

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

Risk Assessment Report

Avian Infectious Bursal Disease • Marek's Disease Avian Infectious Bursal Disease Vaccine, Frozen Live (VaxxitekHVT+IBD) (Veterinary Medicinal Products)

Food Safety Commission of Japan (FSCJ)
October 2020

ABSTRACT

FSCJ conducted a risk assessment of Avian Infectious Bursal Disease • Marek's Disease Avian Infectious Bursal Disease Vaccine, Frozen Live (VaxxitekHVT+IBD), based on data in the written application for the approval of manufacture and sales of new veterinary medicinal products. Main ingredient of this product, vHVT013-69 strain, is genetically modified virus generated by introduction of VP2 gene derived from infectious bursal disease (IBDV) into herpesvirus of turkey (HVT) FC • 126 strain.

Both HVT and IBDV have been classified into herpesvirus family, and their natural host is known to be avian. Both viruses are not human pathogens, not recognized as pathogens of zoonotic diseases.

Gene transcription of VP2 gene and HVT are distinctly regulated, thus insertion of VP2 gene is considered to have no effect on the gene expression of HVT. Moreover, individually expressed VP2 protein probably is not taken up into HVT virions. Consequently, the present strain for producing vaccine is considered to have characteristics the same to the parental strain HVT FC • 126 strain except expression of VP2 protein.

VP protein produced by expression of the inserted VP2 gene was considered to be of little concern for allergenicity.

Hence, the present strain for producing vaccine is considered to be of no pathogenic to humans.

Regarding the additives used in this product, FSCJ concluded that the risk to human health from the use of these additives as ingredient was negligible based on the usage and existing evaluation and the dosage and administration.

No findings of particular concern as effects on chickens due to vaccination of this product was obtained in safety studies.

Regarding VaxxitekHVT+IBD, FSCJ concluded that the risk to human health through consumption of foods derived from chickens vaccinated this product is negligible as long as it is appropriately used.