

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

## Risk Assessment Report

### Zinc bacitracin

(Antimicrobial-resistant bacteria)

Food Safety Commission of Japan (FSCJ)  
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#### ABSTRACT

Zinc bacitracin 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 identified some hazards associated with selection of antimicrobial-resistant bacteria developed by the use of zinc bacitracin in livestock animals.

Zinc bacitracin is a polypeptide antibiotic designated as a feed additive, but not used in veterinary medicine in Japan. There is no food-caused infectious disease against which bacitracin is a recommended medication in human medicine, though ointments with wide antibacterial spectrum resulted by a combination of bacitracin and fradiomycin sulfate are available in Japan.

There is no confirmed information of cross resistance between bacitracin and other major antibiotics. Moreover, cross resistance between bacitracin and other polypeptide antibiotics for human use is assumed to be unlikely based on the differences in antibacterial spectrum, mechanism of action, and point of action.

In antimicrobial susceptibility testing by JVARM on enterococci isolated in domestic healthy animals, bacitracin susceptibility (MIC<sub>90</sub>) of *Enterococcus faecalis* and *E. faecium* was shifting at high levels between 256 ~ 512 µg/ml without big temporal changes.

A bacitracin resistance gene, *bcrD*-gene, has been determined in enterococci isolated from domestic commercial meat, and it was confirmed that resistance to macrolide-, tetracycline-, and aminoglycoside-antimicrobial agents were co-transferred with bacitracin resistance in some of *bcrD*-positive *E. faecalis*. However, bacitracin and those antimicrobials are not used to treat vancomycin-resistant enterococcal infection which is a major infectious disease caused by enterococci in human medicine.

MIC-distribution of bacitracin was not so variable among enterococci isolated from domestic livestock, but many strain with MIC of over 256 µg/ml that seem to be bacitracin-resistant were found among enterococci isolated in domestic livestock. Therefore, bacitracin-resistant enterococci may well pose human hazards through food consumption. However, effective alternative antibiotics of other type are available enough for these infectious

disease caused through food consumption and bacitracin is not the recommended agent.

The result of hazard identification indicates that the use of bacitracin in cattle, pigs, and chicken could cause the selection of resistant bacteria. However, the resistant bacteria would not pose human health hazards via food consumption, because bacitracin is not recommended in human medicines for food-caused infection and effective alternative of other type antibiotics are well available. Thus, FSCJ concludes that the risk to human health via food consumption arisen from the antimicrobial-resistant bacteria selected through the use of zinc bacitracin in livestock animals is negligible.

Since information regarding antimicrobial-resistant bacteria is not sufficient, FSCJ considers that the Ministry of Agriculture, Forestry and Fisheries, a risk management organization, should continue to collect further information.