

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

Risk Assessment Report

Muramidase concentrated and purified product produced using *Trichoderma reesei* JPTR003 strain (Second edition)¹ (Feed Additive)

Food Safety Commission of Japan (FSCJ)
July 2023

ABSTRACT

The FSCJ conducted a risk assessment of a feed additive, muramidase produced using *Trichoderma reesei* JPTR003 strain (hereinafter referred to as "muramidase JPTR003") (CAS No.9001-63-2), based on the evaluation documents for feed additive designation.

The FSCJ conducted a safety assessment of a genetically modified feed additive for muramidase JPTR003² and concluded that there would be no safety concern about human health for the products derived from livestock which consumed this feed additive.

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 dose.

The FSCJ determined that muramidase JPTR003 would not have genotoxicity to cause a particular problem for living organisms as long as it is used as a feed additive, because the genotoxicity study showed negative results in the following tests: *in vitro* reverse mutation and abnormal chromosome.

From the results of a 13-week subacute toxicity study in rats, no toxicity findings were observed due to the administration of muramidase JPTR003. Consequently, the FSCJ identified the no-observed-average-effect level (NOAEL) of 1.132 g TOS/kg bw (384,616 LSU (F)/kg bw per day), which is the highest dose in this study.

In the safety tests on pigs and chickens applying this feed additive, no adverse effects were observed even after 10 times of the maximum recommended additive amount was administered to the target livestock in 6 weeks.

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 FSCJ's first assessment was conducted on June 21, 2021.

² Safety assessment of the FSCJ on June 1, 2021