

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

Risk Assessment Report

Muramidase JPTR 003 product (Feed Additives)

Food Safety Commission of Japan (FSCJ)
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ABSTRACT

FSCJ conducted a risk assessment of Muramidase JPTR003 product which contains technical grade Muramidase JPTR003 produced using *Trichoderma reesei* JPTR003 strain based on the documents to request for designating as a feed additive.

Muramidase JPTR003 is a feed additive which FSCJ has assessed as a genetically modified product and concluded that the food safety risk as the feed-additive active ingredient through livestock products is negative.

FSCJ judged that the risk of the excipients contained in Muramidase JPTR003 product to human health from the intake as components of this product is negligible, considering the usage, the existing evaluation results, and the dosage and administration.

As for genotoxicity of Muramidase JPTR003, both *in vitro* reverse mutation test and chromosome aberration test showed negative results. Therefore, FSCJ judged that Muramidase JPTR003 has no genotoxicity relevant to human health as long as it is used as a feed additive.

Since no toxicity finding was observed with Muramidase JPTR003 administration in a 13-week subacute toxicity study in rats, FSCJ judged that the NOAEL in this study was the maximum dose of 1,132 g TOS/kg bw (384,616 LSU (F)/kg bw/day).

In a tolerance test of chicken with this feed additive product, no adverse effect was observed by even 6-week dietary administration of this product at a dose of 10 times higher than the maximum recommended dose (450,000 LSU(F)/kg feed).

Hence, FSCJ concluded that the risk to human health from the intake of currently assessed Muramidase JPTR003 product through consumption of foods is negligible as long as it is appropriately used as a feed additive.