied at 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.