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

Risk Assessment Report

The product for oral administration via drinking water to pigs containing orbifloxacin as the active ingredient

(Veterinary medicinal products)

Food Safety Commission of Japan (FSCJ)

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ABSTRACT

FSCJ conducted a risk assessment of the product for oral administration via drinking water to pigs containing orbifloxacin as the active ingredient, based on a written application for the marketing approval of new veterinary medicinal products and others.
Orbifloxacin, the major constituent of this product, is used as veterinary medicinal product. This time, FSCJ conducted an assessment for specifying ADI of orbifloxacin as described in Risk Assessment Report of Orbifloxacin. As a result, FSCJ specified the ADI as 0.012 mg/kg bw/day.

Regarding the additives used in this product, FSCJ concluded that the risk to human health from the intake of these additives as ingredients of this product can be negligible, considering the usage, existing toxicity evaluation, dosage and administration,.

It was confirmed that the level of this product would be below the detection limit in all tissues 5 or 6 days after the last administration in the residue test.

Also abnormalities in clinical symptoms or side effects caused by the administration of this product were not observed in safety and clinical studies.

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

In use of this water additive, special attention needs to be paid for the risk from fluoroquinolone-resistant bacteria in pigs since the degree of the risk has been evaluated to be moderate.