

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

Risk Assessment Report

Active substance, 3-nitrooxypropanol (Feed Additive)

Food Safety Commission of Japan (FSCJ)
October 2023

ABSTRACT

The FSCJ conducted a risk assessment of a feed additive containing an active substance of 3-nitrooxypropanol (3-NOP), referring to the submitted documents for feed additive designation. The Ministry of Agriculture, Forestry and Fisheries requested this assessment.

The feed additive containing 3-NOP as an active substance is added to a feed to reduce methane in the cattle's belching while suppressing to produce methane in its first stomach (rumen). The recommended additive amount is 60-100 mg/kg dry matter feed of 3-NOP for dairy cattle feed; and 100-150 mg/kg dry matter feed of 3-NOP for beef cattle feed.

In the October-2023 risk assessment requested by the Ministry of Health, Labour, and Welfare, the FSCJ specified an acceptable daily intake (ADI) of 1 mg/kg bw per day for 3-NOP.

The FSCJ presumed that the diluting agent, etc. contained in this feed additive would have negligible effects on health through consumption of this substance, considering its usage, existing toxicity assessments, directions, and dose.

In the study on residues, the metabolite M2 (NOPA) was below the limit of quantifications in the tissues due to dosing this additive contained in the feed to the cattle. Meanwhile, M2 was detected in milk after 2 days of administration. The concentration tended to increase as the dose amount changed and time went by.

From the studies of safety and feeding tests on cattle (dairy and beef cattle), the FSCJ determined that adding this feed additive at the recommended amount would not raise safety concerns for the cattle.

Given the above, the FSCJ concluded that the probability of causing adverse effects on human health through food would be negligible as long as this additive is appropriately used as a feed additive.