

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

Risk Assessment Report

Flavophospholipol

(Antimicrobial-resistant bacteria)

Food Safety Commission of Japan (FSCJ) November 2013

ABSTRACT

Flavophospholipol is an antibiotic designated as a feed additive in Japan.

Based on the Assessment Guideline for the Effect of Food on Human Health Regarding Antimicrobial-Resistant Bacteria Selected by Antimicrobial Use in Food Animals (Food Safety Commission of Japan, September 30, 2004), FSCJ conducted the identification of hazards associated with selection of antimicrobial-resistant bacteria developed by the use of flavophospholipol in livestock animals.

Flavophospholipol is not used in human medicines. Moreover, there are no human antibiotics with a chemical structure similar to flavophospholipol. An association of flavophospholipol resistance with vancomycin resistance has been suggested in *Staphylococus aureus*, but this co-resistance is not considered to be a cross resistance, because the mechanism of action of flavophospholipol is different from that of vancomycin.

There are no findings in Japan on sensitivity of bacteria from livestock animals to flavophospholipol. In other countries, there are a few reports that have indicated the development of resistance against flavophospholipol in bacteria derived from livestock animals.

It is considered unlikely, however, that bacteria sensitive to flavophospholipol would become resistant by acquiring antimicrobial resistance determinants, because no transferable determinants have been found for flavophospholipol and the transfer of resistance has not been observed in filter mating experiments.

The result of hazard identification indicates that the use of flavophospholipol as a feed additive in livestock animals could cause the selection of resistant bacteria. However, the resistant bacteria would not pose human health hazards via food, because flavophospholipol is not used in human medicines, and there is no reported cross resistance to human antibiotics. Thus, FSCJ concludes that the risk to human health from the antimicrobial-resistant bacteria selected through the use of flavophospholipol in livestock animals via food consumption is negligible.

Since information regarding antimicrobial-resistant bacteria is not sufficient, FSCJ considers that the



Risk assessment report – Veterinary medicinal products FS/921/2013

Ministry of Agriculture, Forestry and Fisheries, a risk management organization, should continue to collect further information.