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## Risk Assessment Report

### Bicozamycin (Bicyclomycin)

(Antimicrobial-resistant bacteria)

Food Safety Commission of Japan (FSCJ)

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#### ABSTRACT

Bicozamycin is an antibiotic designated as a feed additive in Japan. In accordance with 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 bicozamycin as a feed additive and a veterinary medicinal product in livestock animals.

Bicozamycin is an antibiotic used only as a veterinary medicinal product and a feed additive, but not used in human medicines. Moreover, bicozamycin is known not to pose the cross resistance to any other existing antibiotics because there are no human antibiotics with a chemical structure similar to it.

In *Escherichia coli*, high-level expression of *bcr*-gene encoding drug-transporter Bcr is known to cause the cross resistance between bicozamycin, tetracycline, fosfomycin, kanamycin and sulfathiazole. However, the resistance rate for bicozamycin in *Escherichia coli* originated from domestic livestock animals is low without an increasing trend, despite that the domestic situation of *bcr*-gene possession among *E. coli* originated from human and livestock animals and on relationship between bicozamycin resistance and multi-drug resistance were not surveyed. In addition, no *bcr*-gene has been detected in *Salmonella* derived from domestic healthy livestock animals and human.

The result of hazard identification indicates that the use of bicozamycin in livestock animals could cause the selection of resistant bacteria. However, the use of bicozamycin in livestock animals would not pose human health hazards to be identified, because bicozamycin is not used in human medicines, cross resistance to human antibiotics has not been reported, and lack of cross resistance through resistance gene has been reported for wild type strain derived from human and livestock animals. Thus, FSCJ concludes that the risk to human health via food consumption arisen from the antimicrobial-resistant bacteria selected by the use of bicozamycin in livestock animals is negligible.

Consequently, FSCJ concludes that the risk to human health via food consumption arisen from the antimicrobial-resistant bacteria selected by the use of bicozamycin 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 monitor the prudent use and amount used of bicozamycin as well as to collect further information.