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

Risk Assessment Report

An injection for veterinary use in cattle, containing florfenicol as an active substance: Florgane

(Veterinary Medicinal Products)

Food Safety Commission of Japan (FSCJ)
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ABSTRACT

Florgane is an injection for cattle that contains florfenicol (FFC) as an active substance. FSCJ conducted a risk assessment of florgane based on a written application for the marketing approval of new veterinary medicinal products. An ADI for FFC has been specified as 0.01 mg/kg bw/day as is described in the attached Risk Assessment Report of FFC (version 3).

Regarding the additives used in this product, FSCJ concludes that considering the usage, existing assessment results, and the dosage and administration, the risk to human health from the veterinary use of these additives as a component of this product is negligible.
Feeding studies with administration in cattle showed that the average residue at 35 days after the administration was 0.4788 μg/g in the liver.
In safety and clinical studies with administration of recommended dose of this product in objective animals, no issue on safety related to this product was observed in general condition or at the injected site.

Hence, FSCJ concluded that the risk to human health from the intake of this product through consumption of foods is negligible as long as it is appropriately used.

In use of this product, special attention needs to be paid for results from the risk assessment of antimicrobial-resistant bacteria since FFC is a thiamphenicol synthetic antibacterial substance.