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

Risk Assessment Report

Exzolt

(Veterinary Medicinal Products)

Food Safety Commission of Japan (FSCJ)
December 2020

ABSTRACT

FSCJ conducted a risk assessment of exzolt, a drinking water additive for chickens, based on the written application for the approval of manufacture and sales of new veterinary medicinal products. Exzolt contains fluralaner as the active substance.
FSCJ has specified the ADI of 0.01 mg/kg bw/day for fluralaner, as was described in the attached "Risk Assessment Report: Fluralaner (FSCJ 2018)".
FSCJ concluded that the risk to human health from the intake of additives contained in this product was negligible, considering the usage and the dosage and administration.

Residue studies in chickens, with administration of fluralaner through drinking water twice at 7-day interval, showed that concentrations of the residue of fluralaner were high in the liver, skin with under layer of fat, kidney and muscle. The mean residue concentration in the liver was 1,740 ng/g at maximum at 1 day after the last administration, then decreased to 276 ng/g after 10 days. The mean residue concentration in the muscle reached a maximum of 246 ng/g at 1 day after the last administration, then decreased to 35.5 ng/g after 10 days. In the egg (whole egg) from hen administered fluralaner products through drinking water twice with 7 days interval, mean residue concentration of fluralaner reached a maximum (828 ng/g) at 7days after the last administration. Thirteen days after the last administration, fluralaner concentration was below the detection limit.

According to the results of safety studies and clinical studies in chicken, FSCJ considered that this product has no safety issues to chicken as long as used appropriately at the normal dose.
Hence, FSCJ concluded that the risk to human health from the intake of this product through foods is negligible as long as it is appropriately used.