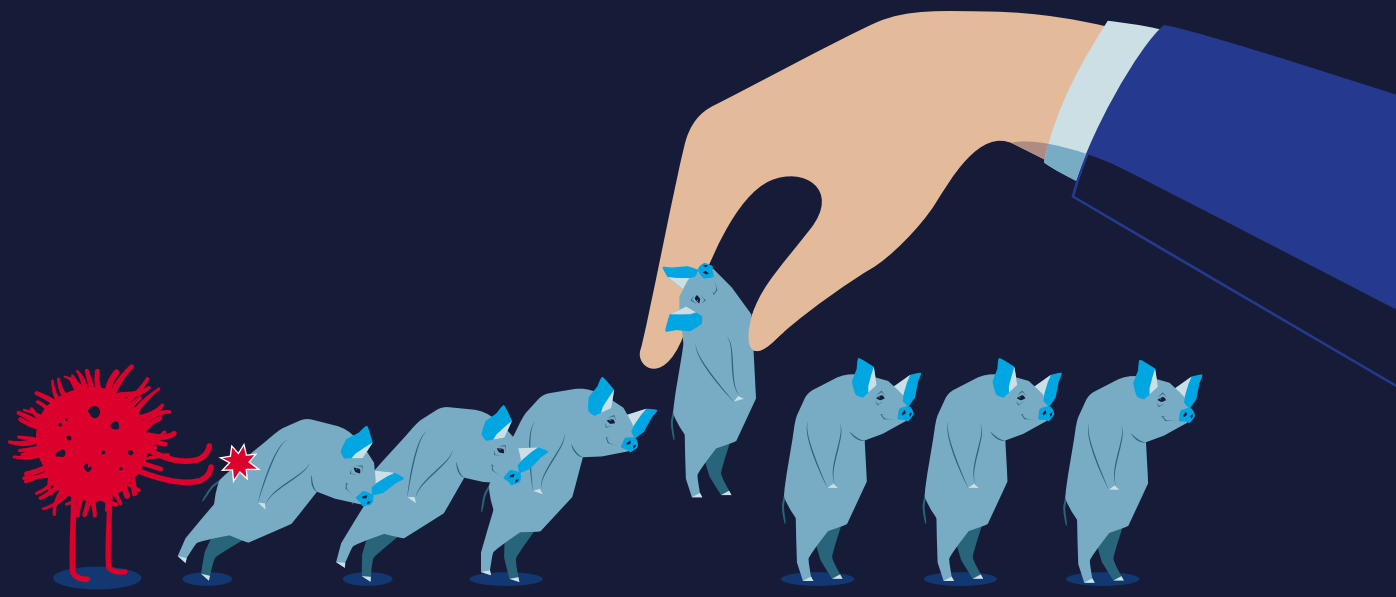
WORLD ORGANISATION FOR ANIMAL HEALTH
Protecting animals, preserving our future

Compartmentalisation Guidelines

AFRICAN SWINE FEVER

The **World Organisation for Animal Health** (OIE) brings together 182 Members, with a mandate to improve animal health and welfare throughout the world. It is the standard-setting organisation of reference for the World Trade Organization (WTO) in matters of animal health. Moreover, it ensures transparency of the global animal disease situation, including those transmissible to humans, and publishes prevention and control methods for these diseases. It accompanies Veterinary Services and facilitates information sharing among experts.

The OIE thus shapes the global governance of animal health.



FOREWORD

Purpose and readership

This set of guidelines aims to assist World Organisation for Animal Health (OIE) Members and stakeholders of the pig industry in the practical implementation of compartmentalisation specifically for African swine fever (ASF). It complements the framework of structured standards provided by the OIE Terrestrial Animal Health Code (*Terrestrial Code*) and the *Checklist on the Practical Application of Compartmentalisation* [1; 2].

This document details specific recommendations and provides guidance on key aspects of the compartmentalisation process. These include the definition of an ASF-free compartment, the pork supply chain, risk assessment, biosecurity, surveillance, diagnostic capabilities and procedures, traceability, public–private partnerships (PPPs), the regulatory framework, approval and recognition of ASF-free compartments, and responses to changes of ASF status, within and outside the compartment. It also provides a number of tools in the Appendices that may be applied to facilitate the implementation and recognition of compartments.

The private sector and Veterinary Authorities are the main target audience of this document. However, it will also benefit third parties and technical service providers, such as auditors and private veterinarians, involved in the implementation and maintenance of compartments. It is expected that government policy-makers and inter-governmental organisations concerned with the animal health and pig industry will also find it useful.

FOREWORD

Achieving **ASF global control** together

African swine fever (ASF) is a highly contagious and severe viral disease of domestic and wild pigs. It is unsurprising, then, that the ASF epidemic has recently escalated, with the OIE receiving notifications of the disease from countries across sub-Saharan Africa, Europe and the Asia-Pacific region. This spread has placed the majority of the world's swine population under direct threat. Due to its virulent nature and high mortality rate, ASF has been responsible for serious decreases in pig production and economic losses; threats to livelihoods, animal health and welfare, and national food security; and knock-on effects on trade and international markets.

Recognising the heightened global risk of ASF, at its 87th General Session in May 2019, the World Assembly of OIE Delegates, through Resolution No. 33, recommended that a global initiative to control ASF be established. Through the same resolution, it was recommended that the OIE develop specific guidelines for the implementation of compartmentalisation for ASF.

I am therefore pleased to introduce this set of guidelines on compartmentalisation for ASF to support Members seeking to establish and maintain a swine compartment free from ASF for the purposes of facilitating safe national and international trade, and promoting disease prevention and control.

With the generous support of the Canadian Food Inspection Agency, these guidelines were developed by a team led by Professor Dirk Pfeiffer from the City University of Hong

Kong, in collaboration with the OIE and its ad hoc Group on Compartmentalisation for African swine fever which comprised experts from diverse professional and geographical backgrounds. The hard work of those involved has resulted in a set of guidelines on the practical implementation of compartmentalisation for ASF, supported by tools that can be used to facilitate the implementation and recognition of ASF-free compartments.

The OIE wishes to thank all of those who contributed to the guidelines, including Members who kindly provided their insights and experiences with compartmentalisation.

While comprehensive in nature, the guidelines are intended to complement existing OIE standards and recommendations on ASF and compartmentalisation. They remain adaptable and applicable to the diverse socio-cultural, geographical, political and economic contexts of our Members.

The guidelines also contribute to the Global Framework for the Progressive Control of Transboundary Animal Diseases (GF-TADs) initiative for the global control of ASF. We believe that the development of technical guidelines to facilitate safe trade based on international standards, including guidelines on compartmentalisation, is a key activity to be implemented under the third objective[1] of the global initiative, namely to 'facilitate business continuity'. These guidelines will be useful not only to Veterinary Authorities and the private sector, but also to third parties and technical service providers supporting Members in their efforts to prepare for and minimise the impact of ASF incursion and spread through business continuity.

Finally, the OIE calls on its Members and partners to join forces against this deadly pig disease by implementing the OIE International Standards on ASF so that together we can achieve its global control.

Dr Monique Éloit, OIE Director General

How to read the guidelines

The guidelines have been divided into three parts. **PART 1** covers the principles and implementation of compartmentalisation for ASF while **PART 2** presents appendices and tools supporting the implementation of compartmentalisation. **PART 3** provides further supplementary information on compartmentalisation as applied by various Members.

Please note that within the guidelines, **COUNTRY EXPERIENCES** of compartmentalisation, not limited to ASF, have also been included only as examples and should not be taken as 'best practices'. Members should take into consideration the specific ASF epidemiology of the country or zone where the compartment is located, as well as other compartment-specific characteristics for ASF compartmentalisation. Members are welcome to contact the quoted country for further information on its compartmentalisation experience.

The **ELECTRONIC VERSION** of the guidelines provide hyperlinks to additional sources of information for the readers.

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[1] **Objective 1.** Improve the capability of countries to control (prevent, respond, eradicate) ASF using OIE standards and best practices that are based on the latest science.

Objective 2. Establish an effective coordination and cooperation framework for the global control of ASF.

Objective 3. Facilitate business continuity

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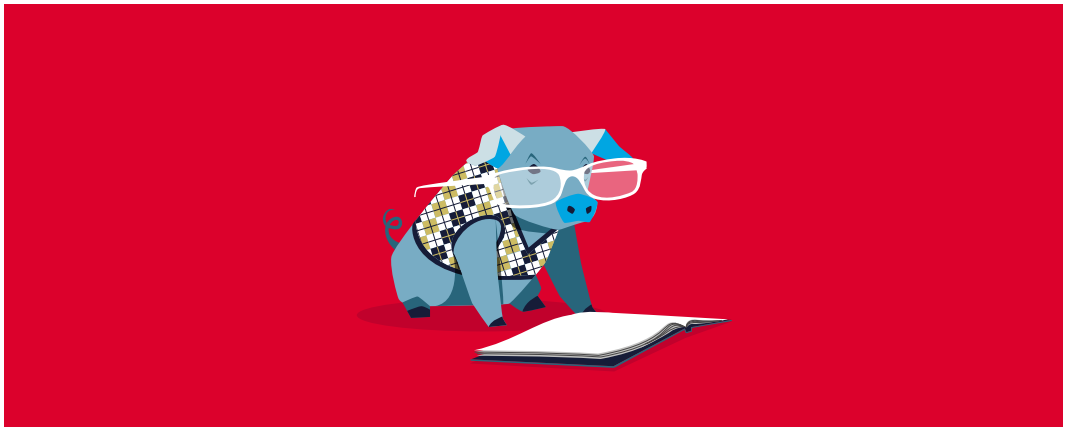
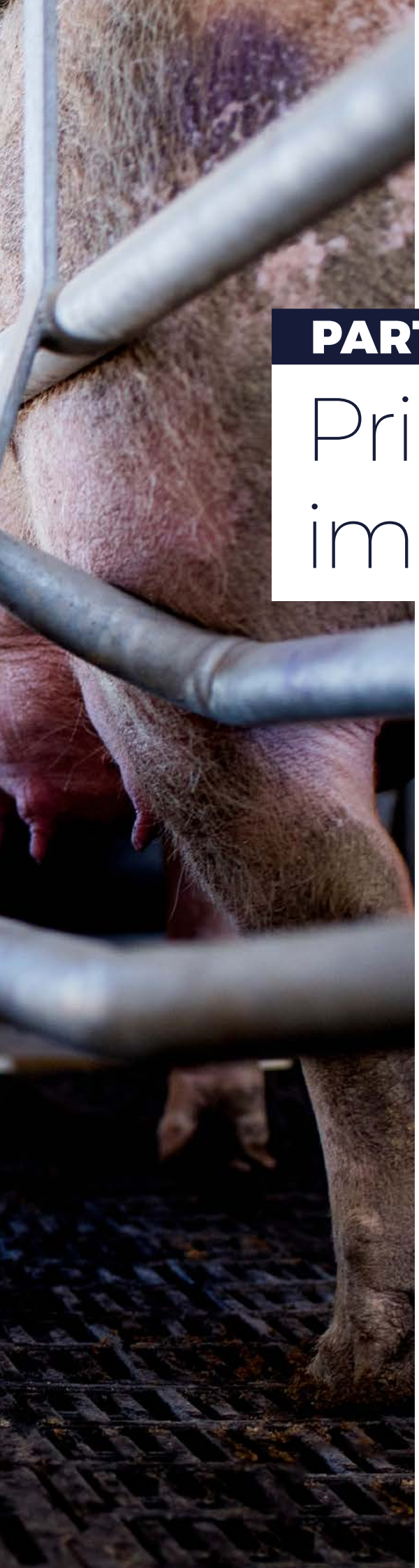




PART 1:

Principles and implementation

INTRODUCTION

The OIE is the intergovernmental organisation responsible for improving animal health and welfare worldwide. It supports Members in their efforts on prevention, control and eradication of animal diseases and provides standards for the improvement of animal health and welfare, outlined in the *Terrestrial Code and the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual)* [3]. Current ASF control and eradication policy, though highly effective when rigorously implemented, has focused mainly on sanitary measures such as biosecurity, stamping-out, movement controls, zoning and other corresponding measures on the trade of pigs and pig products from countries or zones infected with ASF, causing significant socio-economic impacts [1; 4].

Pig production plays a key role in global food security and contributes to livelihoods of those who depend on the pig sector.

Taking the current global epidemiological situation of ASF and the importance of pig production to global food security and livelihoods into account, the application of compartmentalisation and zoning, as described in the *Terrestrial Code*, should be considered as part of an ASF prevention and control strategy. A key argument will be that the use of compartmentalisation and zoning may facilitate business continuity in the pig sector and contribute to food and job security [4]. The concept of a 'commodity-based' approach should also be adopted to facilitate the safe trade of relevant commodities, taking into consideration the risk mitigation measures, as stated in the *Terrestrial Code*.

INTRODUCTION

Zoning and compartmentalisation

While the eventual goal of disease control is ideally to gain disease-free status for the entire country, there are obvious benefits to establishing and maintaining an animal sub-population with specific health status within a territory for the purposes of international trade, as well as disease prevention and control. To achieve this, Members may consider the use of zoning (regionalisation) and/or compartmentalisation, depending on the epidemiological situation within the country, the intended purpose, and the capacities of the Veterinary Authority and the private sector, as well as any other relevant factors. A comparison of these two concepts is presented in Table 1. Members are advised to refer to Chapters 4.4. and 4.5. of the *Terrestrial Code* for OIE recommendations on zoning and compartmentalisation.

Table 1 Comparison of zoning and compartmentalisation [5; 6]

ZONING/REGIONALISATION	COMPARTMENTALISATION
SIMILARITIES	
· Aims to establish and maintain an animal sub-population with specific health status within a territory, to contribute to the progressive eradication of a disease while minimising the impact on trade in relevant commodities · Requires consideration of all epidemiological factors and risk pathways for effective implementation · Spatial considerations and biosecurity management are important in the maintenance of the health status of the animal sub-population · Recognition by trading partners is required to facilitate international trade	
DIFFERENCES	
· Primarily defined by geographical limits	· Primarily defined by common management and husbandry practices relating to biosecurity
· Maintenance of health status is achieved through the application of sanitary measures at the zone level, such as movement control and surveillance, including early detection	· Maintenance of health status is achieved through the application and verification of the integrity of the entire common biosecurity management system implemented in a compartment, and surveillance, including early detection
· Primarily activated in response to disease outbreaks and may not be relevant during 'peacetime' (periods between outbreaks) in disease-free countries or zones	· Primarily and preferably established in 'peacetime' in disease-free countries or zones
· Established and managed by the Veterinary Authority	· Established and managed by the private sector under the supervision of the Veterinary Authority
· The cost for establishment and maintenance is mainly met by public resources, though may also be substantially covered by the private sector	· The cost for establishment and maintenance is met mainly by the private sector

ZONING/REGIONALISATION	COMPARTMENTALISATION	
PROS AND CONS		
✔ Benefits to all animals (including domestic pigs and wild/feral pigs) and business operators within the disease-free zone	✖ Benefits only to the animal sub-population and business operator of the compartment	**General considerations**
✖ Recognised health status of all the animals in the zone would be jeopardised by the occurrence of disease in any animal within the zone	✔ Recognised health status of an animal sub-population within a compartment would not be jeopardised by the occurrence of infection in nearby animal sub-population(s) within the zone/country where the compartment is located	
✖ Implementation of zoning affected by the complexity of epidemiological pathways and the diversity of livestock production systems	✔ Allows functional separation of an animal sub-population from other animals of different or unknown health status through biosecurity, where geographical separation could not be envisaged	
✔ Implementation of zoning policies usually requires only very limited investment from the private sector or none at all, or may otherwise be substantially covered by the private sector	✖ Based on principles of robust biosecurity, a compartment requires significant investment in term of facilities, equipment, human resources, etc. from the private sector to initiate and maintain	
✖ Restrictions on national and international trade, as well as the movement of animals and animal products, would apply to the geographical extent of the zone (Previous circumstances, in which there was no differentiation of status among herds and high-biosecurity farms, might also be affected to a certain extent)	✔ National and international trade, as well as the movement of animals and animal products, can continue for compartments without interruption, regardless of geographical location	**After a disease outbreak in a previously disease-free country or zone**
✖ Limits spread of the disease to within a defined infected area of the territory based on geographical boundaries, while preserving the disease-free status of the remaining territory	✔ Facilitates maintenance of the health status of the animals of the animal sub-population within the compartment, based on a common biosecurity management system, and not limited by geographical location	
✔ In case of disease outbreak in a disease-free country or zone, the establishment of a containment zone under Article 4.4.7. of the *Terrestrial Code* is a fast instrument that can be applied to recover the disease-free status of the rest of the country or zone outside the containment zone	✖ In case of disease outbreak in a compartment, the disease-free status of the entire compartment would be lost, and the compartment should be re-approved and re-recognised after taking the necessary actions to regain disease-free status	

South Africa

CHOOSING COMPARTMENTALISATION OVER ZONING

In 2005, an outbreak of classical swine fever (CSF) in South Africa eventually resulted in trade bans. It caused significant impacts on regional trade as South Africa is the main supplier of pork to the whole Southern African Development Community (SADC) region. Although the CSF outbreak was confined to the south of the country, South Africa chose to implement compartmentalisation, rather than zoning, because of the difficulty of ensuring movement controls between large zones, as well as the nature of the pig sector, which was composed of large commercial farms within the Eastern (ECP) and Western Cape Provinces (WCP), both of which were affected. Subsequently, the South African government rapidly developed a *Procedures manual: CSF-free compartment*, implemented on 1 October 2005. The compartmentalisation initiative resulted in officially approved compartments throughout the country. The proposal of export from compartments was also welcomed by regional trading partners, allowing South Africa to re-open its export of pig products and even some live pigs, rapidly and safely. The fact that the concept of compartmentalisation had been accepted by the OIE in 2004, and added to the *Terrestrial Code* chapter on CSF in 2005, greatly facilitated trade negotiations.

COUNTRY EXPERIENCE

INTRODUCTION

National and international benefits of compartmentalisation

The introduction of ASF virus (ASFV) into a previously ASF-free country or zone would result in significant socio-economic impacts. In the event of an ASF outbreak, the most apparent and immediate effect would be the death and/or stamping-out of pigs on affected farms, causing enormous economic loss to the pork producers and associated actors along the value chain, followed inevitably by indirect costs due to immediate country-wide export bans.

Compartmentalisation, a risk management strategy

When considering the direct and immediate impacts on the private sector resulting from an ASF outbreak, compartmentalisation may offer a risk management strategy for companies to help protect the health status of their animals, and thus their business, if an incursion of ASFV occurs in their country or zone, as well as an opportunity to maintain the pork supply chain at the national and international level. The robust biosecurity management system applied as part of compartmentalisation is intended to protect the compartment against the risk of ASF incursion. In this way, trade and movement of pigs and relevant commodities from the compartment may continue without interruption and the business of the company operating the compartment, as well as the pork supply, can continue with minimal 'downtime'. This is the case even if an ASF outbreak occurs in the country or zone as long as the compartmentalisation has been approved by trading partners during 'peacetime'.

Protecting business continuity, ensuring food security

It thereby offers a mechanism to protect business continuity as well as to maintain access to international markets. At the same time, the biosecurity management system may also protect the animal sub-population within the compartment from the introduction of other infectious diseases, apart from ASF, and thereby reduce production losses for the pig business as well as contribute to ensuring food security at the national level. Compartments are implemented and maintained by the private sector under the supervision and approval of the Veterinary Authority, and may be complementary to national eradication efforts (e.g. zoning). Other animal production industries have also successfully implemented compartmentalisation to manage the threat of various animal diseases.

→ **Appendix 13** provides several countries' experiences with compartmentalisation as a reference.

South Africa

COMPARTMENTALISATION: A "WIN-WIN" SITUATION

In South Africa, compartmentalisation is a voluntary system. The farmer pays to implement the requirements, and in turn obtains animal disease protection and health assurances for trade. In this 'win-win' situation, farmers who invest in animal health and pay for compartmentalisation are rewarded with marketing advantages, while the country as a whole benefits from improved disease control at a lesser cost to government. For instance, the wide-scale adoption of compartmentalisation in the commercial pig industry greatly facilitated South Africa's control of the CSF outbreak in 2005, as well as all subsequent pig disease outbreaks. This was due to compartmentalisation reducing the risk of virtually all diseases in the commercial pig sector, as well as the risk of disease spread via large pork abattoirs. Protecting the majority of pigs in South Africa in compartments enables additional control efforts to be concentrated on informal and semi-commercial pig sectors during outbreaks.

Brazil

COMPARTMENTALISATION MAKES FOR SAFER TRADE

Compartmentalisation in the Brazilian case has not yet been reflected in the expansion of markets for products of animal origin. However, its consolidation, especially in the field of poultry genetics, has made it possible to reduce the risk perception of high pathogenicity avian influenza and Newcastle disease associated with the potential occurrence of either of these diseases in the country, given the need to keep the poultry production chain active. The reduction in risk perception produces positive effects in relation to the cost of financing national poultry production. It is also expected that the effective use of the concept of compartmentalisation in the international trade of animals and products of animal origin, especially when transboundary animal diseases are involved, will allow for a quicker recovery of trade, although possibly more limited at first.

In addition, the compartmentalisation exercise results in investments in biosecurity, both in terms of physical facilities and good production practices, both of which are highly beneficial for increasing animal production and productivity, as well as food safety. The involvement and support of the OIE, at the beginning of discussions on the topic at the national level and during the course of compartmentalisation, was essential to boost initiatives that resulted in more productive discussions on and concrete measures for the construction of the regulatory framework for effective implementation.

PRINCIPLES

Compartmentalisation in the context of ASF

In line with Article 4.5.2. of the *Terrestrial Code* on principles for defining a compartment, the key principle underpinning the establishment of an ASF-free compartment must be to clearly identify the ASF status of an animal sub-population within a compartment. All pigs from an ASF-free compartment must be identifiable and traceable in accordance with the recommendations of the *Terrestrial Code*. It is essential that all establishments and premises under the management of an ASF-free compartment, including holding facilities, vehicles, feed mills and slaughterhouses, are clearly defined. If they are not part of the compartment, then their relationship to the compartment must be clearly outlined. Their functional relationship to the ASF-free compartment, as well as their role in and contribution to epidemiological separation, must be described in the compartment proposal [7]. These principles are directed towards the desired outcome of a complete epidemiological separation of the animal subpopulations within the compartment from animal subpopulations outside the compartment to prevent any introduction of ASFV. The ASFV-free status and feasibility of an ASF-free compartment are influenced by a number of physical and spatial factors. These include the presence of wild or feral pigs and certain soft ticks in the country or zone, proximity to other local pig populations outside the compartment, vegetation, landscape, nearness to highways and slaughterhouses not included in the compartment, etc. To establish and maintain an ASF-free compartment capable of withstanding ASFV pressure from all possible sources, a solid biosecurity plan tailored to the compartment's risk pathways for ASFV introduction must be developed, implemented and evaluated regularly to take into account the possible changes in risk pathways and their characteristics. This biosecurity plan must account for all the factors relevant to the integrity of the ASF-free compartment and must prove that the compartment is resilient to ASFV introduction, which may be demonstrated through risk assessment. By detailing all the potential pathways for ASFV introduction and estimating the risk to the compartment, the resulting biosecurity plan should provide comprehensive evidence of the effectiveness of risk-mitigating actions supported by standard operating procedures.

→ **Appendix 1** provides a graphic illustration of the compartmentalisation concept in the context of ASF.
The principles applied in ASF compartmentalisation are examined below.

PRINCIPLES

Defining an ASF-free compartment

WHAT?

A compartment means an animal sub-population contained in one or more establishments with a specific animal health status, maintained under a common biosecurity management system, that separates it from other animal populations. It is established with respect to one or more specific diseases and is defined by the factors common to the animal sub-population that provide distinct disease risk separation from other animals at higher disease risk. For the purposes of this set of guidelines, that disease is ASF [3; 8]. In defining an ASF-free compartment, there should be full compliance with the relevant recommendations of Chapter 4.4. on zoning and compartmentalisation, Chapter 4.5. on the application of compartmentalisation, and disease-specific Chapter 15.1 on infection with ASFV, of the *Terrestrial Code*.

HOW?

When defining an ASF-free compartment, the following information has to be included as a minimum:

- **identification of the disease for which the compartment is intended, i.e. ASF;**
- **identification of the commodity/commodities of interest to be derived from the compartment;**
- **identification of the components of the compartment (i.e. farm establishments and other related functional units or sub-units), including feed mills, slaughterhouses, processing plants, as well as their location and common biosecurity management system under which they operate [3; 8];**

- With respect to identifying the components of a compartment, it is not required that all functional units or sub-units be included in the compartment, provided that the relevant standards in Chapter 15.1. of the *Terrestrial Code* are complied with, in relation to the introduction of animals, commodities or other entities from the other functional units or sub-units concerned. For example, upstream grandparent breeder farms may not necessarily need to be included in the compartment, provided that the process associated with the input of genetic materials or embryos into the compartment complies with the recommendations for the importation of semen/in vivo-derived embryos, as stated in Articles 15.1.10. to 15.1.12. of the *Terrestrial Code*.

- Irrespective of the overall scope of the compartment, it should always include an 'animal sub-population'. Any downstream functional units or sub-units, up to the point where the commodity of interest leaves the compartment, are part of the compartment and need to be kept at the same health status. This means that functional units or sub-units such as abattoirs, cutting plants and processing units must be defined as part of the compartment when the purpose of the compartment is to produce pig meat as the commodity of interest. They must preferably be dedicated to only receiving animals and products with ASFV-free status or, if also processing animals and products of a different health status, operate strict segregation and biosecurity measures to ensure that the ASF-free status of the animals and products derived from the compartment is maintained. This could be in the form of traceability together with measures to prevent cross-contamination, such as strict segregation measures in time and space when operating with animals sourced from both inside and outside the compartment (e.g. different production lines and processing days). In any case, the process of transportation of animals or products between functional units or sub-units of the compartment must be included as part of the

compartment. Figure 1 depicts some examples for illustration.

- **identification of the animal sub-population comprising the compartment, which should be recognisable through a clear epidemiological separation from other animal populations, with effective mitigation of all risk pathways considered to represent a non-negligible risk [3; 8];**

- **description of the functional relationships between components of the compartment, preferably including maps and diagrams, indicating their contribution to the epidemiological and functional separation between the animal sub-population in the compartment and other animal populations, for example:**

  - compartment ownership and management [3; 8];
  - identification of personnel who have responsibility for key activities, such as disease surveillance, contingency planning and conducting of internal audits [3; 8];
  - the relationship between the compartment and other functional units or sub-units not included in the compartment, such as feed mills and rendering plants [3; 8]. The risk of ASFV introduction associated with inputs entering the compartment from units not included in the compartment (e.g. feed, bedding material, and biologicals) must be mitigated by adhering to relevant standards (e.g. good manufacturing practices) that provide the necessary confidence that these inputs are free from ASF;
  - the adoption of industry improvement plans that contain biosecurity guidelines, e.g. health improvement plans and breed registries [3; 8];
  - a comprehensive biosecurity plan, tailored to the compartment, that addresses its specific ASFV risk pathways and includes reference to 'Biosecurity management system' (see below), and the OIE *Checklist on the Practical Application of Compartmentalisation* [3; 8];

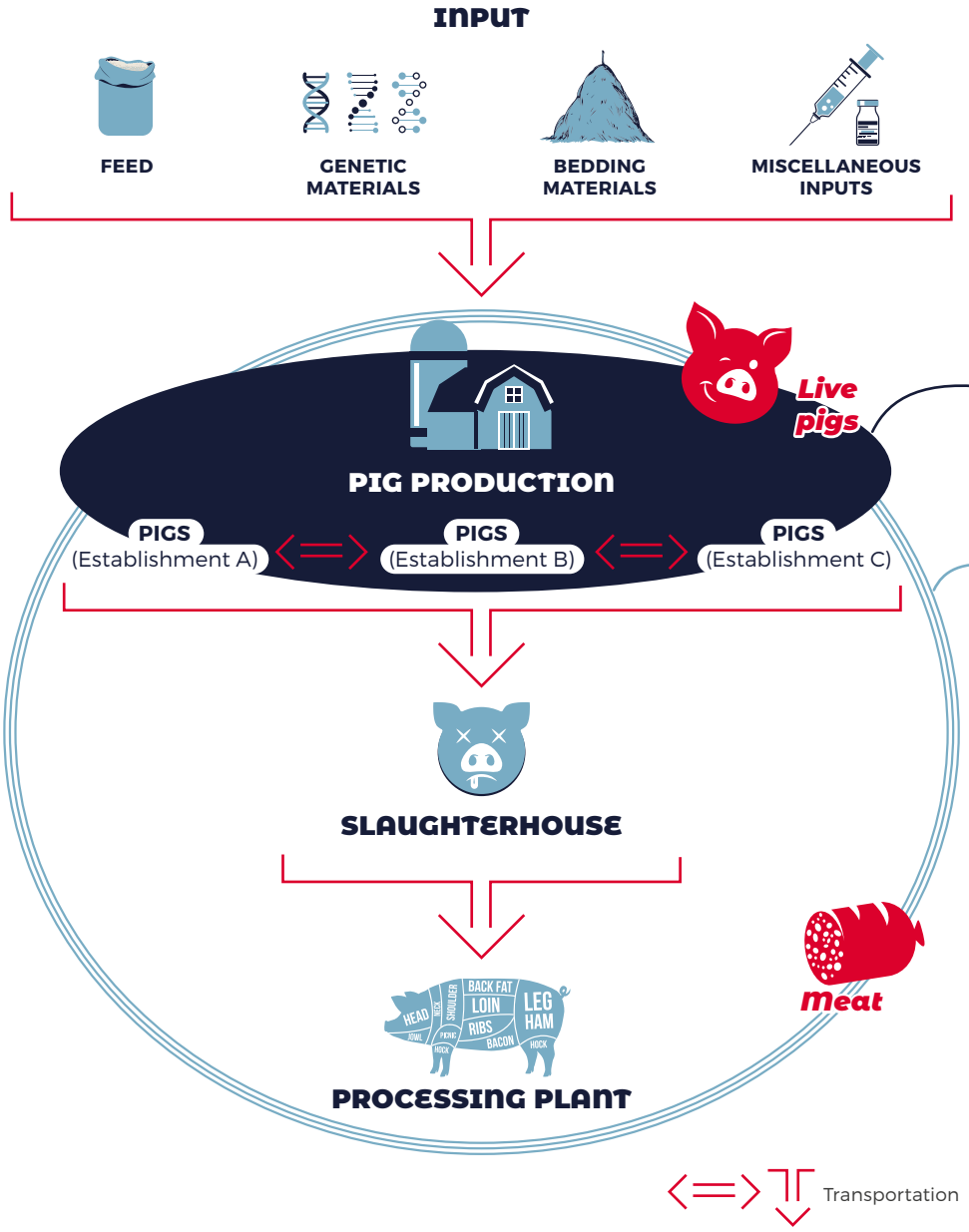
- **implementation of an identification and traceability system for animals and relevant commodities originating from the compartment, as appropriate, with accurate records and proper supervision. This traceability system for animals and relevant commodities must also be in accordance with Chapter 4.3. on the design and implementation of identification systems to achieve animal traceability, and Article 4.5.3., regarding traceability systems, of the *Terrestrial Code* [3; 8];**

- **the establishment of a public-private partnership between the compartment operator and the Veterinary Authority, with respective roles and responsibilities clearly identified [3; 8];**

- **identification of other factors important for maintaining the ASF-free compartment, related to the functional separation of the compartment from other animal populations of unknown or different health status with respect to ASF. These factors include sanitary measures, environmental risk factors, and management and husbandry practices, etc.**

In defining an ASF-free compartment, the identification of factors for maintaining the ASF-free compartment, including environmental risk factors and husbandry practices is important

Figure 1 **Simplified model for illustration of possible components to be defined in an ASF-free compartment**



Compartment A can be defined as a compartment with final product as live pigs (e.g. breeder pigs), which includes the animal sub-population of pigs in various establishments at the pig production level.

Compartment B can be defined as a compartment with final product as processed meat, which includes the animal sub-population of pigs in various establishments at the pig production level and the slaughterhouse and processing plant downstream.

Note that various inputs have not been included within both Compartment A and Compartment B.

Remarks: According to the definition of compartment stated in the Glossary of the Terrestrial Code, a slaughterhouse and/or processing plant shall not be defined as standalone compartments as they do not involve any animal sub-population.

EXPECTED OUTCOME

The ASF-free compartment is a clearly defined compartment indicating the location of all its components, their interrelationships, and their contribution to an epidemiological separation between the animal sub-population within this compartment and other animal populations of unknown or different health status in respect to ASF. The definition of a compartment needs to revolve around ASF-specific epidemiological factors, animal production systems, biosecurity practices, infrastructure factors and surveillance [3; 8].

PRINCIPLES

Pork supply and value chain

An understanding of the pork supply chain, but preferably the value chain, is essential to be able to conduct a thorough risk assessment and permit development of effective mitigation of ASFV risks for an ASF-free compartment. A supply chain is concerned with all physical steps involved in the production of a particular output for consumers.

A comprehensive approach

The value chain approach provides a more comprehensive perspective by also including all activities and interests of different actors along the supply chain [11-15]. The structure of the pork supply or value chain (of which an ASF-free compartment forms a part) accommodates different stages that lead to the final product, which is then delivered to the consumer [16; 17]. These different stages may be broadly divided into three groups, namely:

- feed production, processing and storage;
- pig production (including breeding);
- slaughtering and primary processing.

Each group usually is connected to other supply or value chains, actors and potentially even ASF-free compartments [16; 17].

→ **Figure 6 in Appendix 3** presents an example of a pork supply or value chain.

The feed production stage encompasses all 'trough-to-mouth' processes. These include grains, concentrates, crops, swill feed etc., including their supply and transportation from the source to the compartment.

The pig production stage covers processes from breeding to growing, finishing or fattening for slaughter [18]. Live pigs are a key primary product or can be an input in the case of a fattening enterprise. If only growing, finishing or fattening units are included in a compartment, the ASF-free status of live pigs entering it must be assured. Breeding units, including genetic breeding stock companies, may or may not be compartments on their own, or part of a larger compartment. Within the context of an ASF-free compartment, inputs necessary for production (e.g. semen extenders, medications and vaccines) are potential risk pathways for introduction of ASFV, as are actors involved in the disposal of dead and culled pigs.

The primary products from the slaughtering and processing stage include meat and skin products, among others. The transportation of live pigs to the abattoir and all post-slaughter processing, including transportation to the retailer or storage, needs to be considered as part of risk assessment.

ASFV risk under human influence

Human behaviour has a strong influence on the characteristics of the pork value chain and consequentially also on ASFV risk. This needs to be taken into account in the design of the ASF-free compartment's biosecurity plan. The primary focus of the supply chain approach on physical transformation from raw inputs (feed and pigs) to pork will not adequately reveal the influence of human behaviour on the risk of ASFV infection or contamination of outputs from an ASF-free compartment. It is therefore recommended to aim for a description of the pork value chain.

PRINCIPLES

Epidemiological separation of the compartment from potential ASF virus sources

The complex nature of national and international pork supply and value chains results in a wide range of epidemiologically diverse pathways potentially leading to introduction of ASFV into a country and an ASF-free compartment within a country. To prevent ASFV introduction via these pathways, an ASF-free compartment must have a biosecurity risk management system that is tailored to its particular ASF risk environment.

RISK ASSESSMENT

WHAT?

The risk of ASFV introduction and spread within a compartment should be estimated using a structured scientific risk assessment based on the approach described in the OIE risk analysis framework, in accordance with Chapter 2.1. of the *Terrestrial Code* on import risk analysis, and the OIE *Handbook on Import Risk Analysis* [19-21].

→ **Appendix 3** presents a more detailed example of a risk assessment to assist in creating an ASF-free compartment. An understanding of the pork supply or preferably of the pork value chain is essential for being able to conduct a meaningful risk assessment.

A risk assessment is typically divided into entry, exposure and consequence assessments. The identified risk pathways and the risk estimates associated with each step along the pathways are essential information for optimising new and existing risk mitigation measures that give the key stakeholders sufficient confidence in the resilience of the ASF-free compartment. More specifically, the entry and exposure assessments will inform the design of biosecurity management system, and the risk estimates will express a compartment's resilience to virus introduction. The consequence assessment and the associated risk pathways will inform the design of the ASFV surveillance system. The overall risk estimate will be used by key stakeholders to decide whether it meets their expectations in relation to the acceptable level of ASFV infection/contamination risk of outputs produced by the compartment. If it does not meet their expectations, it can mean that the risk management processes have to be strengthened or that the stakeholders will not accept outputs from the compartment. The whole risk assessment process for a compartment also allows a transparent definition of the compartment's ASFV risk boundaries [6; 22]. The overall risk estimate is usually composed of both the likelihood of a given disease event and its adverse health, environmental or socio-economic impact. In the compartmentalisation process, the likelihood of infection/contamination is usually the focus of the risk assessment.

Recognising that the risk of ASFV infection or contamination is unlikely to be zero, it is recommended that key stakeholders agree on what constitutes an acceptable level of risk at the start of the compartmentalisation process. Alternatively, importing trading partners will have to decide what level of ASFV risk they will accept at a later stage in the approval process. In the context of trade, this will also be called the 'appropriate level of protection' or ALOP [19; 23]. It is important to emphasise to stakeholders that aiming for a zero-risk is unlikely to be realistic, given that even ASF-free countries or zones cannot guarantee a zero risk of incursion [19]. The key stakeholders also need to agree on whether a qualitative, semi-quantitative or quantitative risk assessment will be conducted [19].

It is highly recommended that risk assessments are conducted at the start of the process of developing a compartment, since it will facilitate the design of the tailored biosecurity and surveillance programmes. A risk assessment will be an essential component of the documentation to be included in the application process. The ASFV infection/contamination risk estimate for outputs from a compartment, together with the associated risk mitigation measures, will be key in deciding whether a compartment will be approved by the Veterinary Authority or accepted by potential trading partners.

The risk of ASFV entry into a compartment is strongly influenced by the level of ASFV circulation within the country or zone where the compartment and its functional units or sub-units are located. A prerequisite for a compartment-level risk assessment, therefore, is a country-level risk assessment, which would take into consideration that country's current risk management measures.

The country-level risk assessment will be the responsibility of the Veterinary Authority, taking the international situation into account as well as the latest scientific findings. At the compartment level, it is the responsibility of the compartment operator to ensure that transparent and structured scientific risk assessments are conducted. It is highly recommended that these risk assessments are either conducted by a party that is independent from the compartment operator or that they are audited by an independent third party. The Veterinary Authority may assume the auditing role.

A compartment-level risk assessment needs to be documented in an operational risk assessment document which is to be cross-referenced against the biosecurity and surveillance programmes. The risk assessment process needs to be repeated in response to external epidemiological changes that affect the risk of ASFV introduction into the compartment, or to significant changes in the compartment's characteristics and performance that could affect the ASFV risk for compartment commodity outputs. The outcome of the risk assessment should inform which risk management measures will be instituted. Depending on resource availability and the external ASFV risk, risk assessments may have to be conducted at regular intervals, and whenever the compartment operator or Veterinary Authority has identified changes in the compartment's external or internal ASFV risk situation. As a contingency, stakeholders must agree on a reasonable buffer period within which to complete the assessment of this potential change in risk level.

HOW?

→ **Appendix 3** details a risk assessment example to assist in creating an ASF-free compartment, in accordance with Chapter 2.1. of the *Terrestrial Code* on import risk analysis, and the OIE *Handbook on import risk analysis*.

Since the effectiveness of a compartment's biosecurity management system depends on a very strong culture of compliance among all staff, it is important to ensure that management and personnel working in the compartment understand how ASFV can enter the compartment [2]. For this reason, it is recommended that they are involved in the risk assessment process as they may well be able to identify additional risk factors or even risk pathways. Such involvement in the risk assessment process and the development of risk management policies

will also result in staff taking ownership of these processes and policies.

To serve its purpose of ensuring business continuity, it is essential that the compartment remains active during any changes in the external ASF risk environment, e.g. a country's loss of its freedom from ASF. If that change increases the overall ASFV risk for the compartment above the agreed acceptable level of risk, stakeholders need to be immediately alerted and the ASF-free status of the compartment suspended.

EXPECTED OUTCOME

The compartment operator produces an operational risk assessment document which informs the compartment's risk management policies. The initial risk assessment, which presents the risk pathways in detail, together with the pathway-specific risk estimates and overall risk estimates, will assist in defining required biosecurity measures. The compartment's operational risk assessment document must consider the sensitivity of the risk estimates to changes in the wider risk environment outside the compartment, as well as to any failure in specific risk mitigation measures, i.e. biosecurity breaches. This document must be available for audit and subsequent adjustments in risk management policies, and should be revised, every time a new risk assessment is conducted.

COUNTRY EXPERIENCE

Chile

RISK-BASED BIOSECURITY MEASURES FOR PIG COMPARTMENTS

In Chile, a swine-disease-free compartment for pigs was established, targeting foot and mouth disease, classical swine fever, ASF and Aujeszky's disease (pseudorabies), none of which are currently present in the country. The development of the compartment included a characterisation of the external environment and epidemiological relationships. A risk assessment of the introduction and spread of each of these diseases in the compartment was performed on each of the components of the compartment. Based on the risk assessment outcomes, a set of biosecurity measures was established. The compartment operator developed a technical proposal for the compartment, detailing the implementation of these biosecurity measures in each component of the compartment. The Veterinary Authority was responsible for the initial evaluation, approval and subsequent audit.

RISK MANAGEMENT

The aim of the risk management policy is to achieve an overall risk estimate for the compartment at a level which the key stakeholders, in particular the recipients of the compartment outputs, consider to be acceptable. To identify the necessary components of the compartment's risk management policy, the risk estimates generated by the initial risk assessment associated with each pathway, and the conditional relationships associated with each step on the same pathway, need to be examined in detail, together with their sensitivity to changes in the wider risk context outside the compartment. This will allow stakeholders to identify which pathways, and which steps on each pathway, require feasible and effective risk mitigation measures. For some risk pathways, it may be necessary to introduce risk mitigation measures at sequential steps along the pathway to obtain the desired reduction in the overall risk. It is also necessary to examine the potential of risk mitigation failures.

The risk mitigation measures that make up the compartment's risk management policy must include a biosecurity management system, an ASFV surveillance system and a system for traceability of pigs and pork products, as well as any relevant inputs, such as feed.

BIOSECURITY MANAGEMENT SYSTEM

WHAT?

Biosecurity refers to a set of management and physical measures designed to reduce the risk of introduction, establishment and spread of animal diseases, infections or infestations, to, from and within an animal population [2]. A biosecurity management system must be developed as part of the compartmentalisation process. Since the functional units and sub-units of the compartment are likely to already have biosecurity measures in place prior to the compartmentalisation process, these need to be reviewed and adjusted based on the information generated by the risk assessment. The risk mitigation measures need to aim at minimising the risk of ASFV introduction into functional units or sub-units within the compartment, referred to as bio-exclusion, and the risk of ASFV escape from a functional unit or sub-unit thereby exposing other functional units or sub-units to ASFV, referred to as bio-containment.

The following are the three main components of biosecurity: [21; 24]

- **Segregation/separation:** the creation and maintenance of barriers to limit the potential opportunities for infected animals and contaminated materials to enter a compartment. **When properly applied, this step will prevent most contamination and infection. It is also important to apply these principles between different functional units or sub-units within the compartment.**

- **Cleaning:** materials (e.g. vehicles, equipment) that enter (or leave) a compartment must be thoroughly cleaned to remove visible dirt. This will also remove most of the pathogens that contaminate the materials.

- **Disinfection:** when properly applied, disinfection will inactivate any pathogen that is present on materials that have already been thoroughly cleaned.

A tailored biosecurity management system is fundamental to the establishment of an ASF-free compartment, and is documented as a biosecurity plan. The Hazard Analysis Critical Control Point (HACCP) approach can be considered when developing the biosecurity management system [21; 25].

The biosecurity management system needs to be effective enough to affirm the integrity of the compartment and ensure that its health status

will not be compromised by changes in the wider ASFV risk context of the compartment, e.g. a change in the external ASF epidemiological situation. As a contingency measure, it is also important that the overall biosecurity management system is sufficiently effective that it can absorb potential limited failures in risk mitigation measures. In order to minimise the risk of infection or contamination of outputs from the compartment, the biosecurity management system will have to be able to contain virus within functional units or sub-units into which it has been introduced through effective bio-containment as well as bio-exclusion measures.

HOW?

The compartment operator should work in collaboration with the Veterinary Authority on the development of the biosecurity management system and the associated biosecurity plan. The plan documenting the biosecurity management system should comply with Article 4.5.3. on the separation of a compartment from potential sources of infection, and Article 4.4.3. on principles for defining and establishing a zone or compartment, of the *Terrestrial Code* [3].

The specific risk mitigation measures included in the biosecurity management system should take into consideration the individual steps along each of the risk pathways for ASFV introduction into the compartment, as well as the final risk estimate. As a first step, if the overall risk estimate is not at an acceptable level, risk mitigation measures are required for particular risk pathways. The chosen type or combination of risk mitigation measures must reduce the overall risk estimate for the compartment to an acceptable level or below. It is likely that it will be necessary to implement several risk mitigation measures along the same risk pathway, so that the risk estimate reaches the acceptable level. Again, it is not just important to consider bio-exclusion measures but also bio-containment measures for specific functional units or sub-units inside the compartment, into which virus could have been introduced. The risk mitigation measures need to be practical and cost-effective. Once these risk mitigation measures have been taken into consideration, the sensitivity of the revised risk estimates to changes in the wider risk environment outside the compartment must also be considered. The purpose of this is to provide assurance that the integrity of the compartment and thus its health status would not be compromised by these changes in the wider risk context.

To put the biosecurity management system of a compartment into practice, detailed standard operating procedures (SOPs), addressing each risk pathway and clearly defining the procedures for the risk mitigation measures to be used to enhance biosecurity and prevent the introduction of ASFV, should be developed and documented. The SOPs should be prepared by relevant experts, internal or external, in collaboration with the risk management team of the compartment. The SOPs need to be reviewed on a regular basis for effectiveness, and may have to be revised if the risk context has changed. It is essential to develop a culture of compliance among all staff in relation to the biosecurity plan. To achieve this, it is important to provide relevant and continuous training for staff and, if possible, key staff should be involved in the development of the biosecurity plan. Furthermore, the SOPs should be made available in the working language of all relevant staff of the compartment, and appropriate training should be given to all members of staff. It is also recommended to implement an SOP compliance monitoring programme (CMP), which aims to identify any deficiencies in the implementation of the SOPs and evaluate the effectiveness or potential failure of the risk mitigation measures implemented. The CMP may involve interviews with staff, observation during operations, and assessment of documentation or reports, as appropriate. It is desirable to have a specific staff member who is responsible for the CMP. In addition, independent auditing should be conducted at regular intervals [26].

In general, SOPs should describe the following [3]:

- **the implementation, maintenance and monitoring of the biosecurity measures;**
- **how to apply corrective actions;**
- **verification of the process;**

- **record-keeping and the duration for which records must be stored;**
- **procedures for reporting to the Veterinary Authority.**

In case of biosecurity breaches, a contingency plan is necessary, which should be designed and properly documented as part of the biosecurity plan. The purpose of the contingency plan is to in the first instance prevent the health status of the compartment from being compromised and in case of an ASFV incursion to prepare for necessary response actions in the compartment. The contingency plan should be based on an understanding of the potential areas where biosecurity breaches could occur, based on a sensitivity analysis of the operational risk assessment. The roles and responsibilities of the compartment operator and the Veterinary Authority during biosecurity breaches need to be clearly defined [3].

For specific details of a biosecurity plan, including a description of the biosecurity management system, and the contents of the SOPs and the contingency plan, readers are referred to the OIE *Checklist on the Practical Application of Compartmentalisation*. The compartment operator may refer to the FAO/OIE publication, *Good practices for biosecurity in the pig sector: issues and options in developing and transition countries*, for assistance with the development and implementation of biosecurity measures [24]. A 'compartment checklist', based on the biosecurity outcomes to be achieved in an ASF-free compartment, is also included in **Appendix 5** for practical guidance on implementation.

EXPECTED OUTCOME

The ASF-free compartment effectively implements a biosecurity management system (documented as a biosecurity plan) that is able to prevent the introduction of ASFV and respond to changes in the external ASF risk environment (in which the components of the ASF-free compartment are located) to ensure that all pigs and other relevant commodities inside the compartment are ASFV-free [8; 27]. The biosecurity management system is also able to absorb minor failures in risk mitigation measures. It also needs to be able to contain the virus within affected functional units or sub-units, so that risk of spread to other parts of the compartment is minimised.

The effectiveness of the biosecurity management system can be substantiated by documenting the impact of risk mitigation measures on the risk estimates associated with the different risk pathways identified in the operational risk assessment. This will require that the biosecurity plan and operational risk assessment documents are cross-referenced.

COUNTRY EXPERIENCE

United Kingdom

BIOSECURITY REQUIREMENTS FOR COMPARTMENTS FOR BREEDING POULTRY

The biosecurity requirements for poultry compartments are divided into 'structural features' (i.e. physical biosecurity features) and 'management protocols' (standard operating protocols that must be followed to maintain the required minimum level of biosecurity). Many of the biosecurity measures must also be further strengthened during defined high-risk periods. These biosecurity and surveillance requirements are listed for both flock farms and hatchery premises in the compartment schedules, which are publicly accessible on the British Poultry Council website (www.britishpoultry.org.uk/about-bpc/defra-compartments/). In addition to biosecurity measures, surveillance is required to ensure continuous monitoring of the disease status of the compartment premises at all times. Surveillance includes, but is not limited to, the collection of samples for laboratory testing and regular recording of production and mortality data to observe trends in these variables. Laboratory surveillance is intensified during periods of higher risk of disease introduction. Testing is split between private and public laboratories, with the majority of compartment testing carried out by private laboratories.

Canada

BIOSECURITY PLAN FOR COMPARTMENTS FOR SALMONID GERMPLASM

A biosecurity plan, based on Canada's national compartmentalisation standards and composed of individual standard operating procedures, must be developed that addresses the potential introduction of disease through different risk pathways. The national standards were developed by the Veterinary Authority in consultation with the private sector. An analytical framework for compartmentalisation was developed by epidemiologists from the Canadian Food Inspection Agency (CFIA) and applied to each candidate compartment to evaluate the risks of disease introduction and establish the level of surveillance required. The CFIA is responsible for determining, developing, implementing and adjusting, if necessary, the compartment-specific surveillance plan. The compartment operator is responsible for identifying any inadequacies in the surveillance plan. Operators of officially recognised compartments are responsible for developing and implementing the biosecurity plan and mitigating their risk of disease introduction to an acceptable level, as well as notifying the CFIA of any biosecurity breaches which may affect the corresponding disease introduction risk and, therefore, the surveillance plan.

SURVEILLANCE SYSTEM

The purpose of the compartment's surveillance system is to assure the integrity of the ASF-free compartment to key stakeholders and, ultimately, provide confidence that all outputs produced by the compartment are ASFV-free or their ASFV risk is below the agreed acceptable level.

The compartment operator should work in close collaboration with the Veterinary Authority in the design of the ASF surveillance system [3]. The surveillance system of a compartment must comply with the provisions of the *Terrestrial Code*, Chapter 1.4. on animal health surveillance, and Chapter 1.5. on surveillance for arthropod vectors of animal diseases, as well as the specific recommendations for ASF surveillance defined in Articles 15.1.28. to 15.1.33. The Veterinary Authority shall then approve the surveillance system for implementation. The surveillance system of a compartment must be developed based on an understanding of the risk pathways and significance of each step along the pathways for transmission of ASFV. It needs to be able to detect an introduction of ASFV sufficiently rapidly that the likelihood of outputs produced by the compartment being infected or contaminated with ASFV, and the likelihood of them leaving the compartment remains below the acceptable level specified by the recipients of these outputs [28]. The surveillance system should also be tailored to the epidemiological situation of the country and is likely to require components that are implemented both inside and outside the compartment, taking the specific epidemiological characteristics of ASF into consideration, as outlined in Article 15.1.28. of the *Terrestrial Code*.

The surveillance system needs to target key steps along the risk pathways included in the operational risk assessment. The entry, exposure and consequence components of the risk assessment each have specific significance in the design of the surveillance system. The surveillance system should consist of various components that target critical steps in the risk pathways.

Surveillance reports should be regularly submitted to the Veterinary Authority. In addition, the surveillance system should be subject to formal evaluation on a regular basis, as outlined in Article 1.4.3. of the *Terrestrial Code* on quality assurance of surveillance systems and Chapter 3 of the OIE *Guide to Terrestrial Animal Health Surveillance* [29].

The effectiveness of the surveillance system should be evaluated for the attributes of sensitivity, timeliness and representativeness [30]. The key stakeholders should agree on the target values for these surveillance quality attributes when the compartment is being established. It is essential that the overall effectiveness of the surveillance system is evaluated as a whole, in relation to its agreed objectives and quality attributes.

The surveillance system needs to be based on an optimal combination of surveillance components that, together, will achieve the agreed target quality attributes. There will be surveillance components that are external to the compartment as well as those that are within the compartment.

The surveillance system should be documented as a surveillance plan in accordance with Chapter 1.4. on animal health surveillance of the *Terrestrial Code* and the OIE Guide to *Terrestrial Animal Health Surveillance* [31].

General considerations for ASF surveillance

Reporting criteria

WHAT?

While the case definition for the occurrence of infection with ASFV (i.e. a confirmed ASF case) is stated in Article 15.1.1. of the *Terrestrial Code*, the Veterinary Authority must also establish a definition(s) for the suspicion of infection with ASFV (i.e. a suspected ASF case) that standardises the suspicions of interest relating to ASF for investigation and reporting purposes. Such definitions should be clearly stated in the national ASF surveillance plan, as these apply within compartments as well as for the rest of the country or zone.

HOW?

The specific epidemiological context of the country or zone in relation to ASF and other relevant factors (e.g. available laboratory services) must be considered when Members develop specific definitions for a suspected ASF case. Chapter 15.1. of the *Terrestrial Code* provides a case definition for a confirmed ASF case.

Once the specific definitions of a suspected ASF case are established, any animal meeting any of those suspected ASF case definitions, as well as the confirmed ASF case definition as per Article 15.1.1. of the *Terrestrial Code*, must be reported to the Veterinary Authority immediately, in accordance with the established reporting system. In addition, other samples (e.g. feed, genetic material and meat) may also be included in the surveillance system as appropriate. Any of these samples testing ASFV-positive should also be reported to the Veterinary Authority immediately. On receipt of the report, the Veterinary Authority should initiate a formal investigation as soon as possible and take the necessary follow-up actions [29].

EXPECTED OUTCOME

The Veterinary Authority establishes definition(s) to standardise suspected and confirmed ASF cases for investigation and reporting purposes. These definitions should be well documented in the national ASF surveillance plan and consistent with the OIE case definitions related to ASF, applied in the country or zone as appropriate. Corresponding risk mitigation measures should be linked to the suspected or confirmed cases.

Examples of possible definitions for suspected ASF cases are summarised in Table 2. These include the definition of a suspected case and a presumptive positive case of ASF from the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA), as stated in the *Swine Haemorrhagic Fevers: African and Classical Swine Fever Integrated Surveillance Plan*, and the OIE definition of infection of suids with ASFV given in Article 15.1.1. of the *Terrestrial Code* [32].

Table 2 Case definition examples from USDA and OIE [29]

CASE CATEGORY	DEFINITION
SUSPECTED CASE (USDA)	An animal having relevant clinical signs (e.g. fever, increased pulse and respiratory rate, lethargy, anorexia, recumbency, vomiting, diarrhoea, bloody nasal discharge, eye discharges, abortions, reddening of the skin, lack of coordination (ataxia)) and epidemiologic information consistent with ASF
PRESUMPTIVE POSITIVE CASE (USDA)	A suspected case with a non-negative screening test result for ASFV by polymerase chain reaction or with ASFV antibodies, detected by two different antibody tests at any officially designated laboratories
CONFIRMED POSITIVE CASE (OIE)	· ASFV has been isolated from samples from a suid; or · antigen or nucleic acid specific to ASFV has been identified in samples from a suid showing clinical signs or pathological lesions suggestive of ASF or epidemiologically linked to a suspected or confirmed case of ASF, or from a suid giving cause for suspicion of previous association or contact with ASFV; or · antibodies specific to ASFV have been detected in samples from a suid showing clinical signs or pathological lesions consistent with ASF, or epidemiologically linked to a suspected or confirmed case of ASF, or giving cause for suspicion of previous association or contact with ASFV

Laboratory diagnostic testing

WHAT?

Surveillance may involve the use of laboratory diagnostic testing as necessary, taking the country- or zone-specific ASF epidemiological situation into consideration. The performance of a test together with the infection prevalence would affect the conclusions drawn from surveillance and should be taken into account in the design of surveillance systems and analysis of surveillance data. Laboratory diagnostic tests for ASFV should be chosen, as appropriate, to fit the intended purpose, in accordance with the recommendations in Chapter 3.8.1. of the *Terrestrial Manual* on African swine fever (infection with African swine fever virus) [33]. For compartmentalisation purposes, the diagnostic capacities and procedures for laboratory testing used in the surveillance system should comply with Article 4.5.6. of the *Terrestrial Code* on diagnostic capacities and procedures [8]. Pooled sampling methods using blood or oral fluids from live pigs can be considered to increase cost-effectiveness of virus detection as part of surveillance [34; 35].

HOW?

Laboratory diagnostic testing for ASFV should be conducted by officially designated laboratories, which are under the direct supervision of the Veterinary Authority or otherwise certified by the Veterinary Authority. Private laboratories from the pig industry may also apply for certification as officially designated laboratories by the Veterinary Authority, which should assess their respective competencies individually, as deemed appropriate, taking the OIE and other relevant international standards as the reference. These laboratories should comply with the OIE standards for quality assurance as defined in Chapter 1.1.5. of the *Terrestrial Manual*. The relevant laboratory diagnostic tests and procedures for ASFV used by these laboratories should comply with the recommendations detailed in Chapter 3.8.1. of the *Terrestrial Manual*, with appropriate validation of the diagnostic testing methods given in Chapter 1.1.6. of the *Terrestrial Manual*.

In addition to diagnostic capacities, laboratories conducting testing for ASFV should have systematic procedures and a rapid reporting system to the Veterinary Authority in place. Any inconclusive or positive test results should be immediately reported to the Veterinary Authority and referred to the national reference laboratory, OIE reference laboratory or other reference laboratories for further confirmatory testing, if appropriate [8; 36].

EXPECTED OUTCOME

The laboratory diagnostic tests for ASFV in the ASF-free compartment are conducted by officially designated laboratories with diagnostic capacities and procedures complying with the relevant standards outlined in *the Terrestrial Manual,* in support of the quality attributes of the compartment's ASF surveillance system, in particular, through their diagnostic test sensitivity and specificity. An effective reporting system should also be established in these laboratories for timely reporting of any reportable cases to the Veterinary Authority.

Internal surveillance components

WHAT?

The internal surveillance components of an ASF-free compartment are intended for two purposes:

- **rapid detection of ASFV introduction into the compartment;**
- **demonstration of freedom from ASFV in the animal sub-population in the compartment.**

HOW?

Based on the operational risk assessment, several surveillance components would likely have to be implemented, targeting key steps along relevant risk pathways. The objectives are to demonstrate firstly that the compartment is ASFV-free, and secondly that, if an introduction of ASFV did occur, it would be detected sufficiently rapidly so that the probability of ASFV-infected or contaminated outputs leaving the compartment

would not be higher than the agreed acceptable level of risk. This may include any combination of the following surveillance components to achieve the ultimate goal of rapid detection and demonstration of ASFV freedom:

- **clinical surveillance based on clinical signs consistent with ASFV infection;**
- **surveillance of inputs (e.g. feed, veterinary supplies and bedding);**
- **syndromic surveillance based on production data;**
- **syndromic surveillance based on pig mortality data;**
- **targeted surveillance at key steps of risk pathways (e.g. ASFV testing of finisher pigs at specified intervals);**
- **surveillance in slaughterhouses, including ante- and post-mortem surveillance (e.g. clinical surveillance of ante-mortem pigs and it may include targeted ASFV diagnostic testing of condemned pig carcasses in the slaughterhouse).**

EXPECTED OUTCOME

The ASF-free compartment applies internal surveillance components that are able to detect the presence of ASFV to trigger response actions so that it is possible to prevent ASFV-infected or contaminated outputs from leaving the compartment and to demonstrate freedom from ASFV.

→ **Appendix 8** and **Appendix 9** provide additional guidance for internal surveillance of an ASF-free compartment.

Rapid detection

WHAT?

Rapid detection of ASFV introduction into the compartment is an essential objective for a compartment's internal surveillance components. It aims to provide sufficient assurance to trading partners that any presence of ASFV within the compartment would be detected rapidly and trigger immediate response actions to ensure that the risk of ASFV-infected or contaminated outputs leaving the compartment will not be above the agreed acceptable level.

HOW?

The risk pathways and their associated risk estimates will indicate where it is possible to rapidly detect the introduction of ASFV. When deciding on a compartments' internal surveillance components, a major consideration should be given to the complex epidemiology of ASFV, such as asymptomatic excretion of up to 2 days before the onset of clinical signs and an incubation period that is most likely 7 days but can be up to 19 days [37-41]. Taking these features into account, the sensitivity of each component and of the system as a whole needs to be carefully optimised for rapid detection to provide the necessary assurance to key stakeholders [42; 43]. Key stakeholders need to reflect on the agreed rapid detection surveillance quality attributes, to consider how quickly (timeliness) and with what sensitivity a virus incursion would have to be detected so that the risk of ASFV-infected or contaminated outputs leaving the compartment does not exceed the agreed acceptable level of risk.

EXPECTED OUTCOME

In case of failure of the biosecurity management system, the internal surveillance system must be able to detect ASFV incursion as rapidly as possible, i.e. it must be capable of detecting any presence of ASFV within relevant functional units or sub-units of the compartment to allow a prompt response. Immediate actions must be taken as defined in the contingency plan to prevent ASFV-infected or contaminated outputs from leaving the compartment, in accordance with the requirements of relevant stakeholders and the agreed acceptable risk of ASFV.

Freedom from infection

WHAT?

The internal surveillance components of an ASF-free compartment should comply with the general criteria outlined in Articles 1.4.6., 15.1.3. and 15.1.5. of the *Terrestrial Code* for demonstration of ASFV-freedom.

HOW?

To demonstrate that a compartment is free of ASFV, the internal surveillance components should be ASF-specific in accordance with the relevant Articles of the *Terrestrial Code*, i.e. Chapter 1.4. on animal health surveillance, and disease-specific Chapter 15.1. on infection with ASFV, and there should be no occurrence of ASFV infection. To achieve this goal, three prerequisites must be complied with for a period at least as long as the ASF-specific surveillance has been in place. These are [31]:

- **ASF being a notifiable disease in the country or zone;**
- **an early warning system, as outlined in Article 1.4.5. of the *Terrestrial Code*, being in place for suids;**
- **measures being in place to prevent the introduction of ASFV.**

Freedom from ASF implies the absence of ASFV infection in the animal sub-population in the compartment. The compartment's internal surveillance components must be able to demonstrate freedom from ASFV infection in accordance with the *Terrestrial Code* at the level of confidence agreed to by key stakeholders. This interpretation implies that ASFV infection, if present, is present in less than the specified proportion of the animal sub-population [31].

→ **Appendix 8** provides further guidance on the development of internal surveillance for an ASF-free compartment.

The compartment operator must agree with the key stakeholders, including the Veterinary Authority and trading partners, on the required level of surveillance quality attributes, including sensitivity and representativeness, for this purpose.

EXPECTED OUTCOME

The compartment's internal surveillance components should be able to demonstrate freedom from ASFV at a given level of confidence and design ASFV prevalence, which has been agreed with key stakeholders, including trading partners, if appropriate.

External surveillance components

WHAT?

The country or zone within which different functional units or sub-units of a compartment are located should have a surveillance system for ASF. The choice of external surveillance components of the ASF-free compartment depends on the components and quality attributes of the national ASF surveillance plan. Depending on the actual situation, it is possible for components of the national ASF surveillance plan to be part of the compartment's external surveillance components.

The national ASF surveillance plan is usually part, if not all, of the compartment's external surveillance components and needs to be able to detect epidemiological changes outside the compartment that may trigger an increase in the risk estimate for ASF above the agreed acceptable level.

In the event that the epidemiological context of a compartment requires the implementation of external surveillance components that are not already implemented by the Veterinary Authority or other stakeholders (e.g. ASF surveillance in soft ticks), additional costs that may be incurred by the compartment to implement such surveillance should be taken into consideration, and respective roles and responsibilities should be appropriately identified and documented.

HOW?

For the purpose of external surveillance, risk-based surveillance in accordance with an assessment of risk factors may be the most efficient surveillance approach, based on the recommendations of Chapter 1.4. on animal health surveillance of the *Terrestrial Code*. The external surveillance components of the compartment should target epidemiological units which may influence the risk associated with risk pathways for ASFV introduction into the compartment, as identified in the risk assessment. This may mean units which have a close epidemiological relationship to the functional units or sub-units [8].

The ASF status of the country or zone within which the compartment is located influences the choice of external surveillance components. The structure of the different risk pathways for ASFV introduction into the compartment, together with the risk estimates associated with each step of the operational risk assessment, should inform points at which specific surveillance components should be targeted.

As an example, for a compartment located in an ASF-free country or zone, the national ASF surveillance plan will usually be based on farmer reporting and border inspection surveillance components, although this may vary, depending on the actual ASF epidemiology in a compartment's external environment. In that situation, a compartment's ASF-specific external surveillance component, in accordance with Article 15.1.32. of the *Terrestrial Code*, aimed at wild or feral pigs in the geographical area around each component of the compartment, as well as at pig farms with swill feeding practices, may be sufficient.

For the purposes of rapid detection of ASFV introduction into the country, sick or dead pigs may be examined for ASFV, if this can be justified on the basis of risk assessment and economic considerations [29]. For a compartment located in a country or zone not free of ASF, additional external surveillance components may need to be implemented, depending on the risk assessment results. In order to identify the appropriate additional targets for surveillance, all relevant risk factors associated with the risk pathways should be considered, such as the presence of ASFV in the wild or feral pig populations, outdoor free-ranging pigs, soft ricks, and pig-production premises outside the compartment. For instance, an additional surveillance component could be based on clinical observations in pigs with a higher risk of ASFV infection according to the risk assessment findings, e.g. those pigs adjacent to a non-ASF-free country or zone.

The external surveillance components must be overseen by the Veterinary Authority and comply with the relevant OIE standards. It may also be useful to reach prior agreement with trading partners on the required level of quality attributes of the national ASF surveillance plan.

EXPECTED OUTCOME

External surveillance components of the compartment have been implemented as part of the national ASF surveillance plan or complementing it, and the corresponding quality attributes of sensitivity, representativeness and timeliness are able to identify changes in the ASFV risk outside the compartment associated with risk pathways relevant to the compartment. That information will then be used to examine whether it changes the different risk estimates along the risk pathways and ultimately the overall risk estimate for the compartment.

IDENTIFICATION AND TRACEABILITY SYSTEM FOR PIGS AND PORK PRODUCTS, AND RELEVANT INPUTS INTO THE COMPARTMENT

WHAT?

Identification and traceability of pigs and pork products, and relevant inputs into the compartment requires a system that allows reliable tracing and attribution along the entire supply chain associated with the compartment. This should allow both forward and backward tracing through all stages along the supply chain into, within and outside the compartment. This is a key aspect of being able to give assurance of the compartment's overall integrity to recipients of the compartment outputs. In case of an ASFV incursion, it will allow to rapidly and effectively identify and correct the failures in the biosecurity management system. Irrespective of the specific animal identification and traceability system adopted by the compartment, it should comply with Chapters 4.2. and 4.3. of the OIE *Terrestrial Code*, as well as Article 4.5.3. on traceability systems and Chapters 5.10. to 5.11. for animals and animal products intended for export.

Traceability is essential for effective biosecurity management. Pig and pork product traceability also provides assurance to stakeholders that these products come from the compartment and, consequently, that they are ASF-free. Furthermore, traceability allows the efficient and effective recall of relevant pig products in the event of an ASFV incursion [1; 8; 27]. It is essential that in the country or zone in which the compartment is located a traceability system is also implemented for pigs and pork products not associated with the compartment.

HOW?

Pig and pork product traceability, including animal identification, should come under the responsibility of the Veterinary Authority [44]. In addition, relevant inputs into the compartment, such as feed, need to be traceable. The implementation and enforcement of animal identification and traceability in the country or zone should be detailed in the national ASF compartmentalisation programme. The existence of an animal identification and traceability system in the compartment is an essential prerequisite for recognition. Thus, the Veterinary Authority must ensure that an effective animal identification and traceability system is in place in the ASF-free compartment, which may be done at the group or individual animal level, depending on the type of production, identification and registration. If it is done at the group level, credible evidence will have to be provided that it will not compromise the reliability of forward and backward tracing of individual pigs or pig products.

The identification and traceability system should include the following elements [3]:

- **a description of the method of individual animal or group identification. If group instead of individual animal identification is applied, the identification system needs to provide reliable traceability of the animals included in the group and it has to be approved and verified by the Veterinary Authority;**
- **records must minimally include batch identification of the pigs, as well as the origins and movements of the animals and relevant commodities;**
- **the audit mechanism for this system, including its frequency and relevant procedures, such as reporting audit results and taking corrective actions.**

EXPECTED OUTCOME

The ASF-free compartment is located in a country or zone that has an identification and traceability system for pigs and pork products in place. The compartment itself adopts an identification and traceability system that can be linked to provide a sufficient level of traceability along all relevant steps of the pig and pork product supply chain, taking the relevant OIE and Codex Alimentarius standards into account, as well as the requirements of trading partners [44].

IMPLEMENTATION

The compartment implementation process is a collaboration between the private sector, the public sector and interested third parties. Chapter 4.4. on zoning and compartmentalisation and Chapter 4.5. on the application of compartmentalisation of the *Terrestrial Code* outline general considerations in the compartmentalisation process [2]. When initiating a compartment, these considerations should be duly followed, together with other relevant chapters of the *Terrestrial Code*. The key processes are detailed in this section, with an overview of the sequence of steps in the compartmentalisation process summarised as a flowchart in Appendix 2

Roles and responsibilities

Chapter 4.5. of the *Terrestrial Code,* on the application of compartmentalisation, and Article 4.4.2. on general considerations of zoning and compartmentalisation, outline the roles and responsibilities of the public sector (Veterinary Authority), private sector (compartment operator) and relevant third parties in the implementation of an ASF-free compartment.

The private sector and third parties will mostly be responsible for the business operation of the compartment. The public sector, on the other hand, will be concerned in how the compartment contributes to the improvement of overall animal health and welfare through proper application of biosecurity measures to ensure business continuity and a sustainable pig supply chain. The public sector will also be responsible for the verification and certification of the compartment's integrity. By working together, with each party fulfilling its role in the implementation process, a robust compartment can be established [45].

VETERINARY AUTHORITY

The Veterinary Authority must demonstrate, by means of an appropriate regulatory framework, sufficient financial resources and effective organisation of its mandate in relation to animal health policies. The Veterinary Authority should be responsible for defining the national ASF compartmentalisation programme, including, but not limited to, the establishment of relevant regulations and conditions, supervision of relevant audits, issuing of international veterinary certifications for trade, etc. These responsibilities and the structure of the Veterinary Authority overseeing such activities must be clearly defined and documented [46].

EXPORTING COUNTRY

The primary responsibility of the Veterinary Authority in its role of liaison will be to notify the occurrence of ASF in the country, zone or compartment to the OIE and trading partners. To promote transparency and facilitate inter-country trade, the performance of the Authority's relevant Veterinary Services should be evaluated in accordance with Chapter 3.2. on the evaluation of Veterinary Services, of the *Terrestrial Code* [47]. Moreover, the role of Veterinary Authorities in partner countries also needs to be clearly defined.

The Veterinary Authority of an exporting country should be able to demonstrate to the Veterinary Authority of an importing country the basis for claiming that a given compartment is free of ASF. The exporting country should be able to provide evidence, through detailed documentation provided to the importing country, that it has implemented the recommendations in the *Terrestrial Code* for establishing and maintaining such a compartment [1; 5; 8].

In general, the responsibilities of the Veterinary Authority of an exporting country, as outlined in the established regulatory framework, may include but are not limited to:

- verifying that effective control measures for compartments are carried out in accordance with the relevant standards and requirements of the national ASF compartmentalisation programme;
- carrying out regular audits of the integrity of the ASF-free compartments, at intervals based on the ASF epidemiological situation in the country or zone outside the compartment, and providing to the Veterinary Authority of the importing country information on any amendments or adaptations to the common biosecurity management system or biosecurity plans of the compartment;
- certification attesting that commodities come from an approved ASF-free compartment;
- identification and certification of an approved ASF-free compartment for national and international trade purposes, as stated in Article 5.3.7. of the *Terrestrial Code*;
- supplying relevant information on request by importing countries, as stated in Article 5.1.3. of the *Terrestrial Code* [47].

The Veterinary Authority may also delegate certain responsibilities, as necessary, to a certified third party with appropriate supervision.

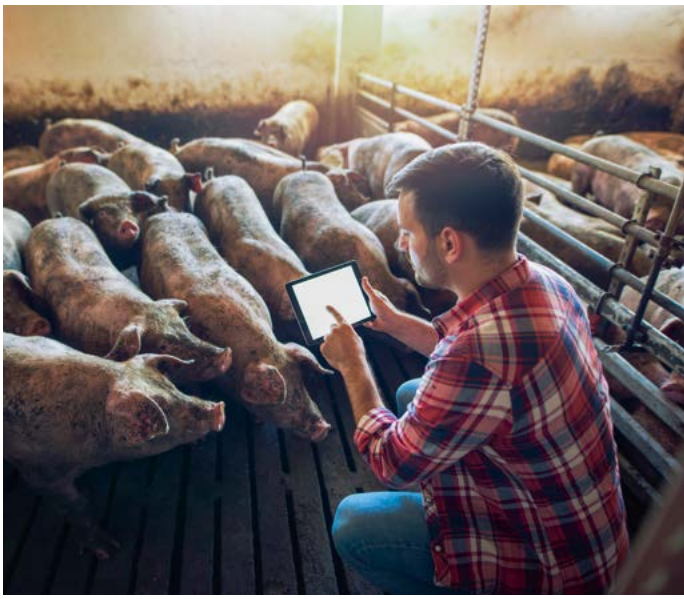
IMPORTING COUNTRY

The recognition of ASF-free compartments should take place bilaterally between trading partners. The Veterinary Authority of the importing country should consider recognising the existence of relevant compartments if the appropriate measures, including those recommended in the *Terrestrial Code*, have been applied, and the Veterinary Authority of the exporting country is able to verify and demonstrate the corresponding compartment status [1; 8; 47]. The responsibilities of the importing country for certification of relevant commodities should accord with Article 5.1.2. of the *Terrestrial Code* [47]. In regard to recognising a compartment, the importing country should, according to its regulatory framework, make an appropriate decision on whether to recognise a compartment for the importation of animals or animal products. This process should be conducted within a reasonable period of time, with reference to Article 5.3.7. of the *Terrestrial Code* on the sequence of steps to be taken in establishing a zone or compartment and having it recognised for international trade purposes [48].

PRIVATE SECTOR

The compartment operators are the private-sector entities responsible for the compartments. They must commit resources sufficient for the purpose of setting up and maintaining a compartment, in cooperation with the Veterinary Authority, which carries out other relevant measures to serve the public good in both economic and food security matters. The compartment operator, as well as other interested private-sector partners, should preferably engage with, and be engaged by, the Veterinary Authority to contribute to the creation of a national ASF compartmentalisation programme that accords with the *Terrestrial Code* to facilitate compliance. In general, the compartment operator should be responsible for:

- establishing appropriate facilities in the compartment, such as buildings and equipment, that comply with the biosecurity requirements of an ASF-free compartment;
- supervision and monitoring of the compartment to maintain compliance with the relevant regulations and requirements in the national ASF compartmentalisation programme, and ensuring that up-to-date information and documentation are readily available for the Veterinary Authority on request;
- risk assessment, internal disease surveillance and other relevant activities related to ASF, as deemed necessary, in accordance with the established biosecurity plan for the common biosecurity management system implemented in the ASF-free compartment. These activities should be subject to verification and validation by the Veterinary Authority or other appropriate third parties;
- regular internal and external audits to provide credible assurance of the integrity of the compartment;
- close and structured communication with the Veterinary Authority for suspicions and disease reporting, as well as for any changes made to biosecurity and surveillance measures [49].



THIRD PARTIES

Third parties are also likely to be involved in the creation and maintenance of the integrity of a compartment [50]. In line with the principles of defining a compartment, all professions with key competencies in regard to compartment-related questions must be identified [3]. In this context, third parties may include various professionals, such as epidemiologists, private veterinarians, veterinary para-professionals, auditors, pharmaceutical companies and other enterprises that provide relevant commodities or services to the compartment [8; 49]. Third parties may operate directly under, or be contracted by, the compartment operator or Veterinary Authority. The activities carried out by third parties should essentially ensure the smooth functioning of the compartment, such as providing essential technical services for compartment operations, especially in regard to internal surveillance, internal and external auditing, and contingency emergency response planning [8].

IMPLEMENTATION

Public-private partnership

Compartmentalisation is not only a trade-facilitating measure, but also a tool to improve animal health, by enhancing biosecurity, and to reduce the probability and impact of disease outbreaks [50]. Although the initiative to establish a compartment normally comes from the private sector, and much of the work that must be done to establish the compartment is the responsibility of the compartment operator, the Veterinary Authority remains responsible for recognising the compartment and certifying the health status of the animal sub-population in the compartment [51]. To achieve this larger goal, Veterinary Authorities are encouraged to undertake public–private partnerships (PPPs) with relevant stakeholders in the private livestock and veterinary sector [50].

Collaborating toward efficiency

Public–private partnerships will greatly facilitate a successful compartmentalisation process. This kind of collaboration allows for an efficient use of limited resources in the veterinary domain [45]. Members should ensure that the compartment is developed in close partnership between the Veterinary Authority and relevant private sectors [50]. Thereafter, the compartment operator and Veterinary Authority should work together to deliver the agreed outcomes of the compartment [45]. The compartment operator and Veterinary Authority must exhibit a high level of transparency in their dealings [45]. In accordance with the OIE *Public–private partnership handbook*, the Veterinary Authority should desist from overly prescriptive oversight whilst allowing the private sector the flexibility to operate within the obligations of the compartmentalisation partnership, provided that equivalence has been taken into consideration [45]. The Veterinary Authority is ultimately responsible for ensuring that the compartment is effective and that any national or international guarantees offered on the basis of the compartment are reliable. It must therefore agree with the private-sector partners on a system for monitoring and evaluating the compartment and applying remedial action or for withdrawing recognition of the compartment, if necessary.

Brazil

PUBLIC–PRIVATE PARTNERSHIPS TO ACHIEVE RECOGNITION BY TRADING PARTNERS

In Brazil, public–private partnerships (PPPs) are particularly important in establishing rules relating to the registration and operation of compartments to achieve a balance between practicability and the certification conditions of the Veterinary Authority. To achieve recognition by trading partners, the Veterinary Authority should ensure that the certification conditions provide sufficient confidence in and assurance of the sanitary robustness of the compartment, even in the face of unfavourable external epidemiological conditions. In this manner, PPPs are particularly important in identifying all risk factors for the introduction and spread of diseases of concern, and defining appropriate risk mitigation measures. The Brazilian government determines the necessary processes, based on principles of trust and clarity supported by science, while still remaining open to the private sector's ability to take part in developing 'rules' related to compartmentalisation. The collection and consolidation of good-quality information from the private sector forms the basis of private-sector engagement. Working groups have also been set up for specific cases, with representatives from both the public and private sector, as well as with companies interested in developing standards and guidance for the implementation of compartments.

South Africa

PUBLIC–PRIVATE PARTNERSHIPS TO DEVELOP STANDARDS FOR COMPARTMENT APPROVAL

For compartmentalisation to be accepted, the Veterinary Authority has to ensure confidence in the integrity of the compartment system. This requires official oversight of the biosecurity and surveillance of compartments. In South Africa, the standards for compartment approval are developed in collaboration with the private sector and then legalised by the national Competent Authority in a signed and published official Veterinary Procedural Notice. Dedicated private veterinarians must visit every compartment regularly. The provincial Competent Authority receives feedback on continued compliance. Provincial officials also visit every compartment at least annually, then make a recommendation to the national authority for registration or re-registration. Based upon such provincial recommendations, the national authority approves, registers or re-registers all compartments and, in case of non-compliance, handles suspensions or de-registrations – all of which are subject to further ad hoc audits. The national authority is responsible for all international trade negotiations.

IMPLEMENTATION

Regulatory framework

Members must establish a national ASF compartmentalisation programme, which must be supported by a regulatory framework that may vary between countries or zones [50]. **Appendix 4** provides guidance for developing a national ASF compartmentalisation programme to formulate the regulatory framework of ASF-free compartments. For most Members, this authority is provided by specific veterinary legislation or in the form of a memorandum of understanding between the private sector and the Veterinary Authority, or other format as appropriate [50]. Regardless of the approach, a regulatory framework is a prerequisite for good governance of compartmentalisation. To encourage PPPs, Veterinary Authorities must ensure that all services provided by the private sector fall within their statutory mandate as well as within the national legal provisions [45]. Most importantly, the Veterinary Authority must ensure that the existing legal framework does not impede the full function of the compartment, either nationally or internationally [50].

In accordance with Article 3.4.4. of the *Terrestrial Code* on drafting veterinary legislation, veterinary legislation related to compartments should:

- be drafted in a manner that establishes clear powers, rights, responsibilities and obligations (i.e. 'normative');
- be accurate, clear, precise and unambiguous, and use consistent terminology;
- include only definitions that are necessary and relevant to the country;
- contain no definitions or provisions that create contradiction or unnecessary duplication;
- include a clear statement of scope and objectives;
- provide for the application of proportionate and dissuasive penalties and sanctions, either criminal or administrative, as appropriate to the situation;
- when relevant, make provision for the collection, use and disclosure of information gathered under the veterinary legislation;
- make provision for the financing needed for the execution of all activities of Competent Authorities; or these activities should be supported by appropriate financing in accordance with the national funding system;
- and indicate when the legislation comes into effect and its impact on similar pre-existing legislation, in particular secondary legislation.

The regulatory framework of the national ASF compartmentalisation programme should be able to provide a basis for actions to address the elements relating to export procedures and veterinary certification [7]. The requirements of the certifying veterinarian and principles of the certificates are stated in Articles 5.2.2. and 5.2.3. of the *Terrestrial Code*, respectively [52].

EXPECTED OUTCOME

The Veterinary Authority has assumed responsibility for the development and formulation of the regulatory framework for the national ASF compartmentalisation programme, based on scientific evidence, PPPs, experience with ASF, and other relevant factors. The national ASF compartmentalisation programme must include various elements for the establishment and maintenance of ASF-free compartments, such as roles and responsibilities, biosecurity standards, descriptions of laboratory diagnostic procedures, and formal supervision and audit procedures.

Thailand

DEVELOPING A REGULATORY FRAMEWORK FOR AVIAN-INFLUENZA-FREE COMPARTMENTS

In July 2006, the Department of Livestock Development (DLD) of Thailand issued a proclamation on the implementation of compartmentalisation in commercial poultry farming to improve all farm biosecurity systems to the same standard and to maintain the avian-influenza-free status of such farms. Any poultry companies wishing to establish an avian-influenza-free compartment must sign a memorandum of understanding with the DLD. For this purpose, the DLD set up a committee to develop requirements for the establishment and implementation of avian-influenza-free compartments, using the relevant OIE standards for reference. The committee included representatives from the public and private sectors, as well as veterinary schools.

IMPLEMENTATION

Submission of compartment application by an industry partner

In accordance with the Member's regulatory framework for the national ASF compartmentalisation programme, the compartment operator should submit to the Veterinary Authority a comprehensive compartment proposal, with a compartment operating manual and/or any other appropriate documentation, describing all the relevant components and aspects of the compartment and providing clear evidence that the risk assessment, biosecurity, surveillance, traceability and management practices defined for the compartment can be effectively and consistently implemented [8; 27]. Sufficient information should be included in the application to provide a detailed description defining the compartment, as outlined in these guidelines.

→ The compartment operator may use **Appendix 10** as a guide to prepare an ASF-free compartment operating manual.

IMPLEMENTATION

Approval of compartment

WHAT?

To enable formal approval, the requirements of the national ASF compartmentalisation programme must be met by the ASF compartmentalisation proposal, and compliance with the biosecurity and management requirements of the candidate compartment must be verified by appropriate audit. This section focuses on the conduct of audits and approval criteria for an ASF-free compartment, depending on the ASF status of the country or zone where the compartment is located.

HOW?

The Veterinary Authority should assess the compartment application by document review and on-site audit of the candidate compartment, as appropriate, to determine whether the requirements of the national ASF compartmentalisation programme are fulfilled [5; 8; 27]. To assess the initial registration of a candidate ASF-free compartment, the Veterinary Authority should assign accredited auditors, either from within the Veterinary Authority or from other independent third parties, to conduct a comprehensive audit to assess all the components of the compartment.

→ **Appendix 6** provides reference assessment criteria as guidance. Only if all the components of the candidate compartment pass the audit may the Veterinary Authority officially approve the candidate compartment as an ASF-free compartment.

The Veterinary Authority is ultimately responsible for the auditing process. If the Veterinary Authority is not itself conducting the audit(s), it must have an appropriate mechanism to oversee the auditing process by independent third parties. After approval of the submitted application documents, accredited auditor(s) assigned by the Veterinary Authority must conduct an initial, on-site audit of the candidate compartment, as appropriate. For initial registration, all components of the candidate compartment will be subject to the audit, which includes all aspects of the compartment, including, but not limited to: evaluation of the critical control points and standard operating procedures applied within the compartment; verification of the health status of the animal sub-population within the compartment; review of the operational risk assessment; and examination of the biosecurity management and surveillance system for the integrated components of the compartment.

→ **Appendix 7** provides an example of the audit process for guidance.

To be accredited, the following requirements should be met by third-party auditors.

→ They should have attended and successfully completed a recognised compartment auditor training course, with re-assurance of auditing capability on a regular basis.

→ Qualified auditors should be registered and officially certified by the Veterinary Authority as an accredited auditor(s). To facilitate standardisation of auditing by different auditors, the Veterinary Authority or an appropriate third party may conduct an induction programme for potential auditors, to train them to perform audits

accurately and consistently. This programme may include mock audits and document reviews. Official audit tools, such as checklists, may also be provided to potential auditors for these purposes [53].

They must have no conflicts of interest with any of the parties relating to relevant compartments or applying for compartment certification.

Auditing should not be a 'one-off' activity. An approved compartment must have regular internal and external audits for continuous assurance, detailed below.

While an ASF-free compartment is expected to be established when a country or zone has ASF-free status, it is also considered feasible to establish an ASF-free compartment in a country or zone that is not free of ASF.

For an ASF-free compartment to be set up in a non-ASF-free country or zone, the candidate compartment should first apply to the Veterinary Authority for initial registration and undergo a qualification period to demonstrate freedom from infection/disease. The Veterinary Authority, or appropriate third party under the supervision of the Veterinary Authority, should conduct comprehensive audits for document review and initial assessment of the compartment, as appropriate, and as previously mentioned in this section. The Authority must approve the biosecurity measures and management provisions of the candidate compartment upon satisfactory audit results and compliance with other relevant conditions. Enhanced biosecurity and surveillance measures would normally be expected, taking into consideration the non-ASF-free status of the country or zone in which the candidate compartment is located.

Upon approval of the compartmentalisation proposal, the operating manual, and the biosecurity and management measures taken by the candidate compartment, as well as any other relevant requirements, the Veterinary Authority shall assign the date for the candidate compartment's ASF-free qualification period to officially commence. The duration of the qualification period should be long enough to provide sufficient assurance that the compartment complies with the requirements for being free of ASFV. This level of assurance then forms the basis on which recognition of the compartment should be negotiated and agreed between trading partners. During the qualification period, ongoing veterinary supervision by dedicated veterinarians, certified by the Veterinary Authority, should take place, as well as ASF-specific surveillance, depending on the ASF epidemiology of the country or region where the compartment is located and the corresponding risk assessment of the compartment. Pigs, embryos and other genetic materials may be introduced into the compartment during the qualification period, but must comply with the standards in Articles 15.1.8. to 15.1.13. of the *Terrestrial Code*. The pigs in the candidate compartment should complete a full qualification period, preferably set out in the national ASF compartmentalisation programme, in order to be certified as originating from an ASF-free compartment, subject to formal approval. At the end of the qualification period, the Veterinary Authority should conduct another audit to inspect the candidate compartment and to check records of veterinary supervision and documentation for compliance with the biosecurity provisions and ASF-specific surveillance activities and results, as well as other relevant requirements. If the audit outcomes are satisfactory, the Veterinary Authority shall then certify the candidate compartment as an officially approved ASF-free compartment, taking any other relevant conditions into account [32; 45].

Figure 2 shows a flow chart summarising the process, in which the red boxes indicate the additional steps required for the implementation and approval of an ASF-free compartment in a non-ASF-free country or zone.

Figure 2 **Flow chart for the implementation and approval of an ASF-free compartment in a non-ASF-free country or zone**

Compartment operator officially submits a compartment proposal

Veterinary Authority assesses the compartment proposal

Veterinary Authority conducts an audit to verify whether the standards of the compartment comply with those of the regulatory framework and relevant requirements

Approval of the compartment proposal depends upon satisfying the relevant conditions of an audit by the Veterinary Authority

The approved candidate compartment starts the qualification period, as negotiated and agreed to by trading partners

Ongoing veterinary supervision and ASF-specific surveillance is carried out during the qualification period, with appropriate documentation

Veterinary Authority conducts another audit to inspect the candidate compartment for compliance with biosecurity provisions at the end of the qualification period

Veterinary Authority decides whether to approve the compartment based on the audit outcomes

EXPECTED OUTCOME

The ASF-free candidate compartment complies with the biosecurity and management standards of the national ASF compartmentalisation programme and is assured by comprehensive audits conducted by accredited auditors under the supervision of the Veterinary Authority.

Brazil

USING THIRD-PARTY AUDITORS

With the benefits that compartmentalisation brings to the private sector, the number of applications for the registration of compartments may exceed the capacity of the direct services that can be provided by the Veterinary Authority. In response to this issue, the government of Brazil accepts certification by a third-party entity as a prerequisite for in-country recognition of the compartment and its maintenance in avian-influenza-free and Newcastle-disease-free compartments for poultry genetics. However, it is necessary to establish robust mechanisms for cooperation with third-party entities in the compartment registration process and this can be difficult to achieve. The government must ensure that the compartment protocols proposed for registration are present and auditable by the Veterinary Authority, to enable certification of the products.

IMPLEMENTATION

Publication of an approved compartment

WHAT?

To facilitate international trade in pigs or relevant commodities originating from an approved ASF-free compartment, the Veterinary Authority of the exporting country is responsible for maintaining transparency of information related to the approved ASF-free compartment for trading partners and other relevant stakeholders.

HOW?

Appropriate information relating to the approved ASF-free compartment should be publicised by the Veterinary Authority of the exporting country and made readily available to trading partners and other relevant stakeholders. This could be done via publicly accessible channels, such as publishing on an official website, in the official journal, on noticeboards or in publications of the Veterinary Authority [54].

Member wishing to publish its self-declaration of an ASF-free compartment on the OIE website should provide the OIE with relevant documented evidence of compliance with the provisions of the *Terrestrial Code*. Publications of self-declaration of disease freedom are dealt with according to the OIE self-declaration SOPs.

→ These self-declaration SOPs and some examples of OIE Members' self-declarations of disease freedom can be found through the following link: **www.oie.int/animal-health-in-the-world/self-declared-disease-status/**. [55].

EXPECTED OUTCOME

The Veterinary Authority of the exporting country maintains transparency of information relating to the approved compartment via publication through officially and publicly accessible channels.

IMPLEMENTATION

Compartment recognition between trading partners

WHAT?

To establish a trading relationship between an approved ASF-free compartment and its trading partners, the Veterinary Authority of the exporting country, or the importing country, should initiate the compartment recognition process with appropriate assurance of the compartment's status. Recognition by the Veterinary Authority of the importing country may then be achieved by negotiation between the Veterinary Authorities of the exporting and importing countries.

HOW?

Government-to-government negotiation plays a crucial role in the ASF-free compartment recognition process. The Veterinary Authority of the exporting country, or the importing country, should initiate the negotiation process, and the Veterinary Authorities of the exporting and importing countries are encouraged to reach agreement on the specified ASF-free compartment(s) [27; 50]. In order to achieve a bilateral agreement, the specified ASF-free compartment(s) should be officially approved by the Veterinary Authority of the exporting country, and fulfil, or otherwise negotiate on, the sanitary import regulations set by the Veterinary Authority in the importing country [1; 27]. Alternatively, government-to-government negotiation may also be conducted on the national ASF compartmentalisation programme as a whole.

The Veterinary Authority of the exporting country should take the initiative to, or on request by the importing country, submit relevant documents providing the necessary information to the Veterinary Authority of the importing country to begin the compartment recognition process. Initial assessment by the Veterinary Authority of the importing country can be conducted using the documents submitted. Additional information can be requested, e.g. by means of questionnaires, followed by site visits (in collaboration with the Veterinary Authority of the exporting country) to relevant ASF-free compartment(s), as well as to other associated facilities, such as laboratories, for verification purposes if necessary [54; 56]. The assessment for compartment recognition should be science-based. Transparency is of crucial importance in achieving successful compartment recognition. Trading partners should always remain open to exchanging relevant information to facilitate the compartment recognition process.

For successful compartment recognition, mutual trust and agreement between trading partners is fundamental, and there is no specific sequence of steps that must be followed to achieve it. The *Terrestrial Code* provides recommendations on steps for determining the equivalence of sanitary measures and recognition of a compartment for international trade purposes in Articles 5.3.6. and 5.3.7., respectively. Therefore, before any ASF outbreak occurs, the Veterinary Authorities of the importing and exporting countries are encouraged to enter into a formal bilateral agreement recognising specified ASF-free compartment(s), or the national ASF compartmentalisation programme as a whole, for international trade purposes. Such an agreement should also take into consideration the actions to be taken if an ASF incursion eventually occurs in the country or zone where the compartment(s) is

located [50]. To demonstrate technical capacity, independence, transparency and other essential factors that contribute towards credibility for consideration by trading partners, the Veterinary Authority of the exporting country may allow the Veterinary Authority of the importing country to conduct a formal evaluation of its Veterinary Services as necessary, as stated in Article 3.1.3. of the *Terrestrial Code*. Alternatively, Members may consider requesting a formal independent evaluation of the quality of the exporting country's Veterinary Services using the OIE Performance of Veterinary Services (PVS) Tool [50; 57]. If it is not possible to achieve compartment recognition, the informal OIE procedure for dispute mediation, as laid out in Article 5.3.8. of the *Terrestrial Code*, offers an avenue for resolving differences between Members by facilitating understanding during trade disputes [2].

EXPECTED OUTCOME

The Veterinary Authorities of the exporting and importing countries should come to a bilateral agreement recognising the specified ASF-free compartment(s), or the national ASF compartmentalisation programme as a whole, for trading purposes.

→ **Appendix 14** provides some Members' experiences and a case study in achieving compartment recognition between trading partners, for reference.

IMPLEMENTATION

Maintenance of a compartment

WHAT?

Once the ASF-free compartment is officially established and approved, the compartment operator should work in close collaboration with the Veterinary Authority to maintain the compartment. The compartment operator must ensure that the biosecurity, surveillance and traceability systems, as well as other relevant conditions, are functioning effectively in all components of the compartment to achieve the ASFV risk specific objectives agreed upon by stakeholders.

HOW?

The management practices of the ASF-free compartment should be subject to appropriate supervision and audit. A surveillance system based on the principles outlined in this set of guidelines should be in place to ensure ASF-free status, as well as to detect any ASFV introduction rapidly. Data generated by each surveillance component should be documented, kept up to date and be readily available. All parts of the compartment's documentation should be properly maintained in accordance with Article 4.5.4. of the *Terrestrial Code* on compartment documentation [9].

To ensure the integrity of the compartment, the compartment operator should establish and document an approved SOP to support the CMP. There should also be documented staff training on the SOP. The compartment operator should conduct regular internal audits on the compliance of biosecurity management and operations, disease surveillance, traceability systems, and emergency response readiness, etc. in the ASF-free compartment. Furthermore, the Veterinary Authority should, in consultation with the private sector, and preferably in agreement with trading partners, set an appropriate frequency for re-evaluation of compartment integrity, taking the epidemiological situation of the country or zone and other relevant factors into consideration. In accordance with the re-evaluation frequency, the Veterinary Authority must assign accredited auditors to conduct official external audits to ensure the integrity of the compartment and subsequent re-certification of the ASF-free compartment, provided that audit outcomes are satisfactory. For compartment maintenance, a complete audit of all compartment components may not be necessary at each audit, but the audit plan should preferably have a timeline that ensures that the entire system will be reviewed within a certain time period. The portion of the components in a compartment to be audited shall be appropriately determined by the Veterinary Authority. The auditing process may include both document and on-site audits, covering, but not limited to, the evaluation of critical control points and compliance with the SOP, verification of the health status of the compartment's animal sub-population, and examination of the biosecurity, surveillance and traceability systems of the components in the ASF-free compartment [9].

→ **Appendix 7** provides an example of the audit process as guidance.

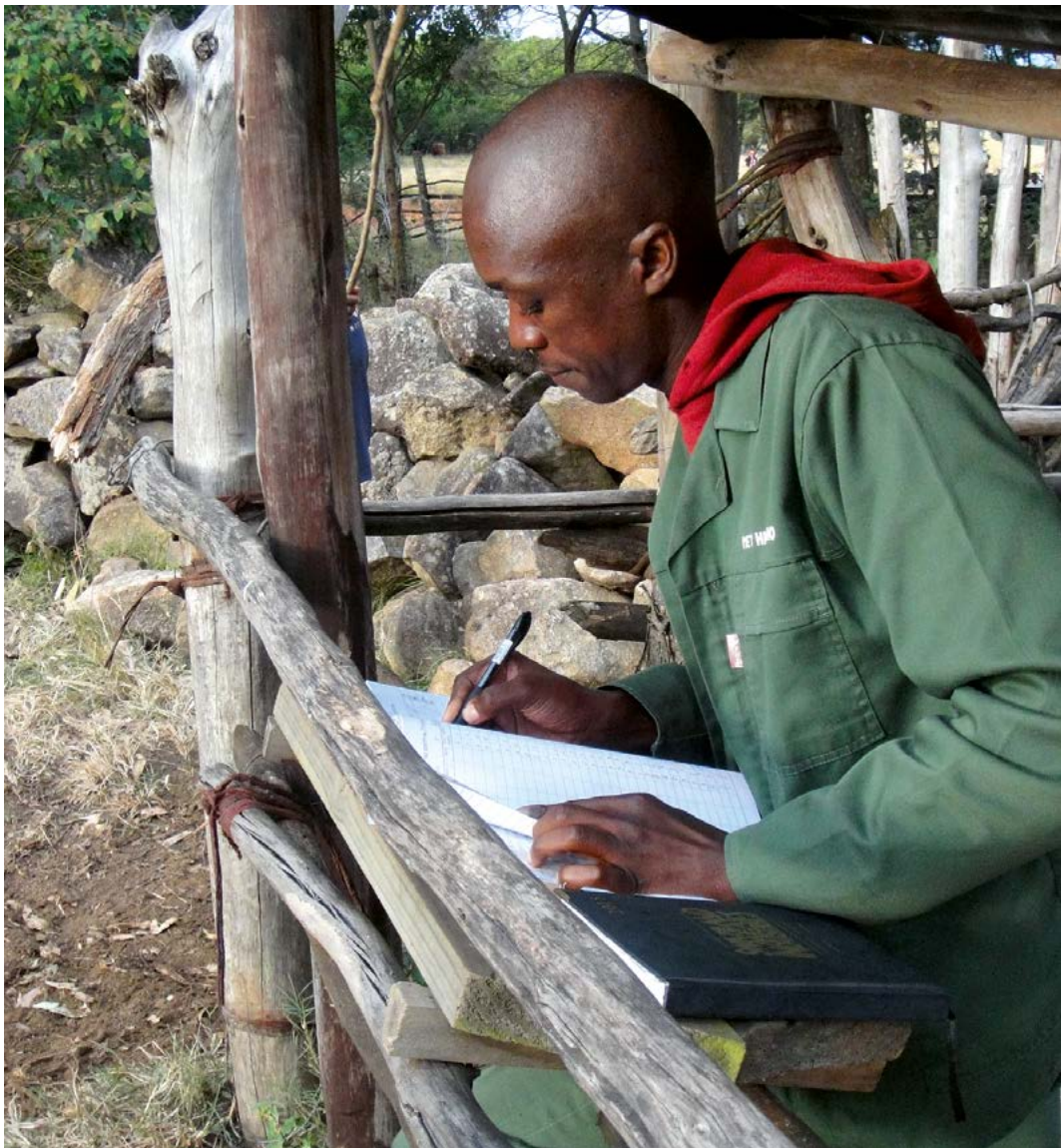
If an approved ASF-free compartment is found to have any non-conformance during an audit, the relevant issues should be clearly recorded in the audit report, according to the severity of the non-conformance (e.g. major or minor). Not all audit findings would require a response or rectifying action, but any non-conformances reported will require corresponding responses

and/or rectifying actions from the compartment operator, and they shall be given a time limit deemed appropriate by the auditor in consultation with the Veterinary Authority to complete the relevant actions.

Depending on the severity of the non-conformance, the compartment may be automatically suspended (due to a critical non-conformance), or given a specific time period proportionate to the risk of the non-conformance to take corrective action. The auditor may revisit the ASF-free compartment after the specified time period to verify whether the issues have been rectified. If the compartment operator fails to rectify the non-conformance within the given time period, the Veterinary Authority of the exporting country shall suspend the certification of the ASF-free compartment, notify trading partners and publicise the suspension in a timely manner [53]. Re-certification of such an ASF-free compartment would be subject to the completion of the rectifying actions and passing a subsequent audit, as well as other requirements deemed appropriate by the Veterinary Authority, taking the particular situation into consideration (e.g. the type of non-conformance and its corresponding severity).

EXPECTED OUTCOME

The result should be an approved ASF-free compartment that maintains and documents strict compliance with the national ASF compartmentalisation programme. Regular audits, both internal and external, and a system that addresses non-conformance and subsequent steps are in place to verify the compliance of the ASF-free compartment. This will assure the compartment's ASF-free status, and ensure that the pigs and relevant commodities originating from the ASF-free compartment are indeed ASF-free and safe for trade.



COUNTRY EXPERIENCE

Thailand

APPROVAL AND CONTINUOUS ASSURANCE OF AVIAN-INFLUENZA-FREE COMPARTMENTS

With a biosecurity management system and traceability system approved by Thailand's Department of Livestock Development (DLD), and one year of avian influenza (AI) surveillance in a candidate AI compartment with negative AI testing results, the candidate compartment shall then be certified by the DLD. The certification is valid for 3 years. During this 3-year period, the DLD audit team will audit the compartment at least once a year to ensure its compliance with compartmentalisation requirements, using a specific checklist for each type of compartment. If any non-conformance is found, the compartment operator must rectify it within the designated time limit. Otherwise, the compartment's certification may be subject to suspension or withdrawal. To renew the DLD certification of a compartment, the compartment operator must apply to the DLD at least 3 months before the expiry date.

Canada

IN-COUNTRY APPROVAL AND CONTINUOUS ASSURANCE OF SALMONID COMPARTMENTS

In Canada, an on-site inspection is necessary to validate the biosecurity plan submitted before official recognition of a compartment for salmonid germplasm. Once the compartment is officially recognised, annual inspections are required to ensure that biosecurity is maintained. Additional reviews are also necessary at each sampling event for surveillance. The Canadian Food Inspection Agency (CFIA) conducts an epidemiological assessment to determine inspection and surveillance frequencies for a compartment and maintenance of the compartment's status. A CFIA veterinary inspector is assigned to each compartment and is responsible for reviewing the biosecurity plan. Standardised inspection forms and other documentation are used to capture compartment information and achieve national consistency in the implementation of the standards and inspection procedures. The CFIA has also developed Records of Decision outlining the surveillance and inspection frequencies for each compartment, for transparency and record keeping. These principles are also reflected in the recognition letter issued for the compartment's records. Disease status for all compartments is also published on the CFIA website.

IMPLEMENTATION

Response to changes in ASF status outside the compartment

WHAT?

Considering the major economic impact of ASFV incursions on the pork industry, the ultimate goal of ASF compartmentalisation is for the compartment operator to have business continuity, in the event of an ASFV introduction into the previously ASF-free country or zone where the compartment is located. An approved ASF-free compartment should, in principle, possess a biosecurity management system that is able to maintain the ASF-free status of the animal sub-population and relevant commodities within the compartment, independent of the ASF status outside the compartment. For this reason, minimal downtime is expected in the event of an ASFV incursion, or change in the epidemiology of ASF, in the country or zone where the compartment is located. International trade in compartment products should therefore remain uninterrupted, or be interrupted only to a limited extent, in case of an ASF outbreak outside the compartment.

HOW?

The biosecurity and management measures implemented in the ASF-free compartment should be robust enough and maintained at the required level to withstand changes in the risk of ASFV introduction. In this way, a complete evaluation of the compartment would not be necessary in the event of changes in ASF status outside the ASF-free compartment, although an updated operational risk assessment may be required, since the ASFV risk outside the compartment is one of the risk assessment's input parameters.

Hence, corresponding follow-up actions should be determined by the need for the exporting country's Veterinary Authority to provide assurance of the continued integrity of the ASF-free compartment to its trading partners. These actions should be discussed during the compartment recognition process and outlined in the bilateral agreement between the Veterinary Authorities of exporting and importing countries. Such actions should demonstrate that the ASFV risk of the compartment is still at an acceptable level and the requirements for ASF freedom are met. The relevant details of these actions, e.g. audits and enhanced internal and external surveillance of the compartment, should also be included in the national ASF compartmentalisation programme. The corresponding management of an ASF-free compartment in case of ASF incursion into the country or zone where it is located should be included in the national contingency plan to ensure that subsequent implementation is not being ignored.

To maintain mutual trust in assuring the compartment's status, prompt communication and transparency on disease occurrence should take place between trading partners and timely epidemiological outbreak investigations should be conducted. The compartment operator should be aware and prepared for the possibility that any changes in the ASF epidemiology outside the compartment may have impacted the risk pathways considered in the operational risk assessment. This would potentially result in the need to strengthen the biosecurity and surveillance systems of the ASF-free compartment, with associated costs, in accordance with the epidemiological

investigations and corresponding risk assessment outcomes validated by the Veterinary Authority.

To maintain preparedness in response to changes in the ASF status outside the compartment, simulation exercises to practise the compartment contingency plan should be conducted on a regular basis, as part of the biosecurity management system within the compartment.

EXPECTED OUTCOME

International trade in pigs or relevant commodities from the ASF-free compartment continues with minimal interruption, with necessary assurances from the Veterinary Authority of the exporting country as appropriate, and agreed by the trading partners.

IMPLEMENTATION

Response to changes in ASF status of a compartment

WHAT?

This section focuses on the actions that should be taken when the ASF status of the compartment changes. These actions should be performed in a rapid and effective manner to limit the potential spread of the virus within and beyond the compartment. In view of the subsequent impact on trade, these response actions should be reflected in the national ASF compartmentalisation programme, planned in consultation with the trading partners, and documented in the bilateral agreement.

HOW?

If ASF is suspected in an approved ASF-free compartment, the certification of the compartment should immediately be suspended until ASF has been ruled out by appropriate epidemiological and diagnostic investigations performed by the Veterinary Authority or under its supervision. If ASF occurrence is confirmed within the compartment, certification of the ASF-free status of the compartment should be revoked and the OIE and trading partners should be officially notified as soon as possible, with the revocation publicised [5; 8].

Following suspension or revocation of the official certification of the ASF-free compartment, the Veterinary Authority should stop any certification of commodities coming from that compartment and an appropriate recall should be initiated for commodities dispatched from the compartment that may pose a risk of infection or contamination [49]. Publicised information on the suspension or revocation may specify the disease occurrence situation, identifying, for example, the date of the disease occurrence, the affected animal sub-population, the samples in which ASFV was detected, and the test methods used for detection. All of these should be outlined in the national ASF compartmentalisation programme.

If any change of ASF status occurs in a previously ASF-free compartment, the Veterinary Authority of the exporting country should promptly inform the Veterinary Authority of the importing countries of any necessary responses and actions to the change and preferably publicise these actions to make them available to all relevant trading partners and stakeholders. The details of such responses and actions, such as suspension or revocation of the ASF-free compartment status, provisions for imposing import restrictions or prohibitions, and lifting of those sanctions once the outbreak has been controlled, should be discussed during the compartment recognition process and outlined in the bilateral agreement for recognition of the ASF-free compartment between the Veterinary Authorities of the exporting and importing countries. Such actions should also be included in the national ASF compartmentalisation programme and/or national contingency plan of the exporting country to ensure their implementation in the event of disease incursions [54].

IMPLEMENTATION

Recovery of the compartment's ASF-free status

WHAT?

In accordance with Article 4.5.7. of the *Terrestrial Code* on emergency response and notification, the revoked ASF-free status of the compartment shall only be reinstated after the compartment has adopted the necessary measures to re-establish ASF-free status and the Veterinary Authority has re-approved the status of the compartment. Therefore, the recovery period for the compartment depends on the time required to conduct investigations to determine the possible source and/or biosecurity breach, implement sanitary measures to eradicate the infection, surveillance to demonstrate ASF freedom, corrective measures to provide assurance, and reinstatement by the Veterinary Authority, etc. The resumption of trade should be subject to agreement by the trading partners to accept the re-approved ASF-free compartment.

EXPECTED OUTCOME

In case of ASFV incursion in the compartment, its ASF-free status is immediately revoked, and appropriate measures are implemented to rapidly detect and effectively minimise the potential spread of ASFV inside the compartment. The re-approval of the ASF-free compartment by the Veterinary Authority occurs only when ASF freedom can be substantiated in the compartment.

PART 2:

Appendices and tools

APPENDIX 1

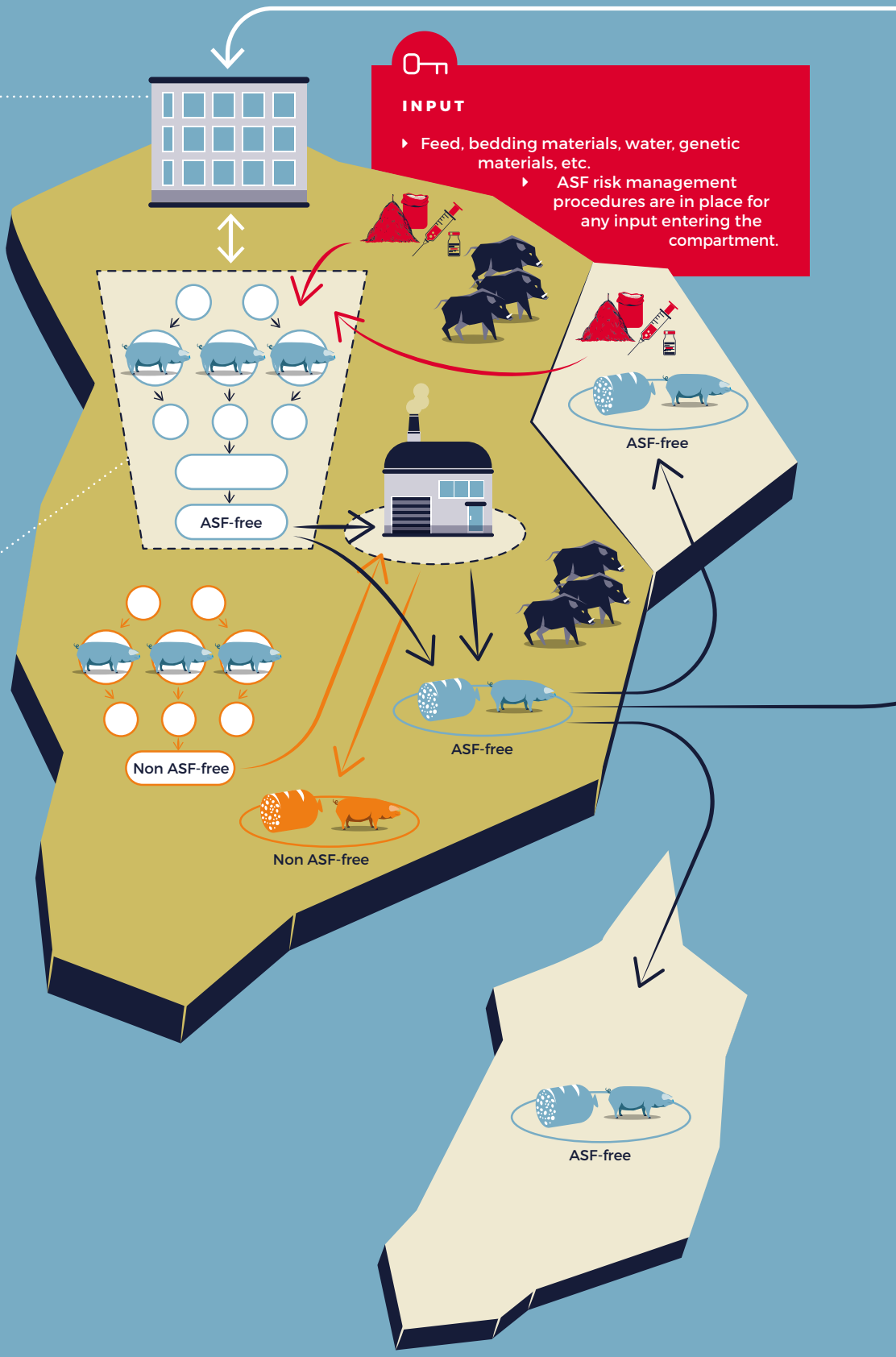
Figure 3 Graphic illustration of the compartmentalisation concept

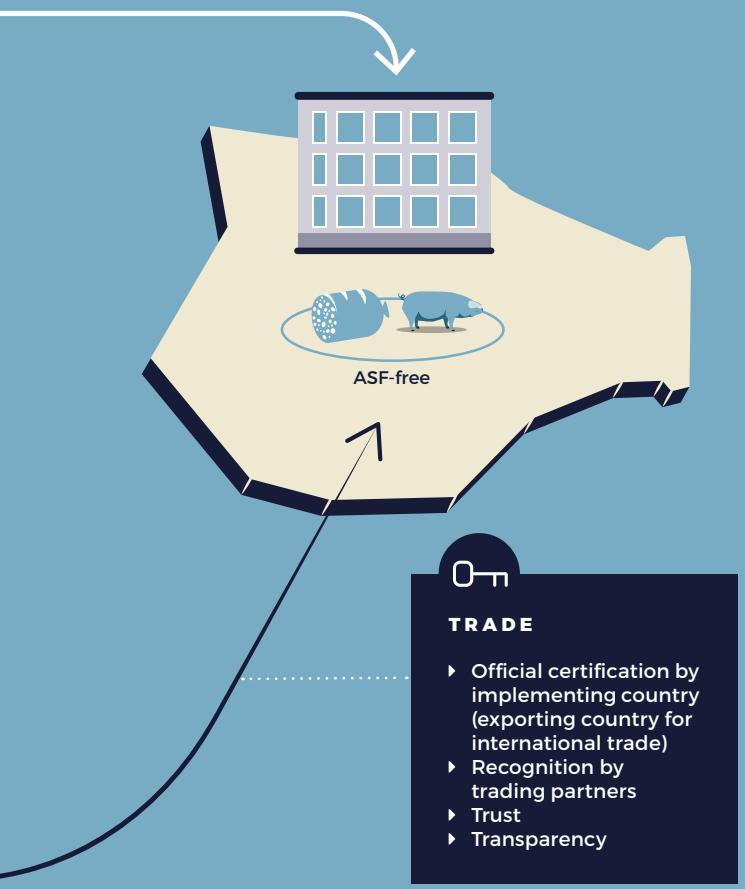
VETERINARY AUTHORITY

- Country-level risk assessment & management
- Regulatory framework
- Supervision and control of compartment
- National biosecurity plan
- National surveillance system
- Evaluation and approval of compartments
- Public-private partnership
- Communication and negotiation with trading partners for compartment recognition

COMPARTMENT

- Animal subpopulation
- Separation from potential sources of ASF
- Compartment-level risk assessment & management
- Common biosecurity management system
- Surveillance system
- Diagnostic capacity
- Traceability system
- Documentation
- Contingency plan
- Public-private partnership





LEGENDS

- ASF-infected country/zone
- ASF-free country/zone/ compartment
- Component of compartment (e.g. feedmills, slaughterhouses and processing plants)
- Component of compartment with animal sub-population
- Movement of ASF-free animals or relevant commodities
- Wild boars
- Live domestic/captive pigs
- ASF introduction risk pathway
- Compartment biosecurity boundary
- Communications
- Units in non-compartment systems
- Slaughterhouse/processing plant processes pigs or commodities from both compartment and non-compartment systems
- Movement of non-ASF-free animals or relevant commodities

A compartment consists of multiple components which are functionally connected along different parts of the supply chain and are all integrated under a common biosecurity management system. It can be established independent of the infection status of the country or zone where the compartment is located. A compartment should always include an animal sub-population. Its biosecurity management system is aimed at producing disease-free compartment outputs for the purpose of facilitating national/international trade and animal movements, which a non-compartment production system could not achieve. Slaughterhouses, cutting and processing plants must be defined as components of the compartment when the output of the compartment is pig meat. These slaughter and processing components should preferably be dedicated to only receiving ASF- free pigs and products, or, if processing pigs and products of a different ASF health status, operate strict and effective segregation and biosecurity measures to ensure that the status of the pigs and products derived from the ASF-free compartment is maintained. As the compartmentalisation process involves both the public and private sectors, effective public–private partnership is a crucial factor for success. In order to achieve recognition of the compartment by trading partners for international trade purposes, effective bi-lateral country communication and transparency are fundamental factors for building mutual trust. The diagram illustrates and highlights the key elements of the compartmentalisation concept.

APPENDIX 2

Figure 4 The compartmentalisation process at national level (within exporting country)

After a request for ASF compartmentalisation, **the Veterinary Authority identifies key stakeholders** to be involved in the compartmentalisation process

The Veterinary Authority communicates with relevant stakeholders to develop the regulatory framework and other relevant requirements for the national ASF compartmentalisation programme

The compartment operator establishes and defines a compartment with a common biosecurity management system, with the biosecurity plan and surveillance plan developed in consultation with the Veterinary Authority

The compartment operator submits an official compartment proposal, describing the compartment with clear evidence of its effective implementation, to the Veterinary Authority

The Veterinary Authority assesses the compartment proposal (e.g. risk assessment, biosecurity plans, surveillance and traceability systems)

The Veterinary Authority conducts audit(s) to verify whether the compartment complies with the standards of the national ASF compartmentalisation programme and other relevant requirements

The Veterinary Authority decides whether to approve the compartment as an ASF-free compartment

COMPARTMENT APPROVED

The Veterinary Authority publishes the decision to approve the compartment including official ASF-free certification for its products

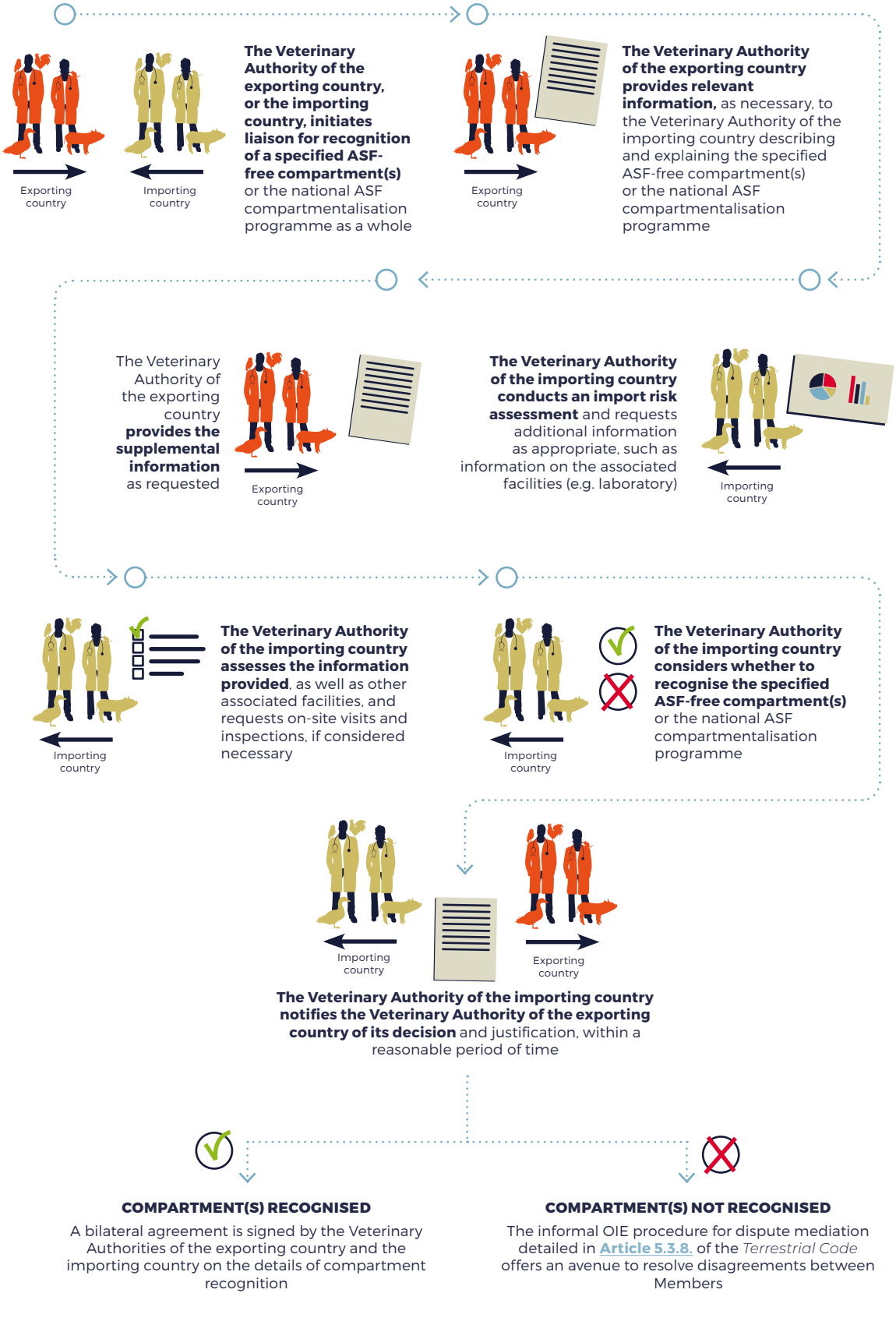
The compartment operator maintains the compartment under the supervision and control of the Veterinary Authority

COMPARTMENT NOT APPROVED

The Veterinary Authority provides explanations to the compartment operator, with the corrective actions required

The compartment operator re-submits the compartment proposal after taking the necessary corrective actions

Figure 5 The compartmentalisation process at international level (between the exporting and importing country)



APPENDIX 3

Risk assessment approach for ASF-free compartments

A transparent scientific risk assessment is required to inform the development and maintenance of the ASF-free compartment's risk management policy (including biosecurity management and the surveillance system). This Appendix presents an example of a risk assessment approach that could be used to estimate the risk of ASFV entry into a compartment. It is based on the OIE framework as outlined in Chapter 2.1. of the *Terrestrial Code* on import risk assessment and the OIE *Handbook of import risk analysis* [19; 20; 58]. It includes all three components of risk assessment: entry, exposure, and consequence assessments. In this example, we use a qualitative rather than a quantitative approach, but both can be used depending on stakeholder preferences.

➔ This Appendix complements the **Section on risk assessment** in the *ASF compartmentalisation guidelines*, by describing in more detail the scientific risk assessment approach.

It also offers guidance on the administration, regulation and auditing of the risk assessment process in accordance with Chapter 2.1. of the *Terrestrial Code*.

The process of developing a risk assessment for an ASF-free compartment should involve a collaboration between persons with relevant expertise and independence, compartment employees and the compartment operator, together with key stakeholders in charge of risk management. The methodology to conduct an ASFV risk assessment for a compartment should follow the steps outlined below.

- ➔ **Step 1:** Identify the risk question(s)
- ➔ **Step 2:** Develop risk pathways for the entry, exposure and consequence assessments
- ➔ **Step 3:** Collect data
- ➔ **Step 4:** Estimate the risk(s)

A risk assessment for an ASF-free compartment will have to be treated as a continuing process, in that the risk estimates need to be revised whenever there are changes in the risk environment inside and also outside the compartment. This should be reflected in a regularly updated operational risk assessment document for the compartment that is included in the documentation provided during any audits. It is also important to recognise that changes in risk mitigation measures will affect the risk assessment, which means that there is a feedback loop between risk assessment and management.

There are also online tools such as Biocheck.ugent which guides through an evaluation of the generic biosecurity on a pig farm. It can be used to complement but not to replace the approach described in these guidelines, because it was not designed to address a specific risk question.

IDENTIFICATION OF RISK QUESTION(S)

The following is an example of an overall risk question for the compartment-level risk assessment:

What is the likelihood of at least one output unit (whole animal or pork product) departing from the compartment being infected or contaminated with viable ASFV per year?

This overall risk question will be of critical importance to all stakeholders, in particular to the recipients of any outputs from the compartment.

Based on the above risk question, the associated epidemiological process should then be broken down into entry, exposure and consequence risk questions, as follows:

- **Entry risk question:** *What is the likelihood that there will be at least one introduction of viable ASFV into the compartment per year?*
- **Exposure risk question:** *What is the likelihood that at least one pig in the compartment will become exposed to viable ASFV per year, as a result of ASFV introduction into the compartment?*
- **Consequence risk question 1:** *What is the likelihood that at least one pig in the compartment will become infected with ASFV per year, as a result of exposure to viable ASFV?*
- **Consequence risk question 2:** *What is the likelihood that at least one output unit (live pig or pork product) departing the compartment will be infected or contaminated with ASFV per year, as a result of direct or indirect exposure to an ASFV infected pig?*

Note that there may be further risk questions that have to be added.

In this Appendix, we are using a hypothetical example based on introduction of live pigs into the compartment from the same country where the compartment is located. For simplicity, we are not considering any other risk entry pathways. It is assumed that the country is historically free from ASFV infection, but that it is at risk of introduction. Pork products are the output unit of interest. We have simplified the above risk questions as follows:

- **Simplified entry risk question:** *What is the likelihood that at least one live pig infected with ASFV will be introduced into the compartment per year?*
- **Simplified exposure risk question:** *What is the likelihood that at least one susceptible pig will become exposed to viable ASFV as a result of introduction of an ASFV-infected live pig?*
- **Consequence risk question 1:** *What is the likelihood that at least one susceptible pig will become infected with ASFV per year as a result of exposure to viable ASFV?*
- **Consequence risk question 2:** *What is the likelihood that at least one output unit of pork products departing from the compartment will be contaminated with ASFV per year as a result of direct or indirect exposure to an ASFV-infected pig?*

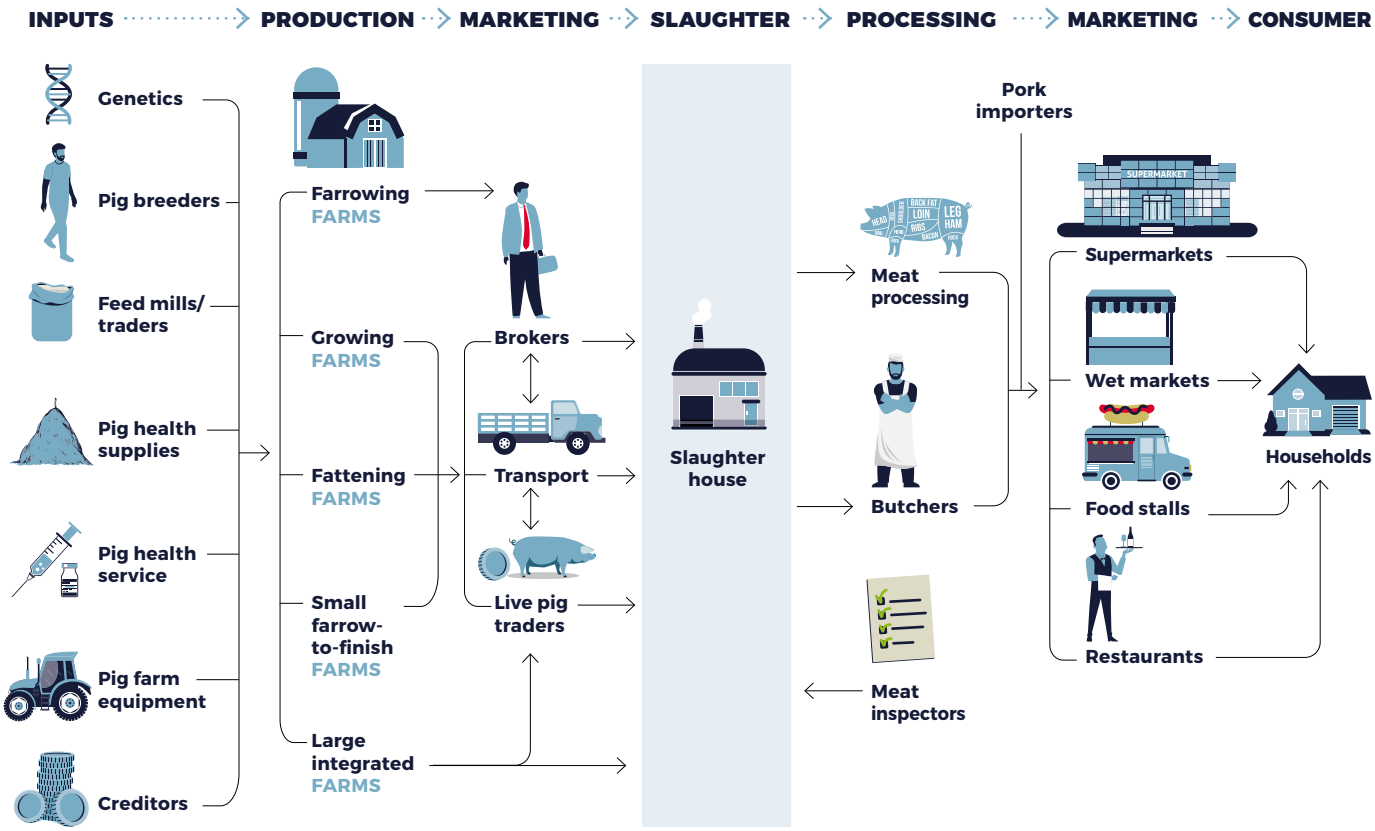
The risk questions inform the next step in the risk assessment process, which is the development of risk pathways that identify all possible routes of ASFV entry, exposure and spread within the compartment.

DEVELOPMENT OF A SUPPLY OR VALUE CHAIN DIAGRAM

The pig or pork supply chain represents all phases or functions involved in producing the end product, i.e. live pigs or pork. A value chain extends this concept to all inputs, processes and services that are associated with the final product [13; 15; 59]. As a minimum, the supply chain should be described, recognising that the full value chain will provide more comprehensive background information for designing the risk pathway diagrams during the risk assessment process. The importance of a detailed description of the supply or value chain should not be underestimated. It will require a good understanding of the industry and associated processes, and if done, as is preferable, using a value chain approach an understanding of the wider socio-economic and governance needs to be developed.

As the characteristics of the supply/value chain will have a major impact on the wider risk context beyond the compartment, it should cover all relevant pig and pork supply/value chain components in the territory. It is not necessary to conduct a value chain analysis, but a value chain map or diagram will be a required input to the risk assessment [13; 60]. A simple diagrammatic overview such as shown in Figure 6 will in most cases be sufficient [13; 14; 61]. But it is important to recognise that pig and pork value chains are dynamic, in that they change in structure and the relative importance of its components, depending on economic or other factors.

Figure 6 Example of pork supply or value chain



DEVELOPMENT OF RISK PATHWAY DIAGRAMS

In this phase of the risk assessment process, all pathways associated with the risk questions need to be expressed as a single or several diagrams. The following list presents examples of the factors which could be considered during risk pathway mapping:

- the prevailing national and international ASF situation
- local ASFV transmission dynamics, including potential wild boar and tick involvement
- proximity to neighbouring territories and other ASF-free compartments and farms
- the history of the introduction of ASFV into the country/territory/compartment and the possibility that it is still present in some parts
- the import of pigs and pig products into the compartment's home territory
- extent of illegal cross-border trade and transport of live pigs and pig products
- the effectiveness of barrier and quarantine procedures for both country-level imports and compartment inputs
- compliance with bans/restrictions on swill feeding in the territory or territories associated with the components of the compartment
- the characteristics of the local supply and value chain.

Table 3 shows examples of ASFV risk factors for a compartment, all of which are also relevant for introduction of other infectious diseases affecting pig production [18; 21; 62-64]. Those that are considered relevant for the specific local risk context should be expanded into one or several risk pathways expressing the sequence of epidemiological probability events associated with each risk question. The likelihood associated with each event along a risk pathway will depend on the likelihood of the event at the preceding step, a relationship that is called conditional dependence and which will be utilised to estimate the overall risk [65]

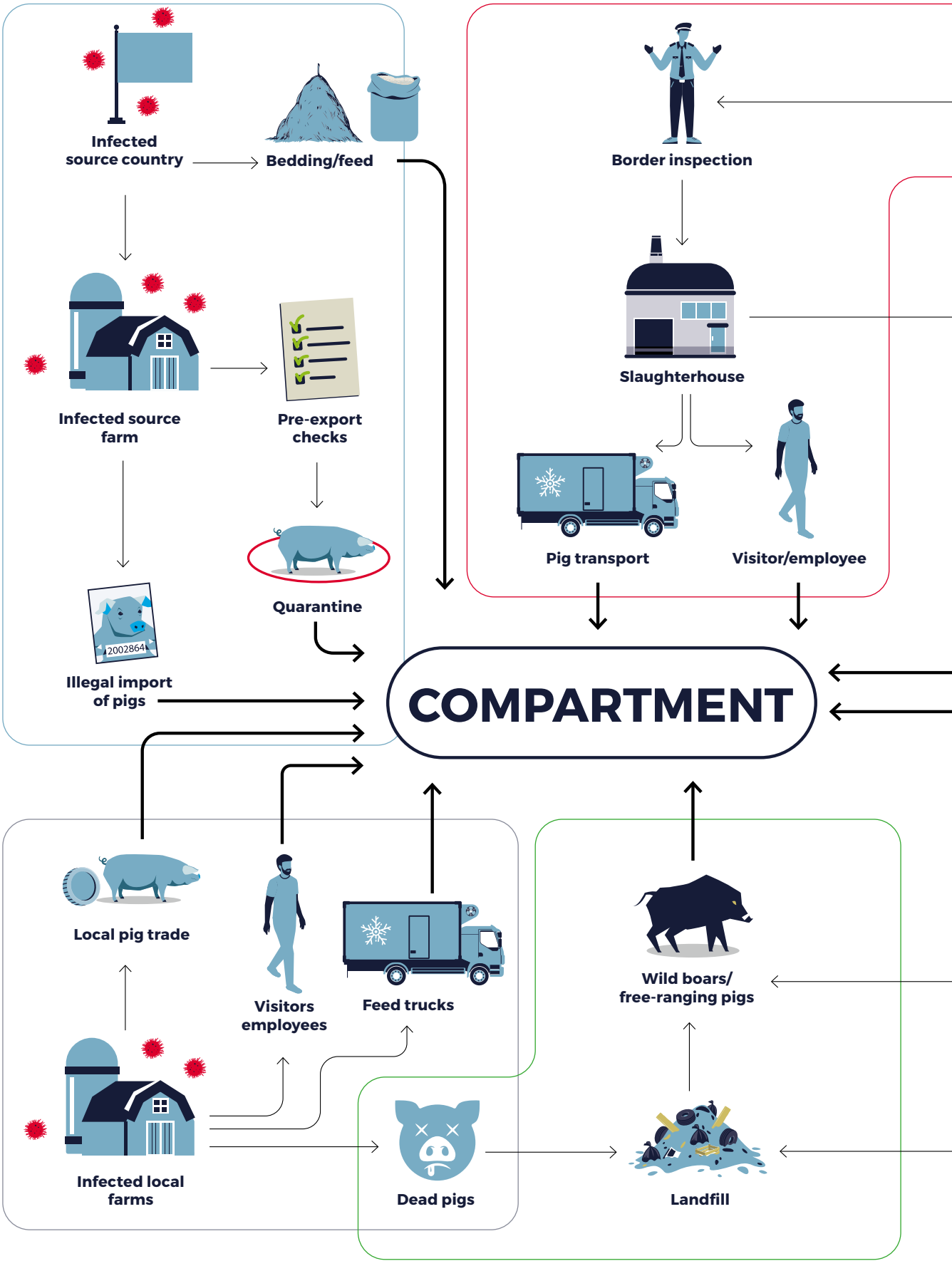
Table 3 Examples of potential ASFV risk factors

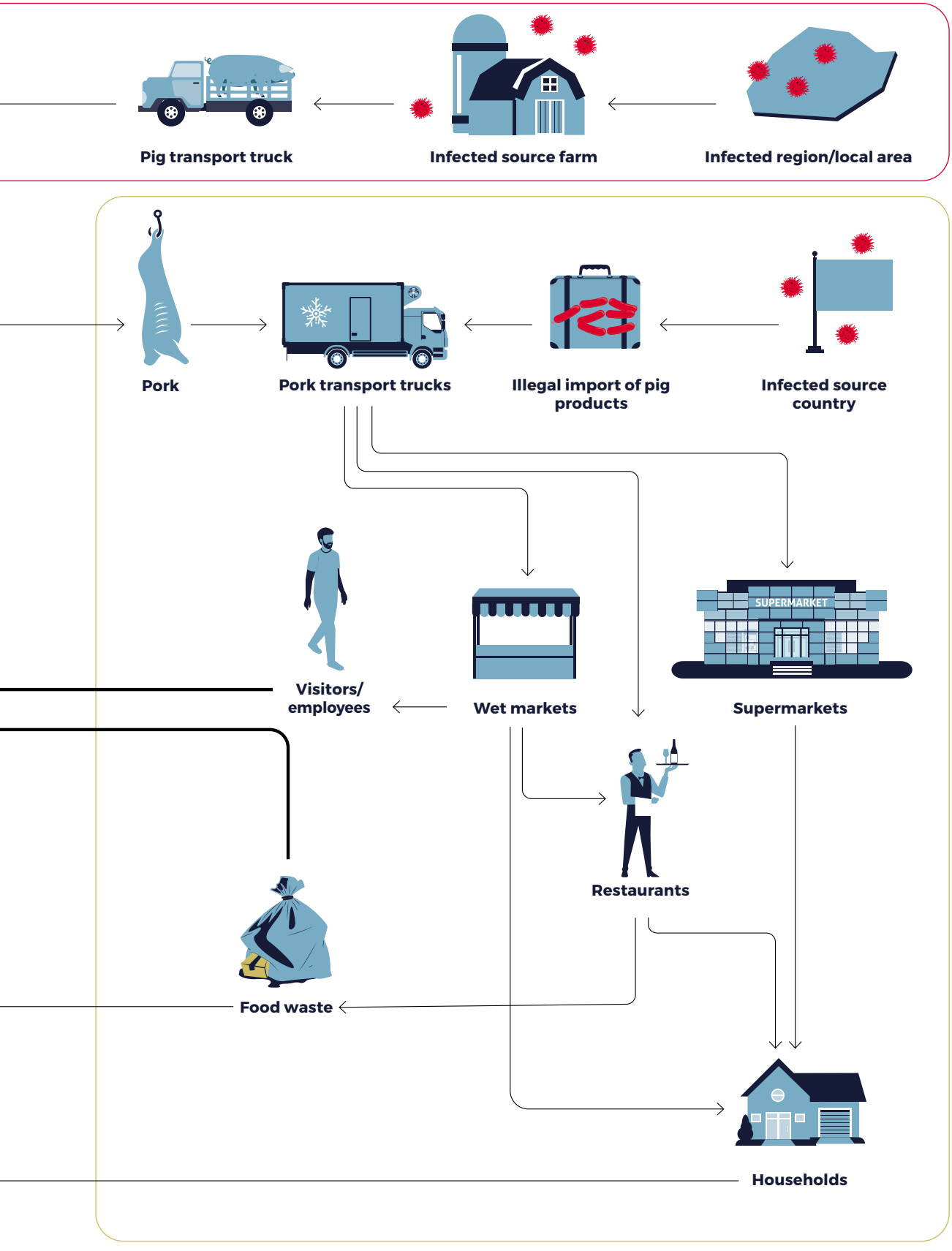
RISK FACTOR CATEGORY	EXAMPLES
INPUTS	· Live pigs · Genetic materials, e.g. embryos and semen · Feed and water · Medication and vaccines · Bedding
WASTE	· Rendering plants · Landfills
FOMITES	· Vehicles · Borrowed equipment · Second-hand equipment · Clothing
BIOLOGICAL	· Pig density (intensive and free-ranging) · Wild pigs · Soft ticks · Companion animals
TRANSPORT NETWORKS	· Highways · Waterways
PERSONNEL/ EMPLOYEES	· Pig-farming and wild-boar-hunting employees · Service personnel, e.g. for gas and electricity · Veterinarians and veterinary paraprofessionals · Staff who also work in non-compartment facilities

Taking into account both the wider context and the compartment-specific risk factors, all pathways for ASFV entry, exposure and consequence that are relevant for the compartment must be identified.

Figure 7 provides an example of several ASFV entry risk pathways for a compartment. It must be emphasised that this figure is generic and not exhaustive, and it is therefore likely that a compartment's ASFV risk pathways are likely to differ from the representation in this figure.

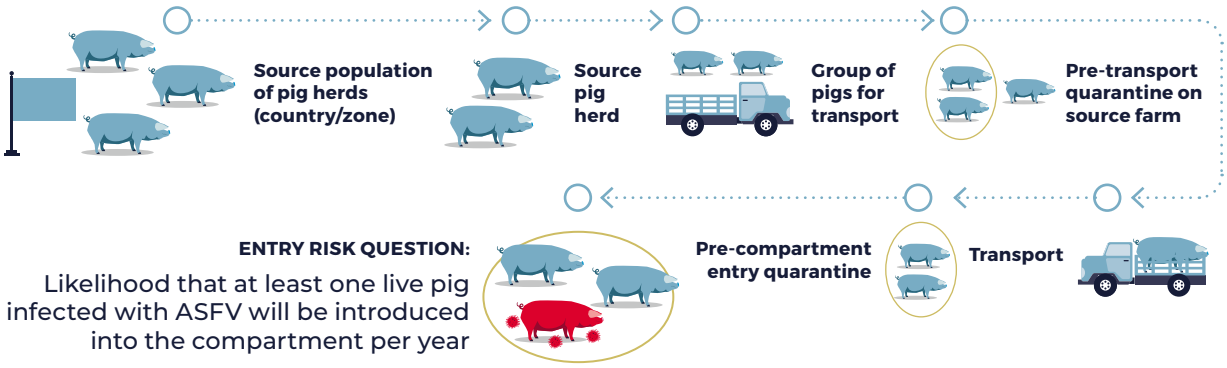
Figure 7 Example of five different risk pathway groups for ASFV entry into a compartment




Pig transport truck
Infected source farm
Infected region/local area
Pork
Pork transport trucks
Illegal import of pig products
Infected source country
Visitors/ employees
Wet markets
SUPERMARKET
Supermarkets
Restaurants
Food waste
Households

The risk question for our hypothetical entry assessment is "What is the likelihood that at least one live pig infected with ASFV will be introduced into the compartment per year?", and Figure 8 shows the associated risk pathway diagram.

Figure 8 Hypothetical risk pathway example for ASFV entry into a compartment via live pigs



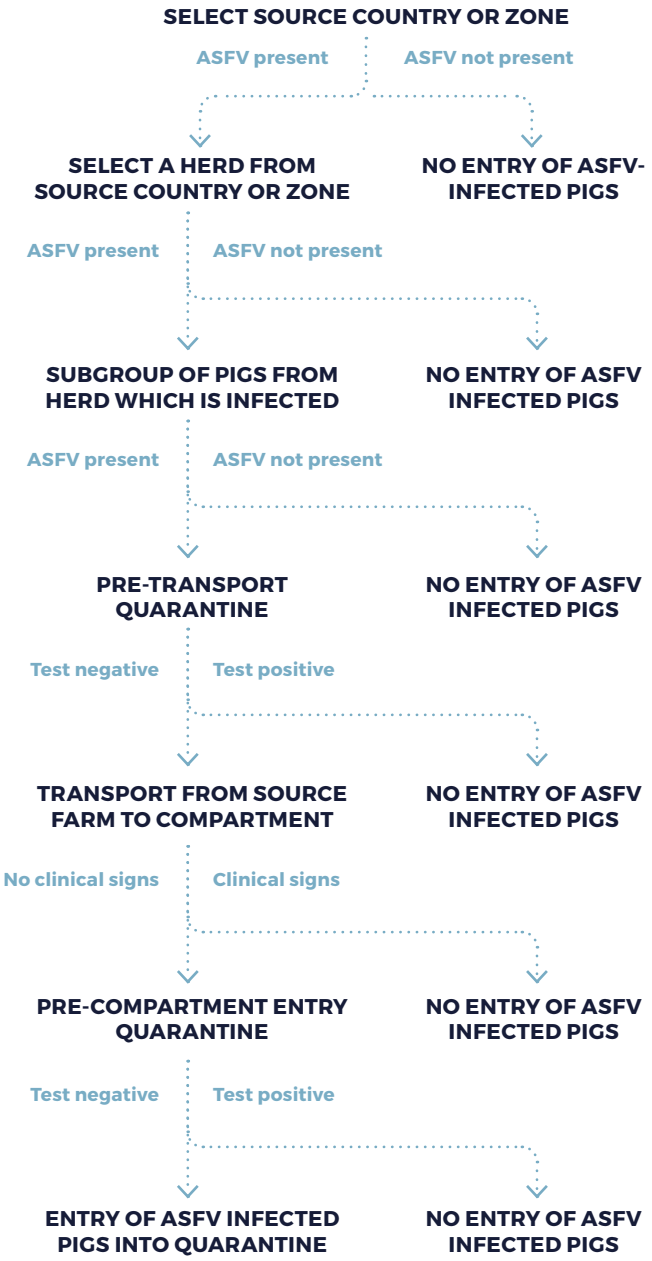
DATA COLLECTION

To be able to estimate the risk for each step, all relevant data must first be collected. This is a very important part of the risk assessment process, and requires a risk pathway diagram that is based on a good understanding of the underlying value chains and epidemiological processes. Possible data sources include peer-reviewed publications, grey literature and expert opinion. It will also require effective communication between the risk assessors and the compartment operator as well as others that have a role in the context of the pathway (such as supply-chain actors). Data quality and uncertainties attached to the data must be expressed explicitly. Peer-reviewed sources should be used as much as possible.

RISK ESTIMATION

As a next step, the risk pathway diagram will be used to produce the risk estimate for ASFV entry into the compartment for this particular risk question. Each of the steps along the risk pathway will inform the data requirements. For the purpose of risk estimation, the risk pathway can be analysed based on the logical chain of events as shown in Figure 8, or it can be converted into a scenario tree, as in Figure 9 [58]. As described in Chapter 2.1. of the *Terrestrial Code* on import risk analysis, the risk estimation can be performed using a quantitative, semi-quantitative or qualitative approach [19; 66; 67]. The decision on which method is most appropriate should consider data availability and cost and access to quantitative risk modelling capacity, as well as the preferences of the key stakeholders [19]. A qualitative risk assessment is less demanding in terms of the quantitative analysis expertise of staff and can therefore be developed and updated much more quickly. A qualitative approach will be used for the hypothetical risk assessment example in this section. The NORA rapid semi-quantitative risk assessment tool is recommended as an example of a semi-quantitative risk assessment [66]. Depending on stakeholders' preferences, and the availability of both data and relevant expertise, a quantitative risk assessment could be conducted instead or subsequent to a qualitative risk assessment. Regardless of the type of approach chosen, the risk assessment should be reported in a transparent manner in the ASF-free compartment's operational risk assessment document.

Figure 9 Hypothetical scenario tree example for ASFV entry into a compartment via live pigs



As a first step in the risk estimation process for a risk pathway (or scenario tree), the risk or likelihood needs to be estimated for each step along the risk pathway. These individual risk estimates then need to be combined into an overall risk estimate for the whole risk pathway, which then provides the answer to the risk question. Since changes in the ASFV risk of the compartment's external environment may result in a change in the overall risk estimate, each pathway must then be examined to identify potential changes in each risk pathway's risk estimate which will determine whether the risk mitigation measures need to be adjusted.

The risk or likelihood estimate for a particular risk pathway is the product of all conditional likelihoods of the sequence of steps along the pathway. Risk estimates for each step can be expressed using the risk assessment and uncertainty terminology, as shown in Table 4 and Table 5 [68-71].

Table 4 Example of qualitative risk (or likelihood) terminology for risk assessments

RISK 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

Table 5 Example of qualitative uncertainty definitions for risk assessments

UNCERTAINTY CATEGORY	DEFINITION
LOW	Solid and complete data available; strong evidence provided in multiple references; authors report similar conclusions
MEDIUM	Some but not complete data available; evidence provided in a small number of references; authors' conclusions vary
HIGH	Scarce or no data available; evidence is from unpublished reports or based on observations or personal communications; authors report conclusions that vary considerably

The overall qualitative risk estimate will be obtained by sequentially combining the risk estimates along the risk pathway, beginning with its origin or starting point. This can be done using a risk combination matrix, such as shown in Table 6. It should be noted that the structure of this matrix needs to be agreed by stakeholders [72; 73]. An example of the result of estimating the risk for each step along the risk pathway is shown in Table 7. The stepwise process of combining the risk estimates from the sequence of steps in a conditionally dependent manner is shown in Table 8. Both tables together allow an assessment of the potential weaknesses in the risk management process as well as a discussion with stakeholders about the risk estimates and the underlying evidence. The same process needs to be used for all risk pathways under consideration, and for the uncertainties associated with each likelihood estimate.

Table 6 Matrix for combining two qualitative likelihood estimates [71; 74]

LIKELIHOOD 2	LIKELIHOOD 1					
	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

Table 7 Data requirements and risk estimates for each step along hypothetical risk pathway associated with ASFV entry into a compartment via live pigs

STEP ON RISK PATHWAY	POSSIBLE DATA/ INFORMATION NEEDED	RISK ESTIMATE	UNCERTAINTY	JUSTIFICATION
Source population of pig herds (country/ zone)	Prevalence of ASFV infected pig herds in source population (country/zone); depends on **1.** evidence of country's ASFV freedom and **2.** surveillance evaluation reports	Very low	Low	Country has never reported ASF outbreaks and the country's ASF surveillance system has high sensitivity, with good rapid detection capacity, but there is ASFV infection present in neighbouring countries
Source pig herd	ASFV prevalence in source pig herd, depends on **1.** effectiveness of farm's biosecurity system, **2.** sensitivity of farm's surveillance system, **3.** reliability of pig health and production monitoring system and **4.** ASFV risk in the local context	Very low	Low	The source farm has an effective biosecurity management system in place, and constantly monitors pig production using electronic herd health management. There has never been any evidence of ASFV on the farm or in its neighbourhood or contact network
Group of pigs for transport	ASFV prevalence among pigs selected for transport while still on source farm; depends effectiveness of biosecurity measures within farm	Very low	Low	Farm operates an effective biosecurity management system, that reduces the risk of spread of pathogens between different sections of the farm
Pre-transport quarantine on source farm	Likelihood of at least one ASFV-infected pig testing negative or clinical signs not being detected during pre-transport quarantine checks; depends on **1.** diagnostic testing and clinical sign detection sensitivity, **2.** effectiveness of pre-transport quarantine biosecurity measures and **3.** duration of quarantine period	Negligible	Low	Pigs are monitored closely during the 15-day quarantine period for any clinical signs, and they are kept in isolation under tight biosecurity measures. The sensitivity of the ASFV PCR test is 99%, which will minimise the risk of false negative results, and all pigs are tested. If any ASFV-infected pigs are present, they should develop clinical signs during the 15 day quarantine period which would be detected by staff
Transport	Likelihood of all ASFV infected pigs not showing clinical signs or dying; depends on **1.** duration of transport and **2.** clinical sign detection sensitivity	Low	Medium	Pigs transported for 6 hours and transport staff monitor the pigs closely, at loading, during transport and when off loading. But the period is too short for a recently infected pig to develop clinical signs
Pre-compartment entry quarantine	Likelihood of at least one ASFV-infected pig testing negative or clinical signs not being detected during pre-compartment entry quarantine; depends on **1.** diagnostic testing and clinical sign detection sensitivity, **2.** effectiveness of pre-transport quarantine biosecurity measures and **3.** duration of quarantine period	Negligible	Low	Pigs are monitored closely during the 15-day quarantine period for any clinical signs, and they are kept in isolation under tight biosecurity measures. All pigs are tested and the sensitivity of the ASFV PCR test is 99%, which will minimise the risk of false negative results. If any ASFV-infected pigs are present, they should develop clinical signs during the 15-day quarantine period which would be detected by staff

Table 8 Obtaining the overall risk estimate for the hypothetical risk pathway associated with ASFV entry into a compartment via live pigs

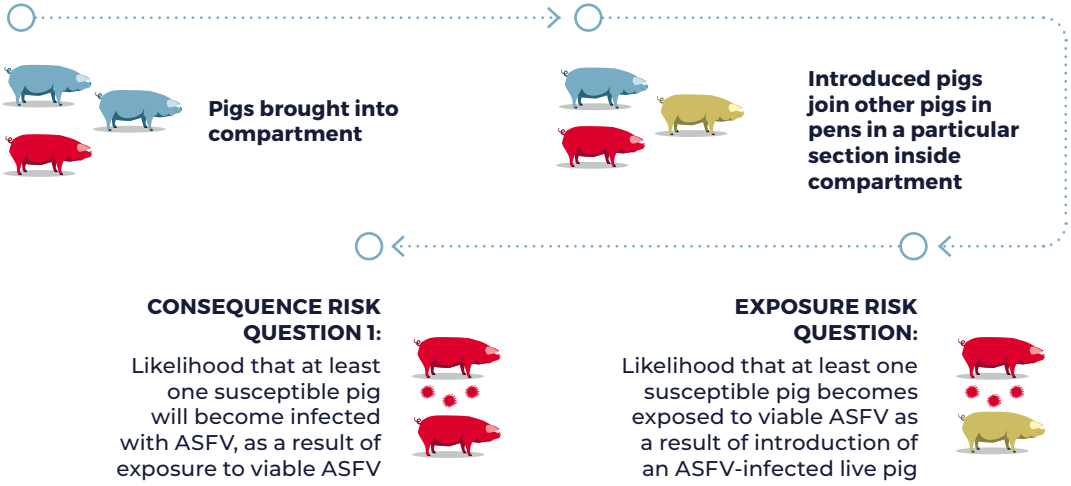
STEP ON RISK PATHWAY	RISK ESTIMATE	UNCERTAINTY	COMBINED CONDITIONAL LIKELIHOOD ESTIMATES	COMBINED UNCERTAINTY
Source population of pig herds (country/zone)	Very low	Low		
Source pig herd	Very low	Low	Very low	Low
Group of pigs for transport	Very low	Low	Very low	Low
Pre-transport quarantine on source farm	Negligible	Low	Negligible	Low
Transport	Low	Medium	Negligible	Medium
Pre-compartment entry quarantine	Negligible	Low	Negligible	Medium
Likelihood that at least one live pig infected with ASFV will be introduced into the compartment per year			Negligible	Low

EXTENDING TO EXPOSURE AND CONSEQUENCE ASSESSMENT

The assessment for the exposure and consequence risk questions should be conducted in a similar manner. It is essential that ASFV exposure and consequence risk pathways are tailored to each compartment, but it is likely that there are broad similarities between ASF-free compartments, and it will therefore be helpful to examine examples from other compartments. This part of the risk assessment also addresses the need for developing an understanding where inside the compartment particularly effective bio-containment as well as bio-exclusion risk mitigation measures need to be applied so that the risk of spread between functional units or sub-units of the compartment can be minimised, in case of introduction of virus into any part of the compartment.

Based on the exposure and consequence risk question number 1, compartment-specific pathways by which pigs within the compartment may become exposed to and infected with ASFV should be identified. Figure 10 provides an example of an ASFV risk pathway diagram combining exposure and consequence risk pathways into a single diagram. In this example, the within-compartment surveillance for the presence of infection and clinical signs may already be able to detect newly introduced infected pigs before they are able to shed ASFV and expose susceptible pigs kept within the same pen or building. It is likely though that it is not sufficiently sensitive to prevent exposure. This suggests that those newly introduced infected pigs are likely to expose susceptible pigs inside the compartment to ASFV, and it emphasises the paramount importance of implementing effective risk mitigation measures before introducing live pigs into the compartment.

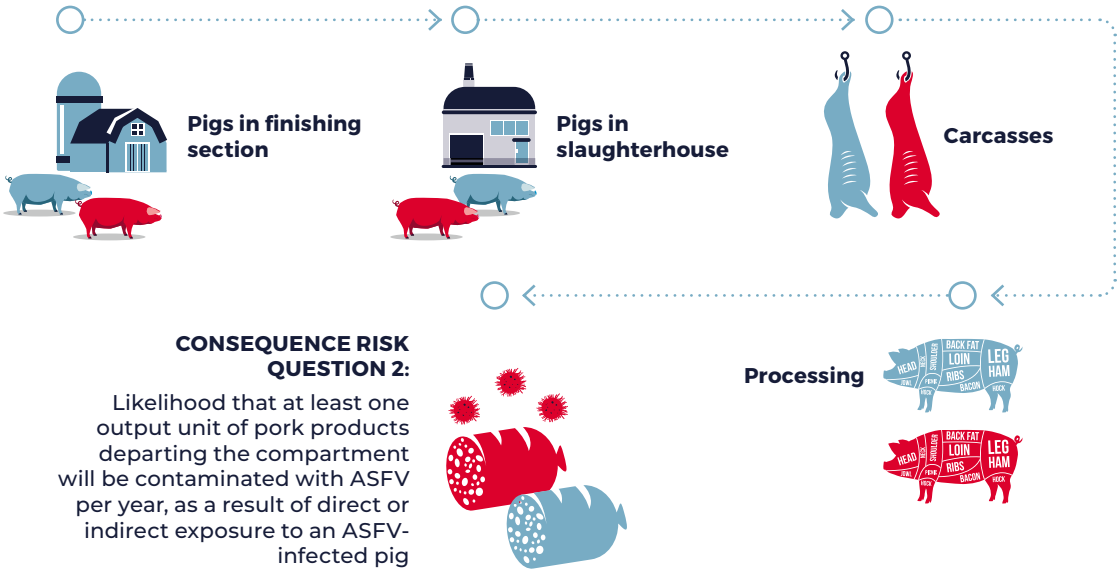
Figure 10 Example of ASFV exposure and consequence pathway diagram following entry of a live pig infected with ASFV into a compartment



There will be many steps which are not captured in this example diagram. They will need to be identified in detail, so that it is possible to develop bio-containment and bio-exclusion risk mitigation measures that minimise the risk of spread between different parts of the compartment. As an example, if gilts are introduced for replacement purposes, they may be introduced into the gilt section then into the farrowing section, and after that into the dry sow section. Furthermore, piglets will be moved into the weaner section and then into the grower/finisher sections. These represent pathways for the flow of ASFV inside the compartment which needs to be captured in the risk assessment, so that it is possible to develop targeted risk mitigation and surveillance measures.

The example consequence risk question 2 focuses on whether pork product outputs of the compartment will be contaminated. Its risk pathways shown in Figure 11 include the steps which influence ASFV spread within the compartment, which in turn will inform the design of the compartment's early detection surveillance.

Figure 11 Example of simplified ASFV consequence pathway diagram following spread of ASFV among pigs inside a compartment



OBTAINING OVERALL LIKELIHOOD ESTIMATES

Following an assessment of the entry, exposure and consequence risks, an overall risk estimate that combines all risk estimates should be produced, using the combination matrix shown in Table 6. In this risk assessment associated with ASF compartmentalisation, the only outcomes are likelihoods as no other consequences will be considered. If stakeholders require that other types of consequences need to be combined with likelihood estimates, such as economic impact of the introduction and spread of ASFV, a likelihood - impact combination matrix as shown in Table 9 can be used [23; 71; 75].

Table 9 Likelihood - impact combination matrix (adapted from [23; 71; 75])

		Impact			
		Negligible	**Low**	**Medium**	**Catastrophic**
Likelihood	**Very High**	Medium	High	Very high	Very high
	High	Medium	High	High	Very high
	Medium	Low	Medium	High	High
	Low	Low	Low	Medium	High
	Very Low	Low	Low	Medium	High
	Negligible	Negligible	Low	Medium	High

FROM RISK ASSESSMENT TO RISK MANAGEMENT

The overall risk estimate for each risk question needs to be examined with respect to how much it will change, if the risk estimates along the respective risk pathways change. Such changes may be due to changes in the risk environment outside or within the compartment or a reflection of the uncertainty associated with individual likelihood estimates. This sensitivity analysis will be essential for defining key focus areas for the biosecurity management and surveillance systems of the compartment.

The overall risk estimate will be essential for the recipients of the outputs from the ASF-free compartment, since it will indicate whether it is below their acceptable risk level. To increase confidence in this estimate, it is useful to present the results of a sensitivity analysis.

The understanding of the importance of each step along the risk pathways will also be of significance in case of an ASF outbreak inside the compartment. And in preparation for such an event, the risk assessment should allow to identify the functional units or sub-units within the compartment that need to be targeted for particularly stringent bio-containment and bio-exclusion risk mitigation measures, as well as require a high level of sensitivity for early detection surveillance. This part is important in that it will give assurance to the recipient of the outputs from the compartment that the risk of receiving infected or contaminated outputs will be at or below their acceptable risk level.

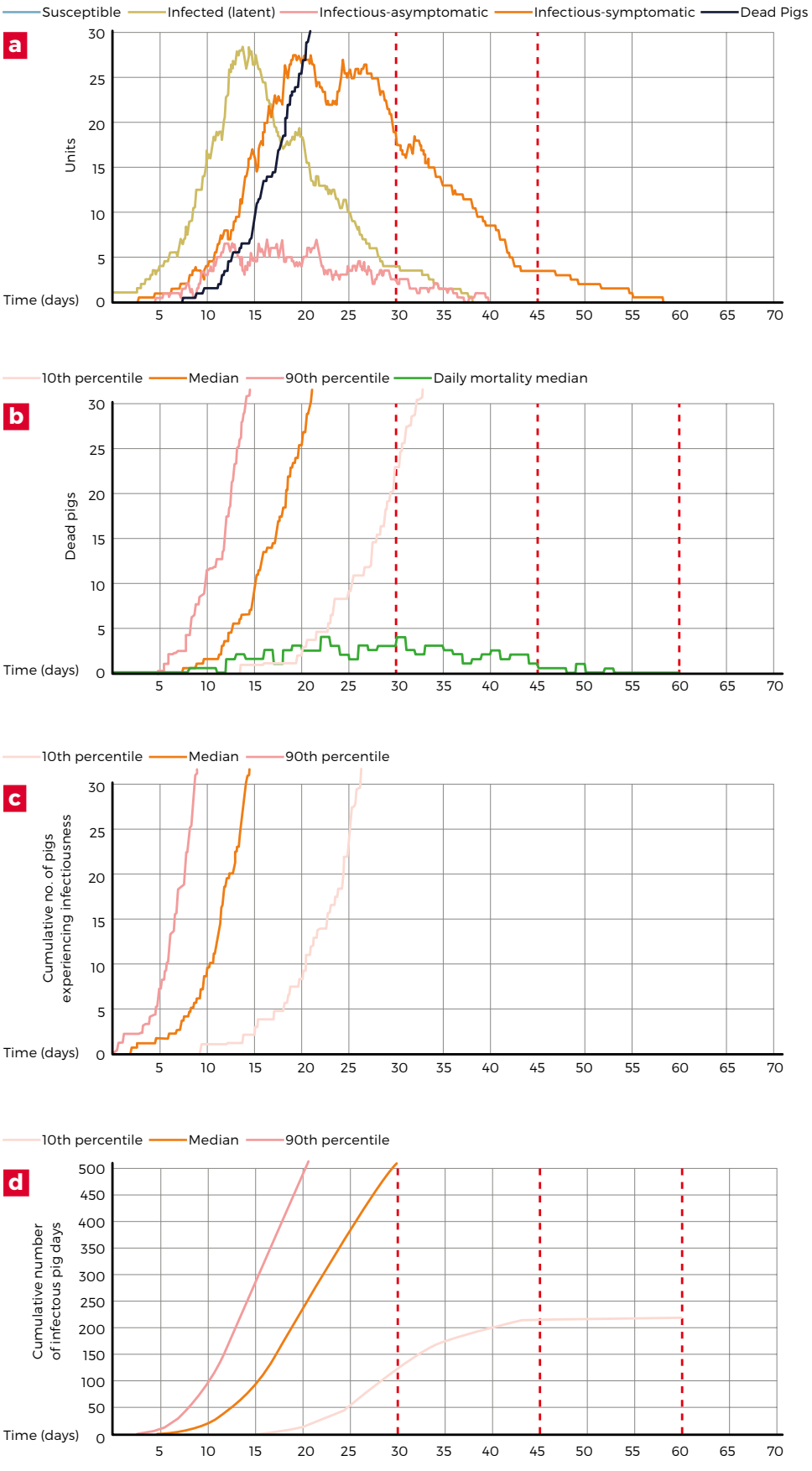
THE ROLE OF DYNAMIC MODELLING

An important consideration for the detection of ASFV along the risk pathways involving direct and indirect transmission among pigs includes the length of latent period, asymptomatic and symptomatic infectious periods and time until death in infected pigs, as well as the ability of diagnostic tests to detect the presence of ASFV. The underlying dynamic process can be examined for the purpose of refining risk management policies and presented to stakeholders using outputs from dynamic modelling such as the examples shown in Figure 12. They will inform the steps in the risk pathways which require the most effective bio-exclusion and bio-containment risk mitigation measures outside and inside the compartment, and generate design prevalence parameters for the development of the rapid detection surveillance system.

The importance of the transmission characteristics of ASFV can be shown using the ASF stochastic homogeneous mixing model implemented in the freely accessible Epidemix App. The example presented here is based on a scenario where one ASFV-infected pig is introduced into a shed with 99 susceptible pigs [76]. This is what might be expected to happen in the context of the exposure risk question and consequence risk question 1. The transmission parameters for this simulation were set to values based on Guinat et al [37; 38]. The model was run for 10 iterations. The simulation results indicate that by about 7 days after its introduction the introduced ASFV-infected pig will have died, and by then it will have infected a median number of about 8 pigs (Figure 12a). The parameters of interest in this simulation for the purpose of the risk assessment for an ASF-free compartment are how long it will take until an early detection surveillance system will be able to detect infection, given the introduction of a single infected live pigs into the compartment. While virus can be detected in single pigs from about 4 days and clinical signs from 5 to 12 days following infection, the surveillance system is unlikely to detect the first few infected or clinically diseased animals. Figure 12b and Figure 12c show the likely numbers of deaths (should be observed by staff) and infectious animals (should be detected by molecular diagnostic tests), respectively. They suggest that by about 10 days post introduction there will be a median cumulative number of 10 infectious pigs (10–90% percentile range: 1 to 42 pigs) and 2 deaths (10–90% percentile range: 0 to 12 pigs). The corresponding figures for 15 days post introduction are a median cumulative number of 35 pigs (10–90% percentile range: 2 to 72) and a median cumulative number of 10 deaths (10–90% percentile range: 1 to 34). Figure 12d shows that by 10 days there will have been a median cumulative number of 20 infectious pig days with (10-90% percentile range: 0 to 92), and by 15 days a median cumulative number of 93 infectious pig days (10–90% percentile range: 1 - 278 days). These latter numbers represent the extent of virus presence within the first 10 to 15 days post introduction, and emphasise the need to detect infection within 10 days of introduction. But this means that the sample size used in the molecular diagnostic surveillance system component needs to be sufficiently large to detect about 1 infected pig among a population of around 100 pigs by 5 days after introduction. The clinical disease surveillance component may not be able to detect the one animal that died from the disease, in addition to 'normal' mortality in that population. The conclusion from this modelling example is that early detection of ASFV will be difficult within 10 days and probably even 15 days. That means that each functional unit or sub-unit inside the compartment where live pigs are kept has to have highly effective bio-containment measures that will minimise the risk of spread of ASFV to other functional units or sub-units in case of an incursion. That is different from bio-exclusion measures which are usually the focus of biosecurity programmes.

The above simulations can be used to explore different scenarios on group sizes, number of introduced infected animals or different assumptions on the simulation model parameters. It may also be desirable to take the structure and relationships between different functional units or sub-units within the compartment into account.

Figure 12 ASF dynamic simulation



ASF dynamic simulation modelling outputs for a sub-unit with 99 susceptible pigs where one ASFV-infected pigs was introduced.

It shows in **a**) the average number of animals in the latent, asymptomatic infectious, symptomatic infectious and the death strata over time, in **b**) the cumulative number of dead pigs over time plus the daily mortality median, in **c**) the cumulative number of infectious pigs over time and in **d**) the cumulative number of infectious pig days over time. The model was run for 10 iterations.

APPENDIX 4

Guidance for a national ASF compartmentalisation programme

This Appendix presents the content to consider when developing the regulatory framework for a national ASF compartmentalisation programme ('the programme'), as well as some of the options that should be discussed between the relevant stakeholders.

→ Figure 13 presents the different elements comprising such a programme, as guidance for setting up such a regulatory framework. The main elements are presented in more detail in the following sections.

The design of the national ASF compartmentalisation programme should also consider the interactions between the regulatory framework of the programme and other regulatory frameworks for ASF preparedness plans, such as the national ASF surveillance plan and the national ASF outbreak contingency plan. The latter should be amended to enable the continuity of operations of ASF-free compartments during ASF outbreaks (movement authorisations, for instance).

The programme should be developed in partnership between public and private stakeholders, with extensive consultation, and the issues of cost recovery and expression of interests at all levels need to be considered and agreed in advance. Final approval of the regulatory framework of the programme remains with the relevant government and/or legal/political entity that adopts the relevant legislation and the Veterinary Authority that will eventually endorse it and have overall responsibility for it. However, the commitment of the private sector is also essential for its success. The first consultations should aim to define a general programme direction, including programme objectives, which can be endorsed by all stakeholders in the PPP.

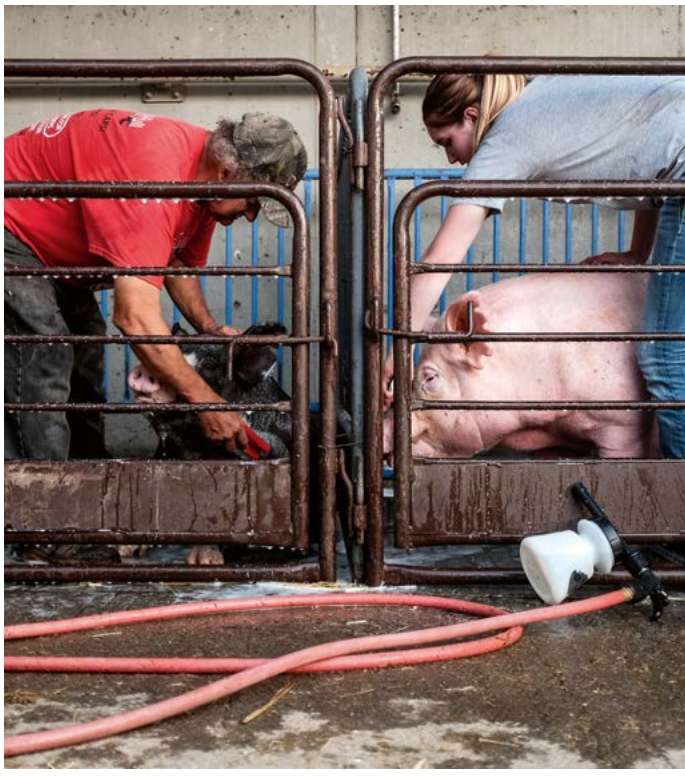
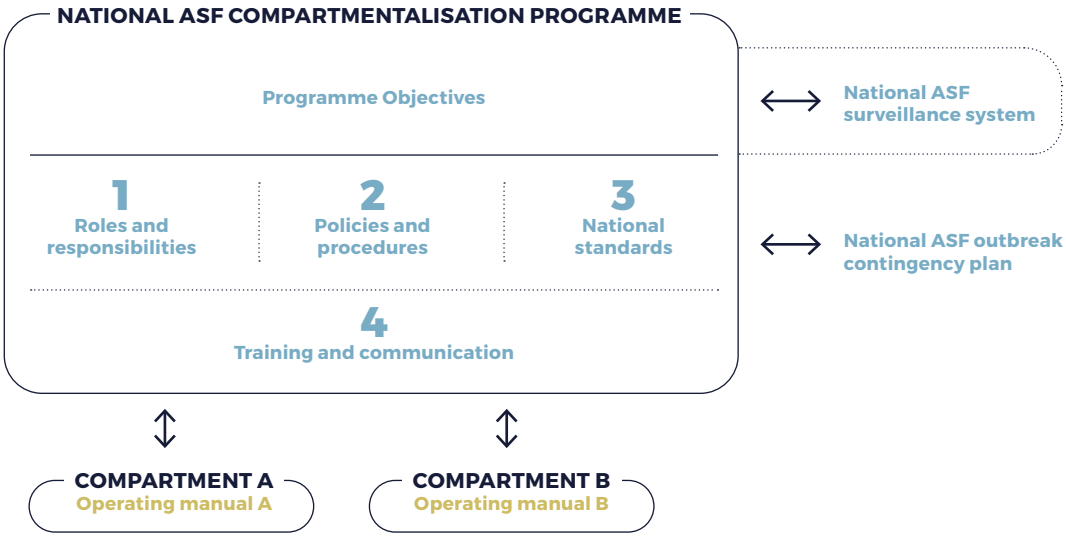


Figure 13 Generic regulatory framework to consider when creating a national ASF compartmentalisation programme



ROLES AND RESPONSIBILITIES

→ Readers should refer to **Articles 4.5.1., 4.5.6.** and **4.5.8.** of the *Terrestrial Code*.

DEFINITION OF ROLES

The programme should first define the different roles and assign organisation(s) to each role. A suggested set of roles, stakeholders and supervision structure is presented in Figure 14 as a starting point. The organisations in charge of each role may vary, depending on country-specific considerations.

→ **Statutory body:** The role must be performed by the Veterinary Authority, as defined by the OIE in Article 4.5.8. of the *Terrestrial Code*. More flexibility can be afforded for the other roles, and the stakeholders should decide which organisation will be in charge of each of them.

→ **Programme administrator:** The programme may be administered by the Veterinary Authority, or this role may be delegated to a relevant private-sector organisation or a private company set up for this purpose.

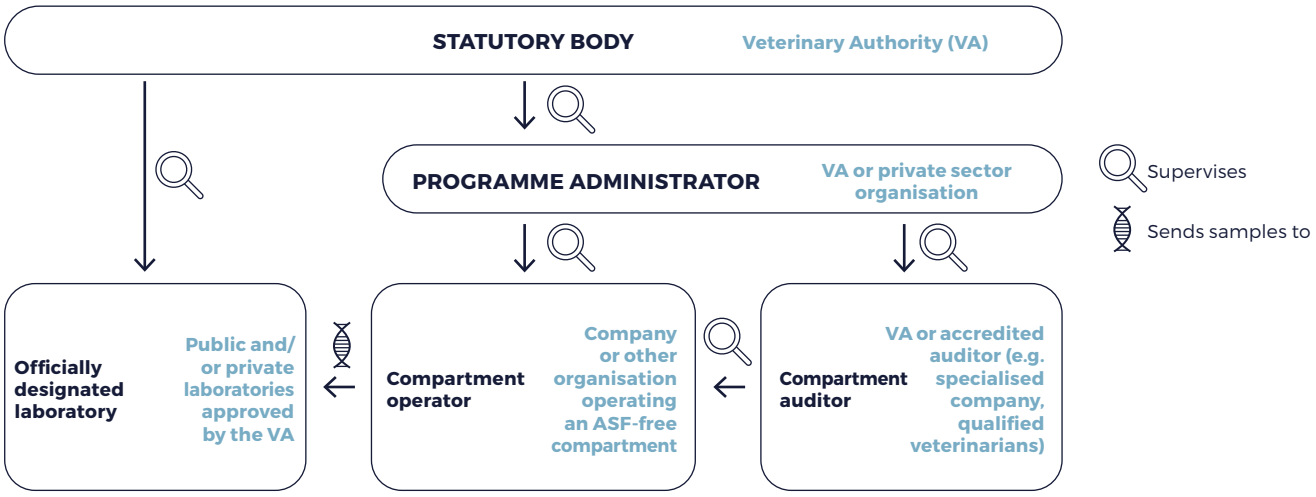
→ **Compartment auditor:** This role could be performed by the Veterinary Authority or by accredited auditors, such as qualified veterinarians or specialised audit companies, under the supervision of the Veterinary Authority.

→ **Compartment operator:** This role is performed by the company or other organisation owning the compartment. This is usually a private entity but could also be a public body in the case of state-owned compartments.

→ **Diagnostic laboratory:** The testing of diagnostic samples for ASFV should be performed by officially designated laboratories, which could be government laboratories and/or private laboratories accredited by the Veterinary Authority. Methods used for this diagnostic work should comply with those in Chapter 3.8.1. of the *Terrestrial Manual*.

The following sections outline responsibilities to consider for each role.

Figure 14 Example of roles within a national ASF compartmentalisation programme and assigned organisations



DEFINITION OF RESPONSIBILITIES

Statutory body

The following should be considered when defining the responsibilities of the statutory body:

- ➜ General supervision of and responsibility for the programme;
- ➜ Endorsement of the national standards of the programme in consultation with stakeholders, as well as regular review and updating of these national standards;
- ➜ Final authority in granting, suspending, reinstating and revoking the ASF-free status of individual compartments within the programme;
- ➜ Responsibility for international recognition of the programme:
  - ⇢ the exporting country should negotiate with the Veterinary Authority of the importing countries for recognition of the programme;
  - ⇢ the importing country should negotiate with the Veterinary Authority of the exporting countries for recognition of its own national ASF compartmentalisation programme, under the reciprocity principle;
  - ⇢ management of export certification for commodities originating from ASF-free compartments (relevant regulations about export certificates may need to be amended to accommodate the certification of products originating from ASF-free compartments);
- ➜ Responsibility for supervision of the external and internal surveillance of the ASF-free compartments under the programme;
- ➜ Direct supervision/oversight of the diagnostic laboratories performing ASF testing:
  - ⇢ approval of officially designated laboratories which can provide diagnostic support to compartments for ASF surveillance testing, e.g. public and/or private (this may require regulatory amendment in countries where such testing is not currently allowed);
  - ⇢ supervision of quality assurance activities, such as proficiency testing by relevant reference laboratories;
  - ⇢ provision of confirmatory testing for non-negative samples at reference laboratories;
- ➜ Direct supervision of the programme administrator;
  - ⇢ approval of the programme administrator's SOPs;
  - ⇢ regular auditing;

- Regular review and updating of the programme, as appropriate;
- Endorsement and communication of changes to the programme to other stakeholders.

Programme administrator

The following should be considered when defining the responsibilities of the programme administrator:

- The design and application of the programme administrator's SOPs, outlining the policies and procedures to be followed to fulfil the role;
- The initial assessment of candidate ASF-free compartments;
- Supervision of existing ASF-free compartments, including compartment status re-evaluation and changes;
- Communication about changes of compartment status with the statutory body, compartment auditors and operators;
- Publication and maintenance of a publicly accessible record of compartments enrolled in the programme and their current status;
- Direct supervision of the compartment auditors:
  - approval of auditors ;
  - approval of the SOPs for compartment auditors;
  - regular auditing;
- Maintenance of up-to-date records of the location of all pig-related premises in the country, to allow candidate ASF-free compartments to conduct a spatial risk assessment;
- Communication of any suspicion of ASF, including but not limited to non-negative ASF diagnostic test results to the statutory body, compartment auditors and operators.

Compartment auditor

A compartment auditor must be qualified against pre-defined standards (e.g. ISO 17020), and be registered and authorised to conduct compartment audits by the statutory body.

The following list should be considered when assigning responsibilities to the compartment auditor:

- the qualifications of the auditor;
- registration with the statutory body;
- the application of SOPs for compartment auditors, outlining the procedures to be followed to fulfil the role;
- audit of each compartment against its operating manual;
- investigation and follow-up of non-conformance;
- communication of audit results to the programme administrator and the compartment operator.

Compartment operator

The following are the responsibilities of the compartment operator.

- operation of a pig (or pig product) production business as an ASF-free compartment;
  - submission of an application for compartment status by submitting all relevant documentation, including the compartment operating manual (see **Appendix 10** for supporting information for the development of this manual);
  - maintenance of biosecurity measures required for the compartment;
  - monitoring of diseases and timely reporting of any suspicion of ASF to the programme administrator;
  - the provision of relevant and appropriate training to staff working in the compartment;
  - internal audit of the ASF-free compartment against the compartment operating manual.

Officially designated laboratory

The following list should be considered when assigning responsibilities to the officially designated laboratories for ASF:

- diagnostic testing, compliant with Chapters 1.1.5., 1.1.6. and 3.8.1. of the OIE *Terrestrial Manual*, of surveillance samples provided by compartment operators for ASF. The national ASF compartmentalisation programme should define how the testing costs are covered;
- communication of non-negative ASF test results to reference laboratories and arrangement of subsequent confirmatory testing;
- regular communication of test results with the statutory body, compartment auditors and operators;
- participation in regular proficiency testing;
- establishing the necessary mechanisms with other reference laboratories to share materials.

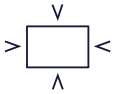
POLICIES AND PROCEDURES

RELEVANT TO PROGRAMME ADMINISTRATION

Policies and procedures relevant to programme administration should be documented and formalised in the SOPs of the programme administrators. The following items should be considered:

- Enrolment in the programme:
  - eligibility criteria, for instance licensing or accreditation requirements, taking into consideration the national standards;
  - specific considerations for multi-premises candidate ASF-free compartments;
  - procedures for candidate ASF-free compartment operators to apply for compartment status for ASF and provision of application guidance and documents;
  - procedures and timelines for the programme administrator to handle these applications.
- Management of compartment status for ASF:
  - initial assessment of candidate ASF-free compartments:
    - review of the operating manual against the national standards;
    - review of the results of the initial audit;
    - a recommendation for granting compartment status for ASF to successful applicants (although the programme administrator may perform the assessment, the authority for granting compartment status remains with the statutory body).
  - re-evaluation of the ASF status of existing ASF-free compartments (periodic, *ad hoc*, and following emergencies, for instance);
  - conditions and reasons for suspension or revocation of compartment status and implications of these events in terms of export certificates;
  - conditions for reinstating ASF-free status following suspension of compartment status and provision of a reapplication form;
  - conditions and reasons for adding or removing component(s) from/to an existing ASF-free compartment and provision of a modification form;
  - rules allowing compartment operators to appeal the decisions of the programme administrator;
  - communication about changes of ASF status in the country to the different stakeholders;
  - communication of any surveillance amendment to the different stakeholders;
  - official publication of ASF status for ASF-free compartments enrolled in the programme.

RELEVANT TO COMPARTMENT AUDITING



External audits (by the compartment auditor)

Policies and procedures relevant to the external auditing of ASF-free compartments should be documented. The relevant elements should be formalised in the SOPs for the compartment auditors. The following items should be considered:

➜ Approval of compartment auditors:

- ⇢ qualifications required by the statutory body;
- ⇢ registration with a statutory body;
- ⇢ approval procedure.

➜ Compartment auditing procedures and timelines:

- ⇢ timing and periodicity of audits: initial assessment of candidate ASF-free compartments, periodic re-evaluation, re-application after suspension of compartment status;
- ⇢ the nature of audits: the contribution of desktop-based documentation review, frequency of site visits, selection of sites for in-person visits;
- ⇢ collation and evaluation of internal audit reports;
- ⇢ audit criteria and checklist, based on the compartment operating manual;
- ⇢ investigation and follow-up of non-conformance;
- ⇢ communication of audit results to the programme administrator and the compartment operator.

Internal audits (by the compartment operator)

The procedures for and frequency of internal audits may be standardised and formalised at the programme level. Relevant stakeholders should be consulted to determine to what degree such procedures should be formalised at the programme level and how much flexibility the compartment operator should be allowed. In any case, the internal audit procedures must be submitted by the compartment operator as part of the compartment operating manual.

RELEVANT TO CONTINGENCY PLANNING AND EMERGENCY RESPONSE

Policies and procedures relevant to contingency planning and emergency response should be documented. The following items should be considered:

➜ The roles and responsibilities of the compartment operator, programme administrator and statutory body regarding contingency planning and emergency response.

➜ Preparedness plans must be submitted by the compartment operator as part of the compartment operating manual. During the design phase of the programme, at least some of these elements should be standardised and formalised at the programme level.

➜ Procedures and timelines for contingency planning:

- ⇢ management of biosecurity breaches (e.g. outbreaks of another infectious disease within the compartment);
- ⇢ management of changes in the exposure risk of ASF-free compartments to ASF.

➜ Procedures and timelines for emergency response, in case of:

- ⇢ the occurrence of a suspected case of ASF within a compartment;
- ⇢ the occurrence of a confirmed case of ASF within a compartment;
- ⇢ the occurrence of an unexpected event threatening the integrity of a compartment (e.g. natural disasters).

NATIONAL STANDARDS

GENERAL STRUCTURE

Establishing national standards provides objective criteria to inform the assessment of the operating manual submitted by candidate compartments for ASF freedom and the decision on whether to grant compartment status. National standards support the continuing supervision of ASF-free compartments by the Veterinary Authority and provide assurance to trading partners of the legal basis for the programme, which complies with the relevant OIE standards. The following general guidelines should be considered when setting national standards:

➜ They should be based on science, with the relevant scientific evidence documented.

➜ They should provide the minimum requirements expected from candidate ASF-free compartments, in terms of three core pillars:

- ASF-specific biosecurity;
- animal health surveillance;
- identification and traceability of live animals and their products.

➜ The national standards should consider the minimum requirements under each pillar for infrastructure, procedures and documentation, where applicable.

➜ They should take into account the different types of production systems and commodities to be traded that will be eligible for enrolment in the national ASF compartmentalisation programme (e.g. pork production, pig genetics companies).

➜ Flexibility in implementation of the national standards should be allowed, provided that the resulting risk assessment of the compartment is acceptable to the relevant stakeholders. For instance, a standard may only specify a targeted output (output-based standards), or it may specify all acceptable versus unacceptable practices (input-based standards).

ASF-SPECIFIC BIOSECURITY

Compartmentalisation is based on the concept of applying biosecurity measures to create a functional separation between animal sub-populations, to establish a disease-free sub-population. The following specific guidelines should be considered when setting the biosecurity national standards:

➜ They should be based on ASF-specific epidemiological features.

➜ They should guide and incorporate explicit requirements for how the compartment sub-population must be separated, both physically and functionally, from potential sources of ASFV. This means that the national standards should address the requirement for a risk assessment to identify all potential pathways for the introduction of ASFV into a compartment.

➜ They should focus on the entry and exposure pathways to ensure effective biosecurity measures against ASFV, with a view to providing high-level confidence in the absence of ASFV in the compartment.

➜ They should address the risk of transboundary introduction of ASFV, as well as the risk from domestic spread, should an outbreak of ASF re-occur.

➜ They should refer to the applicable regulations and clearly set out the additional requirements.

ANIMAL HEALTH SURVEILLANCE IN THE ASF-FREE COMPARTMENT

The following details should be considered when setting national standards for internal surveillance (i.e. in the compartment):

- They should guide how the compartment's internal surveillance is able to ensure rapid detection if ASFV enters the animal sub-population within the compartment, and provide sufficient evidence of ASF-freedom.
- They may be output-based, prescribing what surveillance must achieve, or input-based, prescribing what surveillance activities must be undertaken.
- Example outputs are: the level of surveillance sensitivity that should be achieved and the maximum acceptable time for rapid detection, accompanied by confidence levels.

- For further guidance on internal surveillance for an ASF-free compartment, see **Appendix 8** and **Appendix 9**.

IDENTIFICATION AND TRACEABILITY OF LIVE ANIMALS AND THEIR PRODUCTS

The following specific guidelines should be considered when setting national standards for identification and traceability, both within and outside the compartment:

- They should outline the requirements for the compartment operator to demonstrate that:
  - the operator retains continuous supervision over the compartment's operations
  - the integrity of the ASF-free compartment is maintained at all times
  - commodities originating from an ASF-free compartment can be rapidly traced throughout the supply chain. In the event that ASFV is detected on premises within the compartment, recall of the relevant commodities must be efficient and effective. In case of any change of ASF status outside the compartment, the relevant commodities must be prevented from any possible contact with products outside the compartment to avoid contamination.
- They should comply with the existing applicable identification and traceability regulations.
- They should address the identification and traceability requirements for animals contained in ASF-free compartments, as well as animals or animal products originating from compartment premises (e.g. boar semen, pork products).
- Other traceability requirements that relate to biosecurity (e.g. origin of feed ingredients) are best addressed in the biosecurity national standards.

- Two examples of national standards, related to the introduction of live pigs and internal surveillance in ASF-free compartments, are presented in Figure 15 and Figure 16, respectively. The type of standards and the amount of flexibility for alternative options agreed upon by the stakeholders should be reflected in the level of detail included in the national standards.

Figure 15 Examples of national standards related to the introduction of live pigs into an ASF-free compartment

AN OUTPUT-BASED STANDARD

INFRASTRUCTURAL REQUIREMENTS:

- Quarantine sites, if applicable, meet regulatory requirements for such facilities.

PROCEDURAL REQUIREMENTS:

- Live pigs introduced to the compartment are free from ASFV.

DOCUMENTATION REQUIREMENTS:

- Adequate records are maintained to verify compliance with this standard

AN INPUT-BASED STANDARD

INFRASTRUCTURAL REQUIREMENTS:

- Pigs are housed in fully enclosed barns during quarantine periods.
- Entrances to quarantine facilities have clear signage indicating that unauthorised access is prohibited.

PROCEDURAL REQUIREMENTS:

- Live pigs are sourced from an ASF-free compartment.
- Live pigs not sourced from ASF-free compartment are not introduced directly into the compartment.
- Live pigs not sourced from ASF-free compartment are held in quarantine for 30 days. Negative ASF test results are required before introduction into the compartment, using real-time polymerase chain reaction (PCR) analysis of oral swab samples.

DOCUMENTATION REQUIREMENTS:

- Complete records are kept for each live pig introduced in the compartment, detailing:
  - Identification of farm of origin
  - Number of animals in the batch
  - Date of entry in and release of quarantine, if applicable

Figure 16 Examples of national standards related to internal surveillance in ASF-free compartments

AN OUTPUT-BASED STANDARD

PROCEDURAL REQUIREMENTS:

The internal surveillance system provides:

- A 99% confidence that ASFV is not present in the compartment, with a pig-level design prevalence of 5% and a barn-level design prevalence of 1 infected barn.
- A 95% confidence that the infection would be detected within 15 days of introduction.

DOCUMENTATION REQUIREMENTS:

- Adequate records are maintained to verify compliance with this standard

AN INPUT-BASED STANDARD

PROCEDURAL REQUIREMENTS:

Internal surveillance is based on virological testing of pigs found dead or euthanised for health reasons:

- The first two pigs dying with ASF-compatible signs each week and in each barn are selected for sampling.
- Spleen samples are collected within 24 hours of death.
- Samples are tested by real-time polymerase chain reaction (PCR).

DOCUMENTATION REQUIREMENTS:

- Daily mortality records are maintained at the barn level, indicating the number of pigs found dead or euthanised for health reasons, the date and the mortality category, as per the standard mortality classification provided.

TRAINING AND COMMUNICATION

The programme should cover the following areas:

- training within different organisations, to enable existing and newly recruited personnel to fulfil their roles. Refreshment training should also be considered on a regular basis;
- communication between different organisations involved in the programme:
  - under routine conditions (for example, changes in management practices which may affect the compartment's disease-free status are reported by the compartment operator to the programme administrator; audit results are reported by the compartment auditor to the programme administrator; a routine programme report is compiled monthly by the programme administrator for the statutory body);
  - in emergency situations (for example, immediate notification of biosecurity breaches are reported by the compartment operator to the programme administrator);
- communication between the Veterinary Authority of the exporting country and the Veterinary Authority of importing countries to promote the programme, negotiate its recognition and communicate about potential changes;
- maintenance of up-to-date, publicly accessible programme documentation, including eligibility criteria, national standards and a complete list of ASF-free compartments. This documentation mainly targets producers looking for information about the enrolment programme and stakeholders in importing countries wanting to assess the programme.

3rd Meeting of the Standing Group of Experts on African Swine Fever for Asia & 4th Regional Workshop on Swine Disease Control in Asia, 26-28 November 2019, Ho Chi Minh City, Vietnam.

APPENDIX 5

Outcome-based biosecurity checklist for ASF-free compartments

This Appendix presents a checklist to assess the biosecurity of an ASF-free compartment. It needs to be adapted to the specific country and compartment of interest. In accordance with the principles of an outcome-based approach, measures other than those given in the checklist may also be considered as alternative options, with appropriate justification, provided that they achieve the expected outcomes. There are also online tools such as Biocheck.ugent which guide through an evaluation of the generic biosecurity on a pig farm. It can be used to complement but not to replace the approach described in these guidelines, because it was not designed to address a specific risk question.

→ **The checklist is available for download on the OIE website**

APPENDIX 6

Assessment criteria

This Appendix presents a list of general criteria to be considered by exporting countries, importing countries, auditors and the private sector when conducting an assessment for approval of a candidate ASF-free compartment. It aims to provide general principles as guidance for compartment assessment purposes and should be tailored to the specific country context and to the characteristics of the compartment.

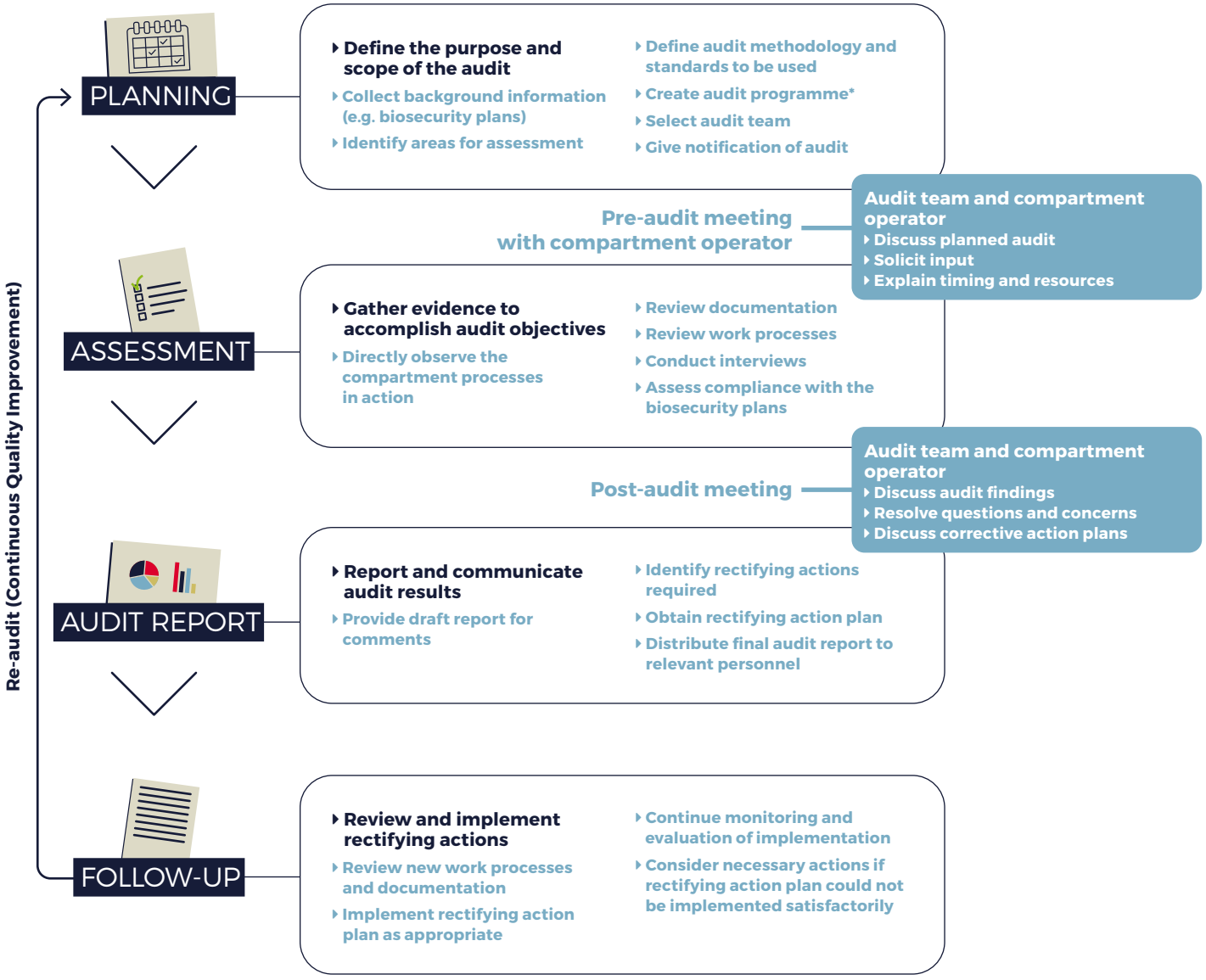
AREA	CRITERIA
Compartment supervision and control	▸ A regulatory framework for a national ASF compartmentalisation programme is available. — Public–private partnerships (PPPs) and the respective roles and responsibilities of different parties involved in ASF compartmentalisation are clearly identified (readers are referred to the OIE *Checklist on the Practical Application of Compartmentalisation*). ▸ The authority, organisation and infrastructure of the compartment and associated facilities (e.g. laboratories) are clearly documented in accordance with Chapter 3.1. of the *Terrestrial Code*. An example is provided in Figure 14 of Appendix 4 for reference. An evaluation of the country's Veterinary Services could be carried out, in accordance with Chapter 3.2. of the *Terrestrial Code* and the OIE Performance of Veterinary Services (PVS) Tool. ▸ Official oversight of the ASF-free compartment is carried out by the Veterinary Authority. — Appropriate supervision is available for factors crucial to the maintenance of the compartment (e.g. management practices, biosecurity, surveillance, traceability and capability of Veterinary Services). — The Veterinary Authority evaluates the compartment on a regular basis to consider any necessary additional precautionary measures to ensure the integrity of the compartment. — The Veterinary Authority certifies that the products of the compartment are ASF-free and fit for national /international trade purposes. — The Veterinary Authority possesses the final authority to approve, suspend and/or revoke the certification of a compartment. — The Veterinary Authority ensures that all relevant information on the ASF-free compartment is readily accessible to trading partners. ▸ An auditing mechanism, both internal and external, is in place to continuously monitor the compliance of the compartment with the regulatory framework for the national ASF compartmentalisation programme and other relevant requirements (e.g. management practices, biosecurity, surveillance and traceability). ▸ There is a fully functional operating manual, in addition to standard operating procedures (SOPs).
Identification and traceability system	▸ The Veterinary Authority, in consultation with the private sector, is responsible for the effectiveness of the animal identification and traceability system. ▸ The method of animal identification (individual or group) and the traceability system are clearly identified and documented in and out of the compartment. ▸ The identification and traceability systems adopted by the compartment comply with the relevant standards laid out in Chapters 4.2. and 4.3., and Article 4.5.3., for traceability systems in the *Terrestrial Code*, as well as Chapters 5.10. to 5.12. on animals and animal products intended for export. ▸ The traceability system includes at least the following information: — batch information on the animal(s) — the origin and movement of the animals and relevant commodities. ▸ All animal movements (including internal and external movements) are recorded and, when needed, certified by the Veterinary Authority. ▸ The traceability system is able to verify that pigs and pig products originated from the ASF-free compartment and/or were introduced into the compartment. ▸ The traceability of other inputs along the pork supply chain (e.g. feed, medicines, and vaccines) other than pigs should also be in place. ▸ An auditing mechanism is in place for the whole traceability system within and out of the compartment.

Biosecurity plan	▸ A biosecurity plan approved by the Veterinary Authority is in operation. ▸ The biosecurity plan complies with Article 4.4.3. and 4.5.3. of *the Terrestrial Code*. ▸ The biosecurity plan addresses all relevant factors, including but not limited to: — a clear definition (which includes a description of the typology) of the compartment — a description of the common biosecurity management system under which the components of the compartment operate, which can be illustrated with diagrams, flow charts or other means to show the functional relationships — a description of potential risk pathways for ASFV introduction and critical control points to prevent that introduction — a description of the physical or spatial factors and infrastructural factors that may affect the biosecurity status of the compartment — a description of regular monitoring and reviewing of procedures in accordance with the most recent scientific information related to the risk pathways and risk factors — a description of the biosecurity measures adopted at critical control points to manage the entry risk of ASFV via the risk pathways. ▸ Standard operating procedures for implementation of the biosecurity plan are in place with a corresponding compliance monitoring programme (CMP). ▸ A contingency plan for adverse events, in particular for changes in ASF status, is in place. ▸ An auditing mechanism is in place, including regular review and updating of biosecurity measures and to determine whether there has been a breach in biosecurity measures. ▸ A reporting mechanism to the Veterinary Authority is in place in case of any biosecurity breaches. (For specific details, the reader is referred to the OIE Checklist on the Practical Application of Compartmentalisation. [1]
Surveillance	▸ A surveillance system for compartmentalisation is in place, under the supervision of the Veterinary Authority. ▸ Necessary surveillance at the national level is appropriately implemented, and procedures for the investigation and reporting of suspected and confirmed ASF cases are in place. ▸ A good knowledge and understanding of ASF within and outside the compartment, including in wild or feral pigs, is available. ▸ Surveillance activities conducted are in accordance with the principles stated in Chapters 1.4. and 1.5. of the *Terrestrial Code*, as well as Articles 15.1.28. to 15.1.33. of *the Terrestrial Code*, which specifically address ASF. ▸ Essential components of the compartment surveillance system, as detailed in the OIE *Checklist on the Practical Application of Compartmentalisation*, are included. ▸ The sensitivity of the internal and external surveillance of the compartment is appropriately adjusted to the corresponding risk levels. ▸ The final authority regarding disease surveillance and reporting, disease control and veterinary certification for international trade from the compartment lies with the Veterinary Authority.
Diagnostic laboratory capacity	▸ Sample testing is conducted in officially designated laboratory facilities that comply with the OIE standards for quality assurance, as set out in Chapter 1.1.5. of the *Terrestrial Manual*. ▸ Laboratory testing methods and procedures for ASF comply with the recommendations of Chapter 3.8.1., with appropriate validation, as set out in Chapter 1.1.6. of the *Terrestrial Manual*. ▸ Samples with positive ASFV test results must be confirmed by the OIE reference laboratory, national reference laboratory or other reference laboratories, if appropriate. ▸ Systematic procedures and a rapid reporting system to the Veterinary Authority are in place to notify test results in a timely and regular manner. ▸ The Veterinary Authority possesses information related to diagnostic laboratory capacity: — a list of the officially designated laboratories for testing and confirmation of test results — the capacity of each laboratory to comply with the surveillance requirements — the type of tests applied for ASFV detection — the volume of samples that can be handled for each test — procedures and methods to ensure quality control — procedures for general reporting of test results and rapid reporting of positive results.

Emergency response and notification	▸ A rapid detection system is in place which is able to detect the introduction of ASFV in the compartment effectively and in a timely manner. ▸ A contingency plan is in place that identifies the actions to be taken if any adverse events occur in the compartment to prevent further spreading of ASFV. ▸ A reporting system is in place for the compartment operators to notify the Veterinary Authority of any adverse events noted in the compartment. ▸ The Veterinary Authority has procedures and measures in place for the following scenarios: — a suspected or confirmed ASF case in the compartment — a breach in biosecurity, regardless of any suspicion of ASF — a change in ASF status outside the compartment.
Documentation	▸ Documentation of the compartment provides clear evidence that the biosecurity, surveillance, traceability and management practices defined are effectively and consistently applied, including measures to rectify non-conformance. ▸ The necessary documentation complying with Article 4.5.4. of the *Terrestrial Code* is available, as appropriate. ▸ A baseline animal health report of the health of the animal sub-population in the compartment is available, which is subject to regular updates to reflect the most current animal health situation. ▸ The time period for record-keeping in the compartment is reasonable and clearly identified. ▸ Transparency is maintained in the documentation of all relevant information, and appropriate records are readily accessible for audit by the Veterinary Authority.

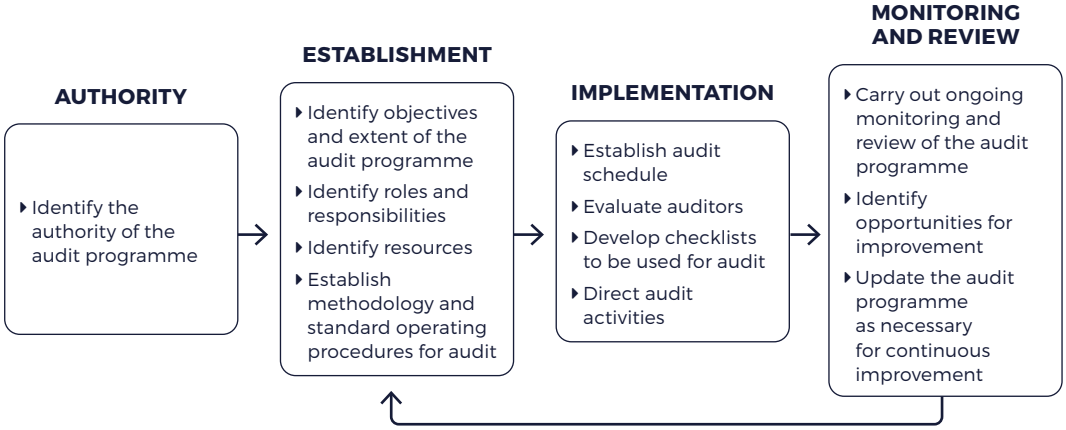
APPENDIX 7

Figure 17 Diagrammatic example of a possible audit process [80-82]



* Examples of audit process and audit programme formulation process

The audit programme should be formulated based on the following process:



APPENDIX 8

General surveillance principles relevant for internal surveillance of an ASF-free compartment

→ The reader should refer to **Article 1.4.6.**; **Article 4.5.3.** (point 3h); **Article 4.5.5.** (point 1); and **Articles 15.1.14., 15.1.15., 15.1.29.,** and **15.1.30**. of the *Terrestrial Code*.

This Appendix presents principles to consider when developing an ASF internal surveillance system for an ASF-free compartment, as well as examples of possible approaches. The guidance provided in the relevant chapters of the *Terrestrial Code* identifies the need for ongoing disease surveillance in ASF-free compartments. The internal surveillance system implemented within each ASF-free compartment must also comply with the Member's national standards.

The purpose of this Appendix is to describe internal surveillance aimed at detecting infection with ASFV in a compartment, in accordance with the provisions described in Chapter 15.1. of the *Terrestrial Code*.

The principles presented here also apply to the external surveillance required in the *Terrestrial Code* to support the demonstration of freedom from ASFV within the compartment.

The compartment's internal surveillance system should adopt a risk-based approach to optimise its overall sensitivity, based on the information obtained by the risk assessment for the compartment which will have identified key areas to be targeted by surveillance components [28; 30; 83; 84].

SURVEILLANCE OBJECTIVES

ASF-free compartments require an internal surveillance system designed to provide evidence of continued ASF-free status to stakeholders and to detect an ASFV introduction rapidly so that the risk of infected or contaminated outputs leaving the compartment can be minimised.

The objectives of internal surveillance are as follows:

1. **Rapid detection of ASFV if it enters the compartment** so that the likelihood of pigs and pig products that are infected or contaminated with ASFV leaving the compartment can be reduced to an acceptable level and the return to ASFV-free status can be achieved as rapidly as possible;

2. **To demonstrate freedom from ASF within the compartment,** which is necessary to initiate and maintain trade, unless the compartment is completely located in an ASF-free country or zone.

SURVEILLANCE SENSITIVITY

For both objectives, the key quality attributes of the internal surveillance system are sensitivity, timeliness and representativeness [28; 30; 83]. This section summarises the principles that influence the sensitivity of an internal ASF surveillance system component aimed at achieving both surveillance objectives [42; 85].

SURVEILLANCE FOR RAPID DETECTION OF ASFV

The sensitivity of a surveillance system component designed for rapid detection of ASFV is measured as the probability that ASFV will be detected in the functional unit or its sub-unit where it was introduced within a specified time frame. The aim has to be that detection should occur before infection has been able to spread from the functional unit or sub-unit of ASFV entry to other components of the compartment. In this context, a key parameter of the surveillance system performance will be the time from ASFV introduction to detection (e.g. 5 days after introduction of the virus into a particular functional unit or sub-unit within a compartment). The length of that time period needs to be agreed with the recipients of outputs from the compartment.

The sensitivity of each internal surveillance system component for rapid detection can be estimated as the product of the following three parameters [42]:

Population coverage of the surveillance component

This is the probability that any given animal or other sampling unit in the animal sub-population will be included by the surveillance system component. If a surveillance component uses simple random sampling to select the sampling units, this probability is equal to the sample size divided by the size of the animal sub-population. It can also be used to make judgements about the representativeness of the animals or units. For clinical surveillance, population coverage approaches 100% as all domestic pigs are under observation. Note that the probability that staff working in the respective functional unit or sub-unit where the pigs are kept will recognise and report disease in affected animals is included in the detection sensitivity explained below.

Temporal coverage of the surveillance component

This is the conditional probability that any given animal or other sampling unit in the animal sub-population will be tested or observed within the specified time frame, given that it is in the surveillance sample. For example, if the target time to detection is 7 days, but testing occurs every 4 weeks, the temporal coverage is 25%.

Detection sensitivity

This is the conditional probability that an infected animal/sampling unit will be correctly detected, given that it is tested or observed within the specified time frame. For an internal surveillance system component based on applying a laboratory diagnostic test to the animals in the surveillance sample, the detection sensitivity is the sensitivity of the laboratory diagnostic test used. For a surveillance system component based on detection of clinical disease, the detection sensitivity is the result of a series of steps leading to detection, each with an associated probability of occurrence, which may include the:

- Probability that the ASFV-infected animal(s) show(s) clinical signs of disease (including death);
- Probability that the staff working in the functional unit or sub-unit notice the potentially affected animal(s) and report it to their manager;
- Probability that the manager of the functional unit or sub-unit reports the suspected case to the compartment management;

- Probability that the compartment operator decides that it may be an occurrence of ASF and notifies the Veterinary Authority;
- Probability that samples are collected;
- Probability that samples are tested for ASFV;
- Probability that the test result is positive (i.e. the laboratory diagnostic test sensitivity).

Therefore, the sensitivity of a surveillance system component aimed at rapid detection can be improved by including more animals or other relevant sampling units, testing or observing animals or other relevant sampling units more frequently, or by improving the capacity to detect a case (through more accurate diagnostic tests or improved clinical observations). For detection of clinical disease, staff awareness of the clinical presentation of ASF will be essential, and it needs to be kept in mind that pigs may show clinical signs 5 to 19 days or longer after infection, whereas ASFV can be detected in blood samples using molecular detection methods from about 4 days [37; 38].

SURVEILLANCE TO DEMONSTRATE FREEDOM FROM ASFV

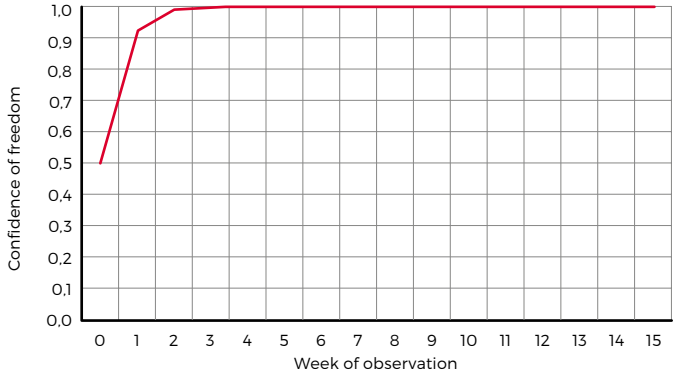
The sensitivity of an internal surveillance system designed to demonstrate freedom from ASFV is measured in terms of the probability that the surveillance activities detect at least one truly infected animal, if the animal sub-population is infected with ASFV at or above the level of the stated design prevalence. The sensitivity of the system is dependent on:

- the design prevalence chosen;
- the diagnostic test sensitivity;
- the sample size (e.g. the number of animals tested or observed).

The relationship between sample size and internal surveillance system sensitivity is exponential, whereas the other two determinants have a multiplicative relationship with surveillance system sensitivity. This means that increasing the sample size (i.e. the number of animals tested or observed) will increase sensitivity much more than increasing the sensitivity of the individual animal test. In other words, an inexpensive test with relatively low sensitivity but very large sample sizes may give a much higher overall system sensitivity than a highly sensitive test and a small sample size.

Weekly sampling with negative test results will generate cumulative evidence of freedom from ASFV [86]. For example, assuming a conservative estimate of the likelihood of ASFV introduction of approximately once every 4 years (which represents a weekly probability of entry of 0.5%), the cumulative confidence of freedom exceeds 99% after 3 weeks of sampling with negative test results, as indicated in Figure 18. An important assumption for this estimation is that the likelihood remains constant over time.

Figure 18 Cumulative confidence of freedom from ASFV based on weekly sampling with negative testing results



APPENDIX 9

Internal surveillance system as part of risk management for an ASF-free compartment

COMBINING SURVEILLANCE SYSTEM OBJECTIVES

As outlined in **Appendix 8**, an internal surveillance system in ASF-free compartments has two objectives: Rapid detection of ASFV and demonstration of freedom from ASFV. The surveillance components selected for the internal surveillance system may contribute to achieving both objectives at the same time; there is no need to separate components by objective. The importance of the objectives depends on the context [30; 42; 83-85].

When considering the implementation of an ASF-free compartment in an ASF-free country or zone, historical freedom from ASF and recent surveillance results should be used to demonstrate that the animal sub-population in the compartment is initially free from ASFV. In this case, the internal surveillance system aims to detect new introductions, and therefore the focus will be on rapid detection. For rapid detection, the aim is to identify the first infected animal in a functional unit or sub-unit (e.g. barn) as rapidly as possible. The requirements in terms of demonstration of freedom will be met by continuous analysis of the surveillance data generated by the surveillance system.

When considering the implementation of an ASF-free compartment in a country where ASF is present, or when insufficient evidence is available to demonstrate that the compartment's animal sub-population is initially free from ASFV, additional emphasis may be needed to demonstrate ASFV freedom. In this case, the internal surveillance system will need to be able to detect ASFV infection, should it be present in the compartment. Such evidence will be required before ASF-free status can be recognised for the compartment. The design prevalence used to demonstrate freedom from infection is typically in the range of 1% to 10%. A lower design prevalence will require a larger sample size. The required evidence can be generated using clinical disease surveillance, syndromic surveillance, etc. (see below for examples of ASF surveillance system components) by analysing data aggregated over time. However, additional surveillance activities, such as ad hoc laboratory diagnostic testing surveys, may be required to meet this objective, due to, for instance, insufficient data availability or regulatory requirements. Once the absence of ASFV infection has been demonstrated, the internal surveillance system becomes focused on detecting new incursions, as presented in the previous paragraph.

RESOURCE ALLOCATION

Surveillance is one of the two main pillars in the overall risk management strategy for ASF-free compartments, alongside biosecurity-related measures. As such, resource allocation to these two pillars should consider the benefits obtained from their implementation alongside the costs incurred, to optimise the overall net benefit for the compartment. For instance, based on a detailed examination of the risk pathways and the associated risk estimates generated by the risk assessment for the compartment, a lower surveillance sensitivity may be acceptable in the context of a compartment, such as multiplier herds, with air filtration and no introduction of live animals. On the other hand, higher surveillance sensitivity may be required in a multi-premises compartment with movement between premises and no air filtration. An important element to consider when allocating resources is the remaining probability of ASFV introduction accounting for the risk mitigation measures in place and the impact of this probability on continued confidence in freedom [43]. Elements to consider in the design of cost-effective surveillance systems may be found in other documents [30; 83; 84]. Online tools, including a design tool for each component of the surveillance system, an evaluation tool, and access to statistical tools to estimate surveillance sensitivity, confidence of disease freedom and other parameters, are also freely available, for example at https://survtools.org/.

INFLUENCE OF THE ASFV RISK ENVIRONMENT EXTERNAL TO COMPARTMENT

→ The reader should refer to **Article 4.5.5.** of the *Terrestrial Code*.

Ideally, the internal surveillance system should be independent of the presence or absence of ASFV in the country or zone and designed to meet surveillance objectives under both conditions. However, it is likely that trading partner expectations with respect to the acceptable risk of ASFV infection and surveillance requirements within the compartment may be change, if ASFV enters the country or zones where the compartment is located. Such considerations should be accounted for when negotiating compartment-related trade agreements, so that potential changes are anticipated (e.g. increasing the sensitivity of the internal surveillance system in response to increasing external ASFV risk), and response plans are agreed upon and documented.

DETECTION OF ASFV BASED ON CLINICAL SIGNS OR LABORATORY DIAGNOSTIC TESTING

Clinical disease surveillance, based on the detection of animals with ASF clinical signs, forms the basis of rapid detection surveillance systems for ASFV in many ASF-free countries around the world. Such surveillance usually takes the form of notification of a suspected case of ASF by staff working with animals, according to the definition(s) outlined in these guidelines. It is a type of screening test, where any case suspected to be diseased will then be subjected to confirmatory testing via highly specific laboratory diagnostic tests. With this surveillance approach every effort needs to be made to maximise the sensitivity of the screening by staff for indicators of clinical ASF.

The effectiveness of clinical disease surveillance for ASF can be compromised by the following two factors:

1. **There can be negative economic or political consequences** of reporting the suspected occurrence of ASF to the Veterinary Authority in some countries or zones.

2. **The positive predictive value of clinical signs for detecting ASF is low,** due to the likely occurrence of other diseases with similar clinical signs and epidemiological characteristics in the country or zone (e.g. classical swine fever, porcine reproductive and respiratory syndrome).

These two factors can adversely impact the reporting behaviour of staff. If this leads to a decreased reporting probability, the confidence in ASFV freedom, calculated in accordance with the approach presented in Appendix 8, may be overestimated. But it will have an even greater adverse impact on the surveillance system's rapid detection performance. In this situation the sensitivity of the clinical disease surveillance system component would be considered too low, particularly in a non-ASF-free country or zone. Additional surveillance system components should then be considered to achieve the desired overall surveillance system performance with respect to sensitivity, timeliness and representativeness. This is likely to include random or risk-based sampling of animals and/or the environment for laboratory diagnostic testing using molecular detection methods.

Even though the specificity of surveillance system components will very likely differ (for example between different types of laboratory tests or for detection of clinical signs), the overall specificity of a rapid detection surveillance system is usually assumed to be 100%. This is because any positives in a surveillance component using a screening test, such as clinical disease surveillance, will be subjected to the full diagnostic testing algorithm for a definitive diagnosis, generally by virus isolation and/or genetic sequencing. Therefore, even if the first test within that sequence of sequential tests is a false positive, the subsequent tests should minimise the probability of an animal sub-population being confirmed positive for ASFV when it is truly negative, and that probability can therefore be assumed to be negligible. The number of false positives obtained during the initial screening phase can be used as a performance indicator of the screening surveillance component, in that if there are no or few false positives the system may not be sufficiently sensitive. A change in the pattern of false positives over time may also be of relevance as an indicator of change in sensitivity. Both these scenarios may be an indication of inadequate detection effort by staff.

The dynamics of ASFV transmission can be examined using the ASF stochastic homogeneous mixing model implemented in the freely accessible Epidemix App [76]. This will assist with developing

an impression of the likely number of symptomatic pigs that will be present in a particular functional unit or sub-unit. It needs to be kept in mind that pigs kept in different sub-units along the production process will remain in the respective production stages for specific periods of time, and group sizes will also vary. Example figures for farrow to finish pig production (not breeding pigs) are 3 weeks in the farrowing, 3 to 8 weeks in the weaning and 16 to 17 weeks in the finishing section. ASFV could be introduced to a group of pigs during any of those stages, as should have been described in detail in the risk assessment when developing the risk pathway diagrams. In 2018, the average pig mortality during the finishing stage was 2.9% and 4.5% in the European Union and in the USA, respectively. And in the European Union in 2018, pigs spent an average of 111 days in the finishing section [87], resulting in a daily average pig mortality of 0.03% for the EU. The simulation output presented in Figure 19 is based on a scenario where one ASFV infected pig is introduced into an epidemiological unit with 99 susceptible pigs. The same parameter settings are used as for the simulation in Appendix 3. The simulation outputs shown in Figure 19a and Figure 19b indicate that the median mortality will reach the average 'normal' finishing pig mortality level of about 3 to 5% by 13 to 15 days. This will also mean that by 15 days there will have been a median of 79 cumulative infectious pig days (10–90% percentile range: 6 to 207) and by 20 days it will have been a median of 227 days cumulative infectious pig days (10–90% percentile range: 39 to 432) (see Figure 19d). This will have resulted in exposure of other pigs to ASFV and of staff or equipment becoming contaminated with virus. This would result in spread within the epidemiological unit, and the potential of ASFV being taken by contaminated staff, equipment, manure, etc.to other parts of the compartment, if biosecurity for the epidemiological unit is inadequate. These figures indicate that if infection is to be detected within 20 days after introduction the 'alarm' trigger level for any surveillance component involving mortality data has to be set very low, and it may result in significant numbers of false-positive 'alarms'.

Figure 19 ASF dynamic simulation modelling outputs for a sub-unit with 99 susceptible pigs where one ASFV infected pigs was introduced

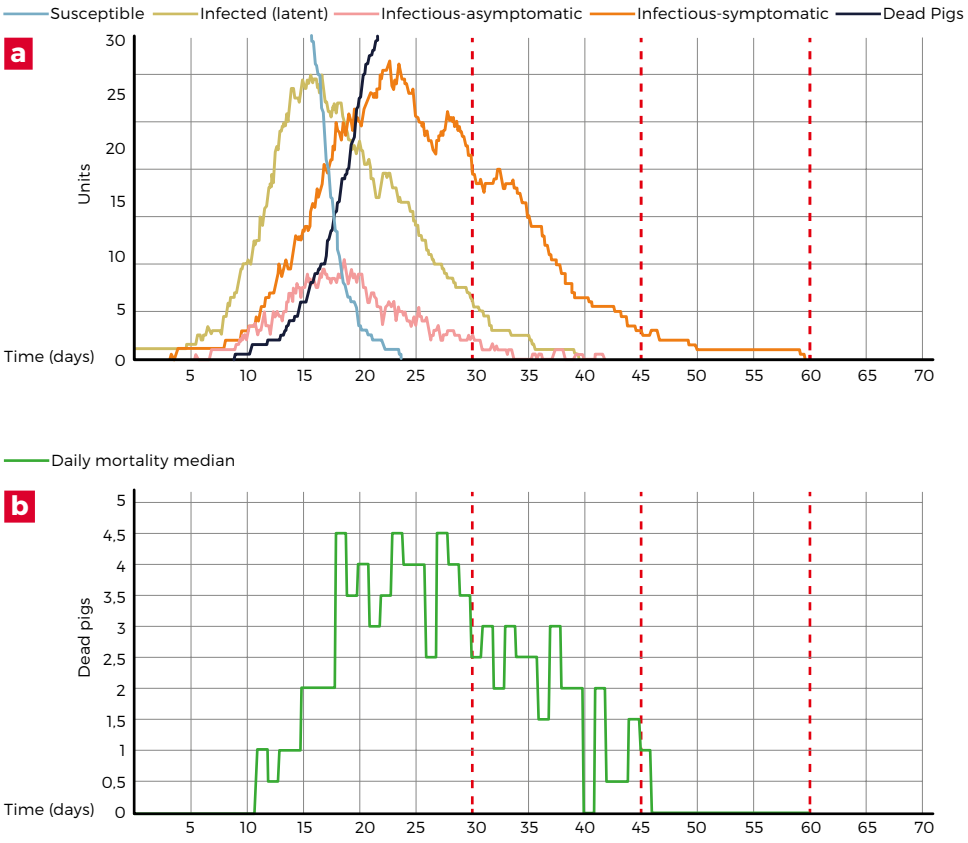
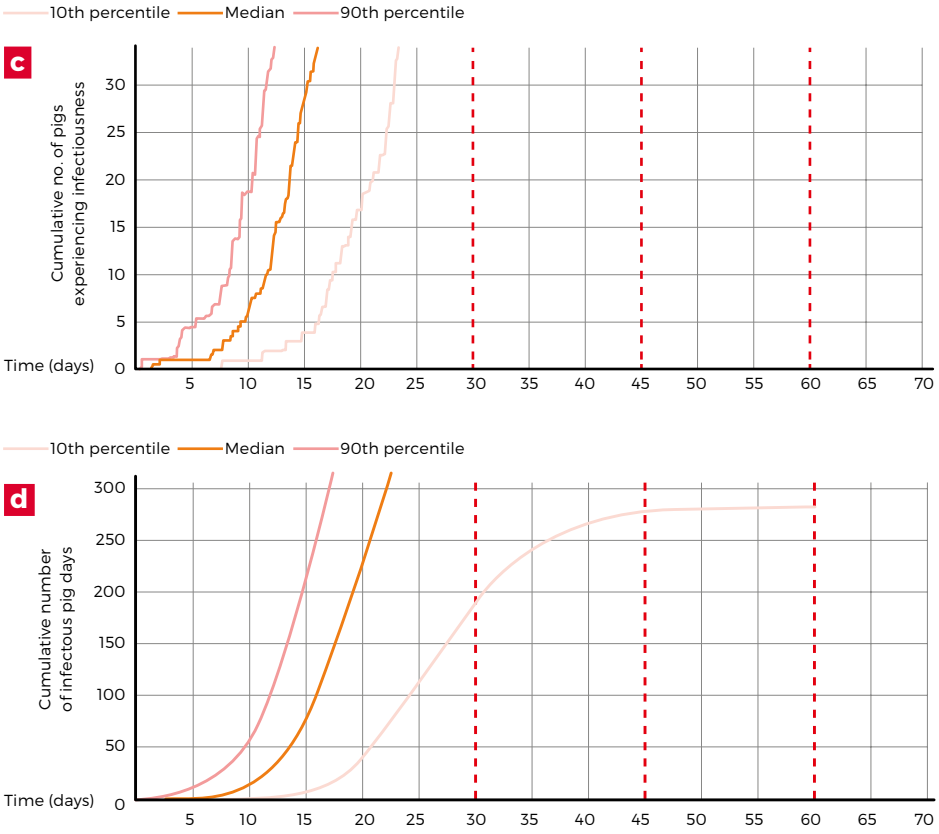


Figure 19 shows in a) the median number of animals in the susceptible, latent, asymptomatic infectious, symptomatic infectious and the death strata over time, in b) the daily mortality median, in c) the cumulative number of infectious pigs over time and in d) the cumulative number of infectious pig days over time. The model was run for 10 iterations.



EXAMPLES OF ASFV SURVEILLANCE SYSTEM COMPONENTS

Below are three examples of typical ASF surveillance system components: Syndromic surveillance, functional unit or sub-unit based observational surveillance, and pre-or post-slaughter diagnostic laboratory testing. The first two approaches are screening pig populations for clinical evidence of ASFV using morbidity or mortality, as diagnostic indicators for an 'alarm' that will trigger a confirmatory or follow-up investigation, involving laboratory diagnostic testing of samples. The third, pre- or post-slaughter diagnostic laboratory testing, uses random or risk-based sampling to select animals for diagnostic testing. The characteristics of all three approaches are summarised in Table 10.

Where or when there is an increased ASFV risk in the external environment, an additional surveillance system component could be introduced, for example, through laboratory diagnostic testing of a random sample of pigs in high risk functional units or sub-units of the compartment at regular intervals, where pooled blood or rope oral fluid sampling can be considered [34; 35; 88; 89].

SYNDROMIC SURVEILLANCE

Syndromic surveillance has been defined as the 'systematic analysis of health data, including morbidity and mortality rates, production records and other parameters' that 'can be used to generate signals that may be indicative of changes in the occurrence of infection' [31]. This approach is based on detecting deviations from the normal range and patterns of one or several indicators, preferably in real- or near-real time, to raise alerts for potential disease events in the animal sub-population. It requires a computerised pig health and production information system that allows monitoring of key health and production indices such as mortality, morbidity, treatments, and feed and water consumption [22; 90]. Many of these may be used as indicators of potential ASFV incursion.

The current value of each indicator (or combination of indicators) is benchmarked against historic levels, often taking other available factors into account (e.g. level of concurrent diseases, seasonal variation), in order to assess whether the current indicator is within the expected range (= signal detection algorithm). If not, an 'alarm' is issued to trigger an investigation. The latter may involve sample collection or require the investigator to first consider the situation and determine whether sampling is required. A decision tree should be developed to standardise the response after each 'alarm'. The process needs to be clearly described in standard operating procedures.

A syndromic surveillance component therefore consists of two sequentially conducted activities:

1. **analysis of computerised health and production data** for indicators of ASFV infection with aim to trigger 'alarms', based on a signal detection algorithm;

2. **a subsequent follow-up investigation of each 'alarm',** which is pursued until a definitive diagnosis has been reached, including ASFV infection has been excluded.

Consequently, a certain number of false positives or false 'alarms' is expected from the first activity (data analysis), but the combination of the two activities provides an overall syndromic surveillance component specificity of 100%. As an indication of adequate sensitivity, there should be a consistent pattern of 'alarms' that turn out to be false positives after detailed follow-up investigation most likely through laboratory diagnostic testing of a random or risk-based sample from the animals in the respective functional unit(s) or sub-unit(s). If there are no 'alarms' over time, one would have to check the sensitivity of the signal detection algorithm.

FUNCTIONAL UNIT OR SUB-UNIT BASED OBSERVATIONAL SURVEILLANCE

Functional unit or sub-unit based observational surveillance is a more targeted form of syndromic surveillance, where changes in the observed patterns of mortality and/or morbidity at the functional unit or sub-unit level are used to trigger an 'alarm' that will lead to a follow-up investigation. With this surveillance approach, all animals are actively observed every day as part of daily routine health monitoring by staff working in the respective functional unit or sub-unit. This requires more intensive observation of the pigs by staff working in the respective functional unit or sub-unit of the compartment than as part of normal clinical disease surveillance which should be conducted by all pig farmers.

When the mortality or morbidity thresholds in an epidemiological unit (functional unit or sub-unit, such as a building or pen) are exceeded, an 'alarm' is triggered which will result in a follow-up investigation, based on random or risk-based sampling of animals. The thresholds for the 'alarm' are based on the upper limit of mortality and/or morbidity indicators that are expected in the animal sub-population under surveillance in the absence of ASFV. Analysis of computerised health data as well as dynamic disease modelling (see **Appendix 3**) can provide supporting information for setting the threshold values.

The number of pigs sampled during the follow-up investigation for a given 'alarm' should be defined considering the desired sensitivity, specificity, laboratory testing capacity and costs. Risk-based sampling may be applied in the follow-up investigation, i.e. samples may be collected from an animal sub-population stratum which has the highest probability of being infected with ASFV (e.g. dead and sick animals). Such a sampling strategy avoids the inefficiencies of sampling healthy animals for which the pre-test probability of infection is likely very low. The results of the risk assessment will inform the design of the risk-based sampling (see **Appendix 3**).

PRE- OR POST-SLAUGHTER DIAGNOSTIC LABORATORY TESTING

This approach involves testing animals within the finishing functional unit or sub-unit of the compartment before transport to the slaughterhouse or at the slaughterhouse itself. Animals may be randomly selected ante- or post-mortem (e.g. every 10th animal) or using risk-based approaches (e.g. deliberately selecting animals with particular lesions on post-mortem examination, animals that are dead on arrival or that die in the pre-slaughter pens). Note that this option is unlikely to detect the disease earlier than a clinical or syndromic surveillance system as it would only consider animals in the later phase of production or animals that have already reached the slaughterhouse. However, it could provide surveillance evidence to demonstrate that the outputs (i.e. animals before or after slaughter) of the compartment are ASFV-free.

Table 10 Summary of the characteristics of three examples of surveillance system components for ASFV detection

SURVEILLANCE SYSTEM COMPONENT	SYNDROMIC SURVEILLANCE	FUNCTIONAL UNIT OR SUB-UNIT-BASED OBSERVATIONAL SURVEILLANCE	PRE- OR POST-SLAUGHTER LABORATORY DIAGNOSTIC TESTING
 Population coverage	Depending on the indicators used, this approach can have very high population coverage, such as for example: ▸ Routine observations and mortality reporting by staff provide full population coverage; ▸ Automated water or feed consumption monitoring can provide full coverage if automated meters are installed or when frequent manual readings are recorded.	Very high (essentially 100%) ▸ Every pig in every functional unit or sub-unit is under observation by staff and may be detected as infected assuming that it shows signs of clinical disease that are recognised by staff.	Coverage involves only samples from finisher pigs going to or at slaughter. No population coverage of other groups of pigs (e.g. sows in production).
 Temporal coverage	Depends on the required timeliness of the indicator: ▸ Daily or real-time behavioural, clinical, mortality and water consumption data provide frequent observations; ▸ Other indicators, even though they occur later in the disease progression, may be of value if rapidly available for analysis	Every pig is observed on a daily basis (100%).	Continuous coverage can take place if samples are routinely collected.

 Detection sensitivity	Detection sensitivity depends on: ▸ Availability of relevant indicators; ▸ Appropriateness of 'alarm' threshold chosen for each indicator or combination of indicators; ▸ Consistency of deviation in selected indicators between ASFV-infected and healthy pigs; ▸ Sensitivity of the laboratory diagnostic test(s) involved in the follow-up investigation process. Syndromic analysis can be highly sensitive and able to detect very subtle changes, but it will then also have very low specificity. 'Alarm' thresholds for the syndromic analysis element need to be adjusted to achieve the desired balance between detection sensitivity and specificity.	As the sensitivity of routine observations for evidence of clinical ASF can be high, the overall detection sensitivity of the surveillance system component including follow-up investigation can also be high depending on: ▸ Thresholds values for 'alarms'; ▸ Number of samples collected for each alarm; ▸ Risk ratio of ASFV infection in dead and sick pigs compared to healthy pigs.	Detection sensitivity depends on the sensitivity of the test used (e.g. polymerase chain reaction), which is likely to be very high.
 Surveillance component sensitivity	Can be high if population coverage, temporal coverage and detection sensitivity are high.	Can be high if population coverage, temporal coverage and detection sensitivity are high.	Low given the low population coverage.
 Cost	The cost of syndromic surveillance comprises: ▸ Cost of operating a computerised pig health and production system (syndromic systems can become inexpensive once data streams are in place); ▸ Cost of any follow-up investigations triggered by the alarm system, largely influenced by the false positive or false 'alarm' proportion generated by the syndromic data analyses.	Observation by functional unit or sub-unit staff is very inexpensive. The cost of this option is entirely dependent on the number of 'alarms' and the number of samples collected as part of the follow-up investigation associated with each 'alarm', and comprises: ▸ Cost of sample collection (e.g. by the farmer, barn personnel, animal health technician, veterinarian); ▸ Cost of shipping samples; ▸ Cost of testing samples.	The cost of data collection depends on whether the samples are collected in the finishing unit of the compartment before shipment, in the pre-slaughter area, or post mortem during regulatory inspections. Processing and testing costs are high, given that a large number of samples are required to achieve satisfactory surveillance sensitivity.

APPENDIX 10

Guidance for Preparing an *ASF-Free Compartment Operating Manual*

This Appendix presents a list of elements to consider for inclusion in the compartment operating manual that should be submitted by a private-sector organisation (e.g. pork-producing company) applying for approval of an ASF-free compartment. This content is suggested as guidance and should be tailored to the specific context of the country and to the characteristics of the compartment, particularly the nature of the commodities to be exported and the functional units or sub-units included in the compartment.

The following icons are used to define the type and format of information that is suggested:

- Describe the relevant information in the text
- Provide a table
- Provide a graphic representation
- Provide a bar or line chart
- Provide a map
- Attach the information as supplementary material

GENERAL INFORMATION

The following general information should be provided about the compartment:

- the business name of the organisation managing the compartment
- the full address of the organisation
- the name and position or job title of the compartment manager
- the telephone number, fax and e-mail details of the compartment manager.

DEFINITION OF THE COMPARTMENT

COMPONENTS OF THE COMPARTMENT

- The reader should refer to **Article 4.5.2.** of the *Terrestrial Code*.

Provide a list of the premises constituting the components of the compartment, e.g. establishments (premises in which animals are kept [1; 8] and related functional units or sub-units, with the following information for each premises, as supplementary material:

- premises identifier
- name of premises
- location of premises (provide a map with defined areas, if possible)
- geographic coordinates of premises
- name of the owner of the premises
- name of the manager of the premises
- contact information of the manager of the premises
- type of premises
- occupancy type of premises
- number of barns (where applicable)
- last pig census (where applicable).

Note: *Depending on the production system and the commodities destined for export, related functional units or sub-units can be divided into:*

- functional units or sub-units providing inputs or services to the establishments included in the compartment, e.g.:
  - feed mills
  - warehouses and equipment storage sites
  - vehicle sanitation stations ('wash bays')
- functional units or sub-units processing the animals and animal products from the establishments included in the compartment, e.g.:
  - slaughterhouses
  - secondary meat-processing facilities, including cutting and packing plants.

ANIMAL SUB-POPULATION IN THE COMPARTMENT

Latest swine stocktake by premises

- Provide the total number of pigs in the compartment by production stage at the date on which the compartment operating manual is submitted.
- Provide the total pig capacity for each establishment.
- Provide the total number of animals of other species held on any of the establishments included in the compartment, if applicable.

Disease and vaccination status

→ The reader should refer to **Article 4.5.4.** of the *Terrestrial Code*.

Compartment health status

- Provide evidence of freedom from ASF in accordance with Chapter 15.1. of the *Terrestrial Code*, if applicable.
- To inform the design and evaluation of the internal ASF surveillance components for the compartment, the health status and vaccination status of all production diseases and any other diseases that may be considered as a differential diagnosis for ASF should be indicated.
- For each of the diseases indicated, state whether the disease occurs in the compartment (supported by the baseline animal health report), and whether vaccination is implemented in the compartment.

COMPARTMENT OPERATIONS

Functional relationships

- Describe the relationships between the components within the compartment, and with other premises outside the compartment.
- Describe inputs and outputs, including:
  - → sources and supply of feed
  - → sources of live animals
  - → sources of genetic materials and/or embryos
  - → live animal transport
  - → the downstream supply chain for products obtained from compartment pigs, if applicable.

Regulatory certification

- Describe the existing regulatory certification that applies to the compartment components, such as authorisations for establishments keeping live animals and authorisations for food-producing premises.

Existing industry plans

- Describe the quality assurance programmes for which the compartment components are accredited. These may include on-farm industry programmes related to food safety and biosecurity, live animal transport programmes and slaughter facility programmes.

MANAGEMENT AND RESPONSIBILITY STRUCTURE

- Present the administrative characteristics of the organisation that owns and manages the compartment. This includes any applicable registration identifiers and addresses.
- Demonstrate that the organisation owns or has complete management oversight of and responsibility for all components included in the compartment.
- Describe the responsibility structure of the organisation.
- List the key personnel responsible for management and oversight of the compartment.

BIOSECURITY PLAN

PHYSICAL FEATURES

→ The reader should refer to **Article 4.5.3.** (Point 1) of the *Terrestrial Code*.

Spatial distribution of compartment components

General distribution of compartment components

- Map and describe the location of all compartment components, in relation to country borders and international ports and airports.

Spatial relationships to non-compartment premises

- Map and describe the location of compartment components, in particular of establishments, in relation to non-compartment, swine-production-related premises.

Note: *Non-compartment premises may include known commercial and backyard pig farms, quarantine sites, boar studs, slaughterhouses, rendering plants, assembly sites, markets, fairs, agricultural shows, laboratories and disposal sites where pigs may be present.*

- Present the distribution of distances between compartment components and non-compartment, pig-production-related premises in general. Highlight the minimum of these values.
- Present the distribution of distances between compartment components and backyard pig farms.

Geographic factors

- Describe the geographic and ecological environment which may affect the exposure of the animal sub-population contained in the compartment to ASFV. This includes factors relating to the presence and distribution of wild or feral pigs.

INFRASTRUCTURAL FEATURES

→ The reader should refer to **Article 4.5.3.** (Point 2) of the *Terrestrial Code*.

Establishments

Site level

Description of establishments

Describe the general layout (or layouts if several types occur) of establishments in the compartment:

- → biosecurity-related zones and access points (e.g. vehicle cleaning and disinfection points)
- → barns and office areas
- → access drives and roads, parking areas
- → garbage and dead stock storage and collection
- → feed bins
- → utilities, such as water, fuel and gas
- → manure lagoons
- → incinerators, if appropriate.

Site-level infrastructure features related to biosecurity

List the site-level infrastructure features of the establishments that ensure adequate biosecurity against ASFV. This includes features linked to the management of the movement of people, vehicles and fomites on the premises, as well as those that aid in preventing contamination by wild or feral pigs, other wildlife and pests.

Functional unit and sub unit level

Description of general functional unit or sub-unit features

Describe the functional or sub unit structures and their general features in the compartment.

Functional unit or sub-unit level infrastructure features related to biosecurity

Describe the infrastructure features related to:

- → human access to the functional unit or sub-unit (e.g. Danish entry set-ups, changing rooms and showers), in particular the configuration of the biosecurity-related zones and access points as they relate to the functional unit or sub unit
- → the entry of inputs into the functional unit or sub-unit, such as farm equipment (e.g. dedicated doors, fumigation rooms, sanitation areas)
- → the entry and exit of live and dead animals.

List the functional unit or sub-unit level infrastructure features of the establishments that ensure adequate biosecurity against ASFV (e.g. physical barriers that separate the functional units or sub-units from the outside environment, disinfection pools and footbaths at the entrance and exit of the functional unit or sub-unit).

Describe the general layout and infrastructure features of any associated functional units or sub-units, including features related to:

- → human access to the buildings, in particular the configuration of biosecurity-related zones and access points
- → the entry of inputs (e.g. dedicated doors, fumigation rooms, sanitation areas)
- → the entry of animals, where relevant.

Associated functional units or sub-units

To be completed for all relevant types of related functional units or sub-units.

Description of related functional units or sub-units

Describe the general layout and infrastructure features of the related functional units or sub-units, including features related to:

- human access to the buildings, in particular the configuration of biosecurity-related zones and access points
- the entry of inputs (e.g. dedicated doors, fumigation rooms, sanitation areas)
- the entry of animals, where relevant.

Infrastructure features related to biosecurity

List the infrastructure features of related functional units or sub-units that ensure adequate biosecurity against ASFV. This includes features linked to managing the movement of people, pigs and pig products, vehicles and fomites on the premises, as well as preventing contamination by wild or feral pigs, other wildlife and pests.

Documentation

Provide individual maps as supplementary material:

- a current site map for each **establishment**, displaying the site layout and clearly indicating:
  - ⇢ the boundaries of the different biosecurity zones
  - ⇢ access points
  - ⇢ the location of the garbage and dead stock bins
  - ⇢ vehicle parking areas
  - ⇢ feed bins
  - ⇢ wells and lagoons
  - ⇢ gates
  - ⇢ fences
  - ⇢ the flow of vehicles, equipment and people as it relates to biosecurity.
- a **functional unit or sub-unit** floor plan, clearly identifying
  - ⇢ the different biosecurity zones
  - ⇢ the lines of separation at each access point (e.g. human access, mortality removal area, pig loadout, equipment entry)
  - ⇢ the infrastructure relevant to these accesses (e.g. boot barriers, fumigation room)
  - ⇢ the flow of people and equipment.
- a current site map for each **associated functional unit** or sub-unit displaying the site layout clearly and indicating, where applicable:
  - ⇢ the boundaries of the different biosecurity zones
  - ⇢ the access points
  - ⇢ the location of the garbage bins
  - ⇢ vehicle parking areas
  - ⇢ feed storage
  - ⇢ gates
  - ⇢ fences
  - ⇢ the flow of vehicles, equipment and people as it relates to biosecurity.

FUNCTIONAL MEASURES

→ The reader should refer to **Article 4.5.3.** (Points 3a to 3c) of the *Terrestrial Code*.

Note: *This section may also be divided by type of compartment, depending on the type of production system, the commodities of interest and the outputs of the risk assessment, as mentioned in Section 8.1 of the ASF compartmentalisation guidelines.*

General situation

List and describe the risk mitigation measures for each exposure pathway identified in the risk assessment. Reference the internal SOP document in which each measure is documented.

For each exposure pathway, present the scientific evidence demonstrating that the mitigation measures in place are sufficient to prevent the introduction of ASFV into the compartment via this pathway.

Provide information on the use of disinfectants (e.g. nature, contact times, and dilution) for different purposes.

Provide the relevant internal SOP documents as supplementary materials.

Additional content for specific situations

Nature of the exported commodity

The mitigation measures in place to meet the ASF- and commodity-related recommendations of the Terrestrial Code for importation of pigs or their products from ASF-free compartments should be described here (see recommendations for some commodities below).

→ The reader should refer to **Chapter 15.1.** of the *Terrestrial Code*. [2]

COMMODITY (ARTICLE REFERENCE)	RECOMMENDATION FOR THE ORIGIN OF ANIMALS	ADDITIONAL RECOMMENDATIONS
Live domestic and captive wild pigs (Article 15.1.8.)	The animals should have been kept in a compartment free from ASF since birth or for at least the past three months	▸ The animals should show no clinical signs of ASF on the day of shipment ▸ If the animals are exported from an ASF-free zone or compartment within an infected country or zone, the necessary precautions should have been taken to avoid contact with any source of ASFV until shipment
Semen of domestic and captive wild pigs (Article 15.1.10.)	The donor males should have been kept in a compartment free from ASF since birth or for at least three months prior to collection	▸ The donor males should show no clinical sign of ASF on the day of semen collection ▸ The semen should be collected, processed and stored in accordance with **Chapters 4.6.** and **4.7.** [91; 92]
***In vivo*-derived embryos of domestic pigs (Article 15.1.12.)**	The donor females should be kept in a compartment free from ASF since birth or for at least three months prior to collection	▸ The donor females should show no clinical sign of ASF on the day of embryo collection ▸ The semen used to fertilise the oocytes should comply with the conditions referred to in **Article 15.1.10.** or **Article 15.1.11.**, as relevant [32] ▸ The embryos should be collected, processed and stored in accordance with the relevant provisions of **Chapters 4.8.** and **4.10.**
Fresh meat of domestic and captive wild pigs (Article 15.1.14.)	The entire consignment of fresh meat should come from animals that have been kept in a compartment free from ASF since birth or that have been imported or introduced in accordance with **Article 15.1.8.** or **Article 15.1.9.**	▸ The animals should be slaughtered in an approved slaughterhouse, where they are subjected to ante- and post-mortem inspections in accordance with **Chapter 6.3.**, with favourable results

As an example, for a compartment exporting fresh meat of domestic pigs, the following additional information should be provided.

- Describe the generic and ASF-specific inspection processes at the slaughterhouses, in relation to the relevant regulatory requirements.

  - inspection of pigs at reception
  - ante-mortem and post-mortem inspections (Chapter 6.3. of the *Terrestrial Code*).

  Attach the relevant internal SOP documents as supplementary materials.

Functional units or sub-units not dedicated only to the compartment

It is possible that the slaughterhouses and secondary processing facilities that process compartment pigs are not dedicated only to the compartment, but also receive and process non-compartment pigs. In this situation, the presentation of the functional measures for these premises should also contain the elements described below.

→ The reader should refer to **Article 15.1.14.** of the *Terrestrial Code*.

- Present the measures in place to prevent the cross-contamination of fresh meat derived from compartment pigs with ASFV at the slaughterhouse and processing facilities, in the situation in which both compartment and non-compartment products are received and processed.

  This includes a description of the segregation of processing lines in time and/or space, i.e. the:

  - management of contacts between live pigs in receiving and lairage areas
  - barn, cooler and line sanitation procedures
  - cleaning and disinfection of the different areas and processing equipment types, including operations, chemicals used, contact time, frequency and verification procedures
  - specific segregation procedures for the different processes: slaughter, carcass cooling, carcass breakdown and processing, product processing
  - processes for switching from non-compartment to compartment pig processing and vice versa
  - traceability of pigs and their products.

IMPLEMENTATION AND AUDITING

→ The reader should refer to **Article 4.5.3.** (Points 3d to 3g) of the *Terrestrial Code*.

Implementation of the plan

Biosecurity and workplace culture

Describe how staff compliance with the biosecurity plan on compartment components is developed and promoted. This includes staff engagement and training.

Auditing of compartment components

Internal audits

Describe the audit activities conducted on compartment components by the organisation managing the compartment, e.g. frequency, personnel, procedures, management of non-conformance.

Provide the audit documentation as supplementary material.

External audits

Describe the audit activities conducted on compartment components by third parties, e.g. frequency, the identity of third parties, the qualifications of auditors, procedures, and the management of non-conformance.

Provide the audit documentation as supplementary material.

Maintenance of the biosecurity plan

Describe the procedures for reviewing and updating the compartment biosecurity plan.

INTERNAL SURVEILLANCE

→ The reader should refer to **Article 4.5.3.** (Point 3h); **Article 4.5.5.** (Point 1); **Article 1.4.6.**; and **Articles 15.1.14., 15.1.15., 15.1.29.**, and **15.1.30.** of the *Terrestrial Code*.

SURVEILLANCE SYSTEM

→ Detailed in **Appendix 8** and **Appendix 9** of the *ASF compartmentalisation guidelines*.

Surveillance purposes

Specify the purpose(s) of the internal surveillance system, given the current status of the compartment and of the country where the compartment is located.

Surveillance objective

Explicitly state the surveillance objective(s).

Description of the internal surveillance system

Provide an exhaustive description of the internal surveillance system. This should cover at least the following elements:

- surveillance method(s)
- population(s) under surveillance
- relevant epidemiological unit(s) and their clustering
- timing, duration and frequency of surveillance activities
- case definition(s)
- processes for sample collection, processing and transport
- diagnostic test(s) used and their performance
- data collection and management
- the estimated performance of the surveillance system (quality attributes, e.g. sensitivity and time to detection).

Attach relevant internal SOP documents as supplementary materials.

CONTINGENCY PLANS

→ The reader is referred to **Article 4.5.3.** (Point 3e); **Article 4.5.7.**; **Article 5.1.4.**; and **Article 5.3.7.** of the *Terrestrial Code*.

Note: *The following plans may be specific to different types of compartments, depending on the type of production system and commodities of interest.*

BIOSECURITY CONTINGENCY PLAN

Biosecurity breaches

Describe the management of biosecurity breaches:

- definitions and ranking by level of risk
- a description of the response
- a presentation of roles and responsibilities (establishment manager, compartment manager, other relevant personnel and teams).

Attach internal SOP documents relevant to biosecurity breaches as supplementary materials.

Changes in the risk of exposure of the compartment components to ASF

Describe the management of events that affect the level of risk that compartment components are exposed to:

- definitions
- a description of the response
- a presentation of roles and responsibilities (establishment manager, compartment manager, other relevant personnel and teams).

Attach relevant internal SOP documents as supplementary materials.

EMERGENCY RESPONSE PLAN

Emergency preparedness

Present the general emergency preparedness procedures in the compartment (e.g. protocols, contact lists, simulation exercises).

Emergency responses

Describe the response plan, including:

- a definition of the event
- a description of the response
- a presentation of roles and responsibilities.

Note: *the emergency response plan should cover at least the following emergency situations:*

- the occurrence of a suspected case of ASF within the compartment
- the occurrence of a confirmed case of ASF within the compartment
- the occurrence of an unexpected event threatening the integrity of the compartment (e.g. natural disasters).

Attach relevant internal SOP documents as supplementary materials.

INFORMATION AND DOCUMENTATION MANAGEMENT

→ The reader should refer to **Article 4.5.3.** (Point 3d); **Article 4.5.4.** of the *Terrestrial Code*.

SURVEILLANCE RECORDS

- Describe the tools used for data capture and management, as well as the nature of the information (e.g. data type, frequency, and scale) collected in relation to animal health surveillance:
  - → inventory records
  - → mortality records, including the standard classification of mortality categories used, if applicable
  - → morbidity records, including records of clinical signs in the absence of treatment, and standard classification for clinical signs observed (or syndromes), if applicable
  - → laboratory records, such as records of sample collection, submission and testing
  - → medication and vaccination records.

TRACEABILITY RECORDS

→ The reader should refer to **Article 4.5.3.** (Point 4) of the *Terrestrial Code*. [8]

- Describe the tools used for data capture and management, as well as the nature of information (e.g. data type, level of detail, and time to availability of digital records) collected in relation to animal identification and traceability. All live animal movements should be covered from and to the compartment components, including between the compartment components:
- Provide an overview of the movements of animals:
  - → within the compartment
  - → into the compartment
  - → out of the compartment.

Note: *describe aspects related to regulatory requirements, as well as those related to the internal processes in place for traceability.*

BIOSECURITY RECORDS

Documentation of compartment-specific practices

Describe the storage, management of and access to internal SOP documents.

The internal SOP documents that should be attached as supplementary materials are mentioned above in the relevant sections.

Documentation of biosecurity implementation

Describe the storage, management of and access to records documenting the implementation and supervision of the biosecurity plan on an ongoing basis (as described above in this Appendix). State at what level these records are collected and managed (individual components or the entire compartment) and who is responsible for these activities.

A non-exhaustive list of records documenting the implementation and supervision of the biosecurity plan. This list should be adapted to the specific biosecurity plan.

- site maps
- barn floor plans
- register of live animal entry
- register of boar semen reception
- register of feed component reception
- register of equipment and supplies reception
- feed composition records
- people entry log
- pest control records
- building inspection and maintenance records
- arthropod control records
- water sanitation records
- live-haul vehicle movement and sanitation records
- feed delivery vehicle movement and sanitation records

It is recommended to attach site maps and barn floor plans as supplementary materials. The other records mentioned here should be available for review or auditing purposes on request to the compartment operator.

The other records mentioned here should be available for review or auditing purposes on request to the compartment operator.

APPENDIX 11

Biosecurity management system as part of risk management for an ASF-free compartment

As indicated in these guidelines, the risk management policy of an ASF-free compartment should be able to achieve an acceptable ASFV risk which has been agreed upon by the relevant stakeholders. The risk management policy has three components, a biosecurity management system, a surveillance system and a traceability system. The design of each of these components will be informed by the outcomes of the risk assessment process. The latter will have identified the different risk pathways, including the steps along each pathway which are suitable for cost-effective risk mitigation. The biosecurity management system consists of scientifically optimised risk mitigation measures with the purpose not only of bio-exclusion, but also of bio-containment. It should be remembered that the risk estimate for a compartment's overall risk question "*What is the likelihood of at least one output unit (whole animal or pork product) departing from the compartment being infected or contaminated with viable ASFV per year?*" will not be zero, but it needs to be at or below the agreed acceptable risk level.

The biosecurity management system will consist of generic biosecurity measures that are aimed at a range of infectious disease affecting pig health and production (including ASFV), and additional specific measures that are aimed at preventing ASFV introduction via specific risk pathways.

GENERIC RISK MITIGATION MEASURES

This section complements **Appendix 5** and **Appendix 12** of these guidelines by providing generic ASFV biosecurity recommendations for compartment risk management. Other sources should be consulted for more detailed information [18; 21; 63; 64; 99]. There are also online tools to facilitate such as Biocheck.ugent. This latter tool guides through an evaluation of the generic biosecurity on a pig farm. It can be used to complement but not to replace the approach described in these guidelines, because it was not designed to address a specific risk question. And the latter is essential for satisfying the needs of recipients of outputs from the compartment.

LOCATION OF COMPARTMENT

Physically siting all the elements of the compartment in a reasonably distant location from slaughterhouses, meat-processing plants, pig markets, rendering plants, hunting grounds, dumping areas, highways, local pig farms and wild boar locations reduces the potential for contact between the pig sub-population within the compartment and other pig sub-populations. This needs to be further enhanced by fencing the compartment's perimeter with appropriate specifications for height and depth, e.g. double fencing.

NEW INTRODUCTIONS, REPLACEMENTS AND RE-STOCKING

To minimise an ASF-free compartment's ASFV risk, the introduction of new and replacement live pigs should be adequately managed. Timing, frequency, duration, loading and unloading should all be appropriately managed. Live pig inputs should only be sourced from trusted ASFV-free sources with health certificates. In addition, appropriate cleaning and disinfection protocols should be put in place.

CARCASS DISPOSAL AND WASTE MANAGEMENT

Appropriately managing the risk posed by the disposal of dead pigs from the compartment may include proper cleaning and disinfection mechanisms for vehicles, and established management practices for the collection of dead pigs. Drivers of vehicles that convey dead pigs for disposal should be adequately trained in all relevant protocols. Ensuring a proper sewerage system for slurry management may help to reduce the possible re-introduction of ASFV into the compartment.

SWILL FEEDING

A compartment must avoid catering waste in general, to avoid the risk of feeding ASFV-contaminated food waste. Risks due to swill feeding with catering or kitchen waste or other leftovers may be mitigated by subjecting food waste to the recommended treatment outlined in Article 15.1.22. of the *Terrestrial Code*, under strict supervision. Some compartments may be assisted by existing legislation that bans swill feeding, depending on their location.

OTHER RISK MITIGATION MEASURES INCLUDE:

screening potentially contaminated genetic materials, e.g. ova and semen

surveillance of soft ticks and wild or feral pigs

record-keeping, identification, traceability, etc.

SPECIFIC RISK MITIGATION MEASURES – ENTRY RISK ASSESSMENT FOR INTRODUCTION OF LIVE PIGS

➔ In this section we are using the results from the risk assessment example presented in **Appendix 3** to define risk mitigation measures that can be included in the compartment's biosecurity management system.

For simplicity, we here only consider the entry risk assessment for the introduction of live pigs to the hypothetical compartment. We use the risk pathway diagram presented in Table 7 of Appendix 3 as the basis for identifying areas in need of further risk mitigation measures. The first issue will be whether the overall risk estimate is at or below the acceptable level of risk. Table 8 shows that the overall risk estimate was considered to be negligible with low uncertainty. This suggests that no further risk mitigation measures are required. It would be advised though to consider the potential failure in any of the measures implemented and how that would affect the overall risk estimate for ASFV entry into the compartment. Also, a change in the wider risk context may occur, such as introduction of ASFV into the source population.

The relationship between the steps along the risk pathway and the risk mitigation measures can be shown together with their impact on the risk of ASFV introduction in a tabulated format (see Table 11). This presentation format will benefit transparency and therefore the communication with key stakeholders. In this example, the additional risk mitigation measures did not change the risk estimates because the existing ones were already effective at reducing the overall risk to the acceptable level. But the explicit definition of each risk mitigation action as a policy measure will benefit review, accountability and transparency.

Table 11 Using the ASFV entry risk pathway to design appropriate risk mitigation measures for minimising ASFV risk via the introduction of live pigs into the compartment

STEP ON RISK PATHWAY	POSSIBLE DATA/ INFORMATION NEEDED	RISK ESTIMATE	UNCERTAINTY	JUSTIFICATION	POSSIBLE ADDITIONAL RISK MITIGATION MEASURES	RISK ESTIMATE AFTER ADDITIONAL MITIGATION
Source population of pig herds (country/ zone)	Prevalence of ASFV-infected pig herds in source population (country/ zone); depends on 1. evidence of country's ASFV freedom and 2. surveillance evaluation reports.	Very low	Low	Country has never reported ASF outbreaks and the country's ASF surveillance system has high sensitivity, with good early detection capacity, but there is ASFV infection present in neighbouring countries.	▸ Policy to ensure that new live pig introductions to the compartment are only obtained from ASFV-free countries/ territories/zones with scientifically sound – rapid detection surveillance with sufficient sensitivity, timeliness and representativeness; – up-to-date evidence of ASFV freedom.	No change

Source pig herd	ASFV prevalence in source pig herd, depends on 1. effectiveness of farm's biosecurity system, 2. sensitivity of farm's surveillance system, 3. reliability of pig health and production monitoring system and 4. ASFV risk in the local context.	Very low	Low	The source farm has an effective biosecurity management system in place, and constantly monitors pig production using electronic herd health management. There has never been any evidence of ASFV on the farm or in its neighbourhood or contact network.	▸ Agreement with source farm and responsible veterinary authorities to ensure that source farm of live pigs has scientifically sound — evidence of ASFV freedom; — a rapid detection surveillance programme for ASFV that has sufficient sensitivity, timeliness and representativeness. ▸ Policy to import live pigs only from recognised ASF-free compartments.	No change
Group of pigs for transport	ASFV prevalence among pigs selected for transport while still on source farm; depends effectiveness of biosecurity measures within farm.	Very low	Low	Farm operates an effective biosecurity management system, that reduces the risk of spread of pathogens between different sections of the farm.		No change
Pre-transport quarantine on source farm	Likelihood of at least one ASFV-infected pig testing negative or clinical signs not being detected during pre-transport quarantine checks; depends on 1. diagnostic testing and clinical sign detection sensitivity, 2. effectiveness of pre-transport quarantine biosecurity measures and 3. duration of quarantine period.	Negligible	Low	Pigs are monitored closely during the 15-day quarantine period for any clinical signs, and they are kept in isolation under tight biosecurity measures. The sensitivity of the ASFV PCR test is 99%, which will minimise the risk of false negative results, and all pigs are tested. If any ASFV-infected pigs are present, they should develop clinical signs during the 15-day quarantine period which would be detected by staff.	▸ Agreement with source farm and responsible veterinary authorities to ensure that — pre-transport testing uses a highly sensitive ASFV test. — a sufficiently long pre-transport quarantine period is in place, e.g. at least for 15 days.	No change
Transport	Likelihood of all ASFV-infected pigs not showing clinical signs or dying; depends on 1. duration of transport and 2. clinical sign detection sensitivity.	Low	Medium	Pigs transported for 6 hours and transport staff monitor the pigs closely, at loading, during transport and when off loading. But the period is too short for a recently infected pig to develop clinical signs.	▸ Policy to incentivise transport to report suspect pigs. ▸ Policy to only compartment transport staff and vehicles.	No change
Pre-compartment entry quarantine	Likelihood of at least one ASFV-infected pig testing negative or clinical signs not being detected during pre-compartment entry quarantine; depends on 1. diagnostic testing and clinical sign detection sensitivity, 2. effectiveness of pre-transport quarantine biosecurity measures and 3. duration of quarantine period.	Negligible	Low	Pigs are monitored closely during the 15-day quarantine period for any clinical signs, and they are kept in isolation under tight biosecurity measures. All pigs are tested and the sensitivity of the ASFV PCR test is 99%, which will minimise the risk of false negative results. If any ASFV-infected pigs are present, they should develop clinical signs during the 15 day quarantine period which would be detected by staff.	▸ Policy to ensure that a sufficiently long pre-compartment entry quarantine period is — in place, e.g. at least for 15 days. — consistently applied. ▸ Policy to ensure that new pigs in pre-compartment entry quarantine are tested with a highly sensitive ASFV test.	No change

APPENDIX 12

Examples of outcome-based criteria of an ASF-free compartment

While the content of the guidelines is not prescriptive, this Appendix outlines more specific recommendations that focus on the criteria and specifications to be met by an ASF-free compartment, in view of the concept of outcome-based biosecurity. In line with Articles 4.5.2. and 4.5.3. of the *Terrestrial Code*, this section provides examples from various available published sources on the physical, spatial and infrastructural factors that contribute towards the biosecurity status of the compartment and, by extension, the epidemiological separation of the constituents of the compartment. As indicated in the Articles mentioned above, these must be clearly defined in detail for every compartment.

These recommendations are based on a combination of peer-reviewed and grey literature and policy documents from the FAO and OIE, and they adhere to biosecurity management best practices. But managers and other stakeholders involved in the compartmentalisation process should still consult additional sources and expert advice on the biosecurity practices, most appropriate for the particular circumstances of their compartment [18; 21; 64; 100].

There are also online tools such as Biocheck.ugent which guides through an evaluation of the generic biosecurity on a pig farm. It can be used to complement but not to replace the approach described in these guidelines, because it was not designed to address a specific risk question. And the latter is essential for satisfying the needs of recipients of outputs from the compartment.

Please note that this Appendix serves only as a series of examples for outcome-based criteria and should not be considered the best practice.

STRUCTURAL AND PHYSICAL REQUIREMENTS

➜ The infrastructure of the compartment and management and biosecurity practices in place must ensure separation of the compartment premises from the surrounding environment.

PREMISES LOCATION

➜ The location of an ASF-free compartment should be sufficiently far from wild or feral pig habitats or waste disposal areas that may attract wild and domestic free-ranging pigs. Hills, mountains and rivers may play a role in limiting the risk of infection transmission [101].

➜ The location preferably must not have any pig farm within 3 km of the compartment [25]. If this is not possible, the compartment must account for the farms within this radius in its risk assessment and mitigation measures.

➜ The location should not be within 1 km of a sludge, garbage dump or landfill site, livestock, a major road or a slaughter facility or rendering plant [25].

➜ The location of the compartment should take into account proximity to vegetation that may serve as potential breeding sites for ticks, e.g. marshy and shrubby areas. If ticks are found near such vegetation types, measures to ensure the total mitigation of any ASFV risks must be implemented by the compartment [101].

PREMISES LAYOUT

➜ An ASF-free compartment must establish clearly demarcated 'clean' and 'dirty' areas for both personnel and visitors in all components. This should apply to changing and shower rooms and to all areas within the perimeter of the compartment [101].

➜ The ASF-free compartment must be surrounded by a robust fence and have a closed entrance to control access by personnel, visitors and vehicles [25]. Components of compartments in different locations should have their own fences, with appropriate cleaning and disinfection facilities.

➜ Entry to an ASF-free compartment or functional unit or sub-unit should be controlled by the biosecurity fence. The main entrance should be equipped with locked secure gates, a buzzer and a two-way communication system for visitors and personnel to indicate their arrival [25].

➜ Parking areas should be situated outside the perimeter fence away from bio-secure areas, and must be designed to take into account cross-contamination risks between visiting and farm vehicles [4].

➜ There must be clear signs at the gate or parking area to provide information on authorised entry through a central sign-in area [25; 101].

➜ The components of an ASF-free compartment must preferably have only one entrance road and a centralised sign-in office, close to the perimeter and the entrance but sufficiently far from bio-secure areas [25].

➜ The layout of an ASF-free compartment should be such that offices, feed storage and isolation units are located closer to the entrance and sufficiently far from the main herd-holding pens [25; 101].

➜ The design of an ASF-free compartment or its satellite components must preferably allow vehicle deliveries without having the vehicles to enter the premises. If this is not possible, loading and unloading areas should be placed at least 20 m away from bio-secure areas within the perimeter of the premises [101].

➜ Vehicles for the collection of dead animals must not enter the establishments.

- Pig holdings on compartment premises should be designed in such a way that boar pens or mating areas are farthest from the entrance, followed by dry sow pens, farrowing pens, weaning pens, grower–finisher pens and, finally, market-aged pig holdings, and separated by reasonable distances and/or partitions [102].

- Every production unit on compartment premises must be considered bio-secure and must have footbaths at its entrance [101].

- Entries into bio-secure areas must be equipped with changing and hygiene facilities, including showers. Physical barriers consisting of a series of rooms must lead through a shower facility before access to the bio-secure zone [25].

BUILDINGS

- All buildings within the perimeter of an ASF-free compartment or one of its functional units or sub-units must be made of robust, moisture-proof construction materials capable of being washed down and disinfected [36].

- All components within the perimeter of an ASF-free compartment must be linked by enclosed passageways, if possible. If not, separate hygiene provisions must be made at each building entrance [25].

- All entrances, exits and walking areas between premises within the perimeter of the compartment must be fitted with concrete aprons [25].

- Sewerage and ventilation openings of buildings within the perimeter of an ASF-free compartment must be adequately protected by structures designed to prevent the entry of rodents and pests [25].

- Vehicles and machinery completely owned and controlled by an ASF-free compartment may be kept within the perimeter of the compartment. Vehicles belonging to visitors, employees and consultants must be kept outside [25].

- There must be a designated washing facility within the perimeter of the compartment or its components for washing all vehicles and heavy-duty machinery used. This facility should be enclosed, heated and well lit, with a concrete surface [25].

- Equipment for cleaning and disinfecting vehicles and machinery must be flexible to access hidden areas of the vehicle/machinery and able to deliver adequate water pressure to remove mud as well as deliver disinfectants [25].

- To avoid feed spillage, a system of well-maintained hoppers and augurs must be installed on the ASF-free compartment premises for feed storage and distribution [25]. The operators of the compartment should conduct a comprehensive risk assessment, taking such factors into account, as indicated above [36].

- Management protocols must contain standing instructions to staff that no gate/doors entering the compartment should be left open and/or unattended [36].

- Management protocols must contain standing protocols discouraging the accumulation of attractants to wild or feral pigs, or other vectors, within the compartment, e.g. spilled feed and exposed carcasses [36].

INPUT CONTROL

FEED

- Swill feeding should be banned in the compartment, with corresponding procedures and protocols in place [103].
- The feed for the compartment should be acquired from clean sources, free of ASFV, and transported in clean trucks. It should be ensured that all diets are properly formulated to meet all macro- and micro-nutrient needs of the pigs to avoid any detrimental health effects [22].
- Feed suppliers should have established HACCP programmes to ensure product quality with clear specifications for the production process. Feed suppliers with International Standard Organization certification, such as ISO 9000, indicating verified high standards in production practices, are preferable [22; 36].
- The compartment operator should request feed suppliers to provide relevant information on the procedures/tests (e.g. protocols and frequency of testing) implemented to prove that source ingredients are not contaminated [22].
- The compartment operator may institute a mechanism to collect feed samples for periodic testing for any potential contamination [22].
- Protocols should be available on how to store the feed at the compartment in proper conditions, where it is protected from possible contamination [36].
- Any feed spill should be removed, following established procedures [53].

PIGS

- New pigs should be acquired from ASF-free sources and transported in clean trucks. The cargo compartment of the vehicle should be disinfected before loading the animals. The pigs should arrive on the farm in a dedicated shipment, meaning that all the animals on the vehicles are for that farm. Procedures should be in place to verify and ensure ASF-free sources and transportation [22; 36].
- A system must be developed to record and trace the source and movements of all the pigs introduced into the compartment [36].
- Pigs sourced from outside the compartment should be isolated and quarantined before being introduced into the compartment. The quarantine facilities should have appropriate physical separation from other areas of the compartment and be thoroughly cleaned and disinfected before the pigs are introduced into them. The completion of quarantine and acceptance of the pigs should be clearly defined and documented. It is recommended that they be quarantined for at least 30 full days [22; 32; 36].
- Laboratory tests should be carried out during the quarantine period to demonstrate that the new pigs are free from ASF. It is recommended that virological and serological tests be performed at least 21 days after the pigs enter quarantine, with negative results [32; 36].
- Staff working in the quarantine facility should not have direct contact with pigs or personnel in any other areas of the compartment for the whole quarantine period, and they should also have separate coveralls, boots and other equipment, that cannot be used in any other areas of the compartment [22; 36].

BEDDING MATERIALS

- The type of bedding materials should be specified, with clear specifications for the production process, and should be acquired from clean sources, free of ASFV, and transported in clean trucks [22; 36].
- The compartment operator should request bedding material suppliers to provide relevant information on the procedures/tests (e.g. protocols and frequency of testing) implemented to prove that the source ingredients are not contaminated [22].
- The compartment operator should have a mechanism to collect samples of bedding material for periodic testing for any potential contamination [22].
- Protocols should be available for the storage and testing of bedding materials in proper conditions in the compartment, where it is protected from possible contamination [36].

WATER

- Surface water should not be used for any purpose. Treated or municipal water should be used [53].
- Water chlorination should be used for drinking purposes, with routine testing to monitor the effectiveness of chlorination, which can be achieved by using swimming-pool kits [22].
- Individual nipple waterers are preferable to cup waterers to prevent disease spread [22].

MISCELLANEOUS INPUTS

- Other miscellaneous inputs should be acquired from clean sources, free of ASFV, and transported in clean trucks and the type of product should be specified, with clear specifications for the production process [22; 36].
- The compartment operator should request the suppliers of miscellaneous inputs to provide relevant information on the procedures/tests (e.g. protocols and frequency of testing) implemented to prove that the source of the inputs is not contaminated [22].
- The compartment operator should have a mechanism to collect relevant samples for periodic testing for any potential contamination [22].
- Protocols should be available on how to store miscellaneous inputs in proper conditions in the compartment, where they are protected from possible contamination [36].

INTERNAL BIOSECURITY

PIG HEALTH MANAGEMENT

The principles of biosecurity should be applied to pig disease and production management in an on-farm food safety programme for:

- consumer confidence in the quality and safety of the food supply
- productivity of healthy animals
- animal welfare
- efficiency and profitability for the pork producer.

Biosecurity is made up of three sets of actions and overlapping components, namely: bio-exclusion, bio-containment and bio-management. The objectives of the compartment will determine how these three elements blend into a biosecurity plan [25].

The HACCP approach should be used in strategies for biosecurity planning. Identifying the critical control points should be based on knowledge from scientific field-trial methodology, peer-reviewed publications and experience in the field. At the early stages of hazard analysis, extensive interviews and inputs from all staff should be included to minimise the possibility of critical control points being overlooked [25].

ALL-IN/ALL-OUT APPROACH

- If the production system allows, pigs in the compartment should be moved as a single group at the same age and at the same time (i.e. same batch) in an all-in/all-out manner during each phase of production (e.g. weaning, nursery, grower and finisher). When a specific batch is formed, young pigs should never be mixed with older pigs and vice versa.
- Thorough cleaning and disinfection of the pen or barn is required between each batch of pigs. A high-pressure jet of hot water and detergent is recommended for this purpose. If possible, the facility should be left completely dry and vacant for 2–3 days before introducing the next batch of pigs. The possibility of aerosolised ASFV from high-pressure water should considered [18; 25].

COLOUR-CODED EQUIPMENT

- Different batches of pigs should be distinguished from one another by designating specific areas with different colours. For example, the pig-farrowing area should have a specific coloured brush and shovel (e.g. red). This method makes breaches of SOPs immediately obvious [26].
- Wearing different-coloured boots in each area reduces the risk of pathogen transfer by reducing faecal transmission. Human error can easily be spotted with this method, when someone is wearing the wrong colour in the wrong area [26].

CLEANING AND DISINFECTION

➜ Preliminary cleaning should always be carried out before the use of any disinfectants. Mechanical brushing with a detergent solution should be used to clean contaminated surfaces and objects for effective disinfection [104].

➜ Freshly prepared disinfectant solutions should be used and sufficient contact time should be allowed for disinfection to be effective, according to the manufacturer's instructions [104].

➜ There must be an established cleaning and disinfection protocol for all premises, vehicles and equipment [25].

➜ Routine cleaning and disinfection of animal pens should follow the procedures given below.

1. Remove bulk manure, litter and adherent dirt and dust from the floor and wall of the establishment and dismantle the equipment.

2. Soak and pre-wash pens and equipment with a suitable detergent. A high-pressure water jet is recommended for cleaning confinement pig barns. The use of hot water can speed up the cleaning process. The cleaning process must remove all visible dirt and faeces. Sufficient time should be allowed for drying after cleaning.

3. Apply an appropriate disinfectant for ASFV, as listed below, to the floor and wall of the establishment, and equipment. Allow sufficient contact time for the disinfectant to be effective, according to the type of disinfectant used, followed by drying. Disinfectants that are effective in the presence of organic matter are preferable.

4. Leave the pens vacant for 2 to 3 days, if possible [18].

➜ Written instructions on how to use the appropriate disinfectant for specific areas, equipment and/or facilities should be in place. Recommended disinfectants for AFSV are listed below [36; 104]:

- ⇢ chlorine (sodium hypochlorite)
- ⇢ iodine (potassium tetraglicine triiodide)
- ⇢ quaternary ammonium compound (didecyldimethylammonium chloride)
- ⇢ vapour-phase hydrogen peroxide (VPHP)
- ⇢ aldehydes (formaldehyde)
- ⇢ organic acids
- ⇢ oxidising acids (peracetic acid)
- ⇢ alkalis (calcium hydroxide and sodium hydroxide)
- ⇢ ether and chloroform.

VECTOR CONTROL

➜ Ticks of *Ornithodoros* spp. can serve as a vector for ASF and are therefore a biosecurity risk for the compartment operator. Integrated pest management should be implemented to eliminate ticks in the compartment [22].

➜ Ensure that all susceptible pigs are in clean paddocks, free of scrub and long grass, to reduce the risk of exposure to ticks [105].

➜ Conduct daily inspections to closely monitor the pigs, especially during tick season (mostly summer), for any tick infestations [105].

➜ If ticks are present in the compartment, collect samples of the ticks for ASF surveillance, in accordance with *Terrestrial Code* Chapter 1.5. and Chapter 15.1.33. [32].

STAFF

- All staff should strictly follow the SOPs and understand the concept of biosecurity in regard to ASFV [25].
- Regular training and discussions with the staff are necessary. For effective implementation of the SOPs, it is recommended to have regular staff meetings throughout the year, with all employees in attendance [25].
- A periodic self-evaluation of biosecurity integrity must be conducted [25].
- Critical control points should be highlighted during induction training for staff [36].
- Staff attitudes should be taken into consideration to ensure the effective implementation of biosecurity plans. A demonstration of pro-active activities to ensure the staff's optimal adherence to the established biosecurity plan is necessary [24].
- Training programmes for staff should be in place, to ensure that all staff have a clear understanding of the following [25]:
  - the purpose of SOPs for biosecurity
  - the risks associated with coming into contact with pigs outside work
  - the links between biosecurity enhancement and animal performance, disease minimisation, reduced deaths, reduced economic losses, reduced medication costs, and improvements in quality assurance for the pork chain
  - that there is no negotiation on biosecurity rules
  - that there is zero tolerance of neglect or ignorance of biosecurity rules
  - that the monitoring system is present to determine whether staff are strictly following the biosecurity procedures
  - that a regular audit will be conducted to monitor the practical implementation of the biosecurity procedures
  - that there is a method to detect signs of tampering with or unauthorised access to the pig production area and farm
  - the reporting mechanism and system for any concerns, suspicious activities and/or unusual signs of disease or unexplained death
  - methods for recognising signs of disease in the herd
  - food rules should clearly prohibit staff from eating in any area where pigs can accidentally get access to human food [22; 25].

PERSONNEL ENTRY AND MOVEMENT

- Authorised personnel may enter the compartment after completing the sanitisation procedures, such as showering and a complete change of clothes and boots [22; 53].
- Authorised personnel should follow the protocols and procedures and meet all biosecurity requirements for employment or contractual agreement before entry into the compartment [53].
- A visitor log should be present to keep track of people traffic on the site [53]. No visitor should have contact with other pigs or pig products outside the compartment within 24 hours of their entry to the compartment and all visitors should follow the established protocols and procedures of the compartment for entry, as well as the policy for personal items and food [36].
- There should be a procedure to identify staff members working in different areas of the compartment, and to identify corresponding areas in the compartment that they can or cannot access [36].
- Staff instructions should be present for using the foot bath, hand wash or hand sanitisation facilities to prevent disease introduction or infection, with the type, concentration and renewal requirements of the disinfectants/sterilising agents being specified [36].

REUSABLE EQUIPMENT

- The items of equipment concerned and the location and details of the corresponding cleaning and disinfection procedures should be specified [36].
- The place and method for storing the equipment after disinfection and before use should be specified to prevent contamination [36].

TRANSPORT

LOADING BAY

- The designation and location of the loading bay should be carefully considered to ensure that any vehicles loading or unloading pigs or other materials are kept on the dirty side of the unit [22].
- Materials used for the loading bay must be easy to clean and disinfect. Staff cleaning the load-out facilities should do this at the end of the day so that personnel do not need to re-enter the building on the same day [22].
- Employees designated to work in pig transport should not come into contact with other farm staff or pig holdings within the compartment [3]

VEHICLES

- Vehicles should only be for the compartment.
- It is recommended that vehicles be specifically designated for different jobs [22].
- Delivery trucks are preferable to unload the goods without entering the pig site [25].
- Vehicles used for pig transport, as well as other vehicles, must be cleaned and disinfected before and after each use. Returning delivery trucks that unload pigs must be cleaned and disinfected on the premises before leaving [25].
- The location of the vehicle disinfection facility should be specified. If vehicles are required to enter the production area, procedures for decontamination/disinfection of tyres, mud flaps and wheel arches in the designated area, as well as the cargo compartment, should be in place [36].
- Recommended procedures for cleaning and disinfecting transport vehicles:

1. Completely remove bedding and large debris before entering the wash area.

2. Use detergents to reduce washing time by loosening debris. Apply detergents on low pressure and by soaking the entire trailer at once and allow some time to loosen debris. However, do not allow the soap to dry or it will be harder to rinse.

3. Start rinsing and cleaning the trailer from the top down, as well as the trailer cab.

4. Rinse and clean each deck from front to back and ceiling down, starting with the top deck. All trailer areas and equipment should be fully cleaned, including unloading ramps, sorting boards, paddles and boots, after every load.

5. After the trailer has been rinsed inside and out, apply the disinfectant at the appropriate dilution rate with sufficient contact time. Start on the inside of the trailer and finish on the outside. Disinfectant should be applied at low pressure.

6. Clean the inside of the cab, including washing and disinfecting the floor mats.

7. After disinfection, park the truck on a slope so that all the remaining water can drain out. Allow enough time for the trailer to fully dry [22].

➜ The type and concentration of the disinfectants used for vehicle disinfection should be specified [22; 36]. Protocols defining and controlling the areas which the driver can access should be in place [36].

➜ The driver should follow the procedure for contacting the compartment manager upon arrival and should not come into direct or indirect contact with the pigs [25; 36].

➜ If it is necessary for the delivery drivers to enter the compartment, all biosecurity procedures must be followed before and after entering the premises [25].

➜ Appropriate records must be kept, including decontamination/disinfection carried out on site and comprehensive vehicle visit records, showing the date and time, vehicle license, driver name, etc. [36].

➜ Vehicles used to transport animal carcasses or biological wastes should not be used to transport live pigs or pig products until appropriately cleaned and disinfected [53; 106].

OUTPUT CONTROL

ON THE FARM

➜ Frequent pig inventories should be taken. A recording system should be in place and the movement of pigs should be recorded, including the number of pig-holding units involved, the number of pigs involved and the date of delivery [25; 107].

➜ Pigs should be accurately identified for production records as well as traceability along the supply chain. Permanent marking is necessary and the identification marks should be easy and painless to apply, legible at a distance, and tamperproof. The methods commonly used include ear marking by notching, tattooing, tagging or body marking (e.g. slap marking) [18].

➜ Before delivery of the pigs to the slaughterhouse, all pigs should be labelled with appropriate tattoo numbers on each ham which identifies the origin to the slaughterhouse. Tattoos should be appropriately placed and should be clearly readable on the carcass hanging on the slaughter line after dehairing [107].

AT THE SLAUGHTERING FACILITY

- Slaughterhouses need to ensure appropriate segregation (e.g. time or spatial separation) for processing pigs from a compartment and pigs from outside a compartment at all times.
- Slaughterhouses should receive pigs directly from the supplying compartment. The transportation of pigs for slaughter should be coordinated by the slaughterhouse with an agreement with each individual carrier for transportation. The carrier should hold information on the place of departure, destination and the owner of the animals during transportation [107].
- Pigs from the same holding should be held in assigned numbered pens to avoid mixing animals from different pig holdings. Pre-slaughter inspections should be conducted and the pigs should be declared healthy [107].
- After post-mortem veterinary inspection, an official stamp should be applied on the principal parts of the carcass, with an appropriate authorisation number for certification [107].
- After slaughter, a standard bulletin should be issued to provide the compartment manager with information for each pig on the identification number, carcass weight, lean meat percentage and the results of veterinary inspection [107].
- Measures to prevent cross-contamination with ASFV should be in place, such as limiting the duration between unloading animals and slaughtering, and strict segregation of pork products during post-slaughter processing [27].

MEAT PROCESSING

- Traceability of the origin compartment should be maintained by appropriate measures such as systemic labelling, rational encoding and appropriate computer usage [107].
- Groups or batches of sorted products should be established, with the slaughter numbers of the carcasses of origin in the batch being recorded [107].
- The identity of the compartment that supplied the batch of meat should always remain visible, either on the skin or on the wrapping, depending on the stage of meat processing [107].

WASTE MANAGEMENT

- All biological or edible animal waste should be kept in closed containers until incineration or until it has left the site to ensure that it cannot attract wild pigs or other pests [36].
- Procedures and protocols for the disposal of dead animals in accordance with OIE *Terrestrial Code* Chapter 4.13. should be in place [2].
- Daily mortality and biological waste should be disposed of in accordance with the biosecurity plan and in compliance with local environmental regulations [53].
- A protocol for the storage of dead pigs and other biological waste pending removal for post-mortem examination, incineration or disposal should be in place [36].
- Procedures and protocols for decontaminating manure should be in place. Examples of recommended protocols are:
  - 40–60 litres of a 40% lime hydrate solution per m^3 of liquid manure at –10 to 0°C
  - 16–30 litres of 50% sodium hydroxide solution per m^3 of liquid manure at 0 to 10°C.
- The manure should be stirred before, during and for 6 hours after chemical disinfection. The manure should be exposed to the chemicals for at least 4 days and preferably 1 week [22].

PART 3:

Compartmentalisation in practice

Member experiences

APPENDIX 13

Country experiences with compartmentalisation

Questionnaires related to compartmentalisation experiences were distributed to selected Members. The responses of some Members are summarised below for reference:

COUNTRY	CANADA	BRAZIL	SOUTH AFRICA	THAILAND	UNITED KINGDOM (UK)	CHILE
BACKGROUND INFORMATION ON THE COMPARTMENT(S)						
Target commodity	Salmonid germplasm	Poultry genetic materials	Pigs and pork	Poultry and poultry products	Poultry genetics	Pork
Target diseases	Specific for each salmonid species, such as infectious salmon anaemia (ISA), viral haemorrhagic septicaemia (VHS), infectious haematopoietic necrosis (IHV), infectious pancreatic necrosis (IPN), and salmon alphavirus (SAV)	Newcastle disease (ND) and avian influenza (AI)	African swine fever (ASF), classical swine fever (CSF), porcine reproductive and respiratory syndrome (PRRS) and foot and mouth disease (FMD)	Avian influenza (AI)	Newcastle disease (ND) and AI	Foot and mouth disease (FMD), classical swine fever (CSF), African swine fever (ASF), and Aujeszky's disease (pseudorabies).
INITIATIVE AND BENEFITS OF SETTING UP A COMPARTMENT						
Origin of initiative for compartmentalisation	Private sector	Both public and private sectors				
Motivation for setting up the compartment	Unable to access export markets due to the presence of regulated diseases, even though biosecurity measures were in place to prevent incursion of these diseases	Continuity of safe trade of the poultry production chain, which is essential to maintain functions in the event of a health crisis	To enable farmers in the area of the country to which ASF is traditionally endemic to access domestic markets for pigs and pork. In case of an outbreak in the rest of the country, to continue international trade, in particular regional trade, from compartments	In response to adverse effects on the poultry industry due to AI outbreaks, resulting in the shutdown of fresh poultry meat exports	To maintain the strategic trade to supply breeding stock to trading partners without interruption, in case of potential isolated notifiable AI or ND outbreaks	To maintain a high standard of animal health management and ensure continuity of production and export against the entry of any exotic disease into the country

COUNTRY	CANADA	BRAZIL	SOUTH AFRICA	THAILAND	UNITED KINGDOM (UK)	CHILE
NATIONAL COMPARTMENTALISATION PROGRAMME/REGULATORY FRAMEWORK OF THE IMPLEMENTING COUNTRY						
Initiation of the process	In consultation with the industry, Canada established a specific Compartmentalisation Programme for International Trade under the oversight of the Competent Authority and based on Chapters 4.1. and 4.2. of the OIE *Terrestrial Code*	The regulatory basis for recognising compartments was established with a series of technical meetings involving primarily the poultry industry and its main representative, i.e. the Brazilian Poultry Union	Prior consultation with industry is necessary for urgent and voluntary implementation for the export trade. The requirements for a compartment for trade purposes are outlined in a Veterinary Procedural Notice (VPN) that is prescribed by the Director of Animal Health, as empowered by the legislation	The Department of Livestock Development (DLD) of Thailand issued a proclamation on the implementation of compartmentalisation in commercial poultry farming. Any poultry companies wishing to establish the AI-free compartment signed a memorandum of understanding (MOU) with the DLD. The DLD set up a committee to develop the requirements to establish and implement an AI-free compartment, using the *OIE guidelines* as references	Following inclusion of the concept of compartmentalisation into the *Terrestrial Code*, the European Union published Regulation No 616/2009, which provided the legal basis for all EU Member States to implement compartmentalisation	The compartment company hired a specialised company to develop the compartment. The specialised company developed a proposal with the compartment company, based on the OIE standards. In parallel, the Official Veterinary Service (OVS) prepared a general regulation covering the development, implementation and verification of compartments. As this was the first compartment, the OIE was invited to verify that the compartment had been implemented in accordance with the relevant standards.
Development process for the regulatory framework	No specific legislative changes were required for the Compartmentalisation Programme, whose requirements were developed by the Canadian Food Inspection Agency (CFIA), based on OIE standards, in consultation with the private sector	The process of developing specific legislation for the establishment of compartments in Brazil has received support from the OIE. A technical document was subsequently developed, forming the basis for the existing legislation	The development of VPNs was initiated by the government to define the scope of considering risk pathways and mitigation measures, followed by internal veterinary interrogation to assess the practicality. Consultation was carried out with the private sector on the draft VPN; all inputs had to be accompanied by a scientific rationale and/or equivalent practical alternatives	Details are available in the 'Principles for establishment of notifiable avian influenza (NAI) free compartmentalisation for poultry farms' (TAS 9038-2013)	After the implementation of the EU Regulation, a public–private working group was set up to develop the UK standards, building on the OIE Terrestrial Code and the EU regulation as guidance. Two different sets of requirements were established for compartment approval – the EU standard and the GB enhanced standard.	The OVS developed an ad hoc regulation, with the relevant OIE chapters as a reference: Resolution 8309 of 2012. Based on this regulation, the internal procedures for documentary and field evaluation were established, and guidelines for auditing were developed

COUNTRY	CANADA	BRAZIL	SOUTH AFRICA	THAILAND	UNITED KINGDOM (UK)	CHILE
PUBLIC–PRIVATE PARTNERSHIP (PPP)						
How was the PPP and engagement of the industry fostered?	Efforts were made to ensure that the timing of engagement was compatible with the private-sector workload. For example, private- sector consultation was scheduled with time zones, the spawning season, etc. in mind	The government remains open to the private sector taking part in the development of 'rules' related to compartmentalisation. A working group was set up for specific cases, with representatives from both the public and private sectors and also companies interested in developing standards-based instruction and implementation of compartments	Since the compartment initiative was mainly driven by private-sector demand to farm in the disease-endemic area, it was relatively easy to extend this to the rest of the country, following the CSF and PRRS outbreaks. Over all, the development of compartments has strengthened cooperation between the commercial industry and the government, as compartments are mutually beneficial	Industry representatives were included in the relevant committee to develop the requirements for the establishment and implementation of an NAI-free compartment	Regular dialogue is maintained between the public and private sectors to achieve success for the compartmentalisation scheme Dialogue and joint work are continuing as new trading partners accept compartmentalisation and the scheme is reviewed with the aim of continuous improvement	The OVS has supported the process of eradicating exotic diseases, maintaining sanitary status and opening up the pig sector to trade. The country and company had the markets opened up for compartment products. Though the development of the compartment was an initiative of the pig company, the OVS considered it to be part of its animal health and commercial strategy, along with zoning
IN-COUNTRY APPROVAL AND CONTINUED ASSURANCE OF COMPARTMENTS BY THE COMPETENT AUTHORITY						
Supervision and audit of the compartment	The CFIA conducts an epidemiological assessment to establish inspection and surveillance frequencies for a disease-free compartment and maintenance of this status. A specialised inspector is assigned to each compartment. Standardised inspection forms and other types of documentation are used to capture compartment information and to achieve national consistency in the implementation of the standards and inspections procedures	Audits are conducted at least annually and carried out in accordance with specifically developed checklists in an audit script. Audit teams are made up of career professionals from the federal and state public service, selected through public tenders and specialising in inspection and auditing in the field of animal health or plant health	A private veterinarian specialising in pigs is designated to each establishment for regular health monitoring and assistance with biosecurity implementation, record-keeping and surveillance. All these measures are under the supervision of the local State Veterinarian, who must regularly inspect the establishment and submit relevant information to the Central Competent Authority (CCA)	Certification is valid for 3 years. During this period, the DLD audit team audits the compartment at least once a year to ensure its compliance with compartment criteria. Specific checklists for each type of compartment are developed and used by the DLD audit team. Any non-conformity found during the audits must be corrected within the designated time or result in certification being suspended or withdrawn	The Animal and Plant Health Agency (the executive agency of the Department of Environment, Food and Rural Affairs) carries out regular audits and approvals using standard operating procedures and checklists	The compartment company has an internal audit system, as part of its management of the compartment. The OVS audit was initially carried out with specialists at the national and regional levels, followed by regular annual audits
Challenges faced	Canada's health status for salmonid diseases is different across the country, so surveillance testing must be specific to the location of the compartment within Canada	The number of applications to register compartments may exceed the capacity of the direct services that can be provided by the Competent Authority	There are shortages of State Veterinarians and some State Veterinarians have limited expertise on pig health	Sometimes a poultry farming component is contracted out (contract farming) from a certified compartment of one company to another company	There must be consistency among the audits conducted	There are challenges in the training of personnel and the availability of regulations related to compartmentalisation standards

COUNTRY	CANADA	BRAZIL	SOUTH AFRICA	THAILAND	UNITED KINGDOM (UK)	CHILE
Response actions taken	▸ A standardised approach to developing surveillance plans ▸ Records of Decision are available, outlining the surveillance and inspection frequencies for each compartment ▸ Relevant information is reflected in the recognition letter issued for the compartment's records ▸ The disease status of all compartments is published on the CFIA website to maintain transparency	Use certification by a third-party entity as a prerequisite for in-country recognition of the compartment and its maintenance	Provide alternative State Veterinarians or authorise private veterinarians for the purpose Provide on-the-ground, hands-on assistance from industry-assigned specialist pig veterinarians	Exempt the compartment from a fixed period of surveillance and apply continued surveillance in such a case DLD audits the biosecurity management system and traceability system of the farm of concern before certifying a new compartment, since the compartment manager and company have both changed	There is a constant need for training to be provided to staff involved in compartment approvals and audits to ensure that audits are carried out on a consistent basis. This is a time-consuming task that must be repeatedly addressed by the government, which continues to seek ways to improve this aspect of the scheme	General regulation has been established on guiding principles, based on the OIE guidelines for the development, implementation and verification of a compartment Staff training has been provided on the development of compartments

APPENDIX 14

Achieving recognition of compartments by trading partners

SUMMARY OF MEMBER EXPERIENCES

Questionnaires on compartmentalisation experiences were distributed to selected Members. The responses of some Members in regard to their experience of gaining recognition of compartments by their trading partners are summarised below as reference:

COUNTRY	CANADA	SOUTH AFRICA	UNITED KINGDOM (UK)
TARGET COMMODITIES	**SALMONID GERMPLASM**	**PIGS AND PORK**	**POULTRY GENETICS**
Initiation of the recognition process	Compartment operators initiated the process by making a request to export markets. The Canadian Food Inspection Agency (CFIA) negotiated the recognition of compartments as an alternative to consignment-based testing for export Attestations such as 'Country, zone or compartment is recognised as free of diseases of concern to which the species is considered susceptible' are proposed	Communication with trading partners is the responsibility of the Veterinary Authority. Once the compartment system was established, negotiations were initiated. Much effort has been put into providing assurances for the compartment, including the Veterinary Procedures Notice (VPN) process, which specifies the requirements of a compartment for trading purposes	The recognition of poultry compartments is always part of a bilateral trade negotiation. It can be proposed by either the UK Government or the government of the receiving country as an addition to regionalisation, to provide an additional 'last resort' option for continuous trade in this strategically important commodity
Main concerns of trading partners and actions to address these concerns	Main concerns of trading partners ▸ Supervision of the compartment by the national Veterinary Authority ▸ Procedures for approval and maintenance of health status of the recognised compartment Actions to address the concerns ▸ Providing the national policy, procedure and national standards for review ▸ On-site audits of compartments and audits of the compartmentalisation programme may be accommodated ▸ Some countries may request the inclusion of non-OIE-listed diseases. In response, CFIA makes adjustments to biosecurity and surveillance to include those diseases	Main concerns of trading partners ▸ Assurance that the biosecurity measures are 'fit for purpose' and that the product brings little risk of disease to the domestic population of importing countries ▸ Potential contamination by products originating from non-compartment systems Actions to address the concerns ▸ Provide scientific support with the utmost transparency, and evidence based on the best, most up-to-date scientific knowledge	Main concerns of trading partners ▸ Continuous evidence of the absence of disease ▸ Compliance of the compartment system with relevant standards and any assurances provided to that effect Actions to address the concerns ▸ Trading partners welcome intensive disease testing to ensure continuous evidence of the absence of disease ▸ Trading partners also require a high level of audit standard by the central Veterinary Authority to underpin the system

COUNTRY	CANADA	SOUTH AFRICA	UNITED KINGDOM (UK)
How to draw up an agreement with trading partners and the important points to be included in the agreement	Country-specific zoosanitary certificates are agreed upon with each trade partner. The important points included in the certificate are: ▸ Exports originate from a country which meets basic OIE biosecurity conditions ▸ All recognised compartments are under an overarching national aquatic animal health programme ▸ All tests are completed in an approved laboratory	Once agreements are reached, they become part of the health attestation. Lists of compartments are available on the website of the Veterinary Authority and regularly updated so that trade partners have easy and quick access to the most up-to-date list.	▸ 'Agreement', for most countries, means that the compartment option is included in the mutually agreed export health certificate ▸ Some countries prefer to agree 'protocols' that include the use of the scheme ▸ Stand-alone formal 'agreement' documents are rare – international agreements can pose legal challenges for some countries
Factors essential for a successful compartment agreement and recognition by trading partners	▸ Veterinary Authority oversight of the legislation for establishing basic biosecurity conditions to cover all aquatic species and diseases ▸ A well-documented and transparent compartmentalisation programme ▸ Transparency maintained with trading partners	▸ Trust and transparency ▸ Proper documentation, which is fully auditable, from the compartment level to the Veterinary Authority level	▸ Freedom from disease through high biosecurity ▸ High testing standards (accreditation of laboratories) ▸ Independent (governmental) audits
How to maintain transparency of information between trading partners?	▸ Provision of all documentation relevant to the compartmentalisation programme, as requested by the trading partners	▸ Sharing Veterinary Procedural Notices with trading partners ▸ Any potential changes would be shared with trading partners before coming into effect as a form of external consultation	▸ In-country visits and audits are always offered and often used to understand the scheme, both from the operational and the audit perspective ▸ This is especially important as compartmentalisation is implemented in different ways in different countries to adapt to local risks and assurance needs
Challenges faced	▸ Access to company-specific information under Canadian laws had to be respected and corresponding agreements are needed to enable the sharing of such specific information ▸ Not all trading partners are willing to negotiate on compartmentalisation	▸ Many trading partners protect their national herd health status so stringently that any perceived threat, whether genuine or not, may take negotiations back to the starting point	▸ The implementation of the scheme is resource intensive to provide the lowest possible disease risk in the face of an outbreak
Response actions taken	▸ Attempts are made to continue negotiations based on the OIE standards which allow for compartments. The success of such negotiations is subject to acceptance of the compartments by the trading partner in question	▸ Provide scientific justification for the measures implemented in compartmentalisation, based on the best, most up-to-date scientific knowledge	▸ The scheme is exclusive to a limited sector to allow for strategically important trade to ensure food security

APPENDIX 15 – CASE STUDY

New Zealand's recognition of UK compartmentalisation

For avian influenza and Newcastle disease to support imports of poultry genetics

In June 2014, New Zealand (NZ) provided the legal formality for an agreement recognising the United Kingdom (UK) compartmentalisation scheme for the poultry industry in relation to avian influenza and Newcastle disease. The mechanism underpinning this legal agreement was an exchange of letters between OIE Delegates in the respective countries, with the UK providing comprehensive information on how the UK compartmentalisation scheme operates, including the biosecurity plan framework within which each approved premises must work, and the roles and responsibilities of agencies with respect to compliance oversight and supervision. New Zealand reserves the right to audit the UK programme or any facility at any time, but this has not been exercised to date.

The conditions that supported this agreement include the following:

1. Legislation (the Biosecurity Act 1993) that supports risk- and science-based import health standards developed through good regulatory practices, including specific reference to relevant international agreements, such as the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).

2. Commodity import health standards that are kept up to date in ongoing review cycles, and which incorporate, by reference, the OIE Terrestrial Code and Manual, and draw from them in specifying requirements. This meant that, where supported by the international standards of the OIE, requirements were already framed in the context of imports from countries, zones or compartments free of risk organisms such as high pathogenicity avian influenza (HPAI) and Newcastle disease. Additional requirements, developed with the support of risk analysis and open consultation, such as post-arrival quarantine periods, achieve the level of protection expected by stakeholders.

3. The poultry industry in NZ is well organised, with an industry association (Poultry Industry Association of NZ) that has broad membership, technical capacity and an active engagement with government. The industry's dependence on imports of genetic stock was clearly understood, as was the need for strong biosecurity protections during imports. New Zealand has developed a culture of open engagement between government, industry and other stakeholders during import standard-setting processes. Many challenging situations arise, and there is robust debate. The government retains decision-making authority, but the views of industry and other stakeholders are carefully considered.

4. New Zealand and the UK have a strong history of veterinary technical cooperation in relation to trade and emergency response. The competence of the respective Veterinary Authorities has been recognised in bilateral trading agreements covering a wide range of animals and animal products. Further, mutual participation in the International Animal Health Emergency Reserve Agreement (IAHER), along

with Australia, Canada, the USA and Ireland, has resulted in shared exchanges and participation in contingency planning, simulation exercises and actual emergency responses over many years. This provided the technical understanding that underpins trust and confidence in the systems, processes and capability that must exist as a foundation for such agreements. The relationship supports the open communications that are required for successful ongoing implementation.

Relevant resource

- NZ Ministry for Primary Industry website
- Import health standard for poultry hatching eggs
- Guidance document, which references the UK-NZ compartmentalisation agreement in section 5.5, on page 4-5

End matter

Abbreviations

ASF	African swine fever
ASFV	African swine fever virus
CMP	Compliance monitoring programme
FAO	Food and Agriculture Organization of the United Nations
HACCP	Hazard analysis and critical control points
OIE	World Organisation for Animal Health
PPP	Public–private partnership
PVS	Performance of Veterinary Services
SOPs	Standard operating procedures
Terrestrial Code	*OIE Terrestrial Animal Health Code*
Terrestrial Manual	*OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*
WAHIS	OIE World Animal Health Information System
WTO	World Trade Organization

Definitions

Biosecurity
set of management and physical measures designed to reduce the risk of introduction, establishment and spread of animal diseases, infections or infestations to, from and within an animal population.

Biosecurity plan
a plan that identifies potential pathways for the introduction and spread of an infectious disease in a zone or compartment, and describes the measures which are being or will be applied to mitigate the disease risks, if applicable, in accordance with the recommendations in the *Terrestrial Code*.

Case
an individual animal infected by a pathogenic agent, with or without clinical signs.

Commodity
live animals, products of animal origin, animal genetic material, biological products and pathological material.

Compartment
animal sub-population contained in one or more establishments, separated from other susceptible populations by a common biosecurity management system, and with a specific animal health status with respect to one or more infections or infestations for which the necessary surveillance, biosecurity and control measures have been applied for the purposes of international trade or disease prevention and control in a country or zone [2]. A compartment consists of physical entities which are connected by movements of pigs, feed, water, commodities, vehicles, people, etc.

Compartment operator
designated person responsible for the animal sub-populations of a compartment.

Competent Authority
Veterinary Authority or other Governmental Authority of a Member Country having the responsibility and competence for ensuring or supervising the implementation of animal health and welfare measures, international veterinary certification and other standards and recommendations in the *Terrestrial Code* and in the OIE *Aquatic Animal Health Code* in the whole territory.

Establishment
premises in which animals are kept.

Exporting country
country from which commodities are sent to another country.

Functional separation
management of the animal sub-population in the compartment based on standard operating procedures that aim to mitigate the risk of exposure to suids that are not of equivalent health status. The determination of the most adequate procedures to ensure an appropriate functional separation should be based on an assessment of the prevailing disease risks.

Functional unit
component of a compartment that is used to keep live animals, such as sheds or barns, to provide inputs or services to the production process, to process the animal products from the establishment, e.g. feed mills, slaughterhouses, and processing plants, etc.

Hazard analysis and critical control points (HACCP)
a system that identifies, evaluates and controls hazards that are significant for food safety.

Importing country
a country that is the final destination to which commodities are sent.

International trade
importation, exportation and transit of commodities.

Pork commodity supply chain
integration of all activities involved in the process of producing and distributing pig commodities to the end consumer.

Pork commodity value chain
full range of activities that are required to bring a product or service from conception, through the different phases of production, to delivery to the final customer, and final disposal after use.

Production
raising and breeding of domestic pigs for meat.

Qualification period
duration of a candidate ASF-free compartment located in a non-ASF-free country or zone being under veterinary supervision, which should be long enough in any case to provide sufficient confidence that the compartment is free of ASFV. The duration of the qualification period should be a direct function of the ASF epidemiological situation in the country and the quality of ASF surveillance carried out on suids.

Risk assessment
evaluation of the likelihood and the biological and economic consequences of entry, establishment and spread of a hazard.

Risk management
process of identifying, selecting and implementing measures that can be applied to reduce the level of risk.

Slaughterhouse
premises, including facilities for moving or lairaging animals, used for the killing of animals to produce animal products and approved by the Veterinary Services or other Competent Authority.

Sub-population
distinct part of a population identifiable in accordance with specific common animal health characteristics.

Sub-unit
part of a functional unit of a compartment, such as for example a shed, barn or pen within a shed where animals are being kept.

Surveillance
systematic ongoing collection, collation and analysis of information related to animal health and the timely dissemination of information so that action can be taken.

Veterinary Authority
Governmental Authority of a Member, comprising veterinarians, other professionals and para-professionals, having the responsibility and competence for ensuring or supervising the implementation of animal health and welfare measures, international veterinary certification and other standards and recommendations in the *Terrestrial Code* in the whole territory.

Veterinary legislation
laws, regulations and all associated legal instruments that pertain to the veterinary domain.

Veterinary para-professional
person who is authorised by the Veterinary Statutory Body to carry out certain designated tasks (dependent upon the category of veterinary para-professional) in a territory, delegated to him or her under the responsibility and direction of a veterinarian. The tasks for each category of veterinary para-professional should be defined by the Veterinary Statutory Body depending on qualifications and training, and in accordance with need.

Zone
part of a country defined by the Veterinary Authority, containing an animal population or sub-population with a specific animal health status with respect to an infection or infestation for the purposes of international trade or disease prevention or control.

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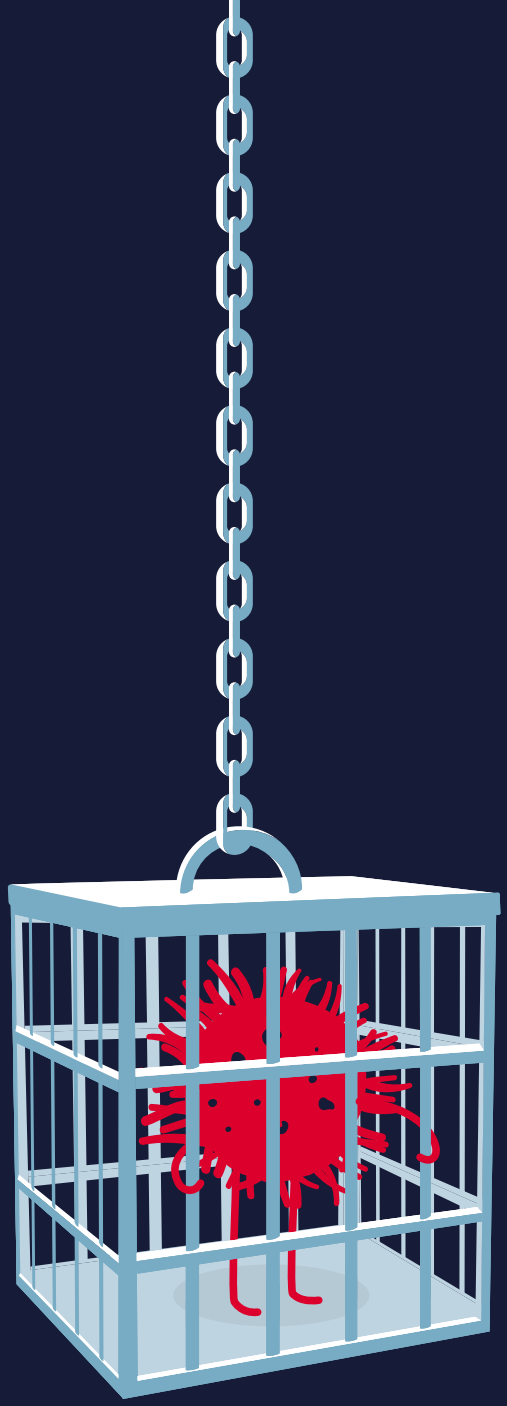

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