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

Risk Assessment Report

Tetracycline-antibiotics

(Antimicrobial-resistant bacteria)

Food Safety Commission of Japan (FSCJ)
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ABSTRACT

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 a hazard associated with selection of antimicrobial-resistant bacteria developed by the use of tetracycline antibiotics in food animals.

The target antimicrobial substances of this evaluation are a group of tetracycline antibiotics (refer to as TC antibiotics hereinafter) including oxytetracycline and chlortetracycline that are used as feed additives and veterinary medicinal products in cattle, pigs and chicken (refer to as food animals hereinafter), and doxycycline which is a tetracycline antibiotics used as a veterinary medicinal product in pigs and chicken. *Staphylococus aureus* infection is an infection which may spread through food products derived from food animals, and against which a TC antibiotic agent is chosen first for clinical treatment of human cases of infection. Therefore, FSCJ identified *S. aureus* which acquired antimicrobial resistance as a result of the use of the target TC antibiotics in livestock as the hazard to be assessed.

The release assessment determined a potential of the assessed TC antibiotics use in food animals to develop any hazard, examining mechanisms for TC antibiotics resistance of *S. aureus*, and the situation of TC antibiotics resistance in domestic food animals. As the results, the level of risk was considered to be moderate. The exposure assessment determined a potential of any hazard to which human may be exposed through livestock products derived from food animals, examining how much the hazard will increase or decrease at each steps of human exposure to the relevant hazard, and the situation of food contamination with the hazard. As the results, FSCJ concluded that the level of risk was negligible.

The consequence assessment determined a risk of therapeutic effects in human to decrease or disappear, examining the therapeutic importance of TC antibiotics for human use which has a certain cross resistance to the assessed TC antibiotics, and the severity of infectious disease caused by the hazard. Consequently, FSCJ concluded that the level of risk was low.

FSCJ estimated comprehensively the risk of hazard based on the abovementioned results from each assessment. The use of the TC for food animals may possibly select hazard, and humans may be exposed to the hazard through livestock products derived from these food animals, resulting in a decrease and/or abolishment

of therapeutic effects of antibiotics for humans. Although this possibility was not excluded, food safety risk of the item was assessed to be low.

Regarding antimicrobial-resistant bacteria, detailed scientific findings and information are not sufficiently available at this point, and an internationally accepted methodology for the risk assessment has not yet been established. Therefore, it is necessary to keep up with the latest scientific findings and information including the development of discussion in international organizations.