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

# Risk Assessment Report

## Resflor

(Veterinary Medicinal Products)

Food Safety Commission of Japan (FSCJ)
September 2015

## ABSTRACT

FSCJ conducted a risk assessment of resflor, an injection for cattle, which contains florfenicol and flunixin meglumine as main active ingredients based on new application documents for marketing approval of veterinary medicinal product.

Florfenicol or flunixin meglumine each has been used as a veterinary medicinal product in Japan and other countries. In Japan, FSCJ has already specified an ADI of 0.01 mg/kg bw/day or 0.098 mg/kg bw/day for florfenicol or flunixin meglumine, respectively.

In this assessment FSCJ compared effects of resflor, mixture use of both substances to those of single use on pharmokinetics and acute toxicities. There was no interaction by mixture. Thus, the toxicities of this product was identified to be attributable to both florfenicol and flunixin meglumine.

FSCJ also considered that the risk of the additives in this product to human health could be negligible based on consideration of the usage, known toxicity data, as well as the dosage and administration for clinical use. In the studies of subcutaneous injection of this product in the neck of cattle at clinical dose, residue levels of florfenicol was 0.06 μg/g in the the muscle at the injection site and the kidney 45 days after the injection. With regard to flunixin and its metabolite, only flunixin was detected in the muscle at the injection site 10 days after the injection at 0.05 μg/g. The residue levels were decreased to a level below the detection limit 15 days after the injection at 0.01 μg/g.

The effects such as swelling and induration were only found at the injection site of cattle in the safety and clinical studies of this product. The induration at the injection site was recovered with time. Therefore, FSCJ identified that there was no clinical or safety concern with those cattle treated with this product.

On the basis of the evidence described above, FSCJ concluded that the risk of this product consumption via foods to human health would be negligible as long as it is appropriately used.
In addition, since florfenicol is known to be a synthetic analogue of antibiotic agent, the risk assessment for antimicrobial resistance in bacteria should be taken into account.