

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

Risk Assessment Report

Florfenicol

(Antimicrobial-resistant bacteria)

Food Safety Commission of Japan (FSCJ)
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ABSTRACT

Florfenicol is an injection for cattle and pigs which contains florfenicol, a family of antibiotic agents of thiamphenicol, as an active ingredient. FSCJ conducted a risk assessment on antimicrobial-resistant bacteria arising from the use of florfenicol in livestock animals in accordance with the Assessment Guideline for the Effect of Food on Human Health Regarding Antimicrobial-Resistant Bacteria Selected by Antimicrobial Use in Food Animals¹.

Florfenicol is designated as a veterinary medicinal product which is not used in human medicines. A human antibiotic with a chemical structure similar to florfenicol is chloramphenicol. Although chloramphenicol resistant bacteria have been identified among the bacteria derived from cattle and pigs by Japanese Veterinary Antimicrobial Resistance Monitoring System surveillance of antimicrobial susceptibility, the rate of resistance to florfenicol has not tended to increase. Florfenicol resistance genes such as *floR*, have been identified in bacteria including *Escherichia coli*, and reported to confer resistance to chloramphenicol. Chloramphenicol, however, is used scarcely in human due to bone marrow toxicity and other adverse effects.

The result of hazard identification based on the said findings indicates that although florfenicol is used only in livestock, florfenicol confers cross resistance to chloramphenicol. Moreover chloramphenicol-resistant bacteria have been identified in bacteria derived from livestock animals. However, 1) chloramphenicol is not used for infectious diseases that could spread through food consumption, 2) Florfenicol antibiotics and its substitute, fosfomycin, are chosen first for clinical treatment of human cases of infection with chloramphenicol-resistant bacteria derived from livestock animals, 3) the surveillance of antimicrobial susceptibility of bacteria derived from domestic livestock animals indicates no tendency of the increase in the rate of resistance to chloramphenicol. Consequently, FSCJ considered that the use of florfenicol in cattle and pigs causes no antimicrobial resistant bacteria that could pose human health hazards via food consumption.

Thus, FSCJ identified no food-mediated hazard in the use of florfenicol in cattle and pigs, mainly because chloramphenicol is not used in human medicines for food-mediated infections, although the said use of florfenicol could cause selection of the bacteria resistant to florfenicol and chloramphenicol. FSCJ concluded,

¹ Food Safety Commission of Japan, September 30, 2004

therefore, that the antimicrobial-resistant bacteria possibly selected through the use of florfenicol in livestock animals pose negligible risks to human health via food consumption.

Since detailed information regarding antimicrobial-resistant bacteria is not sufficiently available at this point, FSCJ considers that the Ministry of Agriculture, Forestry and Fisheries responsible for risk management should continue collection of further information besides implementation of monitoring and the appropriate usage.