The White Paper on considerations for ASF vaccination

5th Meeting of the Standing Group of Experts (SGE) on African swine fever (ASF) of the GF-TADs for Africa

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Food and Agriculture Organization of the United Nations

Considerations for competent authorities and agricultural industries on use of African Swine Fever vaccines (Genotype II) to enhance disease control

FAO ANIMAL PRODUCTION AND HEALTH / **POSITION PAPER 3**

Acknowledgement

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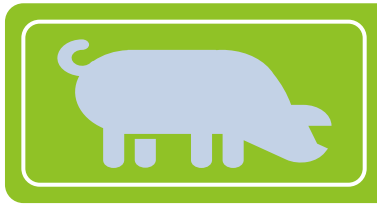
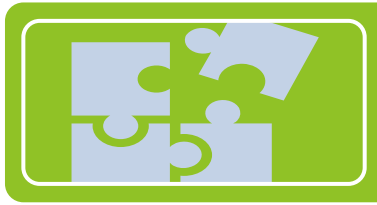
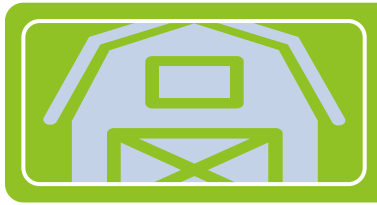
The FAO White Paper on ASF Vaccination



Evaluate if and when ASF vaccine should be used



Key elements to include in the vaccination strategy



Considerations for different epidemiologic situations

Prerequisites and conditions that must be met before vaccination implementation

Does not provide a recommendation to vaccinate or not!

Aligns with Terrestrial Animal Health Code, Chapter 4.18 with additional ASF specific considerations

ASF vaccines: challenges and current status

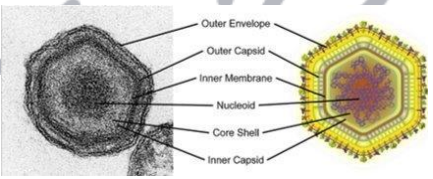
Challenges for vaccine development and production are :

- The identification of ASF viral protein protective antigens
- Limiting infection, replication, and long-term virus persistence
- Possibility to revert to virulence, shedding, recombination with field strains
- Vaccine can mask disease while spread is ongoing
- Issues with growing the vaccine virus in established cell culture lines
- Limited cross-protection against emerging recombinant ASFV strains

Viet Nam approved three first licensed ASF modified-live virus (MLV) vaccines (2022):

1. Genotype IIASFV-G-ΔI177L strain
2. Genotype II ASFV-G-ΔMGF strain
3. Genotype II ASFV-G-ΔI177L/ΔLVR strain
    - Recent research has identified evidence of reversion to virulence for ASFV-G-ΔI177L, while studies on ASFV-G-ΔMGF showed no full reversion but noted increased replication and transient clinical signs upon passaging.
    - **White paper recommendation:** Countries should prepare vaccination frameworks NOW, but implementation should wait for vaccines that meet full international safety and efficacy standards

Genomic Surveillance for ASF



Important findings through ASF genomic surveillance: case studies

Georgia 2007: genotype II introduction from Africa to Europe; genomic tracing showed that index case most closely related to a virus circulating in Mozambique in 2005

Estonia 2007/15: genotype II variants detected which disappeared due to reduced virulence and inability to generate infectious carcasses

Latvia 2017: detected attenuated and non-hemadsorbing genotype II ASFV, representing naturally occurring low-virulence variants

West Africa 2019: Co-circulation discovery: Genotype II emerged in historically Genotype I-only region

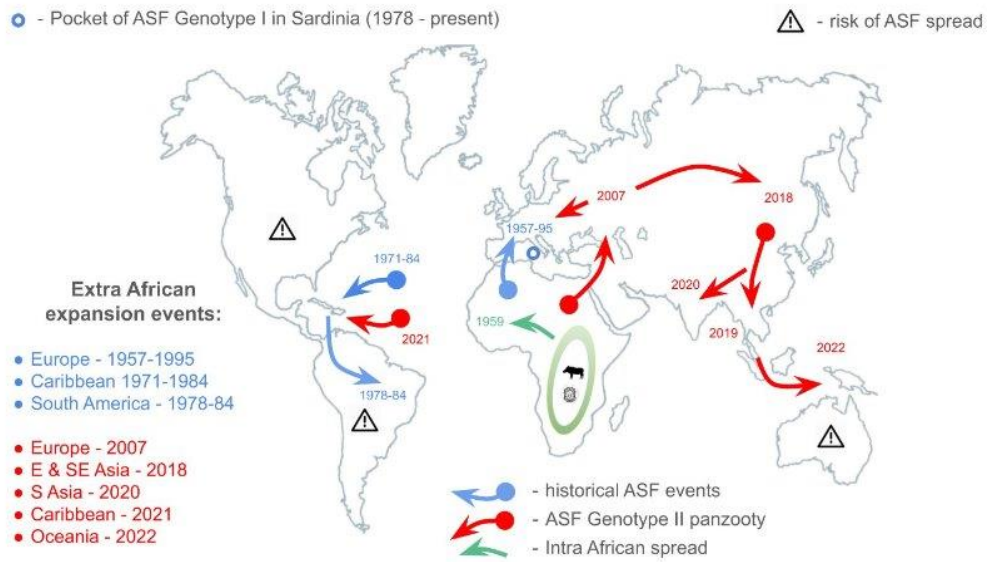
Kenya 2019: IX/X → II genotype transition tracked Ecological vectors identified through genomics

China 2020: Variant Evolution HuB/628/20**:** MGF gene changes → highly virulent variant; HLJ/HRB1/20: EP402R deletion → reduced lethality (75% vs 90%)

China 2021: historical strain reappearance: HeN/ZZ-P1/21, SD/DY-I/21 identical to 1968 Portuguese isolates (Genotype I)

Northern Vietnam 2021: ASFV-GUS Vietnam/ 'VN/sows_32005/23'; Identical to AVAC vaccine virus (ASFV-G-ΔMGF) Detection- before official vaccine licensing

Strategy to streamline ASF genetic surveillance: Regional collaboration and data sharing, Tiered testing approach, Capacity optimization, Risk-based surveillance design



Genomic Surveillance for ASF: Critical Applications in Asia

The evolving nature of ASFV threats includes the co-circulation of virulent and attenuated strains.

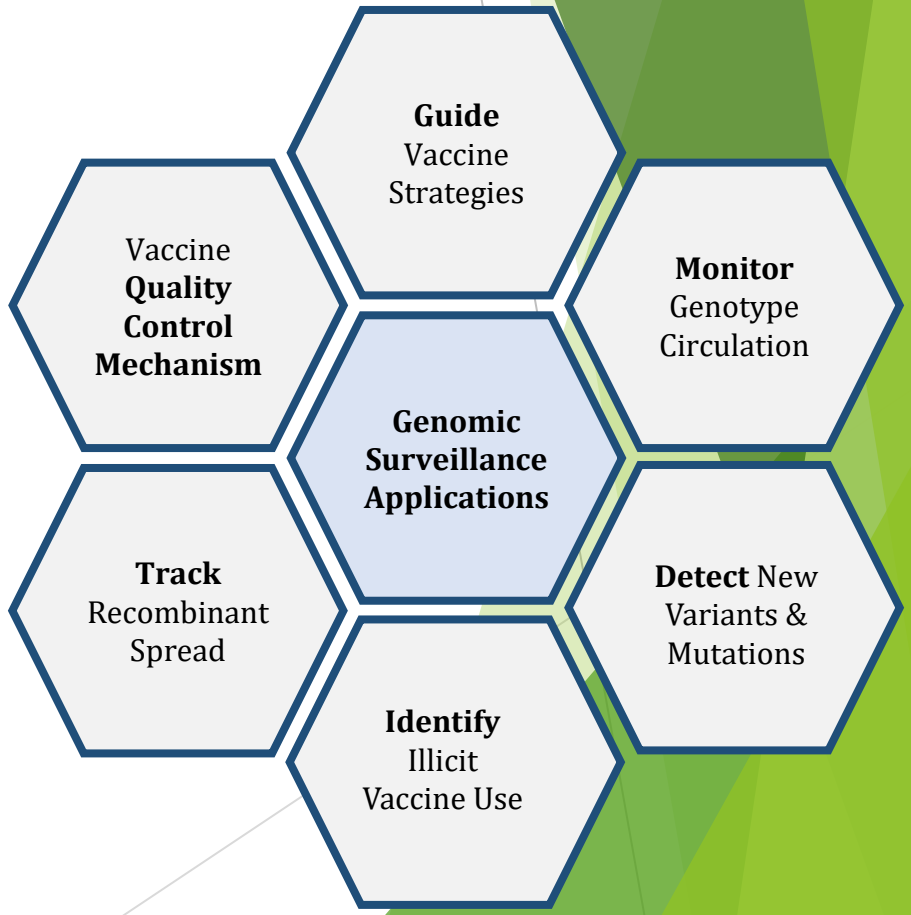
Critical Situation

Asia exhibits unique I/II recombinant strains - first identified in China (2021), subsequently detected in Vietnam and Russia (2023). High lethality combined with enhanced transmissibility. Licensed vaccines show reduced or no protection against recombinants

ASFV-GUS-Vietnam
Vaccine-like strain, low virulence, silent spread without genomic monitoring

Recombinant Strains
78% of current ASF infections in Vietnam are recombinant strains

Surveillance Gap
Insufficient molecular surveillance capacity creates blind spots



General considerations for ASF vaccination programs

VACCINATION OBJECTIVES AND STRATEGIES

INTERNATIONAL STANDARDS AND MITIGATING RISK

OUTBREAKS SPECIFICS AND VACCINE CHARACTERISTICS/PRACTICALITIES

Vaccination Objectives

- What is the purpose and desired outcome of a vaccination program?
- When will you stop vaccination? What does an endpoint look like?
- What are the costs and benefits of a vaccination program?
- What level of vaccine coverage is needed to meet your objectives?
- What level of strategy do you need? State, regional, federal?
- What biosecurity measures are in place?
- What are the consequences of NOT vaccinating?

Recommended: Implement well defined official control programs rather than voluntary vaccinations without monitoring by the authorities.

Monitoring reversion to virulence and persistence

Reversion to virulence and persistent infection are a serious concern!

Field safety testing, thorough post-vaccination monitoring and active surveillance, will help to:

- Identify and timely investigate potential reversion to virulence
- Address potential virus persistence (of vaccine or field strain)

Value chain stakeholders must be trained to detect any ASF clinical signs and react rapidly.

General considerations for vaccination programs - Vaccination strategies

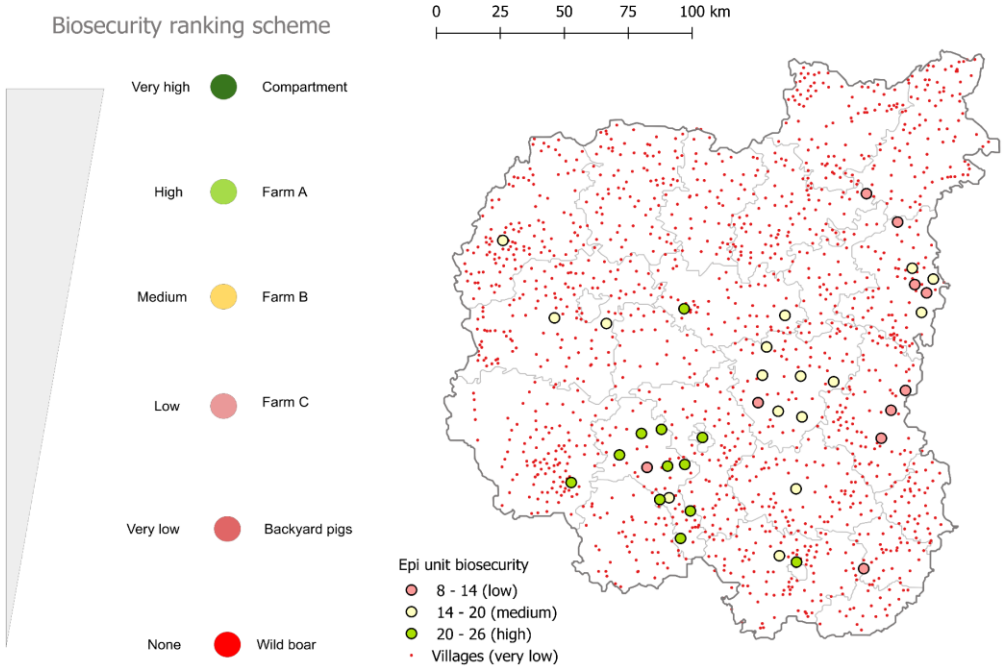
Four vaccination strategies based on the outbreak situation (*see Terrestrial Animal Health Code*):

1. barrier to prevent spread
2. blanket vaccination of all susceptible animals
3. ring vaccination of all susceptible animals in around a known outbreak
4. targeted vaccination of a subpopulation of susceptible animals.

These can serve as a basis for designing vaccination programs

Different combinations of these strategies may be used

Outbreak specifics



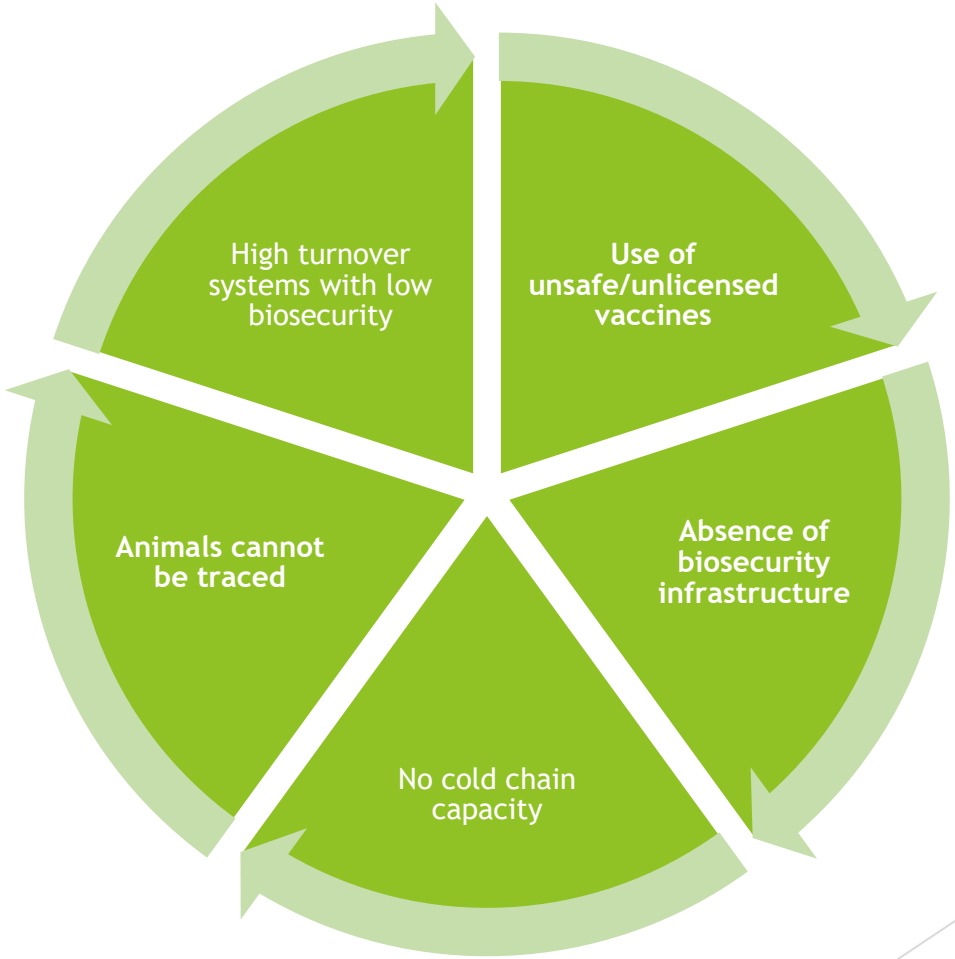
Need for evidence-based decision making, centered on surveillance and field data

- Matching of vaccine and field strain based on sequencing results
- Epidemiologic patterns and affected /at risk populations and their interfaces, movement patterns
- Presence of high value populations to be protected
- Risk assessments must guide targeted vaccination decisions

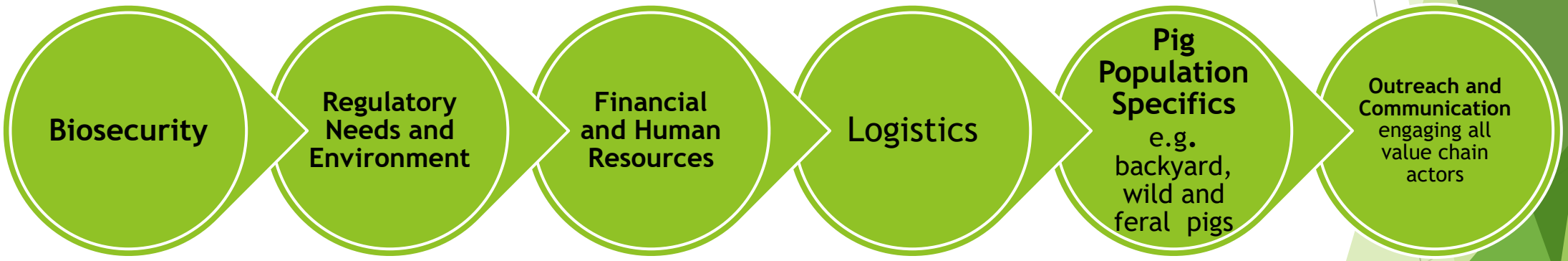
Vaccine characteristics

- Vaccine must be safe, efficacious, potent, and pure → **Use only approved vaccines**
- Importance of vaccine and field strain matching, cost and availability of vaccine
- Practical aspects e.g.
  - vaccine formulation,
  - vaccination protocol,
  - number of doses/vial,
  - storage and cold chain requirements; age and production type of pigs
  - viability of vaccine bottle once open
- **D**ifferentiation of **I**nfected from **V**accinated **A**nimals (DIVA) is desirable but a non-DIVA vaccine which is superior to a DIVA vaccine, should be weighed in the design of the vaccination strategy.

When vaccination is NOT recommended



Essential elements for an effective vaccination program



Remember - Vaccination is not a replacement for good biosecurity!

Specific considerations

Based on Disease Status

Specific considerations - Endemic Countries

- Preservation of animal resources and food security may be most common objective
- Consider limitations of resources in the long-term
- DIVA might not be necessary but thorough post-vaccination surveillance must be in place
- Special consideration should be given to situations where wild pigs serve as main reservoir and overlap with domestic population
- If wild pigs are reservoir, consider the feasibility of vaccinating them to prevent infection in domestic swine
- Vaccination might be the only measure to protect wild pigs species from extinction

Specific considerations Previously Free Countries or Area with New Outbreaks

- Consider a barrier or ring vaccination strategy in addition to vaccination within the control zone
- Ensure emergency authorization of vaccine, if not already approved
- Importance of movement controls, animal identification and traceability
- DIVA would be valuable
- If non-DIVA vaccine is used: permanent identification of vaccinated animals will help determine seropositive non-clinical animal status

Specific considerations - Free countries with exceptionally high risk for ASF

- Ensure emergency authorization of vaccine, if not already approved
- Consider importance of a DIVA vaccine
- Consider potential risk of vaccination to mask infection and thus promote spread
- Base on thorough risk assessment: define areas and populations to be vaccinated and control vaccine distribution and administration
- Movement control and traceability will support an effective vaccination program

Specific considerations - Free countries with exceptionally high risk for ASF

Free countries

- Risk assessment and cost-benefit analysis provide insight into the utility of vaccination
- Consider how a vaccination program might impact the ability for early detection of ASF and subsequent control programs.
- Consider how vaccination would impact the country's ability to regionalize

Thanks for your attention and feedback

GF-TADs Africa

GLOBAL FRAMEWORK FOR THE PROGRESSIVE CONTROL OF TRANSBOUNDARY ANIMAL DISEASES

Food and Agriculture Organization of the United Nations

World Organisation for Animal Health
Founded as OIE

African Union