Report of the *ad hoc* Group meeting on ASF vaccines: field evaluation and post-vaccination monitoring

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1. Background

The continuing spread of African swine fever (ASF) is a global concern. For many years, the lack of a vaccine or effective treatment has made the control of the disease very challenging. The research community has been working to develop a safe and effective vaccine. The announcements of modified live vaccines (MLV) being approved or tested in some Members have raised hopes for the widely availability of new effective tools to contain the current ASF epidemic.

In May 2025, the first standards for the production of safe and effective vaccines against ASF were adopted by the World Assembly of WOAH Delegates. WOAH urges vaccine manufacturers and Members to consider these standards when developing and evaluating ASF vaccine candidates for regulatory approval.

In addition to the standards, it is important to provide Members with the necessary tools and guidance to conduct independent vaccine field trials to generate the evidence that may (or may not) support the quality parameters such as purity, safety and effectiveness of the vaccine as claimed by the vaccine manufacturers. These data are often required as part of the approval process by vaccine regulatory authorities, prior to authorisation for use as part of the national vaccination campaign or as pre-purchase trials before rolling out the vaccination campaign.

The selection of the appropriate vaccine and vaccination strategy are also critical to achieve the objective/s of the vaccination programme. The process of vaccine selection and vaccination needs to be continuously monitored and evaluated to ensure that the vaccination programme fulfils its objectives and contributes to the sustainable control of ASF while optimising the use of the resources. Any adverse impacts, evolution of the circulating strains or generation of recombinant strains should also be closely monitored to inform risk management decisions.

In this context, WOAH launched a consultancy to develop a set of guidelines on the field evaluation of ASF vaccines and how to conduct post-vaccination monitoring, in accordance with WOAH international standards. The primary target audience for the guidelines would include Competent Authorities involved in the regulatory approval of veterinary vaccines and Veterinary Services responsible for the implementation of ASF control strategies.

The *ad hoc* Group (hereafter referred to as 'the Group') was convened to peer-review the first version of the guidelines drafted by the team of consultants which was shared with the Group in preparation of this meeting (see Annex 2).

2. Welcome

On behalf of Dr Montserrat Arroyo, WOAH Deputy Director General for International Standards and Science, Dr Gregorio Torres, Head of Science Department, welcomed the members of the Group and thanked them for their contribution and support. He emphasised that WOAH strongly relies on the scientific expertise of its experts to provide guidance to its Members through the development of standards and guidelines, aiming for their correct implementation. He also highlighted the importance of identifying gaps in scientific knowledge that could support the decision-making process of Members. The Group and the team of consultants noted that the meeting would operate under the confidentiality agreement signed by all.

3. Adoption of the agenda and appointment of Chair

Dr Livio Heath was appointed as Chair for the meeting and the consultants and WOAH secretariat acted as rapporteurs. The *ad hoc* Group adopted the agenda. The list of participants and Terms of Reference are provided as Annexes 1 and 2 respectively.

4. General principles

The Group recommended that the guidelines should refer to modified live vaccines and be practical and avoid prescriptive approach that could restrict their scope or application. It also agreed that the development of the guidelines should remain open for future revisions once further field experience has been accumulated.

Recognising the diversity of production systems across regions and the role of Competent Authorities in defining the objectives of the vaccination programmes and in determining where vaccination can be implemented, the Group noted that these factors may influence field trial design and feasibility. Consequently, it recommended that the guidelines offer flexible yet scientifically sound options for field application. It also suggested including practical examples to assist Members in effectively tailoring the guidelines to their local contexts.

Importantly, making reference to WOAH statement on ASF vaccines, the Group stressed that poor-quality or unauthorised vaccines pose a significant risk not only to the Member using them but also to neighbouring Members, particularly in the context of recombination or vaccine-strain spread. The Group recommended that this statement be reiterated to Members, emphasising that ASF vaccines should only be used following proper field evaluation. The guidelines should explicitly discourage the use of such vaccines and promote transparency to help prevent potential regional consequences.

The Group noted that principles and terminology used in the guidelines should be aligned with the WOAH international standards.

5. Field evaluation of ASF vaccines

5.1. Study design

The Group agreed that the guidelines are intended to provide a clear methodology to support Members in adapting field trial protocols to their specific local contexts. It emphasised the importance of considering the objective of the national vaccination programme (e.g. mitigating the disease impact or achieving disease eradication). This should be defined early in the process, to guide key design elements such as site selection, field trial type, and monitoring tools.

The study design section should include clear case definitions and inclusion and exclusion criteria, taking into account immune status and the presence of coinfections in the target population. The case definition for the purpose of the field trials may differ from the case definition for other purposes (e.g. official disease notification). It should be adapted to the objectives of the field trial. The guidelines should not be too prescriptive but include the minimum elements to be considered when drafting the case definition. The Group recommended to include some practical examples.

The Group noted that the coinfection with other swine diseases such as PRRS, PCV-1, PCV-2 and PED, may affect both the study design and the interpretation of field trial outcomes. Elements such as randomisation and including control group must be preserved regardless of production system or resource level. The Group also recommended that guidelines acknowledge the importance of involving the private sector (e.g. manufacturer and production sector) but noted their involvement may vary by Member.

To support scientifically robust and operationally feasible field studies, the Group recommended developing decision tools (e.g. a matrix or decision tree) to guide the selection of appropriate Randomised Controlled Trial (RCT) designs. These tools should help align the field trial design with specific objectives, production system types, biosecurity levels and local epidemiological conditions, while also reducing the burden on farmers. Given that farm classification systems vary across regions, the decision-making framework should reflect these differences.

The Group noted that when animals are not individually identified or retained throughout the trial period, the feasibility of the trial may be compromised. Therefore, any constraints in this area should inform the selection of field trial designs.

The Group also recommended including a table of the type of RCT to offer different options of study designs that would need to be adapted to the local context and vaccination programme objectives.

Finally, the Group recommended that the guidelines list the minimal requirements for field trial implementation, including funding, human resources, case definitions, and expected outcomes, which should be explicitly linked to the defined objectives of the field trial.

5.2. Importance of transparency and sharing data

The Group agreed that the guidelines include a dedicated section encouraging transparency and the sharing of data generated from the field trials. It acknowledged several caveats to data sharing, including concerns related to commercially sensitive information, particularly when field trials are sponsored or conducted by vaccine manufactures. In such cases, the scope of data sharing may be limited by confidentiality agreements or national legal frameworks. The Group also highlighted the importance of providing incentives for data sharing and suggested that WOAH offer technical advice and feedback on data analysis to encourage Members to share their information.

The Group emphasised that defining the type and format of data to be shared is important. It recommended investigating the minimum data requirements for vaccine registration and data sharing requested by regulatory authorities. The Group recalled the model of the Union Product Database managed by the European Medicines Agency (EMA), which consolidates data on all authorised veterinary medicines via direct reporting from either the EMA or EU Member States as a reference. Furthermore, the Group discussed existing mechanisms and recommended that WOAH explore mechanisms for Members voluntarily share relevant results. It proposed sharing data in accordance with Article 1.1.5. of the *Terrestrial Code*, which encourages Members to share 'important *animal* health information'.

In addition to the collaboration among Members, the Group also recommended encouraging public-private partnership (PPP) to facilitate transparency, including through the publication of summary reports in cases where full data disclosure is not feasible. The aim would be to share meaningful insights related to vaccine field performance, while acknowledging limitations in access to underlying data. The Group also highlighted that field evaluation should be recommended at the regional level, where resources are limited at the country level, and this would help facilitate data sharing.

6. Post-vaccination monitoring of ASF vaccines

National Veterinary Authorities should clearly define the vaccination strategy and ensure its integration into the national ASF control programme. Only quality vaccines, manufactured according to international standards that has received market authorisation should be used. A post-vaccination monitoring programme should be implemented to assess vaccine effectiveness and promptly detect any unexpected and undesired adverse effects that could jeopardise the disease control effort.

6.1. Adverse effects – review of the assessment of causality

The Group acknowledged the inherent challenges of establishing adverse effects causality under field conditions, due to the multifactorial factors such as co-infections that affect the clinical presentation of the disease, environmental variables, diverse farming practices, presence of diseases with similar clinical and pathological presentation, absence of a DIVA test, and expected shedding of the vaccine virus. It noted that all modified live vaccines may cause certain level of side effects and emphasised that Members should avoid assuming causality based on preliminary observations; instead, side effects above an expected threshold (adverse effects) could be used as signal to prompt structured investigations. While clinical indicators such as fever, viremia, or PCR Ct values could be used as signal to trigger further investigation, no universal thresholds could be established. The Group highlighted that practical tools are needed to support informed decision without discouraging vaccine use.

To support this, the Group recommended promoting risk-based post-vaccination monitoring systems, ideally coordinated by Veterinary Authority. Structured observation protocols are essential, including digital tools to support farmer reporting, and to ensure consistent data collection. Members should define their own adverse effect categories and reporting procedures, particularly in the absence of formal pharmacovigilance (vaccinovigilance) frameworks. In this context, the Group identified the lack of harmonised surveillance and reporting frameworks for ASF vaccine side effects. It therefore recommended that WOAH support efforts to address this through global coordination and the provision of technical guidance.

The Group also emphasised the need for a decision-making framework to support Members in assessing suspected adverse events and determining appropriate responses and acceptable levels of adverse effects. It recognised that Competent Authorities should retain the right to request follow-up when strong signals are detected, and vaccine manufacturers need to be called upon to assist in these investigations. Decisions should be guided by risk-benefit assessments, recognising that tolerance for vaccine-related adverse effects may vary depending on national ASF control strategies.

Data should be drawn from both field studies and manufacturer reports, with pre-established baseline data used to contextualise observed effects. Reporting systems should consider whether reporting is mandatory or voluntary, the presence of incentives or compensation mechanisms, and the need for user-friendly tools, especially in low-resource settings. The Group noted that structured data collection is generally more feasible in large commercial farms than in smallholder or backyard systems and emphasised that the guidelines should acknowledge this bias and propose strategies to address it.

To help distinguish between expected side effects and the adverse events that should trigger further investigation, the Group recommended that the guidelines include categorised lists of common and uncommon effects (e.g. redness at the injection site, fever, arthritis), accompanied by clear definitions. These should incorporate case definitions specifically adapted to post-vaccination contexts, distinct from those used for official disease notification purpose, defined in Article 15.1.1. of the *Terrestrial Code*.

6.2. Reversion to virulence and recombination

The Group agreed that the guidelines should address the risks of reversion to virulence and recombination by providing practical recommendations on early warning signals, sampling strategies, and appropriate follow-up actions. These risks were recognised as critical concerns that require ongoing monitoring through a combination of field-level observations and laboratory investigations.

Reversion was considered a rare and difficult event to detect in the early post-vaccination phase. Therefore, early warning indicators, such as increased viremia, relatively low PCR Ct values, unexpected clinical outcomes, identification of vaccine virus in tissue (particularly at relatively low PCR Ct values), or adverse reactions, should prompt further investigation. The Group also noted that clinical signs such as fever or malaise may still warrant closer examination even when viral loads appear low.

The Group identified that whole genome sequencing (WGS) as the most reliable method to detect recombination events or confirm deletions beyond known vaccine markers. However, it acknowledged that WGS remains technically demanding, costly, and time-consuming due to the characteristics of the ASF virus (e.g. large genome size, complex structure, and low viral load associated with low virulent and attenuated strains), and may not be feasible in all settings. In the absence of DIVA (Differentiating Infected from Vaccinated Animals) strategies, targeted sequencing was recommended as a practical alternative to support vaccine traceability and post-vaccination surveillance, although the limited sensitivity of such method, in comparison to DIVA test, was acknowledged.

The Group recommended that the guidelines clearly describe the minimum requirements for detecting signs of reversion or recombination. The guidelines should also outline potential indicators that may trigger investigations, such as unexpected clinical patterns or laboratory anomalies, and emphasise that case definitions and signal interpretation must be adapted to local epidemiological contexts. The Group proposed including a decision tree or algorithm to help Veterinary Authority determine when further investigation is warranted. It also noted that signals must be assessed within a broader risk-based surveillance framework that integrates clinical, laboratory, and epidemiological data. Members are encouraged to establish surveillance systems that link field observations with centralised laboratory analysis to enable timely follow-up and confirmation.

6.3. Vaccine effectiveness

The Group emphasised that the Veterinary Authority should be involved in vaccine effectiveness evaluation. While acknowledging that political or institutional constraints may sometimes reduce Veterinary Authority involvement, the Group agreed that its engagement is essential to uphold the credibility, traceability and reliability of findings. Having an independent third-party evaluator was considered a possible option, ideally supported by an independent advisory committee to maintain objectivity and support stakeholder confidence in the effectiveness of the programme.

The Group recommended that the guidelines encourage the use of diverse indicators to assess vaccine effectiveness, recognising that different metrics may be more suitable depending on the type of farming system and on the objectives of the vaccination campaign (namely, mitigating the disease impact or achieving disease eradication). For example, if the objective is to mitigate the disease impact, production parameters may be most applicable, particularly in commercial farms.

7. Other technical considerations

7.1. Technical and financial support of implementation

The Group recognised that successful implementation of the guidelines will require a range of support mechanisms and encouraged WOAH to assist Members in identifying and accessing relevant resources. It recommended that the guidelines include a list of Reference Centres and regional support centres, such as WOAH or FAO national, sub-regional, or regional offices. Institutions with the capacity to support training and evaluation should also be referenced. Additionally, the Group highlighted that the guidelines should convey a message of encouragement, reassuring Members that they are not alone and can seek tailored assistance in applying the recommendations.

The Group further suggested that the guidelines promote collaborative implementation among Members, particularly through joint resource mobilisation and shared field activities.

7.2. Target species and issues related to wild pigs

The Group emphasised the importance of clearly defining the scope of the guidelines from the outset, including the identification of relevant target species. While the guidelines would focus on the use of ASF vaccines in domestic pig population, the Group noted that significant efforts are invested in the developing of ASF vaccines for wild pigs. Concerns were raised about the potential spread of ASF vaccine strains to wild species, particularly wild pigs and vectors. The Group also highlighted the need for DIVA-compatible strategies to support differentiation and traceability once such tools become available.

7.3. Importance of serology

While recognising the practical value of serology in surveillance, the Group agreed that the guidelines should clearly articulate its limitations within ASF vaccination programmes. Neutralising antibodies are not consistently detectable, and no reliable correlation has been established between antibody presence and protective immunity. As such, serology is not suitable for evaluating vaccine efficacy or for monitoring individual animals' post-vaccination. Nonetheless, baseline serological data may still be useful for estimating population-level exposure or tracking the circulation of field strains or vaccine strains in unvaccinated areas. Despite its limitations, the Group agreed that serology contributes meaningfully to broader surveillance efforts, particularly when used alongside other diagnostic methods such as PCR.

In the absence of a reliable DIVA strategy, Members might consider using tools such as ELISA, where feasible, to monitor trends at the group level. Importantly, any interpretation of seroconversion should be aligned with the specific objectives of the vaccination strategy.

7.4. Future updates of the guidelines

The Group noted that the science around ASF vaccines is evolving fast. It recognised the importance of monitoring the implementation of the guidelines, both to evaluate their effectiveness and to identify when updates may be necessary. It considered that feedback from Members and requests for support would offer valuable insights into emerging needs and areas for improvement.

8. Dissemination strategy

The Group recommended a comprehensive dissemination strategy to maximise the impact of the guidelines. This should include targeted communication campaigns to Members such as a launch webinar and dissemination through internal WOAH channels, including the General Session, WOAH publications, and relevant swine disease meetings (e.g. SGE-ASF). The Group also proposed leveraging global research networks such as GARA and STAR-IDAZ.

Dissemination to local stakeholders should be coordinated through WOAH and GF-TADs to ensure effective outreach. To assess the feasibility of the guidelines, the Group suggested piloting them with a selected group of Members prior to broader implementation. Additional recommendations included engaging donors to support capacity-building efforts and collaborating with relevant sectors and partners to enhance awareness and strengthen dissemination activities.

9. Next steps

The Secretariat informed the Group that the consultants will revise the guidelines based on the recommendation of the Group. The guidelines will also be presented to the Biological Standards Commission (BSC) and Scientific Commission for Animal Diseases (SCAD) for their opinion.

…/Annexes

Annex 1. List of Participants

MEETING OF THE *AD HOC* GROUP ON ASF VACCINES:
FIELD EVALUATION AND POST-VACCINATION MONITORING

Paris, 22-24 July 2025

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Annex 2. Terms of Reference

MEETING OF THE *AD HOC* GROUP ON ASF VACCINES:
FIELD EVALUATION AND POST-VACCINATION MONITORING

Paris, 22-24 July 2025

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1. Purpose

The purpose of the *ad hoc* Group is to review the guidelines developed through the WOAH consultancy project on 'Guidelines for ASF vaccines: field evaluation and post-vaccination monitoring' and provide recommendations and experts' opinion on specific aspects identified by the authors.

The *ad hoc* Group is convened under the authority of the Director General of the WOAH.

2. Background

The ongoing spread of African swine fever (ASF) is a matter of concern for the global swine industry – due to its virulent nature and high mortality rate. ASF has been responsible for serious impacts to pig production and economic losses, threats to livelihoods, animal health and welfare and national food security, with knock-on effects on trade and international markets. For many years, the control of ASF has been limited by the lack of an effective vaccine. The research community has been steadfast in developing vaccines, with forefront MLV candidates being approved or tested in some Members, and many others in the development pipeline.

Through a consultancy project under the WOAH, a review paper on the state of play of modified live vaccine candidates was published in November 2022. More recently, under the same consultancy project, draft standards on the manufacture of safe and efficacious vaccines for ASF have been elaborated, and circulated in the report of the WOAH Biological Standards Commission for Member comments.

It is important to equip Members with the tools and guidance necessary to conduct independent vaccine trials to generate the evidence that may (or may not) support the quality parameters such as purity, safety and effectiveness of the vaccine as claimed by the vaccine manufacturers. This data is often required as part of the approval process by vaccine regulatory authorities, prior to authorisation for use as part of the national vaccination campaign.

The choice of the appropriate vaccine and vaccination strategy are also critical to achieve the objective of the vaccination programme. The process of vaccine selection and vaccination needs to be continuously monitored and evaluated to ensure that the vaccination programme fulfils its objectives and contributes to the sustainable control of ASF while optimising the use of the resources. Any adverse impacts, evolution of the circulating strains or generation of recombinant strains should also be closely monitored to inform surveillance, vaccination strategy and other risk mitigation measures.

In such a context, WOAH has launched a consultancy to provide Members with a set of guidelines on the field evaluation of ASF vaccines and how to conduct post-vaccination monitoring. The guidelines should be in accordance with WOAH international standards, written in a manner that is suitable to the target audience, providing clear and practical tools on how to implement the above, using case examples and referring to current international standards when required. The primary target audience for the guidelines would include Competent Authorities involved in the regulatory approval of veterinary vaccines and Veterinary Services.

At the WOAH *ad hoc* Group meeting, the consultants will present the first draft of the guidelines. Based on the feedback from this *ad hoc* Group, the consultants will revise the guidelines and present the second draft to WOAH Reference Laboratory Network for ASF, Biological Standards Commission and Scientific Commission for Animal Diseases for their opinions and subsequently to the WOAH DG for validation.

3. Actions to deliver

The *ad hoc* Group will:

- Review and discuss the draft guidelines on the field evaluation of ASF vaccines and how to conduct post-vaccination monitoring.
- Provide expert opinion and recommendations on the specific technical content of the guidelines identified by the consultants.

4. WOAH Considerations

Ad hoc Group members are expected to be familiar with:

- Draft guidelines
- WOAH international standards in particular, *Terrestrial Manual* Chapter on ASF.
- All other relevant material shared by the WOAH and *ad hoc* Group's members.

5. Expectations

Ad hoc Group members should:

- Sign the WOAH *Undertaking on Confidentiality of Information* (if not done already).
- Complete the *Declaration of Interests* form.
- Read and study in detail all materials provided by the WOAH prior to the meeting.
- Agree on the appointment of the Chair of the Group.
- Contribute to discussions and recommendations on the first draft.

6. Deliverables

Deliverables of this *ad hoc* Group include:

- Provide feedback on the draft guidelines developed through the consultancy.
- Produce a report of the meeting summarising its recommendations within 2 weeks of the meeting.

7. Tentative timeline

An introductory video call will be organised in July 2025 to provide the *ad hoc* Group with the necessary background information including materials to be discussed during the in-person *ad hoc* Group meeting, which will take place from 22nd to 24th July 2025 at WOAH Headquarters in Paris, France.