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

Risk Assessment Report

Mammary infusion formulation (Orbeseal) for cattle, containing an active substance, Bismuth Subnitrate, Heavy

(Veterinary Medicinal Products)

Food Safety Commission of Japan (FSCJ)
March 2023

ABSTRACT

The FSCJ conducted a risk assessment of a mammary infusion formulation (Orbeseal) for cattle containing an active substance, heavy bismuth subnitrate (BSN), based on the application documents for approval of manufacturing and marketing a veterinary medicinal product.

FSCJ's assessment clarified that BSN, a main agent of this formulation would have no effect on human health through the exposure to the residues in food as long as it is normally used as a veterinary medicinal product.

The FSCJ presumed that the additive included in this formulation would have negligible effects on health in the case of consuming this substance, considering its usage, existing toxicity assessments, directions and dosage.

In a residue test, a single dose of a mammary infusion was administered to dry cows. Bismuth concentration level in milk increased by administration of the formulation while it tended to decline in line with milking frequency and fell further by filtering or centrifuging. For centrifuged samples, no significant difference was observed between the formulation-administered group and the non-administered group.

As a result of safety and clinical studies, the FSCJ determined that there would be no safety issue for giving a customary dose of this formulation to cattle.

Given the above, the FSCJ speculated that the probability of causing adverse effects on human health through food would be negligible as long as this formulation is appropriately applied.