

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

## **Risk Assessment Report**

### **An injection for veterinary use as a superovulation inducer for cattle, containing follicle stimulating hormone (FSH) as an active ingredient:**

#### **Anthorine R10/AI**

(Veterinary Medicinal Products)

Food Safety Commission of Japan (FSCJ)

September 2016

### **ABSTRACT**

FSCJ conducted a risk assessment of Anthorine R10/AI, an injection of a new veterinary medical product for cattle, containing follicle stimulating hormone derived from porcine thyroid (pFSH) as an active ingredient based on the data submitted by the applicant.

Follicle stimulating hormone derived from porcine thyroid (pFSH), main ingredient of this product, is a glycoprotein, and is considered to be inactive due to degradation in the digestive tract when ingested orally. Therefore, FSCJ considered that the risk of this product to human health through the dietary intake was negligible.

Regarding the additives used as ingredients in this product, FSCJ considered that their risk to human health through dietary exposure was negligible taking the usage, the present toxicity data, and the dosage and administration into account.

In feeding studies where Japanese Black and Holstein were administered with regular dose of this product, their maximum levels of plasma pFSH were 2.740 ng/mL at 12 hr after and 1.963 ng/mL at 8hr after the injection, respectively. The plasma levels decreased and were detected as trace amounts after 96 hr.

In livestock feeding studies in lactating cows administered with clinical dose of this product, no pFSH was detected in milk at any time. In addition, the safety studies and clinical studies of this product indicated that this product has no concern for cattle.

Hence, FSCJ concluded that risk of this product for human health through foods is negligible as long as appropriately used.