

Philippines to roll out unproven swine fever vaccine

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Credit: Pixabay/CC0 Public Domain

The Philippines is under global scrutiny as it proceeds with the controlled rollout of an unproven African swine fever (ASF) vaccine from Vietnam amid doubts from experts about its safety and efficacy.

ASF is a highly contagious viral disease that affects domestic and wild pigs and has a mortality rate that can reach 100%, according to the World Organization for Animal Health (WOAH).

There is no internationally approved [vaccine](#) against the virus which has led to huge losses in pig populations following an upsurge in the disease since 2022.

"There is a very big concern," said Ramon Clarete, a professor of economics at the University of the Philippines Diliman who specializes in agricultural productivity. "We really must be careful about this [vaccine], because the swine industry is a very important industry in agriculture."

The concerns stem from a perceived lack of transparency from Vietnam about its trial data and the nature of the ASF vaccine, which consists of a live virus that has been weakened by deleting important parts of its genes. This type, called a live-attenuated vaccine, may still pose a serious risk of mutation and reversion to its viral form.

"The risk with a live-attenuated vaccine is that it may still have a little bit of virulence that can cause either the disease or some form of discomfort or disease," said Baptiste Dungu, professor at University of Kinshasa, Democratic Republic of Congo and vaccinologist with more than 30 years in veterinary vaccine research, manufacturing, and commercialization.

A 2023 [study](#) published in *Nature* tested the virus strain in ten pigs and found that while it did not gain back its virulence, a virus variant emerged in one pig, which eventually spread through all ten pigs. The variant appeared to be slightly more replicative and had an increased risk of "shedding," the study claims.

"Shedding is when a virus is excreted by the animal that has been vaccinated and then it goes to another animal," explained Dungu.

"This phenomenon did not occur in any of the previous studies, but it is relevant because it could also happen in the field during intensive use," the authors said in the paper.

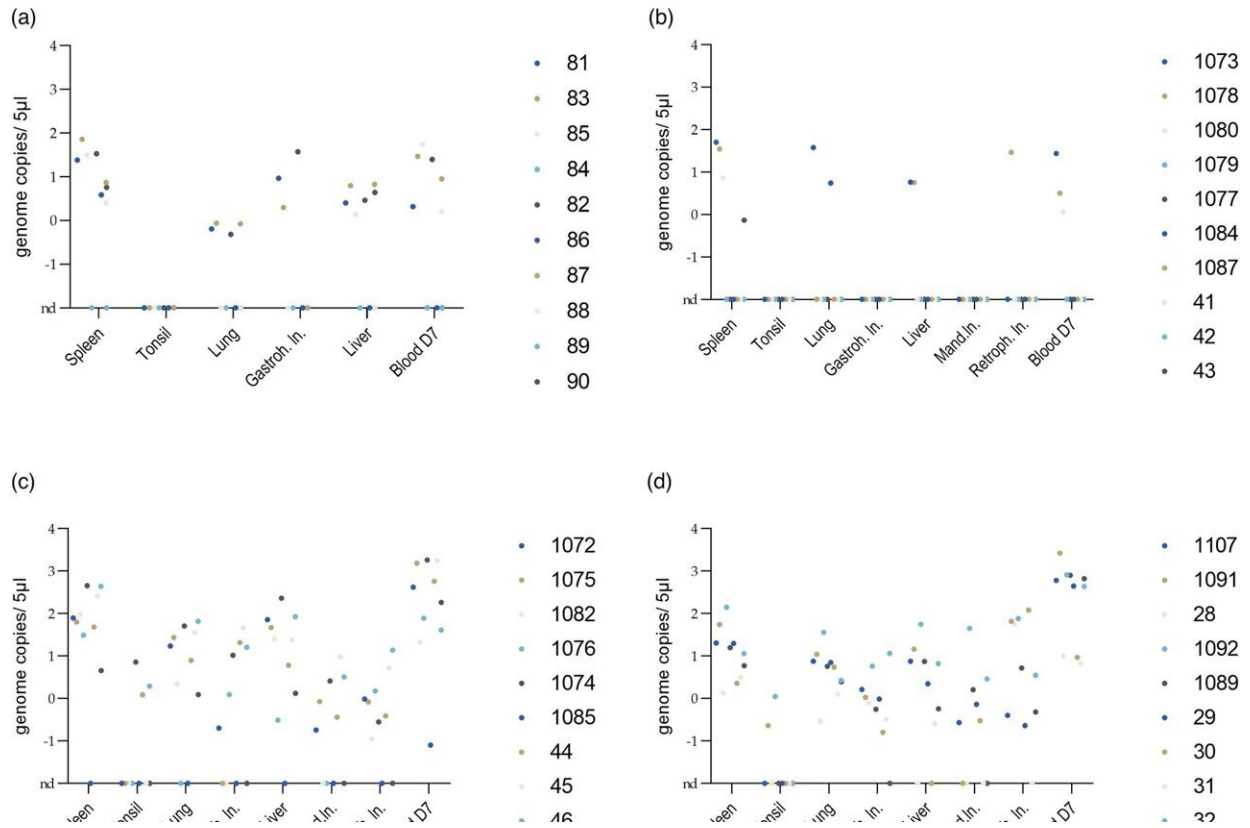
The Philippine Food and Drug Administration (FDA) said they had carefully reviewed the field trial data before granting the vaccine a Certificate of Product Registration under Monitored Release (CPR MR), which allows its controlled use in the country.

"CPR MR is issued by the FDA for new drugs and vaccines that have successfully met the stringent safety, efficacy and quality standards required for approval," the agency told SciDev.Net.

The vaccine, named the AVAC ASF LIVE vaccine, is created by AVAC Vietnam JSC and imported into the Philippines by KPP Powers Commodities Inc. It is derived from a virus strain called ASFV-G- Δ MGF, or Δ MGF for short.

However, on 27 October 2022, the USDA Animal and Plant Health Inspection Service (APHIS) issued a public notice about the withdrawal of MGF from the select agent regulatory exclusions because "it has evaluated new information and determined that they have the potential to pose a severe threat to animal health or animal products."

"It has also determined that the [virus strain](#) is not safe for use in pigs because its genome is unstable, potentially leading to reversion of virulence," the notice warned.



Genome loads detected in different tissues during passages 1-4. Credit: *npj Vaccines* (2023). DOI: 10.1038/s41541-023-00669-z

APHIS cited two journal articles published by the Harbin Veterinary Research Institute in China as the basis for the decision, saying that the studies "identified instability within the MGF genome segments."

In December 2023, WOAHA issued a warning on "the use of sub-standard vaccines" following announcements of export deals between the vaccine maker AVAC Vietnam JSC and Southeast Asian countries including the Philippines. The warning urges authorities to only use high-quality vaccines with proven safety and efficacy.

Despite these concerns, the controlled rollout will proceed next month,

with 150,000 doses to be distributed in pig farms on a voluntary basis. The campaign will begin on 2 September, in Lobo, Batangas, the "ground zero" of ASF outbreaks, according to agriculture assistant secretary and spokesman Arnel de Mesa.

Last month, Agriculture Secretary Francisco Tiu Laurel claimed on the state television PTV that "the vaccine from Vietnam really works."

The Department of Agriculture did not respond to SciDev.Net's requests for more information about the [field trials](#).

The FDA said that field trials have been ongoing in the Philippines for almost two years now and claimed that the vaccine has a 100% efficacy with no side effects. However, no trial data has been made public.

When asked for the field trial documents, the FDA said that they follow strict confidentiality protocols and that "direct access to them is not permitted."

Former Agriculture Undersecretary Jose Reaño questioned the credibility of the trials, explaining that he had not seen the field trial documents.

"If the results were really positive, they should be proud and share the data with the public," Reaño told SciDev.Net, while adding that the government should not rely on the vaccine as the main form of intervention.

Last year, the trials were scrutinized in a senate hearing with Senator Cynthia Villar questioning KPP Powers Commodities Inc. about its involvement in the trials. The senator noted a conflict of interest and said the Department of Agriculture should independently conduct the field trials.

SciDev.Net reached out repeatedly to the company KPP Powers but did not receive a response in time for publication.

"I am for the introduction of this [vaccination] if it has been found by experts that it is safe to use," said Clarete.

However, he said that the FDA should be more transparent with the trials.

The Philippines is one of the 19 Asian countries affected by ASF since 2019, according to data from the UN Food and Agriculture Organization. It has since spread to 74 of its 82 provinces and reduced the swine population from 12.7 million in 2019 to 9.9 million in 2023.

As of July 2023, the hog industry lost at least Php200 billion or about US\$3.5 billion, according to Nicanor Briones, AGAP party-list representative and chair of the Pork Producers Federation of the Philippines.

Provided by SciDev.Net

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