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

Risk Assessment Report

Imrestor

(Veterinary Medicinal Products)

Food Safety Commission of Japan (FSCJ)
January 2018

ABSTRACT

FSCJ conducted a risk assessment of Imrestor, which is an immunostimulant for veterinary use to cattle and contains pegbovigrastim as an active ingredient, using data from the documents for the approval of manufacture and sales of new veterinary medical products submitted by the applicant. This assessment was conducted in accordance with the request from the risk management authority. Pegbovigrastim has been approved and used in abroad as a veterinary medicinal product for use in cattle to suppress pre- and post-partum incidence rate of clinical mastitis. In Japan, the assessment of pegbovigrastim was conducted by FSCJ in 2016, and FSCJ concluded that it is not necessary to specify the ADI.

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

Although there was no data on residue levels of pegbovigrastim in the subjected livestock, pegbovigrastim is considered to be degraded rapidly in the human stomach after the oral intake through food consumption. Thus the adverse effects of human internal exposure to pegbovigrastim are negligible when it is ingested through consumption of foods produced from cattles. Hence, FSCJ judged that the toxicological and pharmacological effects of pegbovigrastim on human health need not be considered. In addition, administration of pegbovigrastim to dairy cattle during peripartum period had no abnormal effects in the safety study.
Consequently, FSCJ concluded that risk to human health from the assessed item through food consumption is negligible as long as it is appropriately used.