

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

Risk Assessment Report

Porcine reproductive and respiratory syndrome vaccine (Fostera PRRS)

(Veterinary Medicinal Products)

Food Safety Commission of Japan (FSCJ)

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ABSTRACT

FSCJ conducted a risk assessment of porcine reproductive and respiratory syndrome vaccine (Fostera PRRS) which was requested by the risk management authority for the approval of manufacture and sales of new veterinary medicinal products, based on the written application.

The main strain used for the production is a strain attenuated toxicity. The parental strain was attenuated by serial passage in cell culture. The passaged viral genome was molecularly cloned and infectious virus was produced upon transfection. Subsequently, the virus strain was repeatedly passaged in cell culture. To insure genetic uniformity, RNA from the same virus isolate was used in molecular cloning of viral genome. FSCJ reviewed the study on molecular cloning of the viral genome as well as virus production from the infectious cDNA clone, and concluded that the strain does not pose safety concerns because the parental strain is attenuated. PRRS virus, known to infect only swine and boar, is not considered to be zoonotic since no cases of human infection has been reported. Consequently, FSCJ considered that the strain used to produce the product is not pathogenic to humans. Reversion to virulence did not occur among the five passages of strains tested for pathogenicity noticeably in pigs.

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 through the intake of these additives as ingredient of this product is negligible.

Adverse effects were not observed in one-day-old-pigs in safety and clinical studies.

Hence, 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.