

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

Risk Assessment Report

An injection for veterinary use in cattle and pigs, containing amoxicilline hydrate as an active substance:

Amostuck LA Injection

(Veterinary Medicinal Products)

Food Safety Commission of Japan (FSCJ)
June 2019

ABSTRACT

FSCJ conducted a risk assessment of amostuck LA injection using the documents provided with the application for reevaluation. Amostuck LA injection is an injection for veterinary use in cattle and pigs, which contains amoxicilline hydrate as an active substance.

FSCJ has previously specified the ADI for amoxicillin (AMPC), the main ingredient of this product, 0.0013 mg/kg bw/day (17th July, 2018).

FSCJ concludes that the risk of the additives used in this product to human health through foods is negligible based on the usage, existing toxicity data, and the dosage and administration of this product.

There is no new evidence suggesting any concern for food safety in the data submitted for the reevaluation. In addition, any finding suggesting adverse effects of this product on human through foods was not reported in the risk assessment of AMPC in 2018 and in the results of reference survey afterward.

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

FSCJ noted that AMPC is a β -lactam antibiotic. When use this product, special attention is needed for the risk assessment of drug-resistant bacteria that is planned to be conducted soon.