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

Risk Assessment Report

Safety of food derived from cattle injected with live vaccine (Bovilis Lumpyvax-E) against lumpy skin disease

(Veterinary Medicinal Product)

Food Safety Commission of Japan (FSCJ)
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ABSTRACT

The FSCJ conducted a risk assessment of the safety of the food produced from cattle injected with live vaccine (Bovilis Lumpyvax-E) against Lumpy Skin Disease (LSD), based on the documents submitted by the Ministry of Agriculture, Forestry and Fisheries (MAFF).

The main ingredient of vaccine, Lumpy Skin Disease Virus (LSDV) Neethling strain, is a live-attenuated vaccine strain derived from pathogenic wild strains. LSDV exhibits high host specificity. Susceptible animals include those of the bovine species, water buffalo, and wild ruminants. LSDV is not a zoonotic pathogen and does not transmit to humans.

Based on the above, the main ingredient, the LSDV Neethling strain, was considered to have no pathogenicity to humans.

The FSCJ presumed that the additives in this formulation would have negligible health effects on humans when used in the target animals and subsequently ingested by humans, considering their usage, existing toxicity assessments, directions and dosage.

In safety and clinical studies, no findings of significant concern were noted in cattle as a result of the administration of this formulation or Lumpyvax, which also contains the LSDV Neethling strain as the main ingredient, while minor effects at a very low incidence were observed.[1]

Given the above, the FSCJ concluded that the probability to cause adverse effects on human health through food derived from cattle vaccinated with this formulation would be negligible as long as it is appropriately used.

[1] Lumpyvax vaccine was approved in 2006 in South Africa and it has no record of use in Japan. MSD-Animal Health obtained the license to produce Lumpyvax vaccine in 2015 and has produced Bovilis Lumpyvax-E vaccine since 2022. Bovilis Lumpyvax-E and Lumpyvax have the same vaccine composition.