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

Risk Assessment Report

Macrolides

(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 some hazards associated with selection of antimicrobial-resistant bacteria developed by the use of macrolides in livestock animals.

The target antimicrobial substances of this evaluation are a group of macrolide antibiotics including 16-membered cyclic macrolides (tylosin, tylvalosin, tilmicosin and mirosamicin) and a 14-membered cyclic macrolide (erythromycin). Among these, tylosin is used as feed additive for use in pigs, and all other macrolides are used as veterinary medicinal products in cattle, horses, pigs, chicken and honey bee. FSCJ considered that there is no hazard to be identified for honeybee based on the characteristics of their product, honey, and for horses based on the lack of sales results of macrolide antibiotics for more than recent ten years. Campylobacter infection is an intestinal infection which may spread through food products derived from cattle, pigs and chicken, and against which a macrolide antibiotic agent is chosen first for clinical treatment of human cases of infection. Therefore, FSCJ identified *Campylobacter jejuni and coli* which acquired antimicrobial resistance as a result of the use of macrolide in livestock as the hazard to be assessed.

The release assessment determined a potential of the assessed macrolide used in cattle, pigs and chicken to develop any hazard, examining mechanisms for macrolide resistance of *C. jejuni* and *C. coli,* and the situation of macrolide resistance in domestic cattle, pigs and chicken. As the results, the level of risk was considered to be low in cattle and chicken, and moderate in pigs.

The exposure assessment determined a potential of any hazard to which human may be exposed through livestock products derived from cattle, pigs and chicken, examining how much the hazards will increase or decrease at each steps of human exposure to the relevant hazards, and the situation of food contamination with the hazards. As the results, FSCJ concluded that the level of risk was negligible in cattle, low in pigs and moderate in chicken as long as the relevant foods were appropriately managed and consumed.

The consequence assessment determined a risk of therapeutic effects in human to decrease or disappear, examining the therapeutic importance of macrolide for human use which has a certain cross resistance to the assessed macrolides, and the severity of infection disease caused by the hazards. Consequently, FSCJ concluded that the level of risk was low in cattle, pigs and chicken.

FSCJ estimated comprehensively the risk of hazard based on the above mentioned results from each assessment.

The use of the macrolide of target for cattle, pigs and chicken may possibly cause hazards, and humans may be exposed to the hazards through livestock products derived from these livestock 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 evaluated to be low. Moreover, the level of risk in honeybee and horses was considered to be negligible since particular hazard to be identified has not been determined

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.