



ADMINISTRATIVE CIRCULAR

No: 05
Series of 2024

SUBJECT: GUIDELINES ON THE CONTROLLED USE OF VACCINE FOR AFRICAN SWINE FEVER

WHEREAS, African Swine Fever (ASF), a high-impact transboundary animal disease (TAD), was first detected in the country in 2019 and gradually spreading to other disease-free areas, consistent with its description as a highly contagious viral disease of domestic and wild pigs, in which mortality rate can reach 100%;

WHEREAS, the Bureau of Animal Industry (BAI) is mandated to promote the development of the livestock industry through the control and eradication of dangerous communicable diseases of domestic animals pursuant to Act 3639;

WHEREAS, pursuant to Executive Order No. 338, series of 2001, BAI is mandated to adopt measures that would prevent the entry of exotic and communicable diseases into the country consistent with international standards, statutes, and protocols set for inter-country and intra-regional cooperation;

WHEREAS, in the absence of an authorized or registered vaccine, the Department of Agriculture (DA) issued the Administrative Circular 02, Series of 2022 otherwise known as the National Zoning and Movement Plan (NZMP) for the Prevention and Control of ASF to guide the movement of swine and its related commodities across different defined zones in the country;

WHEREAS, the recovery of areas affected by ASF, in accordance with DA Administrative Order 30, Series of 2021, or the "Guideline on the Recovery and Declaration of Freedom from ASF for Local Government Units (LGU)," and DA Memorandum Circular (MC) 28 Series of 2024, Guidelines on the Implementation of the Modified Integrated National Swine Production Initiatives for Recovery and Expansion (INSPIRE) Under FY 2024, provide detailed guidelines for recovery and repopulation protocols to ensure uniform implementation of LGUs and clarify the roles of different agencies involved in the recovery effort;

WHEREAS, vaccination in general, is also a valuable complementary tool to control animal disease outbreaks through designing a strategic vaccination program using quality, effective, and safe vaccines in accordance with the World Organisation for Animal Health (WOAH) Terrestrial Code;

WHEREAS, to effectively control ASF, a combination of proactive measures must be continuously implemented. These include a robust surveillance and monitoring program,

active and participative reporting from stakeholders in cases of suspected disease outbreaks, and strict adherence to biosecurity protocols.

WHEREAS, The DA will provide, distribute, and monitor the controlled-use of ASF vaccine in coordination with the Food and Drug Administration (FDA) and Local Government Units.

NOW THEREFORE, I, FRANCISCO P. TIU LAUREL JR., Secretary of the Department of Agriculture, by the power vested upon me, do hereby issue the following guidelines on vaccination for the control of African Swine Fever:

SECTION 1. OBJECTIVES

The following are the objectives of the controlled use of vaccine for African Swine Fever (ASF):

1. To assess the safety and efficacy of the ASF vaccine under controlled use in eligible farms.
2. To utilize the result of the controlled use of the vaccine to assist FDA in their evaluation of ASF vaccine.

SECTION 2. DEFINITION OF TERMS

African Swine Fever (ASF) - according to the World Organisation for Animal Health (WOAH), ASF is a highly contagious viral disease of domestic and wild pigs, whose mortality rate can reach up to 100%. African swine fever virus (ASFV) is a DNA virus in the Asfarviridae Family; genus Asfivirus. ASFV is the sole member of its Family.

Biosecurity Level - refers to the minimum level of farm biosecurity measures for smallhold, (Level 1), semi-commercial and commercial farms (Level 2) that systematically prevent the entry and spread of disease-causing agents, as described in BAI MC No. 20, Series of 2022.

Certificate of Free Status on ASF (CFS-ASF) - is a certificate issued by BAI or DARFO to individual commercial farms, which serves as one of the requirements for the local transport of live pigs and genetic materials for Local Shipping permit according to BAI MC No. 24, Series of 2023.

Clustered smallhold farms - are smallhold farms that have met the criteria for clustering as specified in Annex 4 of DA AO No. 07, Series of 2021.

Commercial Farm - is a farm tending 51 sow level and above or 501 heads and above as defined in the Philippines Statistics Authority (PSA) Board Resolution No. 11, Series of 2023.

Controlled Use - use of vaccines that is confined only to eligible farms and under strict monitoring of the government and not for commercial distribution.

Department of Agriculture Regional Field Office (DARFO) - is the regional branch of the DA that facilitates and supervises the formulation and execution of policies, plans and programs of the Department in the respective regions.

Differentiating infected from vaccinated animals (DIVA) - reliable discriminatory tests that allow the differentiation between vaccinal antibody and that induced by natural infection.

Local Government Unit (LGUs) - are political units composed of provinces, cities, municipalities and barangays. They have long been existing with their own legislative bodies that are endowed with specific powers as defined in the Revised Administrative Code and individual local government unit (LGU) charters.

Pink (Buffer) Zone - cities or municipalities where ASF is not detected but demarcated immediately around the RED Zone when an area has been confirmed as an infected zone. The PINK (Buffer) Zone is aimed at preventing and managing spillover of cases from the Red (Infected) Zone through risk mitigation measures such as biosecurity and surveillance.

Recognition of Active Surveillance on ASF (RAS-ASF) - certificate issued by BAI to Cities and Municipalities, serves as an equivalent of CFS-ASF to cover small hold and semi-commercial farms and recognizes the compliance of LGUs with regular surveillance and testing as required for local transport of live pigs, genetic materials and application for local shipping permit according to BAI MC No. 24, Series of 2023.

Red (Infected) Zone - cities or municipalities with confirmed outbreaks of ASF. A confirmed outbreak is defined as having ASF detected in domestic and/or wild pigs in affected farms (smallhold, semi-commercial or commercial) in one barangay and spreading to other barangays of the same city or municipality occurring within 15 days. The zone color around the Red (Infected) zone may reach or expand across the boundary of the adjacent city or municipality.

Semi-commercial Farm - is a farm tending 21-50 sow level or 101 to 500 heads as defined in the Philippines Statistics Authority (PSA) Board Resolution No. 11, Series of 2023.

Smallhold Farm - is a farm tending 1 to 20 heads of sows or 1 to 100 heads of pigs as defined in the Philippines Statistics Authority (PSA) Board Resolution No. 11, Series of 2023; also referred to as a backyard farm.

Supervising Veterinarian - a licensed veterinarian responsible for overseeing vaccine administration and monitoring pigs during controlled use. This may be either a private or public veterinarian.

Upgraded Pink Zone - municipalities or cities that were previously Red (Infected) Zone that have upgraded to Pink Zone after complying with the requirements for zone upgrade as stated in DA Administrative Order No. 30, Series of 2021.

Vaccination - refers to the administration of a vaccine, in accordance with the manufacturer's instructions and the WOAHP Terrestrial Manual, when relevant, with the intention of inducing immunity in an animal or group of animals against one or more pathogenic agents (WOAHP, 2022).

Vaccine - a product designed to stimulate immunity to a particular infectious disease or pathogen, typically prepared from an inactivated or weakened form of the causative agent or from its constituents or products.

Vaccination Certificate - certificate issued by BAI through the vaccine monitor to the farm that has undergone vaccination duly signed by the supervising veterinarian.

Vaccine Monitor - a representative from BAI and/or DARFO responsible for overseeing and witnessing the administration of the vaccine.

Veterinarian-Client-Patient Relationship (VCPR) - a professional relationship in which the veterinarian takes responsibility for an animal's care, the client agrees to follow veterinary advice, and the veterinarian has adequate knowledge of the animal through recent examination. The VCPR must be signed by the supervising veterinarian of the farm.

Viral Shedding - refers to the release of a virus to the environment following successful replication of the virus in a host cell.

SECTION 3. MINIMUM REQUIREMENTS FOR THE CONTROLLED USE OF ASF VACCINE

A. Vaccination against ASF shall be permitted only in the following areas:

1. Barangays that are unaffected by ASF or are ASF-negative within a Red Zone.
2. Cities or municipalities that have been upgraded to Pink Zone status.

B. Requirements for Commercial and Semi-Commercial Farms:

1. DA and/or BAI registration (e.g. RSBSA/Animal Welfare Compliance Registration,).
2. LGU registration (Business Permit/Mayor's Permit).
3. Compliance with Farm Biosecurity Classification Level 2.
4. Duly signed Veterinarian-Client Patient Relationship (VCPR)
5. Farm Vaccination Program, if any
6. Accomplished Intent to participate (letter of intent) Form
7. ASF-negative test before vaccination
8. Compliance with the monitoring schedules.

C. Requirements for Smallhold Farms:

1. Registration with the Registry System for Basic Sectors in Agriculture (RSBSA).
2. Compliance with Farm Biosecurity Classification Level 1.
3. Duly signed Veterinarian-Client Patient Relationship (VCPR)

4. Farm Vaccination Program, if any
5. Accomplished Intent to participate (letter of intent) Form
6. ASF-negative test before vaccination
7. Compliance with the monitoring schedules.

D. Requirements for Pigs Eligible for Vaccination:

1. A minimum of 50 eligible pigs per farm or cluster must be identified for vaccination.
2. Pigs must be of the same age group within the farm.
3. Eligible pigs must be at least 4 weeks of age or older.
4. Pigs must be healthy and tested negative for ASF before vaccination.

SECTION 4. APPLICATION PROCEDURE

- A. Farms intending to participate in the controlled use of the ASF vaccine shall submit all the requirements to their Municipal/City Agriculture or Veterinary Office (MAO/MVO/CAO/CVO).
- B. The MAO/MVO/CAO/CVO shall conduct an initial review and approval of the submitted application to ensure compliance with the requirements. The reviewed application shall then be forwarded to the Provincial Veterinary Office (PVO) for preliminary clearance. For Independent Cities, applications may be endorsed directly to the BAI, with copies furnished to the PVO and the DARFO.
- C. Upon clearance, the PVO shall endorse and approve the application to the BAI and shall furnish copies to the DARFO.
- D. The BAI shall then review the application to assess eligibility of the farm and determine the appropriate vaccine allocation.
- E. Upon approval, the BAI shall issue a notification to the PVO through the DARFO, specifying the approval and the allocated vaccine quantity. The PVO shall, in turn, notify the relevant City/Municipal Veterinary Office (CVO/MVO) or City/Municipal Agriculture Office (CAO/MAO), and the farm concerned regarding the approval and vaccine allocation.

SECTION 5. VACCINE DISTRIBUTION

- A. The vaccine supplier shall provide the BAI with comprehensive details of the vaccine shipment, including but not limited to:
 1. Volume of vaccines (in doses and bottles)
 2. Batch number and/or Lot number
 3. Manufacturing Date
 4. Expiration date
 5. Additional shipment details as required
- B. The DA through BAI will designate an appropriate cold storage facility for vaccine storage. The BAI shall oversee the control, maintenance, and distribution of vaccines, ensuring adherence to cold chain protocols and quality standards.
- C. The BAI shall record all vaccine releases from the cold storage facility using the prescribed ASF Vaccine Dispensing Log.

- D. Vaccines must be dispensed to the DARFO and/or the concerned Local Government Units (LGUs). The cold chain and proper handling procedures must be strictly observed during transportation.
- E. The DARFO and/or LGUs are responsible for distributing the vaccines to eligible farms. They shall also monitor the administration of vaccines to ensure compliance with program guidelines.
- F. The BAI shall maintain an inventory of all vaccines and provide regular updates to the Food and Drug Administration (FDA) regarding vaccine stocks and distribution.

SECTION 6. VACCINE UTILIZATION AND ADMINISTRATION

- A. All pigs intended for vaccination must test negative for ASF prior to the administration of the vaccine.
- B. Vaccine administration must adhere strictly to the manufacturer's prescribed indications, program and schedule. Extra-label use of the vaccine is prohibited.
- C. Vaccination procedures must be supervised by a licensed veterinarian to ensure compliance with established protocols.
- D. The vaccine shall be administered to healthy pigs that are 4 weeks of age or older (weaning to growing). A minimum of 30 days post-vaccination monitoring is required.
- E. Upon completion of vaccination, the farm must complete the ASF Vaccination Form. The form must be signed by the supervising veterinarian and vaccine monitors.
- F. The completed ASF Vaccination Form must be submitted to the BAI through the vaccine monitors. Copies of the form must also be provided to the DARFO and the relevant LGU.
- G. The BAI shall maintain a database of all ASF Vaccination Forms to facilitate monitoring and record-keeping.

SECTION 7. DECONTAMINATION AND DISPOSAL OF VACCINES

- A. All used and unused vaccine bottles and related paraphernalia must be accounted for; none should be left on farms. Any remaining or excess doses of vaccines must be destroyed and must not be reused.
- B. Vaccine monitors are responsible for initial decontamination of all vaccine bottles and paraphernalia immediately following vaccination activities, in accordance with the recommendations provided by the vaccine manufacturer.
- C. Decontaminated vaccine bottles should be submitted to the DARFO and subsequently turned over to the BAI. This is to ensure proper accounting and adherence to medical waste disposal guidelines.

SECTION 8. MONITORING OF VACCINATED FARMS

- A. Farms must adhere to a monitoring period ranging from a minimum of 30 days to a maximum of 120 days post-vaccination. During this period, all monitoring activities and results must be documented and submitted to the LGU, DARFO, and BAI as part of the controlled use process.

- B. Farms must observe and document daily clinical signs related to ASF throughout the entire controlled vaccination cycle using the Monitoring Form. The supervising veterinarian is responsible for verifying and attesting to the accuracy of the monitoring records.
- C. Determination of sample size for testing:
 - 1. Whole blood, serum and nasal swab samples must be collected on days 0, 14, 28 post-vaccination for antigen RT-PCR and ELISA for antibody tests.
 - 2. If the pig remains under monitoring beyond the initial 30 days, additional samples must be collected on days 60 and 120. These samples must be tested for antigen RT-PCR and ELISA antibody tests.
 - 3. A total of 30 blood samples must be collected from each cluster or farm, with an equal number of 15 samples from vaccinated pigs and 15 from unvaccinated pigs.
 - 4. The Differentiating Infected from Vaccinated Animals (DIVA) test must be conducted on ASF-positive samples. Additionally, pigs that fail to seroconvert will undergo genome sequencing.
 - 5. BAI may perform additional sample collection and testing as necessary.
- D. Any observation of at least one clinical sign or mortality indicative of ASF must be immediately reported to the LGU, DARFO, and BAI.
 - 1. In the event of a suspected ASF case, a composite team from BAI, DARFO, and LGU must conduct a disease investigation and submit samples for testing.
 - 2. Samples may be tested for other pig diseases, as deemed necessary by the competent veterinary authority.
 - 3. Control measures must be promptly implemented following the disease investigation and confirmation of ASF.

SECTION 9. MOVEMENT OF VACCINATED PIGS FOR SLAUGHTER PURPOSES

- A. The movement of vaccinated pigs for slaughter is permitted only if all the following conditions are met:
 - 1. The pigs have completed a minimum of 30 days of post-vaccination monitoring.
 - 2. The pigs have tested negative for ASF virus antigen through RT-PCR.
 - 3. Clearance for the movement of vaccinated pigs must comply with current regulations, including securing a Certificate of Free Status on ASF (CFS-ASF).
- B. Pigs that test positive for ASF via PCR and display clinical signs must be depopulated in accordance with the guidelines set forth in DA Administrative Order No. 22, Series of 2020. Additionally, a DIVA test must be performed.
- C. Pigs that test positive for ASF through RT-PCR but do not exhibit clinical signs must undergo further monitoring and testing:
 - 1. The sample must be tested immediately using the Differentiating Infected from Vaccinated Animals (DIVA) test.
 - 2. Movement of these pigs shall be suspended for 7 days while observing for any clinical signs.
 - 3. After the 7-day holding period, the pigs must be retested for virus clearance:

- a. If the pigs test negative through PCR, they may be allowed for slaughter.
- b. Any pigs that remain PCR-positive must be depopulated in accordance with existing guidelines.

SECTION 10. DUTIES AND RESPONSIBILITIES

A. Farm Owners/ Swine raisers

1. Breeder pigs must not be vaccinated, and any pigs that have been vaccinated are prohibited from being used as breeding animals.
2. Pigs must not be moved or slaughtered during the post-vaccination monitoring period.
3. Submit all necessary documentation and reports, including the ASF Vaccination Form to authorities.
4. Ensure compliance with the post-vaccination monitoring schedule, and immediately report any adverse reactions or clinical signs indicative of ASF to the LGU and/or DARFO.
5. Adhere to all guidelines and requirements for the controlled use of the ASF vaccine.

B. Vaccine Monitors

1. Witness the administration of the vaccine and ensure adherence to established protocols.
2. Collect all vaccine bottles and related paraphernalia used during vaccination and conduct initial decontamination.
3. Prepare and submit all required reports and documentation, including but not limited to ASF Vaccination Form.
4. Regularly coordinate with the LGU on the status of vaccinated farms.

C. Supervising Veterinarian

1. Enter into a Veterinarian-Client-Patient Relationship (VCPR) agreement with farm owners.
2. Supervise and/or conduct the vaccine administration, ensuring compliance with vaccination and biosecurity protocols.
3. Monitor pigs for any clinical signs of ASF and immediately report findings to the appropriate authorities.
4. Provide technical guidance and support to swine raisers throughout the vaccination process.
5. Complete and issue the vaccination certificate upon successful completion of the vaccination activity

D. City/Municipal Local Government Unit

1. Grant initial approval for farms intending to vaccinate. The LGU must demonstrate willingness and commitment to conduct monitoring of these farms.
2. Witness or conduct the administration of vaccines, particularly for smallhold farms.
3. Assist in implementing the ASF vaccination program and ensure adherence to local biosecurity measures and vaccination protocols.
4. Monitor farms and report all vaccination activities and any ASF-related issues to the DARFO and BAI.

E. Provincial Local Government Unit

1. Grant initial approval for farms intending to vaccinate. The LGU must demonstrate willingness and commitment to conduct monitoring of these farms.
2. Oversee the implementation of the ASF vaccination program at the provincial level and ensure compliance with protocols.
3. Participate in or conduct vaccine administration, particularly for smallhold farms.
4. Provide technical assistance and support to City/Municipal LGUs and farms.
5. Monitor farms and report all vaccination activities and any ASF-related issues to the DARFO and BAI.

F. DA Regional Field Office

1. Lead coordination with LGUs and BAI for the implementation of the ASF vaccination guidelines.
2. Designate and oversee vaccine monitors responsible for the vaccination process, including the submission of decontaminated vaccine bottles and adherence to vaccination schedules.
3. Review and prepare reports from farms and LGUs and provide updates to the BAI.
4. Assist the BAI in the implementation of ASF Vaccination.

G. Bureau of Animal Industry

1. Provide overall guidance, supervision, and project steering for the controlled-use ASF vaccination program.
2. Oversee vaccine distribution, monitoring, and control, ensuring proper documentation of vaccine releases.
3. Designate vaccine monitors and offer necessary technical support to ensure compliance with vaccination protocols and guidelines.
4. Maintain a database of vaccination activities and prepare and submit regular reports to the Department of Agriculture (DA) and the Food and Drug Administration (FDA) on vaccine-related matters.

H. Other Private Veterinarians

1. Members of the Philippine Veterinary Medical Association (PVMA), Philippine College of Swine Practitioners (PCSP), and other veterinary organizations may assist with the Controlled-use of ASF Vaccine.
2. May act as supervising veterinarians for farms lacking their own veterinary services.

SECTION 11. CREATION OF THE ADVISORY COMMITTEE ON CONTROLLED USE OF ASF VACCINE

Prior to the controlled use of ASF vaccination, an independent advisory committee shall be created and shall be composed of the representatives from the following scientific and technical organizations/institutions, as follows:

- A. **Chair:** National Academy of Science and Technology (NAST)
- B. **Co-Chair:** Philippine College of Swine Practitioners (PCSP)
- C. **Members:**

1. National Advisory Committee on Animal Disease Control and Emergency (NAC-ADCE)
2. Philippine College of Veterinary Public Health (PCVPH)
3. Philippine College of Veterinary Epidemiologists (PCVE)
4. Department of Science and Technology (DOST)
5. Philippine Genome Center (PGC)
6. Representatives from the Academe

Qualifications:

1. With technical knowledge on vaccines
2. No conflict of interest, including:
 - a. No involvement in ASF vaccine production, sale, distribution, or use.
 - b. No role in the implementation or regulation of the ASF vaccine program.
3. Transparent and independent

Responsibilities:

1. Review/evaluate the results of the controlled use and any reports of participating farms as submitted by the BAI;
2. Evaluate findings of disease investigation in the event that the participating farms have reported suspect or confirmed cases;
3. Provide recommendation/report of the controlled use to FDA.

SECTION 12. INDEMNIFICATION OF VACCINATED PIGS

- A. Pigs that die as a direct result of the ASF vaccine or its administration shall be eligible for indemnification.
- B. In the event that pigs die due to ASF infection, the existing indemnification guidelines for ASF outbreaks shall apply.
- C. Farms that do not comply with the provisions of this guideline, including any violations of the required protocols, will be deemed ineligible for any form of indemnification or compensation.

SECTION 13. AMENDMENT CLAUSE

The provisions and annexes of this Administrative Circular may be amended or supplemented as may be deemed necessary in order to effectively implement and realize the objective of this AC.

SECTION 14. SEPARABILITY CLAUSE

In case any provision of this AC shall be declared invalid, ineffective, or unenforceable, the validity, legality, and enforceability of the remaining provisions shall not in any way be affected or impaired thereby.

SECTION 15. REPEALING CLAUSE

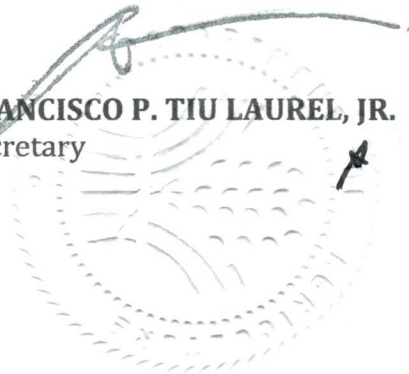
All other existing Orders, Circulars, Issuances, Rules and Regulations that are in conflict with or inconsistent with any provisions of this Administrative Circular, are hereby repealed, amended or modified accordingly.

SECTION 16. EFFECTIVITY

This Circular shall take effect immediately upon its complete publication in the official website of the Department of Agriculture and filing of three (3) certified copies thereof with the Office of the National Administrative Register (ONAR) at the University of the Philippines (UP) Law Center, Diliman, Quezon City.

Done this 29th day of AUGUST 2024.

FRANCISCO P. TIU LAUREL, JR.
Secretary



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