

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

Risk Assessment Report

Terramycin powder for fishery use (Veterinary Medicinal Products)

Food Safety Commission of Japan (FSCJ)
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ABSTRACT

FSCJ conducted a risk assessment of Terramycin powder for fishery use, a feed additive for use in the Order *Tetraodontiforme* which contains Oxytetracycline Hydrochloride as the active substance based on application documents for the reevaluation of veterinary medicinal products.

As for an ADI for oxytetracycline hydrochloride, the active substance of this product, FSCJ has specified an ADI of 0.03 mg/kg bw/day as a group ADI for oxytetracycline, chlortetracycline and tetracycline. Regarding the additives used in this product, FSCJ concluded that considering the usage, existing toxicity data, and the dosage and administration, the risk to human health from the intake of these additives through this product is negligible.

Although a drug use surveillance was not conducted during the period of reevaluation, no research suggesting concerns about food safety and residues of this product was reported during the period of reevaluation. Hence, as well as considering the types and doses of the active substance and the additives in this product, FSCJ concluded that no finding to suggest any concern for food safety of this product is available at present.

Accordingly, FSCJ concluded that the risk to human health from the intake of this product through consumption of foods is negligible as long as it is appropriately used.

In addition, a drug use surveillance should be conducted after the launch of the product to collect data regarding the food safety.

In use of this product, special attention needs to be paid for the risk assessment of antimicrobial-resistant bacteria that will be conducted later since oxytetracycline chloride is a tetracycline antimicrobial agent.