

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

## **Risk Assessment Report**

## Enramycin Used for Food Producing Animals: Risk of Antimicrobial-resistant Bacteria (Antimicrobial-resistant Bacteria)

Food Safety Commission of Japan (FSCJ) October 2014

## ABSTRACT

The Food Safety Commission of Japan (FSCJ) conducted a risk assessment on antimicrobial-resistant bacteria resulting from the use of enramycin designated as a feed additive in livestock animals according to the Assessment Guideline for the Effect of Food on Human Health Regarding Antimicrobial-Resistant Bacteria Selected by Antimicrobial Use in Food Producing Animals (Food Safety Commission of Japan, September 30, 2004).

Enramycin is not used in human. Moreover, no reports are available on bacterial cross-resistance between enramycin and other antimicrobials with enramycin-like chemical structures and modes of action. The lack of the cross resistance has also been suggested by differences in precise mechanisms of their actions. Investigations of acquiring antimicrobial-resistance have suggested possible generation of enramycin resistance in Gram-positive bacteria such as enterococcus and *Staphylococcus aureus*, but enramycin-resistant enterococcus has not been reported. Field investigations on drug susceptibility of *Clostridium perfringens* derived from chickens have shown low values of Minimum Inhibitory Concentration (MIC) of enramycin without significant annual variations.

Emergence of food-derived antimicrobial-resistant bacteria hazardous to human health is unlikely based on these results of hazard identification, although a possible selection of enramycin-resistant bacteria due to its use in livestock animals cannot be neglected.

Thus, FSCJ concluded that the risk to human health of the food-derived antimicrobial-resistant bacteria selected through the use of enramycin in livestock animals is "Negligible".

Regarding enramycin resistance including cross-resistance with other human antimicrobials such as vancomycin, detailed scientific findings and information are not sufficiently available at this point. Therefore, it is necessary for the Ministry of Agriculture, Forestry and Fisheries of Japan (MAFF) as a risk management organization