Food and Agriculture Organization of the United Nations

Guidelines for
African swine fever (ASF)
prevention and control in
smallholder pig farming in Asia

CLEAN CHAIN APPROACH FOR AFRICAN SWINE FEVER IN SMALLHOLDER SETTINGS

USAID
FROM THE AMERICAN PEOPLE

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Abbreviations and acronyms

ACMSF	Advisory Committee on the Microbiological Safety of Food
ASF	African swine fever
ASFV	African swine fever virus
EFSA	European Food Safety Authority
FAO	Food and Agriculture Organization of the United Nations
ILO	International Labour Organization
NGO	Non-governmental organization
OIE	World Organisation for Animal Health
PPP	Public-private partnership
TAD	Transboundary animal disease
USDA	United States Department of Agriculture

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Summary of key points

1. Scope

This guideline outlines the principles of an African swine fever (ASF) clean-chain system for smallholder pig producers in Southeast Asia.

2. Introduction

ASF is a highly contagious viral disease of pigs, causing high morbidity and mortality. Due to limited resources for preventive and control measures and the complexity of the pig value chain, smallholder pig producers are particularly susceptible to ASF virus (ASFV) introduction and spread and thereby devastating socioeconomic consequences from ASF outbreaks. For the same reason, the implementation of risk-based tools that are epidemiologically effective and socioeconomically sustainable (e.g. zoning, compartmentalisation and commodity-based trade) is challenging for smallholder pig production systems.

Considering these challenges, this document proposes a new concept, called a clean-chain system, suitable for smallholders. An ASF clean-chain system aims to ensure the continued production and supply of pigs and pork products irrespective of the prevailing ASF risk situation.

This document defines an ASF clean-chain system as a sub-entity of the pig value chain whose ASFV-free status is maintained through a public-private partnership. This sub-entity works under risk-based tools and standard ASF management concepts adapted to better suit smallholder pig production systems. Such a risk-based approach is guided by the agreed purpose, acceptable level of ASF risk, and standard operating procedures of the ASF clean-chain system laid out in its business plan.

Therefore, its success requires an understanding of (i) ASF epidemiology, (ii) the production system of pigs and pork products, (iii) epidemiological situations, and (iv) establishing a public-private partnership between veterinary authorities and key private sector stakeholders.

3. Setting up an ASF clean-chain system

All partners capable of influencing ASF risk can initiate the process of setting up an ASF clean-chain system as a core group. In general, public partners include governmental organisations such as veterinary authorities, while private partners include pig farmers and other commercial entities in the value chain. These partners should develop a business plan where the ASF clean chain is defined and the steps of its implementation are described. In particular they should agree on the acceptable level of ASF risk, keeping in mind that the ASF risk cannot be reduced to zero.

All partners can benefit from an ASF clean-chain system. For example, private partners will benefit from the reduced risk of losses due to ASF and other production-limiting disease outbreaks, while also befitting from the perception that pigs and pork products produced within the clean-chain system are safe, sustainable and of high quality. Public partners will benefit from reduced ASF risk across the whole pig industry.

The ASF risk context needs to be understood by describing the smallholder value chain for pigs and pork products, and performing a risk assessment for ASFV introduction and spread. Based on risk assessment outputs, risk mitigation measures can then be implemented to reduce the overall risk estimate to, or below, the agreed acceptable level of ASF risk. Such measures fall under the risk management themes of (i) biosecurity, (ii) surveillance, and (iii) identification/record-keeping/traceability.

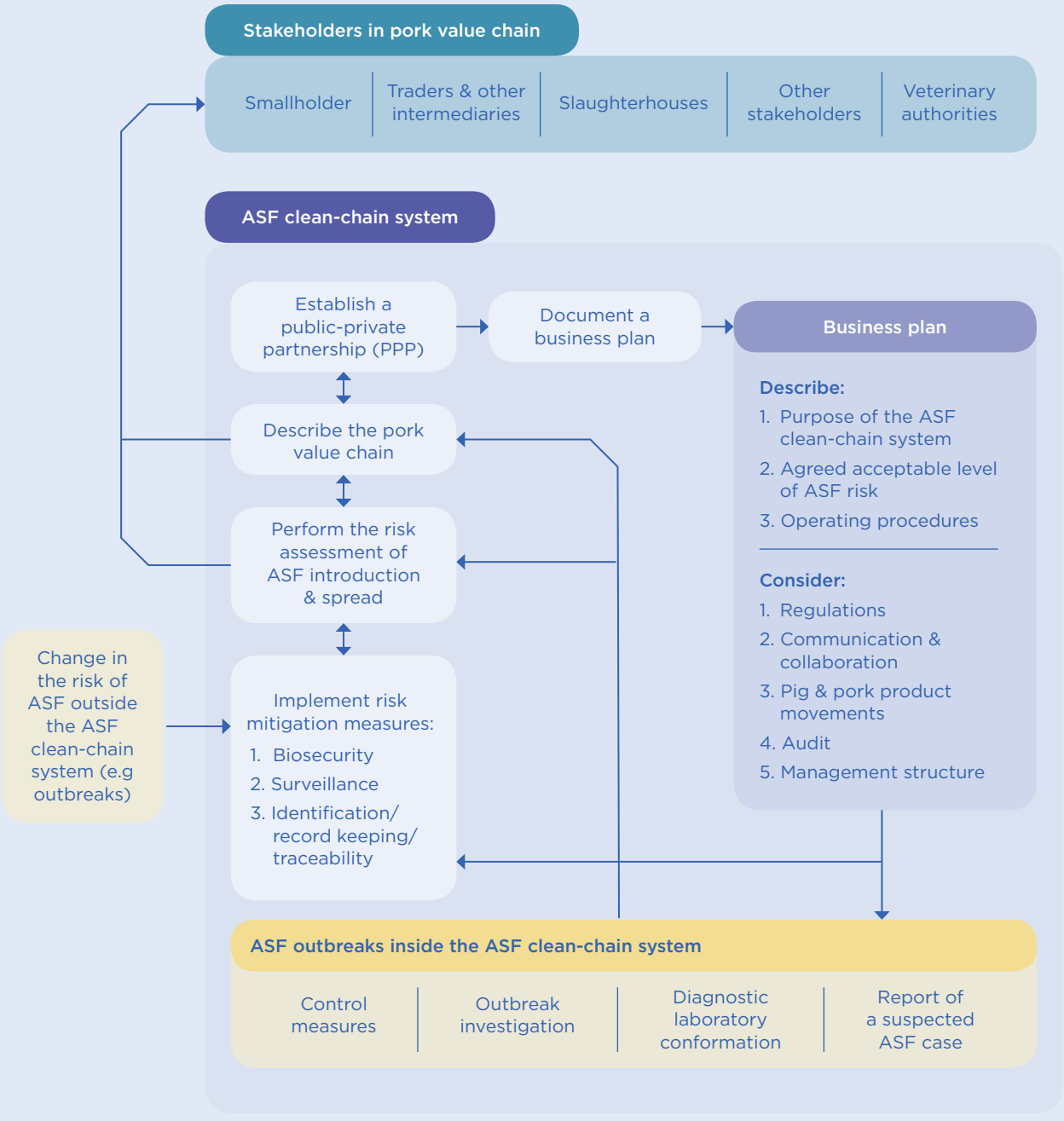
In the event of ASF outbreaks inside the ASF clean-chain system, reporting, diagnostic laboratory confirmation, and epidemiological investigation should be conducted. Control measures should be implemented, as agreed amongst partners. In the event of ASF outbreaks outside the system, risk mitigation measures agreed amongst partners should be implemented.

Therefore, the ASF clean-chain system's business plan will describe: (i) the purpose of the ASF clean-chain system, (ii) the agreed acceptable level of ASF risk, and (iii) standard operating procedures. Such a business plan should consider (i) consistency with regulations, (ii) communication and collaboration amongst partners, (iii) pig and pork product movements to, within, and from the ASF clean-chain system, (iv) auditing the compliance of risk management procedures, and (v) a management structure.

4. Future considerations

> Setting up an ASF clean-chain system should remain practical in smallholder production contexts while reducing the ASF risk to, or below, the agreed acceptable level. A public-private partnership, including the veterinary authority and key stakeholders in the pig value chain, is critical for the success of the ASF clean-chain system.

Mindmap


Stakeholders in pork value chain
Smallholder
Traders & other intermediaries
Slaughterhouses
Other stakeholders
Veterinary authorities
ASF clean-chain system
Establish a public-private partnership (PPP)
Document a business plan
Business plan
Describe:
1. Purpose of the ASF clean-chain system
2. Agreed acceptable level of ASF risk
3. Operating procedures
Consider:
1. Regulations
2. Communication & collaboration
3. Pig & pork product movements
4. Audit
5. Management structure
Describe the pork value chain
Perform the risk assessment of ASF introduction & spread
Change in the risk of ASF outside the ASF clean-chain system (e.g outbreaks)
Implement risk mitigation measures:
1. Biosecurity
2. Surveillance
3. Identification/ record keeping/ traceability
ASF outbreaks inside the ASF clean-chain system
Control measures
Outbreak investigation
Diagnostic laboratory conformation
Report of a suspected ASF case

1 Scope

This guideline outlines the principles of an African swine fever (ASF) clean-chain system for smallholder pig producers in Southeast Asia. This document provides recommendations for smallholder pig production systems on the practical application of good biosecurity management practices necessary for the continued production and supply of commodities along the pork value chain, irrespective of the prevailing ASF risk situation. The concept of an ASF clean-chain system is presented here as a novel approach to ASF control based on an organised public-private partnership. This guideline is intended for all actors involved in this partnership. As the information presented is theoretical, no practical examples are currently available.

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2 Introduction

2.1. ASF in Asia and the Pacific

African swine fever (ASF) is a highly contagious viral disease of pigs, causing high morbidity and mortality (Dixon *et al.*, 2020). The disease has complex epidemiology with the potential for rapid spread in domestic pig populations and devastating socioeconomic consequences (Sánchez-Vizcaíno *et al.*, 2019). Transmission of the ASFV can occur by numerous pathways with risk arising at multiple points of the supply chain. Modes of viral transmission include (but are not limited to) contact with infected live pigs, farm waste materials, pig carcasses and pork products. Furthermore, the ASF virus can remain viable for extended periods in contaminated material. The multi-factorial nature of disease transmission makes ASF a particularly challenging disease to control using individually implemented biosecurity measures. A collective, clean-chain approach involves a toolbox of measures aimed at minimizing the impacts of ASF on stakeholder's livelihoods. The ASF virus (ASFV) continues to spread in Asia and the Pacific where smallholder farms account for approximately 80 percent of the total pig population (Smith *et al.*, 2019; Dixon *et al.*, 2020). This not only threatens the main source of income for local households involved in different parts of the pig value chain, but also the diversity of local wild and domestic pig species. Furthermore, ASF adversely affects the production and trade of pigs and pork products, human nutrition and food security at the global level. There are genuine concerns, particularly amongst stakeholders in the Asian pig industry, about the ability to control and prevent the further spread of the disease. Preventing ASF spread often relies on strengthening border biosecurity; however, while this is indeed necessary, it has not always been successful, especially for low- to middle-income countries where the resources for implementing increased measures are often limited. If the virus does eventually enter the country, it can have a devastating impact on pig population. As a result, many governments, inter-governmental organisations, and non-governmental organisations intend to adopt a more collaborative and regional approach to managing ASF outbreaks. At the local level, taking a collaborative approach for the implementation of an ASF clean-chain system would help with the protection of smallholder pig health and stakeholder livelihood.

2.2. Impact of ASF outbreaks on the smallholder pig industry

In the event of an ASF outbreak, national veterinary authorities implement sanitary measures as an emergency response to contain the outbreak. Once an animal is tested positive on a farm, a control area is immediately established to allow for the implementation of movement restrictions in addition to culling and disposal, decontamination, disinfection and surveillance activities (OIE 2019a, 2019). Also, according to the operating procedures of the national control program, outright trade bans, movement restrictions or bans, and strict biosecurity will be enforced. These control measures may extend to the entire pig population beyond the control area, thereby affecting the value chain of all pigs and pork products. Therefore, controlling ASF outbreaks is not only expensive to governments but also places significant stress on national veterinary service resources. As an example, China's direct economic cost from ASF a year after experiencing the first ASF outbreak amounted to USD 141 billion (Berthe, 2020). In smallholder communities, the pork value chain relies on a high frequency of movement of live pigs and pork products. Therefore, strict outbreak control responses will occasion severe disruption in that sector and these impacts will be exacerbated in the absence of compensation schemes. In addition to the direct cost of increased pig mortalities or ongoing feeding of finisher pigs unable to be transported to slaughter, there may also be indirect costs associated with trade bans, reduced productivity of chronically infected pigs, or difficulties in sourcing replacement pigs. These costs can considerably increase the economic impacts of an ASF outbreak. Consequently, households who depend on pigs for their livelihood are likely to experience significant economic losses and may have to discontinue pig farming.

2.3. Options for continued trade and market access for smallholders in geographical areas with epidemic or endemic ASFV

Zoning, compartmentalisation, and commodity-based trade have been used over the years for international disease risk mitigation (Scott *et al*., 2006; Cowled *et al*., 2019). These risk-based tools have been applied worldwide to manage ASF outbreaks, based on the concepts of traceability, biosecurity, and epidemiological separation of pig sub-populations from potential ASFV sources (Scott *et al*., 2006; Pfeiffer *et al*., 2021). However, these risk-based tools require significant human and capital resources to be epidemiologically effective and socioeconomically sustainable, thus limiting the extent to which they are compatible with smallholder pig production systems. (Cowled *et al*., 2019). This document proposes a new approach, called an ASF clean-chain system, based on an adaptation of these risk-based tools and standard ASF risk management concepts to circumstances particular to smallholders.

2.4. Clean-chain systems in smallholder pig production systems

A pathogen clean-chain system is defined as a sub-entity of the value chain where public and private partners work together to keep their disease-free status and therefore ensure the continued production and supply of commodities. This sub-entity works under risk-based tools and standard pathogen management concepts adapted to better suit smallholder production systems. Such a risk-based approach is guided by the agreed purpose, acceptable level of pathogen risk, and standard operating procedures of the clean-chain system set out in its business plan.

Control measures against a transboundary animal disease (TAD) outbreak often have unintended adverse consequences on the livestock industry. For example, sanitary measures such as quarantine, movement restrictions or transport bans are frequently used to separate infected or exposed animals from uninfected animal sub-populations; however, implementing these measures will inevitably disrupt the value chain. A successfully implemented clean-chain system uses a risk-based approach that can minimise interruptions to trade in animals and their products along the value chain before, during and after TAD outbreak situations.

The effective implementation of a clean-chain system for preparedness, disease management and ultimately business continuity in livestock systems relies on the synergistic operation of several key components. These include epidemiological separation, biosecurity, traceability and surveillance as the core principles upon which the clean-chain system must operate in order to be truly risk-based (Scott *et al*., 2006). In implementing the clean-chain system for disease management, consideration must be given to the epidemiology of the disease agent, the production and trade system and the commodity in question. A clean-chain approach must be tailored to each disease and each particular epidemiological situation to be effective. In the smallholder context, additional considerations need to be given to the socioeconomic factors that directly or indirectly affect the feasibility and uptake of the approach.

The establishment of a public-private partnership between veterinary authorities and key stakeholders is an important prerequisite for the successful implementation of a clean-chain system. Under the clean-chain system, producers act as primary implementers, along with veterinary authorities, consumers and all other stakeholders along the value chain. All stakeholders should engage, and reach an accepted consensus on their individual and collective responsibilities. An essential part of stakeholder engagement is to agree on an acceptable level of disease risk. This risk will be relative to any background disease risks outside the clean-chain system, and cannot be reduced to zero. The objective for all parties involved is to limit any disease risks to, or below, an agreed acceptable level to assure the continued production and supply of commodities for all stakeholders.

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3 Setting up an ASF clean-chain system

The first and most important step of setting up an ASF clean-chain system is to develop a business plan that describes the implementation and maintenance of the clean-chain system (see Section 3.6). This business plan needs to be based on an agreement on the purpose of the ASF clean-chain system and, more specifically, on the acceptable level of ASF risk at which it will operate. This section describes different steps of implementing the ASF clean-chain system that should be set up in the business plan.

3.1. General comments about the approach

The principle of an ASF clean-chain system is to establish a public-private partnership (PPP) between smallholder pig farmers, veterinary authorities and other relevant stakeholders in the pork value chain. It is essential that an appropriate balance is found between scientific rigour and the reality of the situation in the field. For example, smallholder farmers and other local stakeholders must be able and motivated to implement an ASF clean-chain system. Effective communication between all the clean-chain system members is important. For this, it is recommended to organise focus group meetings for setting up an ASF clean-chain system. However, ASF risk management must also be based on sound epidemiological principles. To achieve this, structured scientific risk assessments will inform the risk management approaches with which the ASF clean-chain system will operate. This document outlines the steps that should be included in this process and documented in the business plan (Section 3.6), and proposes how each step can be carried out. Nevertheless, it is ultimately up to the partners involved in the ASF clean-chain system to decide how much depth is required for each step, or whether they need to adapt the approach to specific local circumstances. An effective partnership amongst all those involved in the ASF clean-chain system will be key to its success – this cannot be emphasised enough.

3.2. Relationship with prevailing ASF risk situation

A clean-chain system can be set up in geographical areas that are ASFV free, or those subject to epidemic or endemic ASFV occurrence. The incentives to commit to an ASF clean-chain system are more likely to be understood by partners if they have experienced or witnessed the impact of ASF on smallholder farms. Stakeholders should be aware that the presence of ASFV in the local pork food system will increase the likelihood of ASFV introduction into the ASF clean-chain system, thereby testing the ASF clean-chain system's ability to provide the benefits that partners expect. It should also be emphasised that, even in the absence of ASF, economic incentives will still arise from the overall improvement of biosecurity, disease surveillance and trust between partners (amongst other benefits).

3.3. Establishing a public-private partnership

The principle of an ASF clean-chain system is to establish a public-private partnership (PPP) between smallholder pig farmers, veterinary authorities, and other relevant stakeholders in the pork value chain. The *OIE PPP Handbook: Guidelines for Public-Private Partnerships in the veterinary domain* can be used for guidance in the process of setting up a PPP. The ASF clean-chain system is likely to function as a cooperative, with explicit inclusion of the veterinary authority as a public partner. The International Labour Organization (ILO) provides free online documents courses and videos about participatory approaches to setting up a cooperative (ILO 2019).

NOTE THAT

The My.COOP training package can be used during the process of developing and running an ASF clean-chain system. It is also available as an online interactive self-paced course called My.Coop Smart.

3.3.1. Identifying partners

A group of core actors, such as a collective of smallholder pig farmers, will likely initiate the process of setting up an ASF clean-chain system. These core actors generally include those who perceive potential benefits in establishing an ASF clean-chain system. They are likely to play an initial steering committee role, and may be based on an existing cooperative, or exclusively established to set up an ASF clean-chain system. Later, the primary group should be expanded to involve all private and public partners who can influence the risk of ASFV introduction or spread within the clean-chain system. It is, therefore, imperative to determine the boundaries of the clean-chain system, i.e., which parts of the value chain are to be included and which are not. It may then be necessary to add further partners as it becomes apparent who will be required and who is interested in taking part.

In most cases, public partners are represented by veterinary authorities as they hold a regulatory role in ASF risk management. Other potential partners, additional to pig farmers and veterinary authorities, include transporters, traders, butchers, retailers, or other relevant stakeholders across the value chain.

To set up an ASF clean-chain system, it may be necessary to obtain funding from a government or non-government organisation (NGO), or to obtain credit from a financial institution. Ideally, these organisations may wish to be included as partners.

NOTE THAT

The document "Start-COOP. Module 1 – Identifying Core Members and Business Idea" published by International Labour Organization (ILO) provides guidance for defining the membership of a cooperative using a participatory approach (ILO 2020a). This document is freely available online.

3.3.2. Agreeing on purpose and acceptable level of ASF risk

The ASF clean-chain system can only be successful if all partners are committed and share a common goal. This goal will most likely be to improve ASF risk management by maintaining the risk of ASF occurrence at, or below, an agreed acceptable level while still trading in live pigs and their products. The agreed acceptable level of ASF risk may be relative to 1) the current risk for domestic pig populations in an endemic ASF situation outside the clean-chain system or 2) the potential risk in the case of ASF introduction to the surrounding domestic pig population. Most importantly, partners need to accept that while pig production continues, reducing the ASF risk to zero is not possible. Therefore, partners must determine the expected frequency of ASF introductions/outbreaks over time within the clean-chain system, i.e., the expected number of introductions/outbreaks over a given period (six months, one year, two years or whatever period is considered realistic). Accordingly, an epidemiological and economic management plan must be in place for dealing with such events. This plan may include implementing control measures and providing a compensation policy for affected partners.

Communication about an acceptable level of risk is not easy, because the general expectation is that it will be zero. Discussing the difference between the likelihood of an event occurring and its likely consequences may help partners make a realistic judgment about what they want and can achieve within their ASF clean-chain system. For example, if a qualitative risk scale is being used, such as shown in Annex 1, partners need to realise that the risk of ASFV introduction is not going to be negligible (= 'so rare that it does not need to be considered'), but it should be possible to reduce it to a low (='rare but does occur') and may be even to a very low (='very rare but cannot be excluded') likelihood. Partners also have to recognise that this risk estimate does not yet take into account the consequences of an ASF outbreak. The partners need to decide whether to estimate costs associated with an ASF outbreak. Understanding the potential cost of an ASF outbreak will be useful when reflecting on the business rationale for establishing an ASF clean-chain system.

Establishing an ASF clean-chain system will result in additional fixed and variable costs for the partners, for example, due to enhanced biosecurity. It may be possible to reduce the costs by sharing facilities and therefore costs amongst farmers and other partners as part of a clean-chain system (e.g. common feed, drugs, veterinary services) (Baltenweck *et al.*, 2018; Cowled *et al.*, 2019). For public partners, there will be costs associated with diagnostic testing, auditing etc.

Tangible benefits must offset additional costs; otherwise, the clean-chain system will not be sustainable. Private partners can gain economic benefits from their involvement in the clean-chain system as they are less likely to suffer financial losses from ASF outbreaks. Economic benefits can also include improved market access because live pigs or pork outputs produced within a clean-chain system can be considered of higher quality and safety, therefore fetching a higher price. Furthermore, enhanced biosecurity can also reduce associated losses from other endemic and epidemic production-limiting diseases. For public partners, ASF clean-chain systems can serve the public good as ASF risk will be reduced for the whole pig industry creating greater economic stability and improved food security.

Other possibilities exist for offsetting costs. For example, third parties such as large pig enterprises can benefit from ASF risk reduction within the vicinity of their farms. As a result, they may be prepared to invest in improved biosecurity management for surrounding farms. Another example includes partnering with insurance companies that offer reduced premiums for members of the ASF clean-chain system. In the case of an ASF outbreak, veterinary authorities may consider increasing compensation for members to reimburse them for efforts and investments in implementing the ASF clean-chain system.

NOTE THAT

"Start-COOP. Module 1 – *Identifying Core Members and Business Idea*" and "Start-COOP. Module 2 – *Researching the Feasibility of the Business Idea*" documents are freely available online and are published by ILO. These provide guidance for identifying business ideas and their feasibility for a cooperative using a participatory approach (ILO 2020a, b).

3.4. Understanding the ASF risk context

To prioritise interventions for risk management, it is necessary to examine the eco-social context within which ASFV can be introduced and spread. This context is broadly similar between pig production systems in Southeast and East Asia. However, the relative importance of different drivers of ASFV transmission can still differ between or even within countries. Processes for understanding the ASF risk context should be practical, involve relevant participants, and should not be a purely academic exercise.

The first step in understanding the ASF risk context is to describe the smallholder pig production value chain. The second step is to perform a risk assessment, including describing the risk pathways for ASFV introduction and spread. These steps can be carried out using simple diagrams and limited analysis to produce qualitative risk estimates. This process is essential for ensuring that the clean-chain system business plan (section 3.6) is based on rational decisions. In addition, this allows all partners to be aware of required actions and the risks associated with non-compliance. The boundaries of the clean-chain system should be defined during this process. Eventually, it will become apparent that further actors can influence the risk of ASFV introduction or spread within the clean-chain system and should be invited to join the PPP. All partners should remember that the risk context can change over time and therefore risk assessments should be reviewed or repeated regularly. A detailed methodology of qualitative risk assessment in the context of clean-chain systems is described in Annex 1.

3.4.1. Risk assessment methodology

The purpose of risk assessment is to disaggregate epidemiological processes that result in an adverse event, such as a sequence of conditionally dependent events resulting in ASFV introduction into a farm (OIE 2010; FAO 2011). This can be expressed using one or several risk pathway diagrams. This disaggregation allows for producing meaningful risk estimates and determining where risk mitigation measures can be implemented most effectively and sustainably. The risk assessment process consists of defining risk questions, producing risk pathway diagrams, and estimating the risk associated with each pathway.

To carry out a meaningful risk assessment, it is important to have a good understanding of the local pork value chain and the general principles of pig health management. It is also important to understand the epidemiology of ASFV. The epidemiological features of ASFV in smallholder pig production are summarised in the ASF disease cards published by the OIE (2019b). More detailed information can be found in Sanchez-Vizcaino *et al*., (2019).

The FAO document *Guidelines for African swine fever (ASF) prevention and control in smallholder pig farming in Asia – Farm biosecurity, slaughtering and restocking* describes biosecurity measures relevant to smallholder farming. Further information on farm biosecurity can also be obtained from Alarcon *et al*., (2021) and Dewulf *et al*., (2019).

Conducting an objective, scientific and transparent ASF risk assessment in a clean-chain system can be challenging given the limited resources and expertise available to national veterinary services. Moreover, the assessment must take account of practicality issues and socioeconomic factors relevant in smallholder pig production systems. Such challenges and contexts suggest that a clean-chain system risk assessment could benefit from a participatory approach. A participatory approach involves data collected through focused group discussion. Such discussion is best led by the trusted members of the clean-chain system who hold appropriate technical expertise. Ideally, this means that the veterinary authority should be involved in leading the process. The participatory risk assessment will bring together all actors involved in the smallholder pig value chain as a focus group. Discussions will be held regarding the value chain structure, ASF risk factors, and biosecurity measures amongst this focus group. Based on the findings of these discussions, the veterinary authority should then determine an appropriate means of collecting data and estimating risks associated with different risk pathways in the ASF clean-chain system.

Risk assessments should be repeated at regular intervals to detect any changes in value chains and stakeholder behaviour. The frequency of repetition should be decided during the establishing phase of the ASF clean-chain system and documented in the business plan. This process will also help maintain continued awareness amongst members of the ASF clean-chain system about ASF risks and the importance of compliance with mitigation measures.

3.5. Managing the ASF risk context

The success of the ASF clean-chain system depends on how well any risk mitigation measures are tailored to the specific characteristics of the risk context that are ascertained using the risk assessment. There is often a temptation amongst farmers and animal health specialists to immediately decide on risk mitigation measures without first performing a risk assessment. However, doing this increases the chances of missing important risk pathways for ASFV introduction and spread and, therefore, incorrectly reflecting important risk factors. As a result, it will become difficult to make a rational decision about the relative importance of different risk mitigation measures. Furthermore, deciding on risk mitigation without a risk assessment means not appropriately acknowledging the conditional dependence between the different sequential steps along the risk pathway and how risk mitigation measures can be targeted at key steps 'upstream' along a particular risk pathway for the most effective impact.

The first step in the process of managing the ASF risk context is to compare the overall risk estimate with an agreed acceptable level of risk. If the conclusion is that risk mitigation is required, then the potential for effective risk mitigation along each of the risk pathways and the impact it will have on the overall risk estimate need to be examined. The aim should be to bring the overall risk estimate down to or below an acceptable level of risk.

3.5.1. Risk management themes

There are a number of generic risk mitigation measures that should be considered when setting up an ASF clean-chain system. They can be grouped under the risk management themes of biosecurity, surveillance, and identification/record-keeping/traceability.

It is important to keep in mind that the effectiveness of the risk mitigation measures depends on the compliance of partners responsible for the implementation of each measure (Collineau and Stärk, 2019). The complexity of the value chain and the number of people with different socioeconomic priorities indicate that achieving and maintaining the necessary level of compliance must be a strategic priority of the ASF clean-chain system. Incentives for compliance need to be developed by the partners in the ASF clean-chain system, and they should be supported by regular audits. It is also recommended that biosecurity refresher courses that foster the desired biosecurity behaviours are carried out regularly.

3.5.1.1. Biosecurity

All components of the ASF clean-chain system need to operate at a level of biosecurity that reduces the risk of ASFV introduction into and spread within the ASF clean-chain system by live animals as well as contaminated commodities, such as animal feed, food waste, meat, or fomites. To achieve its desired impact, it is important to prioritise what risk mitigation measures to focus on. There are three key areas for virus circulation, i.e., farms, transport, and slaughter facilities.

3.5.1.1.1. Farm biosecurity

A key requirement for an ASF clean-chain system is that all farms have to achieve and maintain an adequate standard of biosecurity that effectively reduces the risk of ASFV entry into and spread within their farms based on an understanding of the relevant risk pathways. The ASF clean-chain system should develop a biosecurity plan that will form part of its standard farm management procedures. The ASF biosecurity recommendations and tools described in the FAO document *Guidelines for African swine fever (ASF) prevention and control in smallholder pig farming in Asia – Farm biosecurity, slaughtering and restocking* should be taken into consideration. Farm biosecurity consists of external components aimed at preventing disease introduction and internal components aimed at preventing spread within the farm. Table 1 provides an example of the main areas of risk mitigation measures that are associated with external farm biosecurity. Partners involved in the ASF clean-chain system need to assess which measures are relevant, practical, and likely to be effective. Table 2 describes selected risk mitigation measures for enhancing internal farm biosecurity.

The use of quarantine (or segregated confinement) is an essential risk mitigation measure for reducing the likelihood of ASFV introduction into a farm. Live pigs sourced from inside or outside the ASF clean-chain system must be quarantined either at the source and/or the target farm. For the quarantine facilities to be effective, they need to be isolated from other animal facilities, access must be restricted, and cleaning and disinfection protocols need to be followed strictly. To fulfil its purpose, i.e., prevent the introduction of infected pigs into the farm, quarantine measures must be combined with effective surveillance for early detection of infection or disease. The choice of surveillance approach will determine the duration of the quarantine period. For surveillance based on viral detection using a molecular diagnostic test, such as PCR, quarantine periods can be shorter than those in farms conducting surveillance based on the detection of clinical signs alone. Partners in the ASF clean-chain system need to decide which duration is economically and operationally feasible for them. In that process, the incubation period of ASFV (i.e., 4–19 days) must be kept in mind (OIE 2019b).

Table 1. External farm biosecurity: examples of possible risk mitigation measures (see FAO document *Guidelines for African swine fever (ASF) prevention and control in smallholder pig farming in Asia – Farm biosecurity, slaughtering and restocking* for further information)

ASF risk pathway	Possible risk mitigation measures
Neighbouring pig farms	▪ Presence of a physical barrier (natural or artificial) that separates the herd from neighbouring herds
Wild/feral/ free-ranging pigs	▪ Presence of structure to prevent contact with free-ranging and wild boars
Visitors	▪ Prevent access to a farm by casual visitors ▪ Minimise access to farm by professional visitors (transporters, feed suppliers, veterinarians etc.) ▪ Introduce clean and dirty areas in relation to farm access ▪ Strict adherence to cleaning and disinfection protocol by all visitors
Farm staff	▪ Establish a culture of compliance with biosecurity management requirements through regular training, adequate supervision and an effective incentivisation scheme ▪ Introduce clean and dirty areas in relation to farm access ▪ Strict adherence to cleaning and disinfection protocol by all farm staff
Vehicles and equipment	▪ Strict adherence to cleaning and disinfection for visitors ▪ Equipment is not shared between farms ▪ Introduce clean and dirty areas in relation to farm access
Pig introductions	▪ Implement quarantine for any new pig introductions
Ticks (where relevant)	▪ Prevent contact with tick sources

Table 2. Internal farm biosecurity: examples of possible risk mitigation measures (see FAO document *Guidelines for African swine fever (ASF) prevention and control in smallholder pig farming in Asia – Farm biosecurity, slaughtering and restocking* for further information)

ASF risk pathway	Possible risk mitigation measures
Farm staff	▪ Establish a culture of compliance with biosecurity management requirements through regular training, adequate supervision and an effective incentivisation scheme ▪ Strict adherence to cleaning and disinfection protocol for farm staff
Pig flow	▪ Maintain physical separation between different pig production stages (e.g. sows, weaners, growers) ▪ Strict adherence to cleaning and disinfection protocol ▪ Implement an all-in and all-out system
Sick pigs	▪ Introduce sick bay for sick pigs ▪ Keep sick bay isolated from other parts of farms
Dead pig carcases	▪ Safe disposal of pig carcases
Manure	▪ Safe management of manure

3.5.1.1.2 Transport and slaughterhouse biosecurity

One of the most important factors in mitigating ASFV spread along the value chain is effective transport biosecurity (Yoo *et al.*, 2021). Of particular importance are pig and pork product movements associated with slaughterhouses. The veterinary authority, together with the other partners in the ASF clean-chain system, can work with the slaughterhouse operators and transporters to establish appropriate procedures that will minimise the risk of ASFV spread via transport and people. It is recommended that a system of protocols and audits be developed to maintain ASF risk posed by these contacts below the agreed acceptable level for the ASF clean-chain system. This may include issuing transport permits to slaughterhouses following periodic audits of their transport biosecurity.

3.5.1.2 Surveillance

Surveillance in an ASF clean-chain system must be aimed at early detection of ASFV infection after introduction into any of its components, most likely pig farms. Another objective is to reassure external stakeholders that ASFV is absent within the system or the commodities produced by it, or at least the risk of ASFV presence is at or below the agreed acceptable level. This means that the performance of a surveillance system needs to achieve a certain level of sensitivity, timeliness, and representativeness, which has to be agreed upon amongst partners in the ASF clean-chain system. An example of target performance parameters might be a 95 percent sensitivity of detecting ASFV no later than seven days following introduction into the ASF clean-chain system.

During the implementation of the surveillance system, the partners in the ASF clean-chain system need to consider the feasibility, sustainability and cost-effectiveness of various possible components. They can refer to the ASF surveillance recommendations and tools described in the FAO document *Guidelines for African swine fever (ASF) prevention and control in smallholder pig farming in Asia – Surveillance for monitoring of ASF*.

The findings from the risk assessment will inform key steps along the risk pathways where surveillance components should be introduced. This allows for the implementation of risk-based surveillance, thereby enhancing cost-effectiveness (OIE 2015; Backx *et al*., 2016).

The ASFV surveillance conducted by the veterinary authority in the geographical region where the ASF clean-chain is located generates essential information for effective ASF risk management. If ASFV infection has been identified in the area surrounding the ASF clean-chain system, additional risk mitigation may be required to prevent ASFV introduction into the system.

It is the responsibility of the veterinary authority to supervise all surveillance activities in and outside of ASF clean-chain systems. The veterinary authority has to ensure that the system of reporting allows for immediate notification following ASF suspicion in any part of the ASF clean-chain system. At the level of the ASF clean-chain system, roles should be clearly identified for reporting ASF suspicion. After confirmation of ASF, the veterinary authority must notify all relevant stakeholders.

NOTE THAT

The FAO document *Guidelines for African swine fever (ASF) prevention and control in smallholder pig farming in Asia – Surveillance for monitoring of ASF* should be consulted for detailed recommendations on ASFV surveillance in smallholder pig farms.

3.5.1.3. Identification, record keeping and traceability

Another important requirement for establishing an ASF clean-chain system is the existence of a practical method for identifying and tracing pigs and their products. This is a key animal health tool normally employed to manage disease control, surveillance, trade and food safety activities (OIE 2019a). In an ASF clean-chain system, the identification and traceability of pigs and pork products can ensure that all commodity movements along the value chain traced at any point in time in either direction. Partners need to agree on a reliable system that is practical and cost-effective.

Record keeping by smallholder farmers and other actors involved in the ASF clean-chain system is an important requirement for effective ASF risk management (USDA 2016). As a minimum, this needs to be about pig production, but it is encouraged to also maintain records on production inputs, personnel traffic and the movement of equipment, as that will be required for forward and backward tracing as part of an epidemiological outbreak investigation.

3.5.2. Response to ASF occurrence

3.5.2.1. ASF outbreaks inside the ASF clean-chain system

The veterinary authority and the members of the ASF clean-chain system need to agree on how to handle the occurrence of ASFV infection within the ASF clean-chain system. This is an important process during the establishment phase of the ASF clean-chain system. An appropriate balance must be found between protecting members' livelihoods, food security, the level of biosecurity implemented, and the needs of pig farmers within and outside the ASF clean-chain system in the event of ASFV introduction. The outcome of that process will be one of the most important considerations for or against the involvement of farmers and other actors in the ASF clean-chain system.

Step 1 Partners in the ASF clean-chain system will have an agreement regarding trigger events for reporting suspected ASF occurrence to the veterinary authority. Trigger events may include single or multiple animals showing suspect clinical signs, or an aggregate parameter, such as increased morbidity/mortality at the group or herd level. Therefore, the first step in response to a suspected ASF case will be detection and reporting of a trigger event.

Step 2 In response to reporting, the veterinary authority will investigate the presence of ASFV infection, based on diagnostic laboratory confirmation. While this is undertaken, the veterinary authority can decide whether to halt all movements of pigs from the farm and enhance biosecurity measures. It may also be necessary to apply these measures to all farms and other components of the ASF clean-chain system, such as transporters and slaughterhouses.

Step 3 After the diagnosis is confirmed, the veterinary authority will conduct an epidemiological investigation to determine the extent of the outbreak, its likely source (tracing back), and to where the infection may have spread from this farm (tracing forward).

Step 4 The findings from the epidemiological outbreak investigation will inform the next steps in the outbreak response, including what measures to take on the infected farm and the ASF clean-chain system as a whole. This is a critical decision-making point where the veterinary authority must work with other partners to provide an appropriate balance between the interests of the community involved, and those within and outside the ASF clean-chain system. It is important to have agreed upon control strategies for outbreak scenarios prior to an actual outbreak event. Key decisions include the extent of culling of clinically diseased or in-contact pigs, the duration of movement restrictions, and restocking rules.

NOTE THAT

The FAO document *Guidelines for African swine fever (ASF) prevention and control in smallholder pig farming in Asia – Culling and disposal of pigs in an ASF outbreak* can be consulted for technical details.

3.5.2.2. ASF outbreaks outside the ASF clean-chain system

Risk management strategies to be implemented within the ASF clean-chain system during outbreak situations outside the system must be agreed on in advance of such an event. These strategies should be agreed between veterinary authorities and the other partners. A key rationale for involvement in the system will be the ability to continue to trade during ASF outbreaks outside the ASF clean-chain.

Enhanced biosecurity measures may be required to facilitate continued trade and protect the ASF clean-chain system from ASFV introduction. This may include limiting or even halting the movement of live pigs, pig feed, vehicles and personnel between farms and other facilities involved in the system. During periods of increased risk, it may be necessary for the veterinary authority and other partners to audit the biosecurity measures implemented in the ASF clean-chain system.

NOTE THAT

The FAO document *Guidelines for African swine fever (ASF) prevention and control in smallholder pig farming in Asia – Farm biosecurity, slaughtering and restocking* provides an ASF-specific biosecurity checklist that can be used to evaluate biosecurity in the ASF clean-chain system with the help of a trained official.

3.6. Content of the business plan

It is always recommended that the ASF clean-chain system has a documented business plan. This should clearly identify the purpose of the system, agreed acceptable risks and its operating procedures, including the measures to be taken in response to an ASF outbreak inside or outside the clean-chain system.

A business plan is essential for identifying an effective mode of operation for the ASF clean-chain system. The plan must be reviewed and, if necessary, revised regularly. Business plan reviews can be conducted by the partners and may also involve external stakeholders. Regular annual reviews are recommended; however, during the initial stages of implementation, they may be required more frequently.

NOTE THAT

The freely available online document "Start-COOP. Module 3 – *Preparing the Business Plan*" published by ILO guides producing the business plan for a cooperative using a participatory approach (ILO 2020c).

Issues that should be considered for inclusion or referencing in the ASF clean-chain business plan are outlined below.

3.6.1. Regulations

It is assumed that the veterinary authority is mandated under a specific legal provision that allows them to implement disease control policies. They must ensure that the implementation of ASF clean-chain systems is consistent with the legislation.

3.6.2. Communication and collaboration

The implementation and sustainability of an ASF clean-chain system are dependent on the knowledge and attitudes of partners in relation to ASF risk pathways and how technical interventions and behavioural change must be used to mitigate risk. This means that there has to be effective communication amongst partners, including the veterinary authority. Such communication must involve the development of technical knowledge and deal with the motivations and barriers for actors within the ASF clean-chain system to adopt and reliably implement appropriate risk mitigation measures (Collineau and Stärk, 2019).

The successful implementation and sustainability of an ASF clean-chain system requires active collaboration between its partners, i.e., those from the smallholder pig value chain and the veterinary authority.

3.6.3. Pig and pork product movement

The safe movement of live pigs and their products is a key requirement for achieving the purpose of the ASF clean-chain system. There are three broad categories of such movements, including (i) live pigs into the ASF clean-chain system, (ii) pig or pork product movements inside the system, and (iii) all such movements away from the ASF clean-chain system. Partners should agree on how these movements can be managed to maintain the risk of ASFV introduction and spread at or below the agreed acceptable level of risk. A risk-based transport permit process is described in Umber *et al*., (2019).

3.6.4. Audit

The utility of an ASF clean-chain system for all stakeholders is dependent on their trust in its risk management. A reliable auditing process will be key to generating and maintaining the trust. Auditing can be performed by the veterinary authority or an independent auditor as agreed by all partners in the ASF clean-chain system. Auditors will check the compliance of actors in the ASF clean-chain system using risk management procedures, including biosecurity, surveillance, pig identification, traceability and record keeping. All partners need to agree on the frequency of audits and be aware that an auditing process will critically influence the clean-chain system's credibility with external stakeholders.

Standardised checklists can be used to perform audits. As an example, the biosecurity and surveillance audit checklist may be adapted from the checklist provided in the FAO document *Guidelines for African swine fever (ASF) prevention and control in smallholder pig farming in Asia – Farm biosecurity, slaughtering and restocking* The results of the risk assessment should be used to tailor the checklist to local conditions.

3.6.5. Management structure

For the ASF clean-chain system to achieve its purpose in a sustainable fashion, it is essential that the partners agree on an effective management structure. It is recommended that the clean-chain system is led by a steering committee that can direct and perform all the steps described above.

NOTE THAT

The open access online document Start-COOP. Module 4 – *Organizational Setup* published by ILO outlines how to set up the management structure of a cooperative using a participatory approach (ILO 2020d).

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4 Future considerations

This document outlines the principles and processes for setting up an ASF clean-chain system that aims to facilitate the continuity of pig and pork product trade in smallholder pig production contexts. As a new concept, it is proposed to work under risk-based tools and risk management concepts adapted to better suit smallholder pig production systems. Therefore, the clean-chain system's implementation must be based on sound risk assessment and management approaches, whilst considering specific local circumstances, for its effective, practical, and sustainable implementation. Most importantly, the partners must agree on the acceptable level of ASF risk, acknowledging that the ASF risk cannot be reduced to zero.

For the ASF clean-chain system to be viable, the reduced ASF risk within the system must deliver economic benefits to its partners through a public-private partnership. Stakeholders who are capable of influencing the risk of ASFV introduction and expect potential benefits from the system can initiate its implementation as a group of core actors. A cooperative of smallholder pig producers could be a good example of these core actors, considering that its purpose is to deliver economic benefits to its members, similar to the motivations for clean-chain implementation, and the structure and size of a cooperative likely allow participation in decision-making processes and dynamic adaptations to changing the ASF risk context. The veterinary authority must be involved as a public partner because ASF control, including the response to outbreak occurrences, is their responsibility. It is also essential that if an ASF outbreak occurs within the ASF clean-chain system, processes have been agreed upon with the veterinary authority so that effective control measures can be implemented, enabling the system to continue its pig and pork product trade promptly.

Annex 1: Methodology of risk assessment and risk mitigation in the context of clean-chain systems

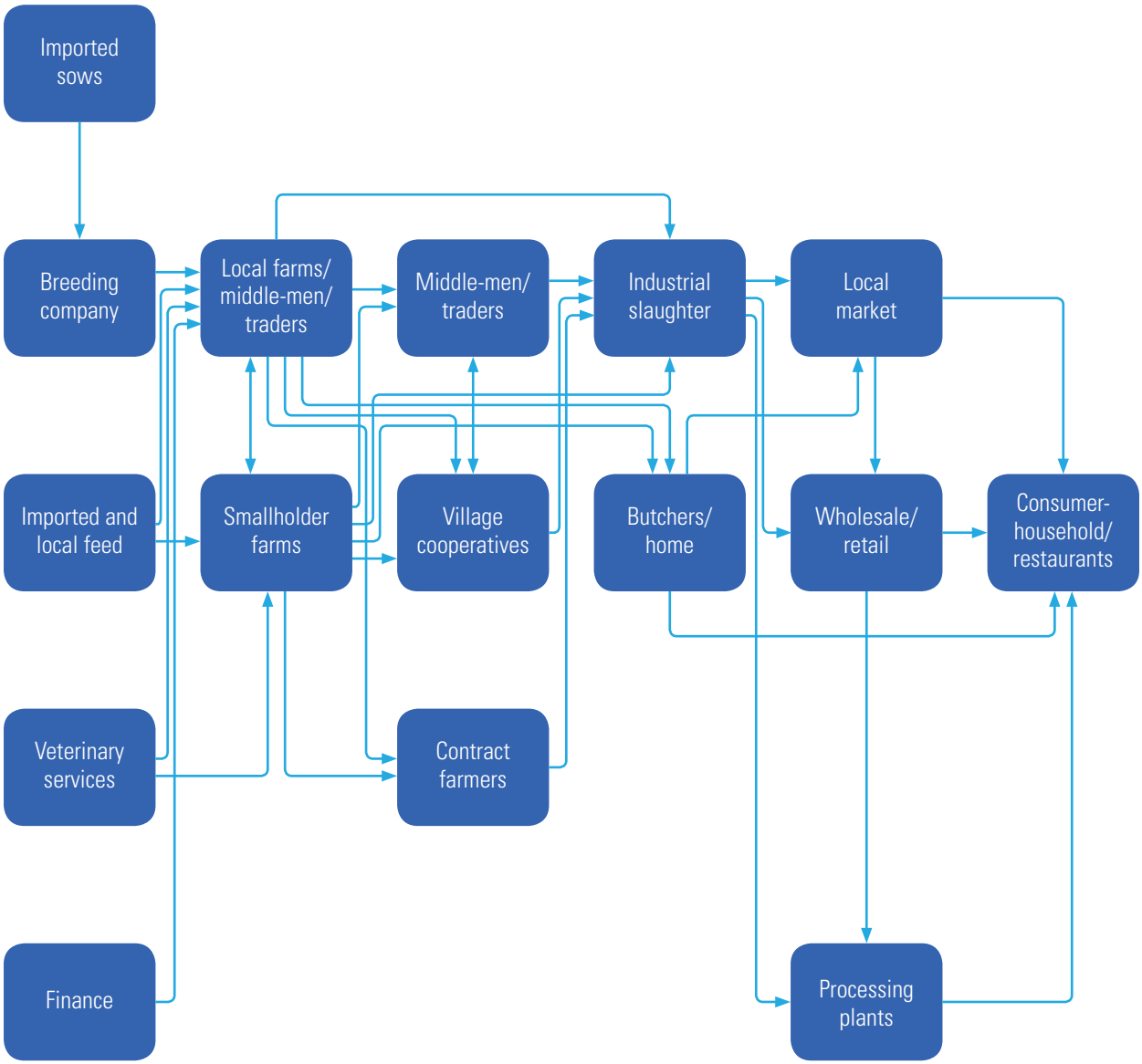
This annex describes the different steps of the risk assessment and risk mitigation that need to be performed before initiating the clean-chain system.

1. Describing the smallholder value chain for pigs and pork products

The first step is to understand the value chain for pigs and pork products in the local environment where the clean chain system will be implemented. The aim is to produce a value chain diagram that describes various steps involved in processing pigs and pork products and delivering pork products to consumers. Therefore, the diagram typically starts with pig farms and finishes off with consumers, and all steps in-between are connected by directional arrows (see Figure A1). It is also necessary to identify the actors involved in the process since they may have a role in ASF risk management. In smallholder pig value chains, the common main actors include input and service providers for pig production, pig producers, pig collectors or traders (including middlemen), slaughter unit operators, butchers, wholesalers, retailers and consumers (Baltenweck *et al.*, 2018; Qiu *et al.*, 2020). The smallholder value chain may often be isolated from larger pig producers. But if there exists a link with large commercial pig farms through feed, live pigs, people or anything else, that fact needs to be reflected in the value chain diagram.

The smallholder value chain in resource-poor settings often has limited genetic input services but diverse commercial feed supplies via a network of actors (Baltenweck *et al.*, 2018). Many smallholder producers source piglets from their own sows, while some may source piglets either locally or from other regions. Feed inputs include swill, self-prepared feed from local maize produce, forage crops and commercial feed. Most smallholder pig producers rely on a mixture of feed types and sources. Producers may receive the feed directly from commercial suppliers via small vans and motorbikes. Some value chain actors are involved in more than one process within the smallholder pig value chain. Some producers may deal directly with retailers to slaughter, butcher and sell their pigs as pork. However, in most cases, middlemen and collectors play a crucial role in trading live pigs between producers and slaughter units. These actors may use their own forms of transport or commercial transport (e.g. drivers specialised in livestock transport services) to and from live pig markets. In particular, pigs and pork products from ASF clean-chain systems can be mixed with those from other pig farms in live pig markets, posing an increased risk of ASFV introduction. Therefore, the role of live pig markets, traders, intermidiaries and collectors in ASFV introduction and spread cannot be overstated (Baltenweck *et al.*, 2018; Qiu *et al.*, 2020). Finally, wholesalers and retailers then become the main linkage from slaughter units to consumers.

Figure A1. An example of a smallholder pig value chain



2. Assessing ASF risk

2.1. Defining risk questions

The agreed purpose of the ASF clean-chain system is likely to minimise the likelihood of introduction of ASFV into and spread within the ASF clean-chain system. This has to be translated into one or more risk questions, depending on what risk pathways are being considered. The partners involved in the ASF clean-chain system may wish to focus on one or two main risk questions to prevent the task from becoming too time-consuming or complex. Further risk questions could then be added at a later stage, once the partners are comfortable with the utility of the approach. The complexity of the risk questions is also up to the partners in the ASF clean-chain system, and in fact, they may decide to simplify further the example risk questions shown below to make communication amongst the partners easier:

Risk question A What is the likelihood that the introduction of live pigs via legal trade from a farm outside the ASF clean-chain system will result in at least one pig on one of the smallholder farms inside the ASF clean-chain system becoming infected with ASFV per year?

Risk question B What is the likelihood that vehicles used for transport of live pigs to the slaughterhouse outside the ASF clean-chain system will result in at least one pig on one of the smallholder farms inside the ASF clean-chain system becoming infected with ASFV per year?

Risk question C What is the likelihood that pig feed introduced from outside the ASF clean-chain system will result in at least one pig on one of the smallholder farms inside the ASF clean-chain system becoming infected with ASFV per year?

Risk question D What is the likelihood that transport of live pigs within the ASF clean-chain system from one smallholder farm to another will result in at least one pig on at least one receiving smallholder farm becoming infected with ASFV per year?

NOTE THAT

The transport of pigs and pork products within the pig value chain and into the clean-chain system has to be considered to be one of the most important factors influencing the risk of ASFV contamination of outputs from an ASF clean-chain system. It is therefore important to perform a risk assessment for ASFV that considers the risk pathways associated with live pig transport to smallholder farms or from such farms to slaughterhouses and pork transport to wholesalers, retailers, or consumers (Scott *et al.*, 2006; Ramirez and Zaabel, 2012; Patterson *et al.*, 2016)

2.2. Developing risk pathway diagrams

Based on a combination of knowledge about ASF epidemiology and the value chain, a risk pathway diagram has to be developed for each of the risk questions to describe the underlying epidemiological process as a sequence of steps. This activity is also important as it visualises the mechanisms for ASFV introduction into and spread within the ASF clean-chain system and thereby helps strengthen compliance with risk mitigation measures. The sequential stepwise structure of risk pathway diagrams needs to be used to communicate the importance of 'upstream' activities in determining ASF risk 'downstream'. An actor in the value chain influencing 'upstream' events can therefore have critical importance for effective risk management, which the respective actor may not be aware of.

This step in the risk assessment process can be completed using generic risk pathway diagrams provided below, but they may have to be adapted to the characteristics of the local ASF risk context. As indicated in the previous section, it may be sensible to start with 1 or 2 risk questions and then produce one risk pathway diagram per risk question. Table A1 shows examples of possible risk pathway diagrams for the risk questions proposed above.

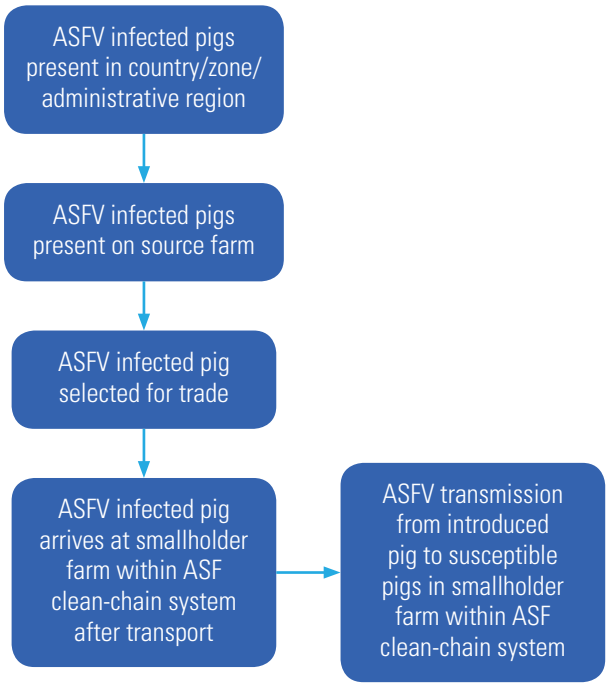
NOTE THAT

These example risk pathway diagrams are very simple, and during the discussion with the clean-chain partners, it is likely that other important steps in the risk pathways become apparent. If this happens, it should be seen as a success because it means that the participatory engagement with the partners has worked. It is likely that at the start of the risk assessment process, some, most or all of the partners struggle with the concept of risk. It is the role of the veterinary authority staff to guide the ASF clean-chain partners through the process of developing an understanding of risk.

Furthermore, these risk questions deliberately do not have any specific risk mitigation measures included. They will be added when planning the risk management.

Table A1. Example risk pathway diagrams for selected risk questions

A: What is the likelihood that the introduction of live pigs via legal trade from a farm outside the ASF clean-chain system will result in at least one pig on one of the smallholder farms inside the ASF clean-chain system becoming infected with ASFV per year?



B: What is the likelihood that vehicles used for transport of live pigs to the slaughterhouse outside the ASF clean-chain system will result in at least one pig on one of the smallholder farms inside the ASF clean-chain system becoming infected with ASFV per year?

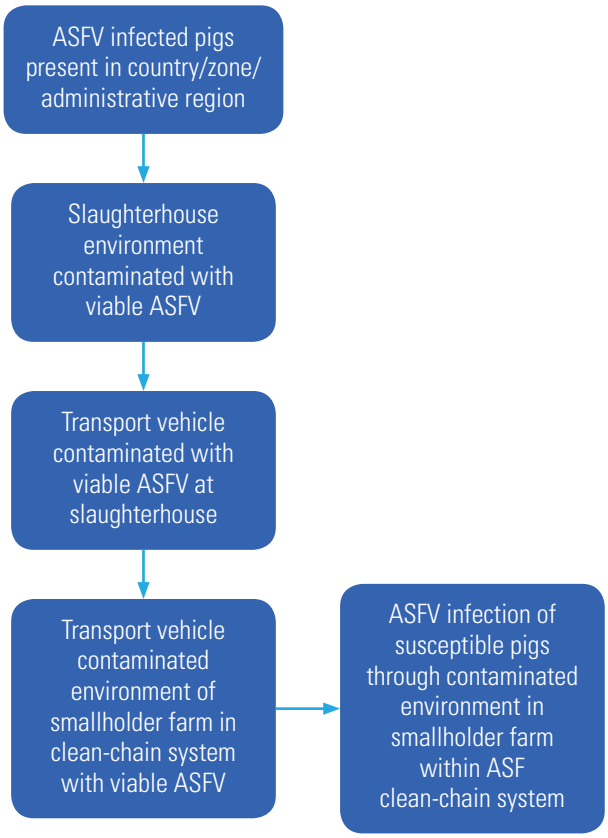
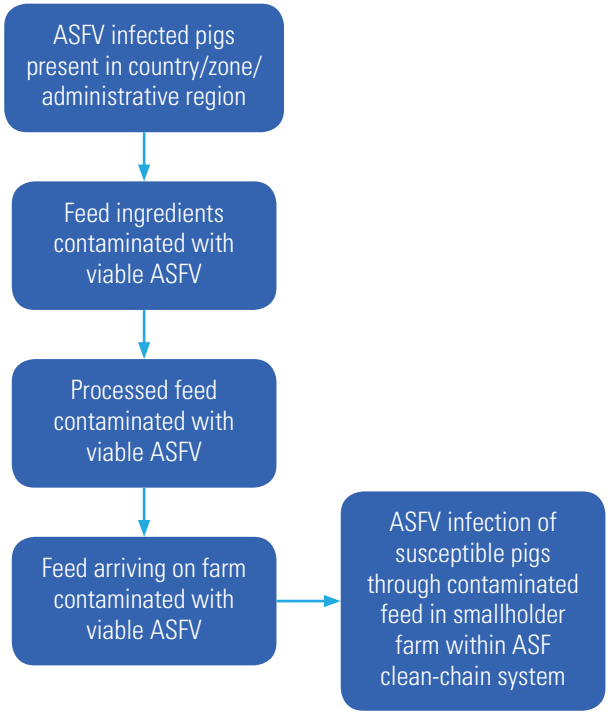
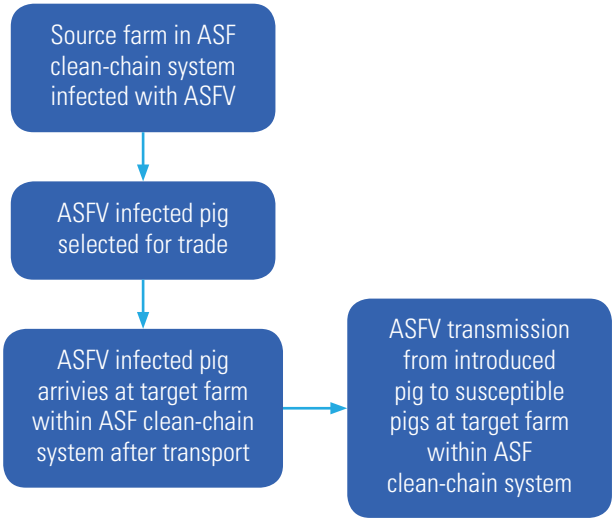


Table A1. Example risk pathway diagrams for selected risk questions *(continued)*

C: What is the likelihood that pig feed introduced from outside the ASF clean-chain system will result in at least one pig on one of the smallholder farms inside the ASF clean-chain system becoming infected with ASFV per year?



D: What is the likelihood that transport of live pigs within the ASF clean-chain system from one smallholder farm to another will result in at least one pig on at least one receiving smallholder farm becoming infected with ASFV per year?



2.3. Estimating ASF risk

The risk estimation process is important because, first, it determines the level of risk, which should then be compared with the agreed acceptable risk for the ASF clean-chain system. Second, it allows an assessment of the effectiveness of any existing risk mitigation measures, which should then inform decisions about potential areas along the risk pathway where additional risk mitigation measures should be introduced to reduce the risk level.

NOTE THAT

It is up to the partners involved in the ASF clean-chain system to decide how detailed this part of the risk assessment process will be.

The first part of the risk estimation process is to define data needs and identify data sources based on risk pathway diagrams. The second part is to collect data and assess their completeness and accuracy. The third part will be to estimate the likelihood at each step, and the fourth part is to combine them into an overall risk estimate for the risk pathway. And if there are several independent risk pathways, such as the example risk pathways A, B, and C, it may be necessary to include the fifth part for combining the risk estimates into an overall risk estimate that can then be considered against the agreed acceptable risk.

2.3.1. Risk estimation part 1 – Determine data needs and identify data sources

Table A2 shows the data needs for risk question A. It is often only possible to develop qualitative expressions for these values. The likelihood and uncertainty categories listed in Table A3 and Table A4 can be used. After defining data needs, potential sources of such data need to be identified.

Table A2. Data collection needs to be associated with risk question A "What is the likelihood that introduction of live pigs via legal trade from a farm outside the ASF clean-chain system will result in at least one pig on one of the smallholder farms inside the ASF clean-chain system becoming infected with ASFV per year?"

Steps along risk pathway	Data collection needs
ASFV infected pigs present in country/zone/ administrative region where source farm is located	ASFV infection status of the geographical area where the source farm is located
ASFV infected pigs present on the source farm	Prevalence of ASFV infected farms in the geographical area of origin, and potential differences in prevalence between farm types, biosecurity measures on the source farm
ASFV infected pig selected for trade	Prevalence of ASFV on source farm, use of diagnostic testing and quarantine for pigs to be traded
ASFV infected pig arrives at smallholder farm within ASF clean-chain system after transport	Information on transport duration, pig mortality etc., and diagnostic testing and quarantine measures during transport or after arrival
ASFV infected pig infects other pigs at target farm	Incubation period of ASFV, virus shedding, infectiousness, survival of infected pigs, virus survival in environment

2.3.2. Risk estimation part 2 – Data collection and assessment

The data need to be collected from the identified sources, and their completeness and accuracy assessed. If the collected data were considered incomplete and/or inaccurate, it should be considered when assessing uncertainty associated with likelihood estimates. An example of uncertainty categories is presented in Table A4.

2.3.3. Risk estimation part 3 – Estimate likelihood and uncertainty for each step along the risk pathway(s)

Here, the data collected for each step along the risk pathway will be used to produce a likelihood estimate for that particular step. It is important that this involves looking only at each step, and it is not about combining the likelihood estimates of that step with those of previous steps. That will happen in part 3 of the risk estimation process.

Table A3 shows an example of different qualitative likelihood categories and their interpretation that can be used in the risk assessment. Table A4 shows an example of different uncertainty categories. For both tables, the number of categories and their interpretation can be changed by the partners involved in the ASF clean-chain system.

Table A3. Definitions of qualitative likelihood categories

Likelihood estimate	Definition
Negligible	So rare that it does not need to be considered
Very low	Very rare but cannot be excluded
Low	Rare but does occur
Medium	Occurs regularly
High	Occurs very often
Very high	Almost certainly occurs

Source: European Food Safety Authority (EFSA), 2006; Advisory Committee on the Microbiological Safety of Food (ACMSF), 2019

Table A4. Example of qualitative categories for expressing uncertainty in relation to qualitative risk estimates

Uncertainty category	Interpretation
Low	There are solid and complete data available; strong evidence is provided in multiple references; authors report similar conclusions. Several experts have multiple experiences of the event, and there is a high level of agreement between experts.
Medium	There are some but not complete data available; evidence is provided in a small number of references; authors report conclusions that vary from one another. Experts have limited experience of the event and/or there is a moderate level of agreement between experts.
High	There are scarce or no data available; evidence is not provided in references but rather in unpublished reports or based on observations, or personal communication; authors report conclusions that vary considerably between them. Very few experts have experience of the event and/or there is a very low level of agreement between experts.

Source: Fournié *et al.*, 2014

Table A5 presents the likelihood and uncertainty estimates with their justification for each of the steps along the risk pathway. It needs to be kept in mind that each of the steps, except for the first one, assumes that the event of interest, in this case, ASFV infection, has happened at the previous step. So, the likelihood for the step "ASFV infected pig selected for trade" assumes that there is an infection on the farm. It is also worthwhile to consider at this stage whether some of the likelihood estimates may be too low or too high, for example, where we can be confident that the level of biosecurity on the source farm is sufficiently high to keep infection out reliably. Based on the assessment of the collected data, one could argue that it may be more appropriate to give it a low (='rare but does occur') rather than a very low (='very rare but cannot be excluded') likelihood. Others could also produce different likelihood estimates with their own justification. These types of discussions should be held amongst the partners when performing these risk assessments.

Table A5. Likelihood and uncertainty estimation for each step along the risk pathway for risk question A "What is the likelihood that introduction of live pigs via legal trade from a farm outside the ASF clean-chain system will result in at least one pig on one of the smallholder farms inside the ASF clean-chain system becoming infected with ASFV per year?

Steps along risk pathway	Data collection needs	Likelihood estimate	Uncertainty	Justification
ASFV infected pigs present in country/ zone/ administrative region where source farm is located	ASFV infection status of the geographical area where the source farm is located	Medium	Low	The source farm is located in a neighbouring province where ASF outbreaks occur on a regular basis.
ASFV infected pigs present on the source farm	Prevalence of ASFV infected farms in the geographical area of origin, and potential differences in prevalence between farm types, biosecurity measures on the source farm	Low	Medium	The source farm has never experienced ASF outbreaks and has good biosecurity.
ASFV infected pig selected for trade	Prevalence of ASFV on source farm, use of diagnostic testing and quarantine for pigs to be traded	Medium	Medium	The source farm does not use diagnostic testing or quarantine prior to transport.
ASFV infected pig arrives at smallholder farm within ASF clean-chain system after transport	Information on transport duration, pig mortality etc; Incubation period of ASFV, survival of infected pigs; diagnostic testing and quarantine measures during transport	High	Low	There is no quarantine on the target farms, there is no diagnostic testing, and there is very low mortality during transport.
ASFV infected pig infects other pigs at target farm	Incubation period of ASFV, virus shedding, infectiousness, survival of infected pigs, virus survival in environment	High	Low	Infected pigs are likely to shed large amounts of virus, ASFV can survive for several days to weeks in environment.

2.3.4. Risk estimation part 4 – Estimate overall risk for the risk question(s)

Using the risk combination matrix shown in Table A6, the likelihoods between successive steps have to be combined to estimate the overall likelihood or risk of ASFV infecting susceptible pigs on the smallholder farm involved in the ASF clean-chain system. The result of that process is shown in Table A7 in the column "Combined likelihoods". The result of the estimation process for the likelihood that the introduction of live pigs via legal trade from a farm outside the ASF clean-chain system results in at least one pig on one of the smallholder farms inside the ASF clean-chain system becoming infected with ASFV per year is 'low'.

Table A6. Matrix used for combining two conditionally dependent qualitative likelihoods in that Likelihood 2 is conditionally dependent on Likelihood 1

Likelihood 1	Likelihood 2					
	Negligible	**Very low**	**Low**	**Medium**	**High**	**Very high**
Negligible	Negligible	Negligible	Negligible	Negligible	Negligible	Negligible
Very low	Negligible	Very low	Very low	Very low	Very low	Very low
Low	Negligible	Very low	Low	Low	Low	Low
Medium	Negligible	Very low	Low	Medium	Medium	Medium
High	Negligible	Very low	Low	Medium	High	High
Very high	Negligible	Very low	Low	Medium	High	Very high

Source: Gale *et al.*, 2010; Peeler *et al.*, 2015

Table A7. Combining likelihoods between steps along the risk pathway for risk question A "What is the likelihood that introduction of live pigs via legal trade from a farm outside the ASF clean-chain system will result in at least one pig on one of the smallholder farms inside the ASF clean-chain system becoming infected with ASFV per year?

Steps along risk pathway	Data collection needs	Likelihood estimate	Justification	Uncertainty
ASFV infected pigs present in country/ zone/administrative region where source farm is located	ASFV infection status of the geographical area where the source farm is located	Medium	The source farm is located in a neighbouring province where ASF outbreaks occur on a regular basis.	
ASFV infected pigs present on the source farm	Prevalence of ASFV infected farms in the geographical area of origin, and potential differences in prevalence between farm types, biosecurity measures on the source farm	Low	The source farm has never experienced ASF outbreaks and has good biosecurity.	Medium * Low = Low
ASFV infected pig selected for trade	ASFV prevalence within infected farms	Medium	Once ASFV has been introduced to the farm, it is likely to spread widely within the farm.	Low * Medium = Low
ASFV infected pig arrives at smallholder farm within ASF clean-chain system after transport	Information on transport duration, pig mortality etc.; Incubation period of ASFV, survival of infected pigs; diagnostic testing and quarantine measures during transport	High	There is usually very low mortality during transport, no diagnostic testing.	Low * High = Low
ASFV infected pig infects other pigs at target farm	Incubation period of ASFV, virus shedding, infectiousness, survival of infected pigs, virus survival in environment.	High	Infected pigs are likely to shed large amounts of virus, ASFV can survive for several days to weeks in environment	Low * High = Low
What is the likelihood that introduction of live pigs via legal trade from a farm outside the ASF clean-chain system will result in at least one pig on one of the smallholder farms inside the ASF clean-chain system becoming infected with ASFV per year?				Low

The likelihood uncertainties also need to be combined through the risk pathway. A logical rule is to attribute the highest of the individual uncertainty estimates to the overall estimates. In our example, the uncertainty of the likelihood rule would be 'Medium'.

2.3.5. Risk estimation part 5 – Combining risk estimates for multiple independent risk questions

The estimation of an overall risk across multiple independent risk questions can be challenging since it is highly subjective, but it should be possible to agree amongst the partners on the interpretation. If each of the example risk questions A to C results in a 'low' risk estimate, this means, according to the definitions in Table A3, the event that at least one pig on one of the smallholder farms inside the ASF clean-chain system becomes infected with ASFV per year is 'rare but does occur'. And it does that for each of the three risk pathways, indicating that the combined risk estimate across all three risk pathways will be higher than 'low'. It would be plausible that the overall risk is 'medium', i.e., the 'event occurs regularly'. It would not make sense to consider it as being 'high', i.e., the 'event occurs very often'. But, for example, if there are only two risk questions, it may be possible to conclude that the overall risk remains 'low'. While such interpretation should be made through a discussion amongst the partners, still, the overall risk should not be lower than the risk estimate for any particular risk question. It could actually be considered an advantage to do it by consensus rather than establishing a rigid rule for combining these qualitative risk estimates since it will require partners to understand the additive nature of risks associated with different risk pathways. But it may also be considered sufficient only to list the risk and uncertainty estimates for each risk question, such as in Table A8, as was done in EFSA (2005, 2006).

Table A8. Summary table of the hypothetical risk estimates and their uncertainty for the three example risk questions for entry of ASFV into the clean-chain system, plus a possible overall risk estimate

Risk questions	Risk estimate	Uncertainty
A: What is the likelihood that the introduction of live pigs via legal trade from a farm outside the ASF clean-chain system will result in at least one pig on one of the smallholder farms inside the ASF clean-chain system becoming infected with ASFV per year?	Low	Medium
B: What is the likelihood that vehicles used for transport of live pigs to the slaughterhouse outside the ASF clean-chain system will result in at least one pig on one of the smallholder farms inside the ASF clean-chain system becoming infected with ASFV per year?	Low	Medium
C: What is the likelihood that pig feed introduced from outside the ASF clean-chain system will result in at least one pig on one of the smallholder farms inside the ASF clean-chain system becoming infected with ASFV per year?	Low	Low
Overall risk estimate	Low to Medium	Medium

3. Managing the ASF risk context

3.1. Comparing acceptable risk with risk assessment results

The partners in the ASF clean-chain system should have agreed on an acceptable level of ASF risk, as outlined in Section 3.3.2. As suggested there, the overall level of acceptable risk is likely to be either very low or low in most clean-chain systems.

Assuming that the partners had agreed on a very low risk as the acceptable risk, a low or medium overall risk, as indicated in our example shown in Table A8 means that risk mitigation measures have to be implemented along all three risk pathways to reduce the overall risk to or below 'very low'.

The partners in the ASF clean-chain system now need to use their understanding of the ASF risk environment that they have developed during the risk assessment process to agree on suitable risk mitigation measures for each of the risk questions where the respective risk level contributed to the overall risk exceeding the acceptable risk level. In our example, this was the case for all three risk questions presented in Table A8.

3.1.1. Analysing the risk pathway diagram to determine potential areas for risk mitigation

The risk pathway diagrams for each of the risk questions should be examined to determine which steps have particular importance for the overall risk estimate. We will use risk question A "What is the likelihood that introduction of live pigs via legal trade from a farm outside the ASF clean-chain system will result in at least one pig on one of the smallholder farms inside the ASF clean-chain system becoming infected with ASFV per year?" as an example.

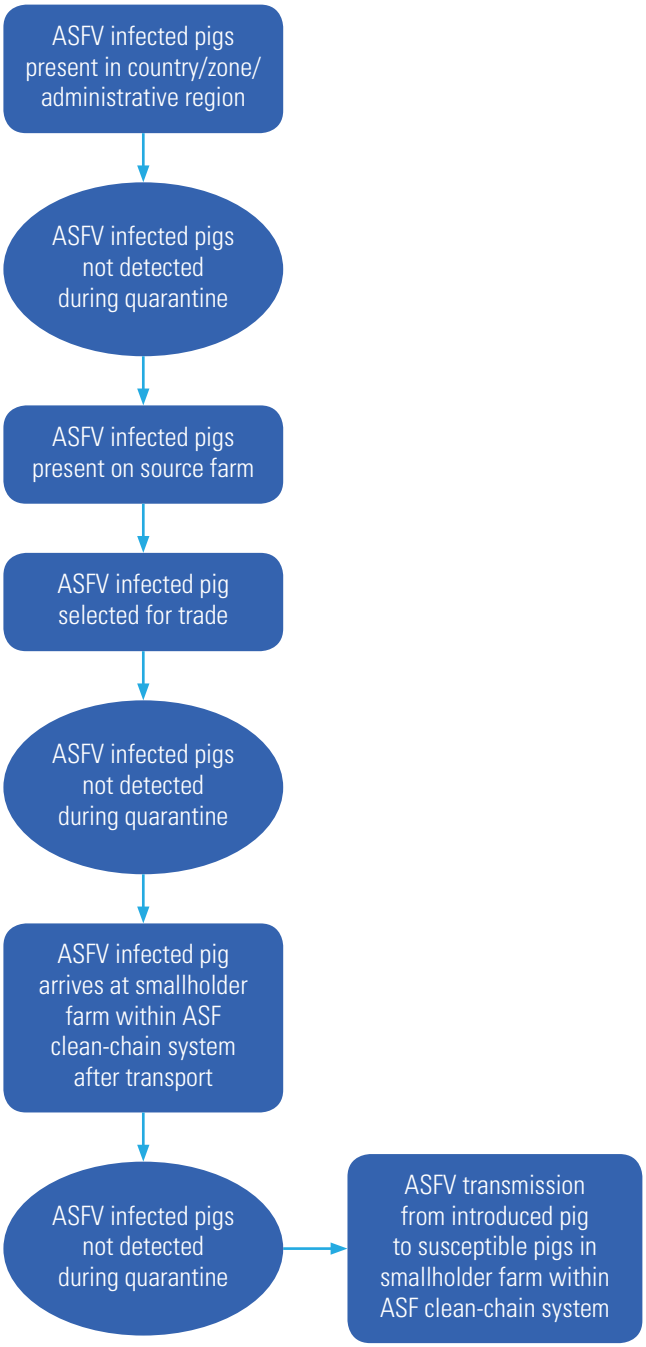
An inspection of likelihoods associated with each step along the risk pathway indicates that the validity of the overall risk estimate of 'low' is mainly dependent on the effectiveness of the biosecurity measures at the source farm. If that were considered not sufficiently effective, the overall risk would be 'medium' because there are no subsequent steps where the risk of ASFV spread would be reduced. That is based on the assumption that once ASFV has been introduced to a typical smallholder farm, it will almost inevitably spread amongst its pigs given the absence of or only a low level of within-farm biosecurity. This suggests that additional risk mitigation should be implemented before the pigs arrive at the target farm that is part of the ASF clean-chain system.

3.1.2. Identifying appropriate risk mitigation measures

Now that the key areas where ASF risk needs to be reduced have been identified, i.e., introduction to and departure from the source farm and introduction to the target farm, the partners in the ASF clean-chain system need to consider which risk mitigation measures are effective, practical, and sustainable. This is a critical part of the communication process associated with setting up an ASF clean-chain system.

For this particular risk pathway, there are a number of risk mitigation measures that could be implemented. The first that comes to mind is the use of diagnostic testing and/or a period of quarantine for new pigs that are introduced from another herd and also prior to moving any pigs to other farms. This is illustrated in Figure A2. Whether all three risk mitigation steps (prior to entry to source farm, prior to exit from source farm and prior to entry to target farm) are required needs to be discussed amongst partners and with external stakeholders, such as the owner of the source farm. But as a minimum, separation of pigs into quarantine while they are subject to virus or clinical disease surveillance prior to entry to the target farm will be required. It is also useful to consider other risk mitigation measures, such as enhanced biosecurity at the source farm and for the transport vehicles.

Figure A2. Risk pathway diagram for risk question A with potential risk mitigation measures



The impact of these measures on the overall risk estimate for the pathway needs to be examined. This requires examining their impact on each of the likelihoods, and whether the measures can be reliably implemented. The latter is critical, and any risk mitigation measures that are under the direct control of the partners involved in the ASF clean-chain system may be considered to be more reliable than those implemented by outside stakeholders. In our example risk question, the quarantine performed after arrival at the target smallholder farm that is part of the ASF clean-chain system would probably be considered to be most reliable (Table A9). This means that to reduce the ASF risk associated with introduction of pigs from outside the ASF clean-chain system, this particular risk mitigation measure needs to be put in place. But in addition, it would still be recommended that the source farm introduces quarantine for entry and exit of pigs from their farm, as shown in Figure A2.

Table A9. Impact of risk mitigation measures on likelihoods at each step and the overall risk estimate

Steps along risk pathway	Data collection needs	Likelihood estimate	Justification	Combined likelihoods
ASFV infected pigs present in country/ zone/administrative region where source farm is located	ASFV infection status of geographical area where the source farm is located	Medium	The source farm is located in a neighbouring province where ASF outbreaks occur on a regular basis	
ASFV infected pig not detected during quarantine prior to introduction into source farm	Sensitivity of diagnostic test (immunological and clinical), duration of quarantine	Very low	High test sensitivity, at least 20 days quarantine	Medium * Very low = Very low
ASFV infected pigs present on source farm	Prevalence of ASFV infected farms in the geographical area of origin, and potential differences in prevalence between farm types, biosecurity measures on source farm	Low	The source farm has never experienced ASF outbreaks and has good biosecurity	Very low * Low = Very low
ASFV infected pig selected for trade	ASFV prevalence within infected farms	Medium	Once ASFV has been introduced to the farm, it is likely to spread widely within farm	Very low * Medium = Very low

Table A9. Impact of risk mitigation measures on likelihoods at each step and the overall risk estimate *(continued)*

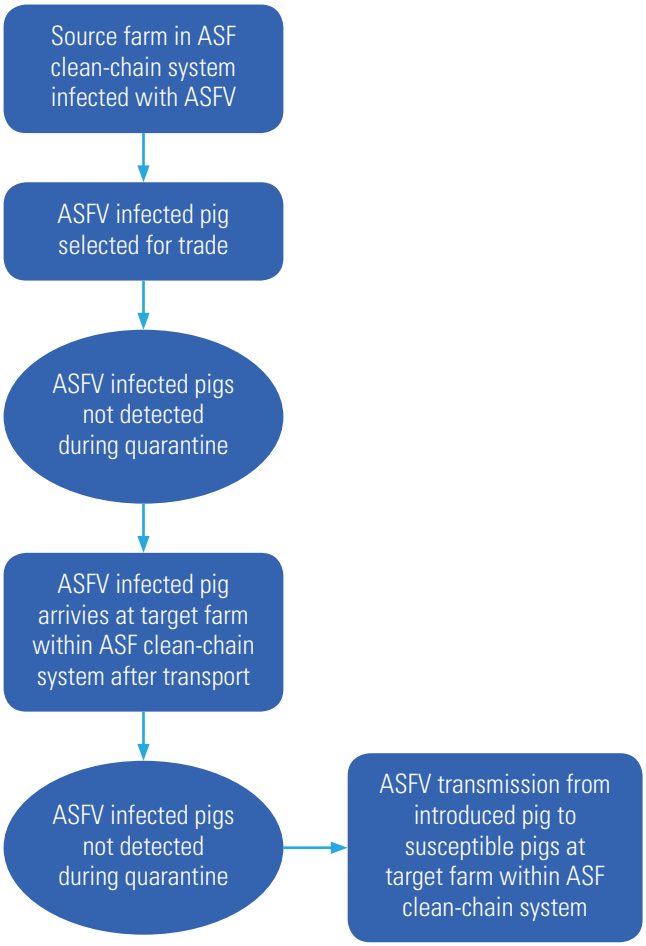
Steps along risk pathway	Data collection needs	Likelihood estimate	Justification	Combined likelihoods
ASFV infected pig not detected during quarantine prior to transport from source to target farm	Sensitivity of diagnostic test (immunological and clinical), duration of quarantine	Very low	High test sensitivity, at least 20 days quarantine	Very low * Very low = Very low
ASFV infected pig arrives at smallholder farm within ASF clean-chain system after transport	Information on transport duration, pig mortality etc and diagnostic testing and quarantine measures during transport	High	There is usually very low mortality during transport, no diagnostic testing	Very low * High = Very low
ASFV infected pig not detected during quarantine after introduction into target farm	Sensitivity of diagnostic test (immunological and clinical), duration of quarantine	Very low	High test sensitivity, at least 20 days quarantine	Very low * Very low = Very low
ASFV infected pig infects other pigs at target farm	Incubation period of ASFV, virus shedding, infectiousness, survival of infected pigs, virus survival in environment	High	Infected pigs are likely to shed large amounts of virus, ASFV can survive for several days to weeks in environment	Very low * High = Very low
What is the likelihood that introduction of live pigs via legal trade from a farm outside the ASF clean-chain system will result in at least one pig on one of the smallholder farms inside the ASF clean-chain system becoming infected with ASFV per year?				Very low

3.2. Risk management and risk-based surveillance

The findings from the risk assessment will inform key steps along the risk pathways where surveillance components should be introduced. This thereby will allow the implementation of risk-based surveillance, which should enhance cost-effectiveness (OIE 2015; Backx *et al.*, 2016). An example is the strategic use of quarantine, a biosecurity measure combined with a surveillance system component aimed at detecting ASFV and/or ASF disease. It should be targeted at steps along the risk pathway where it is feasible and has the desired impact on the overall risk.

Figure A3 shows the risk pathway for trade between pig farms inside the ASF clean-chain system. The partners in the ASF clean-chain system would have to decide whether it is cost-effective to have a single quarantine step (only at the target farm) or two quarantine steps (both at the source and target farms). It may also be worth considering whether it would be feasible to share quarantine facilities between farms involved in the ASF clean-chain system.

Figure A3. Risk pathway diagram for risk question D with potential risk mitigation measures



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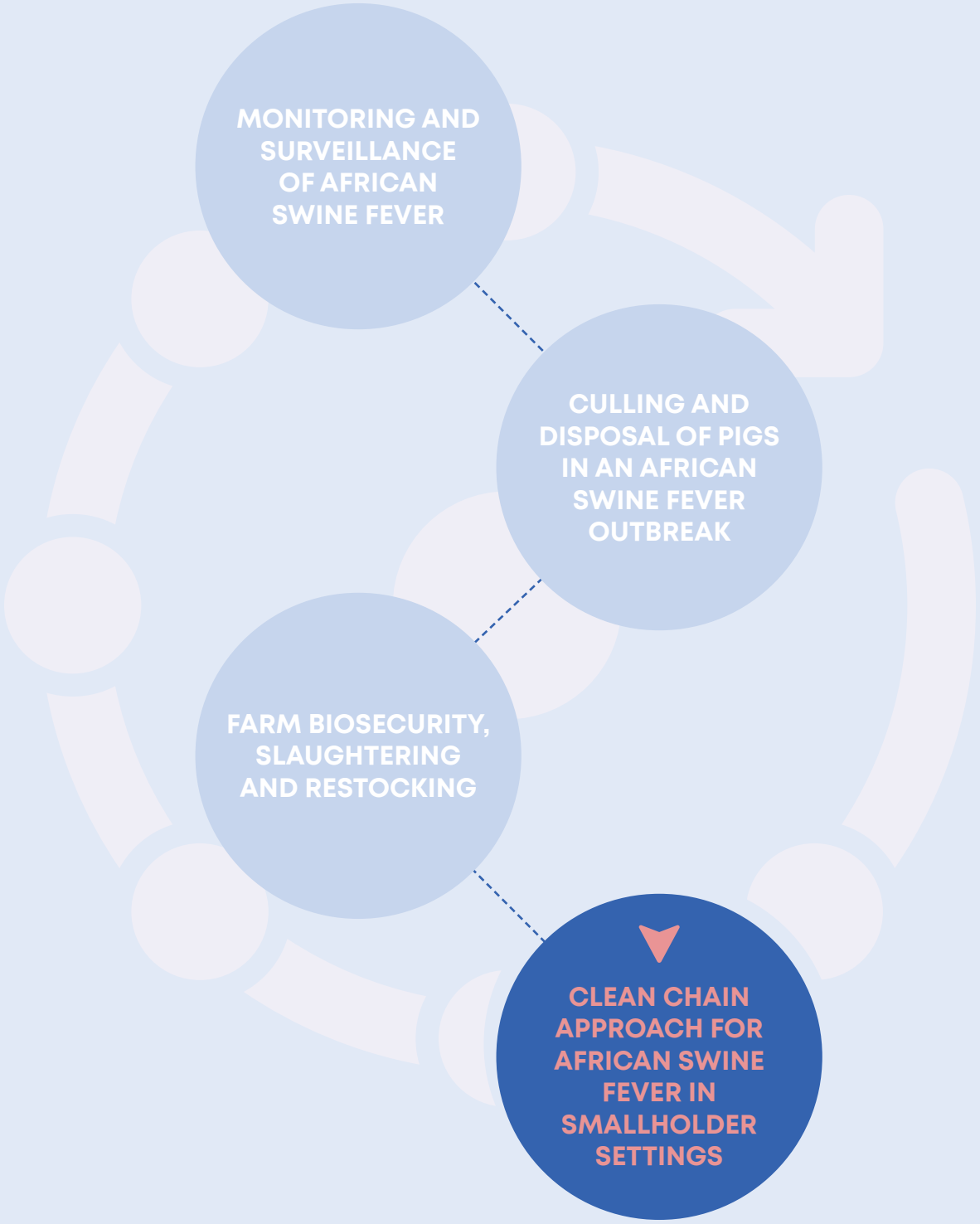

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