

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

Risk Assessment Report

Suvaxyn® CSF Marker (Veterinary Medicinal Products)

Food Safety Commission of Japan (FSCJ)
November 2019

ABSTRACT

FSCJ conducted the safety assessment of foods derived from pigs received suvaxyn® CSF marker vaccine, based on the documents provided from the Ministry of Agriculture, Forestry and Fisheries.

This marker vaccine strain assessed is an attenuated live vaccine strain, a chimeric pestivirus CP7_E2alf, whose coding sequences for the major envelope protein E2 of BVDV strain CP7 are replaced by E2 of the CSFV strain Alfort187. The E2 protein is the major immunogen in the infectious cDNA clone.

CSFV is classified into the Genus Pestivirus in the Flaviviridae, and its natural reservoir is domestic pigs and wild boar. BVDV is also classified into the Genus Pestivirus in the Flaviviridae, and cattle is most susceptible while Artiodactyla such as buffalo, goat, sheep, pigs and deer is also susceptible. Both viruses are not pathogenic to humans, thus are not pathogens of zoonotic diseases.

As for CP7_E2alf strain, FSCJ considered it as negligible possibility that an artificial replacement of E2 gene of BVDV with that of CSFV results acquisition of human infectivity by raising a new host affinity, except changes in the immunogenicity and host affinity of CSFV raised by the replacement.

Regarding the additives used in this product, FSCJ concludes that the risk to human health from the use of these additives as a component of this product into target animals is negligible based on the previous evaluation of their usage, existing evaluation, and the dosage and administration.

In the safety studies with pigs, FSCJ recognized no particular issue as the effects on pigs from the inoculation of this product.

Hence, FSCJ concluded that the risk to human health through consumption of foods derived from pigs inoculated this product is negligible as long as it is appropriately used.