

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

Risk Assessment Report

Bopriva (Veterinary Medicinal Products)

Food Safety Commission of Japan (FSCJ)
July 2015

ABSTRACT

FSCJ conducted a risk assessment of Bopriva, in accordance with the request from the risk management authority for the approval of manufacture and sales of new veterinary medicinal products, based on the written application. Bopriva is an injection for veterinary use in cattle, containing a conjugate of 2-10-gonadotropin releasing hormone (2-10-GnRH) analogue with diphtheria toxoid (DT) as an active ingredient, and suppresses the hormonal action of gonadotropin releasing hormone (GnRH) through immunological mechanisms mediated by the immunogen of 2-10-GnRH/DT conjugate.

Intravenous administration studies in sheep and oral administration studies in rats and pigs indicated that 2-10-GnRH/DT conjugates, the active ingredient of this product, have neither GnRH-like activity nor an antibody response to GnRH. In addition, no toxic effect was observed in the oral administration studies. Therefore, FSCJ considered that 2-10-GnRH/DT conjugates have no concern relevant to human health.

2-10-GnRH/DT conjugates are peptides, nevertheless it did not activate immune responses in pigs in oral administration studies. This suggests that 2-10-GnRH/DT conjugates are digested into smaller peptides or amino acids in gastric juice, losing the immunogenicity, when humans ingest the conjugates through livestock products derived from cattle exposed to it.

Regarding the additives used in this product, FSCJ concludes that considering the usage, existing toxicity data, and the dosage and administration, the risk to human health from the intake of these additives as ingredient of this product is negligible.

An ordinal dose of the conjugates in safety studies and clinical studies in cattle exerted no adverse effect on general conditions and body weights, except for reactive changes in the application site.

From these results, 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.