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ECONOMIC EVALUATION OF BIOSECURITY MEASURES AND SURVEILLANCE IN PIG FARMS

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Preface

Earlier in life, I never would have imagined pursuing a PhD, especially in veterinary economics field. With a background in economic and management, it certainly would not have been my first choice for the next step in my career after the graduation.

Before the years as a PhD student, I had a year of scholarship that provided me with the opportunity to immerse myself in the veterinary sector, completely unfamiliar to me at the time.

What I have come to realize is that the veterinary field is vast and can be approached from many different perspectives, including economics.

It is funny to look back from where I stand now, and it is fascinating to reflect on how much I have learned and experienced throughout this PhD project.

Over the years, I have had the privilege of meeting many remarkable individuals and working alongside experts in the field as part of the Italian research team. This has been made possible through the support of international projects and networks, particularly those linked to the Department of Agricultural and Food Science at the University of Bologna. In particular, I would like to extend my sincere gratitude to all those involved in the European BIOSECURE project, the COST Action BETTER, the ROADMAP project, the Experimental Zooprophylactic Institute of Lombardy and Emilia Romagna (IZSLER), and the CoEvalAMR network for their invaluable contributions.

I hope that with this thesis I will be able to give the reader a good insight into what I have been working on for the last three years. I also hope to demonstrate to those who have supported and guided me that this project has yielded some meaningful and valuable outcomes. I believe that this work will contribute to important future studies, discussions, and decisions within the realm of Italian swine production, productivity, and the economic impacts of biosecurity measures, particularly through the support of the ClassyFarm surveillance system..

Foremost, I would like to express my deepest gratitude to my supervisor, Dr. Massimo Canali for his exceptional guidance and unwavering support throughout the entire process of completing this study. His expertise and encouragement have been invaluable.

I also extend my sincere thanks to Prof. Maurizio Aragrande, whose consistent support, insightful suggestions, and encouragement have been instrumental in shaping my research and fostering my professional development.

I am equally grateful to the other members of my research team: Costanza Romanelli, Giulio Paolo Agnusdei and Zahra Ardakani. The personal and professional relationships I have built with them have enriched my experience and made the research process all the more rewarding.

Sometimes, I feel as though we are just at the beginning of a process, as the topics we explore and the challenges we address evolve and transform with every new step in the project. This continuous progression provides an ongoing source of motivation for further research.

Summary

According to the World Health Organization (WHO), antimicrobial resistance (AMR) represents one of the greatest threats to public health, due to the epidemiological and economic consequences. The overuse and misuse of antibiotics can lead to the growing difficulty of treating infections. Current estimates suggest that around 700,000 people worldwide die each year from infections caused by antimicrobial-resistant pathogens. Alarmingly, this number is projected to rise to 10 million by 2050 if no significant action is taken. A large portion of global antibiotic consumption is driven by the demand for animal proteins in industrial livestock production, where antibiotics are used not only to prevent infections and treat diseases but also as growth promoters. This is especially important in the pig sector. By 2030, global antimicrobial use across human, terrestrial animal, and aquatic animal sectors for food production is projected to reach 236,757 tons annually. Of this, human use is expected to account for 48,608 tons, while terrestrial animals used for food production will consume 174,549 tons, and aquatic animals will contribute 13,600 tons. These figures represent 20.5%, 73.7%, and 5.7% of global antimicrobial consumption, respectively. In 2018, 4,264 tons of antibiotics were used in humans and 6,358 tons in animals for food production across 29 EU/EEA countries. Italy ranks among the European countries with the highest levels of veterinary antimicrobial use (AMU) and antimicrobial resistance (AMR). The Italian ClassyFarm surveillance system was designed to provide technical support for farmers in addressing these issues. Data from ClassyFarm checklists indicate that pig farming is the sector most impacted by these challenges. High standards of animal welfare and biosecurity are recognized as essential to improve animal health and significantly reduce antibiotic use in livestock farming while maintaining optimal productivity. Biosecurity refers to a set of practices designed to minimize the risk of infectious diseases entering or spreading within farms. It focuses on preventing infections, improving overall animal health, and minimizing the risk of disease transmission, and effectiveness, when applied correctly, has been repeatedly demonstrated. It involves both management strategies and the physical infrastructure of the farm. Despite the implementation of EU Regulation 2019/6, which enforces strict guidelines on the use of antibiotics and other veterinary medicines in livestock – including a ban on the preventive use of antibiotics, restrictions on critically important antibiotics, and a requirement for veterinary prescriptions – many pig farmers continue to be reluctant or hesitant to adopt these measures, even in the face of the well-documented, scientifically proven benefits of biosecurity practices for both animal health and farm profitability. Significant barriers to the adoption of biosecurity practices are primarily linked to the economic and financial costs of implementing these measures and upgrading farm infrastructure, such as fencing, disinfection stations, quarantine systems, equipment to control vehicle access, entry points, which may not yield immediate returns to farmers.

Therefore, the main goal of this thesis is to generate new insights into the economic impact of biosecurity measures, with a particular focus on the costs associated with their implementation in Italian pig farming. Additionally, the thesis assesses ClassyFarm components that could be further improved to optimize the integrated nature of the system concerning AMU and AMR, considered as indirect indicators of the effectiveness of biosecurity measures implemented in farms.

To achieve the objectives of this thesis, five research questions have been developed:

RQ1. Is economic sustainability of biosecurity measures an emerging topic in pig farming research?

RQ2. How does economic sustainability affect biosecurity at farm level?

RQ3. What are the potential economic impacts of biosecurity according to a One Health perspective?

RQ4. How can we categorize and evaluate the costs of biosecurity implementation in pig farming?

RQ5. How can we evaluate the different aspects of the ClassyFarm surveillance system with respect to AMU/AMR from a biosecurity perspective?

Both qualitative and quantitative methods were employed in the research. A Systematic Literature Review was conducted to address the first two research questions, supported by bibliometric analysis, network analysis, and content analysis. This review provided in-depth insights into the economic aspects of biosecurity in research, identified trends, gaps, and potential areas for future study. The articles were selected following the PRISMA guidelines. A systems thinking approach within conceptual framework analysis, the theory of change, and cause-effect analysis, was used to assess the potential impacts of biosecurity measures from a One Health perspective, answering the third research question. This approach considered the broader context in which systems, sectors, and the food supply chain are interrelated. The systems thinking framework was also applied to address the fifth research question, focusing on the role of the ClassyFarm surveillance system from a cross-sectoral perspective. For the third and fifth research questions, a semi-structured interview method was employed. For RQ3 a questionnaire was administered to 13 Italian experts in the pig sector (veterinarians, farmers, and animal scientists) to identify the costs associated with the biosecurity measures outlined in the Biocheck.UGent™ checklist. For RQ5, 16 participants were selected and ClassyFarm was further evaluated using: the FAO PMP-AMR tool, the Network for Evaluation of One Health tool, and OH-EpiCap tool.

The key findings derived from addressing the five research questions are as follows:

RQ1. Identification of trends, research gaps, emerging areas of focus, and on ongoing debates within the academic community. It offers a comprehensive understanding of multidisciplinary research efforts on the economic sustainability of biosecurity measures.

RQ2. Identification of research gaps related to the economic costs of implementing biosecurity in pig farming.

RQ3. Establishment of an overview of the economic impact of biosecurity, correlations between various levels and areas of the farm, system, sector, and food-supply-chain, as well as between different stakeholders affected by the adoption of biosecurity measures.

RQ4. Definition of cost categories associated with internal biosecurity and creation of a list of variable and fixed costs involved in its implementation.

RQ5. Evaluation of the ClassyFarm components that could be further improved to optimize the integrated nature of the system concerning AMU and AMR, considered as indirect indicators of the effectiveness of biosecurity measures implemented in farms.

Riassunto

Secondo l'Organizzazione Mondiale della Sanità (OMS), la resistenza antimicrobica (AMR) rappresenta una delle maggiori minacce per la salute pubblica, a causa delle conseguenze epidemiologiche ed economiche. L'uso eccessivo e scorretto degli antibiotici può portare alla crescente difficoltà nel trattamento delle infezioni. Le stime attuali suggeriscono che circa 700.000 persone nel mondo muoiono ogni anno per infezioni causate da patogeni resistenti agli antimicrobici. In modo allarmante, si prevede che questo numero salga a 10 milioni entro il 2050 se non verranno adottate azioni significative. Una grande parte del consumo globale di antibiotici è guidata dalla domanda di proteine animali nella produzione industriale di carne, dove gli antibiotici vengono utilizzati non solo per prevenire infezioni e trattare malattie, ma anche come promotori della crescita. Questo è particolarmente rilevante nel settore suinicolo. Entro il 2030, si prevede che l'uso globale di antimicrobici nei settori umano, animale terrestre e animale acquatico per la produzione alimentare raggiunga 236.757 tonnellate all'anno. Di queste, si prevede che l'uso umano rappresenti 48.608 tonnellate, mentre gli animali terrestri utilizzati per la produzione alimentare consumeranno 174.549 tonnellate e gli animali acquatici contribuiranno con 13.600 tonnellate. Queste cifre rappresentano rispettivamente il 20,5%, il 73,7% e il 5,7% del consumo globale di antimicrobici. Nel 2018, sono stati utilizzati 4.264 tonnellate di antibiotici per gli esseri umani e 6.358 tonnellate per gli animali destinati alla produzione alimentare in 29 paesi dell'UE/EEA. L'Italia è tra i paesi europei con i livelli più elevati di uso antimicrobico veterinario (AMU) e resistenza antimicrobica (AMR). Il sistema di sorveglianza ClassyFarm in Italia è stato progettato per fornire supporto tecnico agli allevatori nell'affrontare queste problematiche. I dati dalle liste di controllo di ClassyFarm indicano che l'allevamento suinicolo è il settore più colpito da queste sfide. Alti standard di benessere animale e biosicurezza sono riconosciuti come essenziali per migliorare la salute degli animali e ridurre significativamente l'uso di antibiotici nell'allevamento, mantenendo al contempo la produttività ottimale. La biosicurezza si riferisce a un insieme di pratiche progettate per ridurre al minimo il rischio di malattie infettive che entrano o si diffondono all'interno delle fattorie. Si concentra sulla prevenzione delle infezioni, sul miglioramento della salute animale generale e sulla minimizzazione del rischio di trasmissione della malattia, con un'efficacia che, se applicata correttamente, è stata ripetutamente dimostrata. Includendo sia strategie di gestione che l'infrastruttura fisica della fattoria. Nonostante l'attuazione del Regolamento UE 2019/6, che impone linee guida rigorose sull'uso di antibiotici e altri medicinali veterinari negli animali da allevamento – compreso il divieto sull'uso preventivo di antibiotici, restrizioni sugli antibiotici di importanza critica e la richiesta di prescrizioni veterinarie – molti allevatori di suini continuano a essere riluttanti o esitanti nell'adottare queste misure, anche di fronte ai ben documentati e scientificamente provati benefici delle pratiche di biosicurezza per la salute animale e la redditività delle aziende agricole. I principali ostacoli all'adozione delle pratiche di biosicurezza sono legati principalmente ai costi economici e finanziari necessari per implementare queste misure e aggiornare le infrastrutture aziendali, come recinzioni, stazioni di disinfezione, sistemi di quarantena, attrezzature per il controllo degli accessi ai veicoli, punti di ingresso, che potrebbero non produrre ritorni immediati per gli allevatori.

Pertanto, l'obiettivo principale di questa tesi è generare nuove conoscenze sull'impatto economico delle misure di biosicurezza, con un focus particolare sui costi associati alla loro implementazione nell'allevamento suinicolo italiano. Inoltre, la tesi valuta i componenti di ClassyFarm che potrebbero essere ulteriormente migliorati per ottimizzare la natura integrata del sistema in relazione all'AMU e all'AMR, considerati come indicatori indiretti dell'efficacia delle misure di biosicurezza implementate negli allevamenti. Per raggiungere gli obiettivi della tesi, sono state sviluppate cinque domande di ricerca:

RQ1. La sostenibilità economica delle misure di biosicurezza è un tema emergente nella ricerca sull'allevamento suinicolo?

RQ2. In che modo la sostenibilità economica influisce sulla biosicurezza a livello aziendale?

RQ3. Quali sono i potenziali impatti economici delle misure di biosicurezza secondo una prospettiva One Health?

RQ4. Come possiamo categorizzare e valutare i costi di implementazione della biosicurezza nell'allevamento suinicolo?

RQ5. Come possiamo valutare i diversi aspetti del sistema di sorveglianza ClassyFarm rispetto all'AMU/AMR da una prospettiva di biosicurezza?

Nella ricerca sono stati utilizzati metodi sia qualitativi che quantitativi. È stata condotta una Revisione Sistematica della Letteratura per affrontare le prime due domande di ricerca, supportata da un'analisi bibliometrica, analisi di rete e analisi dei contenuti. Questa revisione ha fornito approfondimenti sugli aspetti economici della biosicurezza nella ricerca, identificando tendenze, lacune e potenziali aree di studio future. Gli articoli sono stati selezionati seguendo le linee guida PRISMA. Un approccio di pensiero sistemico nell'analisi del quadro concettuale, la teoria del cambiamento e l'analisi causa-effetto sono stati utilizzati per valutare i potenziali impatti delle misure di biosicurezza da una prospettiva One Health, rispondendo alla terza domanda di ricerca. Questo approccio ha preso in considerazione il contesto più ampio in cui i sistemi, i settori e la catena di approvvigionamento alimentare sono interconnessi. Il quadro di pensiero sistemico è stato applicato anche per affrontare la quinta domanda di ricerca, concentrandosi sul ruolo del sistema di sorveglianza ClassyFarm da una prospettiva intersettoriale. Per la terza e quinta domanda di ricerca, è stato utilizzato un metodo di intervista semi-strutturata. Per la RQ3 è stato somministrato un questionario a 13 esperti italiani nel settore suinicolo (veterinari, allevatori e scienziati degli animali) per identificare i costi associati alle misure di biosicurezza delineate nella checklist Biocheck.UGent™. Per la RQ5, sono stati selezionati 16 partecipanti e ClassyFarm è stato ulteriormente valutato utilizzando: lo strumento FAO PMP-AMR, lo strumento Network for Evaluation of One Health e lo strumento OH-EpiCap.

I principali risultati derivanti dall'affrontare le cinque domande di ricerca sono i seguenti:

RQ1. Identificazione delle tendenze, delle lacune di ricerca, delle aree emergenti di interesse e dei dibattiti in corso all'interno della comunità accademica. Offre una comprensione completa degli sforzi di ricerca multidisciplinari sulla sostenibilità economica delle misure di biosicurezza.

RQ2. Identificazione delle lacune di ricerca relative ai costi economici dell'implementazione delle misure di biosicurezza nell'allevamento suinicolo.

RQ3. Stesura di una panoramica sull'impatto economico della biosicurezza, le correlazioni tra i vari livelli e aree dell'impresa, del sistema, del settore e della catena di approvvigionamento alimentare, così come tra i vari soggetti coinvolti nell'adozione delle misure di biosicurezza.

RQ4. Definizione delle categorie di costi associati alla biosicurezza interna e creazione di un elenco dei costi fissi e variabili coinvolti nella sua implementazione.

RQ5. Valutazione dei componenti di ClassyFarm che potrebbero essere ulteriormente migliorati per ottimizzare la natura integrata del sistema riguardo all'AMU e all'AMR, considerati come indicatori indiretti dell'efficacia delle misure di biosicurezza implementate negli allevamenti.

Abbreviations

AM – Antibiotics

AW – Animal Welfare

AMU – Antimicrobial Use

AMR – Antimicrobial Resistance

ASF – African Swine Fever

ASL – Public veterinary services

AI/AO – All In-All Out

B – Benefit

BS – Biosecurity

BDN – National Database of Livestock Registry

BSM – Biosecurity Measure

BETTER – Biosecurity Enhanced Through Training Evaluation and Raising Awareness

C – Cost

CAP – Common Agricultural Policy

CSF – Classical Swine Fever

CoEvalAMR – Convergence in Evaluation frameworks for integrated surveillance of AMU and AMR

DDDAit – Defined daily dose nimal for Italy

E-risk – Epidemic risk

EU – European Union

ECDC – European Disease Prevention and Control

ESBL – Escherichia coli-positive farms

FAO – Food and Agriculture Organization of the United Nations

FMD – Foot and Mouth Disease

FSC or FSCh – Food Supply Chain

FAIR – Findability, Accessibility, Interoperability and Reusability

FAO PMP-AMR – Food and Agriculture Organization of the United Nations Progressive Management Pathway for AMR

HE – Horizon Europe

HPCIAs – Highest priority critically important antimicrobials

HORECA – Hotellerie-restaurant-café

IF – Impact Factor

ISMEA – Agricultural and Food Market Services Institute

ISTAT – Statistical National Institute

IZSLER – Experimental Zoo-prophylactic Institute of Lombardy and Emilia Romagna

K – Costs

KPI – Key Performance Indicators

MA – Meta-Analysis

MCP – Multiple Country Publications

MCDM – Multi-Criteria Decision Models

MRSA – Methicillin-Resistant Staphylococcus Aureus

NEOH – Network for Evaluation of One Health

OH – One Health

OECD – Organization for Economic Cooperation and Development

OH-EpiCap – One Health epidemiological surveillance capacities and capabilities

PAN – National Action Plan

PED – Porcine Epidemic Diarrhea

PPE – Personal Protective Equipment

PEDV – Porcine Epidemic Diarrhea Virus

PMWS – Post-weaning Multi-systemic Wasting Syndrome

PRDC – Porcine Respiratory Disease Complex

PRRS – Porcine Reproductive Respiratory Syndrome

PNCAR – National Plan to Combat Antimicrobial Resistance

PRRSV – Porcine Reproductive Respiratory Syndrome Virus

PCV2SI – Porcine Circovirus type 2 Subclinical Infection

PRISMA – Preferred Reporting Items for Systematic reviews and Meta-Analyses

PMP-AMR – Progressive Management Pathway for Antimicrobial Resistence

Q – Quantity

RQ – research question

REV – Veterinary prescription required

ROADMAP – Rethinking of Antimicrobial Decision-systems in the Management of Animal Production

SCP – Single Country Publication

SOP – Standard Operating Procedures

UGent – University of Ghent

VetInfo – National Veterinary Information System

WHO – World Health Organization

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1. Introduction

This section begins by outlining the motivation and background for undertaking the research, followed by a clarification of the study's scope. It also highlights the international projects and networks involved in the development of this thesis. Next, the initial hypotheses, research objectives, and key research questions are presented. Finally, for readers who may be interested in specific aspects of the work, a brief overview of the content and structure of each section is provided to guide navigation through the study.

1.1. Research motivation

After the successes of vaccines and antibiotics in the field of animal health in the 1960s, experts thought that infectious diseases would gradually disappear. On the contrary, the last decades have been characterized by a resurgence of infectious diseases, both zoonotic and human pathogens originating from animals (Renault *et al.*, 2021).

The causes of infectious disease spread have been multiple and interconnected: globalization, population growth, new production systems, new technologies, as well as the shift from small family-run farms to a large-scale pig farming industry, together with increased movement of people, animals, and goods.

This resurgence has been particularly evident in industrial pig farming, where the emergence of new infectious diseases has had devastating consequences across various sectors, including animal health, public health, the economy, and environmental sustainability. Infectious diseases could cause high rates of mortality and morbidity among pigs, leading to the culling of animals to prevent the spread of infection, resulting in significant economic losses for farmers.

This shift highlights the need for more preventive approaches to animal health, as the emergence of diseases can drastically reduce pig production, increase management costs, and lower profits. Additionally, if the disease spreads within a country, pig exports could be delayed or banned, causing substantial economic damage. Infectious diseases also have the potential to contaminate the food supply chain, creating further risks to food safety.

Some zoonotic pathogens, such as African Swine Fever (ASF), can even adapt to infect humans and be transmitted to them, creating potential outbreak scenarios, and posing a serious public health risk. The spread of infectious diseases would represent an additional risk to both veterinary and human health, primarily due to the widespread and often uncontrolled use of antibiotics in industrial farming, particularly for disease treatment or prevention.

According to the World Health Organization (WHO), antimicrobial resistance[1] (AMR) represents one of the greatest threats to public health due to the epidemiological and economic impact of the phenomenon, as the

[1] is the ability of a microorganism to resist the action of an antibiotic.

abuse or misuse of antibiotics used to treat animals contributes to the development of antibiotic-resistant bacterial strains.

Due to antimicrobial resistance, antimicrobials lose their effectiveness, and many infections are becoming increasingly difficult or impossible to treat in both human and veterinary medicine (WHO, 2015).

The emergence and spread of resistant bacteria on farms, both commensal and zoonotic, represents a risk factor for public health and can cause losses and inefficiencies in agricultural production (Hickman *et al.*, 2021; Marshall and Levy, 2011; Van Asseldonk *et al.*, 2020). The human health repercussions can occur through the transfer of resistant bacteria from animals to humans, either by direct contact with infected animals or through contaminated food along the food supply chain, or indirectly through more complex cycles of environmental contamination (Innes *et al.*, 2020; Lhermie *et al.*, 2020; Manyi-Loh *et al.*, 2018).

The majority of antibiotics used worldwide are consumed to meet the demand for animal proteins in industrial farming, mainly to prevent infections and otherwise unavoidable diseases (Kirchhelle, 2018; Van Boeckel *et al.*, 2015), but also as promoters of growth performances (Dibner and Richards, 2005; Muurinen *et al.*, 2021).

Antimicrobial resistance is a global problem that must be addressed with appropriate solutions at the regional, national, and international levels, promoting global cooperation. Current estimates indicate that every year around 700,000 people worldwide die from infectious diseases caused by antimicrobial-resistant pathogens, and it is estimated that by 2050, deaths will increase to 10 million (Naghavi *et al.*, 2024).

Global statistics on veterinary antimicrobial use (AMU) are fragmented due to the lack of data collection and reporting from many countries (Tiseo *et al.*, 2020; Van Boeckel *et al.*, 2015). Although Europe is one of the largest consumers, AMU for livestock appears to be much higher in Asia and America. According to recent estimates, China is by far the largest global consumer, followed by Brazil, the United States, Thailand, and India, all showing increasing trends (Tiseo *et al.*, 2020).

Italy is among the European countries with the highest levels of veterinary AMU and antimicrobial resistance (European Centre for Disease Prevention and Control (ECDC) *et al.*, 2017) and, like others, has implemented a National Action Plan (PAN) since 2017 to encourage more prudent AMU and combat antimicrobial resistance. In the veterinary sector, the plan aims to reduce the use of antimicrobials, with a focus on those of critical importance (Italian Ministry of Health., 2017).

As antibiotics are administered to animals on a recurring basis, the demand for reducing their use on farms is increasing. However, the issue is complex. These challenges highlight the need for a fundamental shift in how we approach animal health management. This shift has led to a move away from focusing solely on post-infection treatments, instead placing greater emphasis on prevention as the primary strategy (Renault *et al.*, 2021).

The strategies to reduce the use of antibiotics in livestock farming offer many possibilities: vaccines and immune-related products, microbial-derived products, such as probiotic feed additives, innovative drugs, chemicals and enzymes, and phytochemicals (Callaway *et al.*, 2021; Hu and Cowling, 2020; Kumar *et al.*, 2021; Streicher, 2021; Thacker, 2013). But there is not a one-fits-all solution, and antibiotic alternatives need to be integrated within wider strategies of farm animal health management and require, as precondition, high levels of farm animal welfare and biosecurity (Alarcón *et al.*, 2021; Caekebeke *et al.*, 2020; Laanen *et al.*, 2013; Leinonen *et al.*, 2014; Lewerin *et al.*, 2015; Postma, M. *et al.*, 2016; Rodrigues Da Costa *et al.*, 2019; Sasaki *et al.*, 2020; Vissers *et al.*, 2021).

High standards of animal welfare and biosecurity are recognized as critical to improve animal health and significantly reduce the use of antibiotics in livestock farming by maintaining optimal production performances, especially in the pig sector (Postma *et al.*, 2015; Raasch *et al.*, 2020).

Farm biosecurity is a preventive action that refers to the combination of all the different measures (a set of management, protocols, practices, and physical measures) designed to reduce the risk of introduction, establishment and spread of disease agents to, from and within an animal population (Amass, 1999; Saegerman *et al.*, 2024; Shortall *et al.*, 2017). There are two main components to farm biosecurity: external biosecurity and internal biosecurity. The former encompasses all the measures designed to prevent the introduction of infectious agents to uninfected farms and to limit the spred of diseases from already infected farms. Internal biosecurity, on the other hand, focused on strategies adopted to prevent the transmission of pathogens within the farm.

The proper application of biosecurity measures plays a crucial role in keeping the risk of epidemics low, preventing the spread of diseases, and therefore minimize the need for treatment and use of antimicrobials (Collineau *et al.*, 2017; Laanen *et al.*, 2013; Postma *et al.*, 2016). These measures improve animal health, help combat antimicrobial resistance (Alarcón *et al.*, 2021; Rodrigues Da Costa *et al.*, 2019), enhance overall technical performance (Laanen *et al.*, 2013; Postma *et al.*, 2016), and contribute to increase farm profitability (Rojo-Gimeno *et al.*, 2016).

Despite the implementation of EU Regulation 2019/6, which enforces strict guidelines on the use of antibiotics and other veterinary medicines in livestock – including a ban on the preventive use of antibiotics, restrictions on critically important antibiotics, and a requirement for veterinary prescriptions – many pig farmers continue to be reluctant or hesitant to adopt these measures. This reluctance persists even in light of the well-documented, scientifically proven benefits of biosecurity practices for both animal health and farm profitability.

Several key factors contribute to farmers' reluctance to adopt biosecurity measures, including economic, cultural, and practical considerations. Some may underestimate the risk of infectious diseases or believe that the likelihood of an outbreak is low, especially if they have not experienced significant health issues on their farms in the past. Many farmers, who are accustomed to traditional methods and established routines, may see biosecurity measures as an intrusion into their tried-and-true operations.

This resistance to change behavioral habits is common across many agricultural sectors and is often compounded by a lack of awareness about the long-term benefits of adopting new practices. In many instances, farmers may not fully understand how to implement biosecurity measures effectively or how these can be integrated into their operations without compromising productivity. Limited training and support from experts or industry associations can create further barriers to adoption. Additionally, some farmers are concerned that biosecurity measures involve complex, ongoing management, and substantial costs in the long term.

Previous studies (Valeeva *et al.*, 2011) emphasize that farmers' perception of the benefits of biosecurity measures, their risk aversion in farming decisions, and their behavior towards adopting protective measures all play a significant role in the decision to implement biosecurity practices.

Results of several studies indicate that the application of biosecurity measures can lead to high profits (Fasina *et al.*, 2012). However, for farmers, this often means having to invest in additional costs, which may not always result in immediate or sufficient gains (Niemi *et al.*, 2016).

From an economic perspective, the optimal use of biosecurity measures is determined by the cost-benefit ratio (Gramig *et al.*, 2009), and different levels of biosecurity can occur depending on economic factors (Hennessy *et al.*, 2005). Implementing biosecurity often require significant investments in infrastructure, including fencing, disinfection stations, quarantine systems, and equipment to control vehicle access and entry points. Managing supplies and enforcing strict controls also require ongoing effort. However, these investments may not seem worthwhile to farmers without the assurance of immediate financial returns.

Pig farmers are also frequently under economic pressure, facing challenges such as fluctuating commodity prices, intense market competition, and narrow profit margins. In this competitive environment, some may perceive biosecurity as an additional cost that offers no immediate, tangible benefits – particularly if their farms have not been impacted by major disease outbreaks (Lhermie *et al.*, 2020; Van Asseldonk *et al.*, 2020; Visschers *et al.*, 2015, 2016).

Furthermore, in some regions, the lack of economic incentives or supportive agricultural policies that encourage the adoption of biosecurity measures adds another layer of resistance, hindering widespread implementation.

In the Italian context, the ClassyFarm surveillance system was developed as a technical tool to support farmers' decision-making and monitor veterinary public health risks on farms, including biosecurity. ClassyFarm is a specialized unit with a clear mission and strategy: to provide valuable information to both public and private stakeholders by collecting new data and processing existing information. This supports decision-making across various operational levels, including production, technical guidance, and public health management.

Promoted by the Italian Ministry of Health through the Directorate General of Animal Health and Veterinary Drugs, ClassyFarm also plays a key role in monitoring antimicrobial use (AMU) in animal farming and tracking antimicrobial resistance (AMR) on farms. The adoption of the system by pig farmers is voluntary.

ClassyFarm covers four main interconnected areas: animal welfare, farm biosecurity, slaughterhouse data, and antimicrobial use (AMU) and resistance (AMR). The system evaluates farm performance and can highlight best practices related to biosecurity, management, and farm structure.

Beyond Italy, the ClassyFarm project has the potential to be implemented and adapted in other countries, serving as a benchmark to promote farming practices that focus less on antibiotic use and more on sustainable animal husbandry.

The study will focus on pig farming, since the ClassyFarm checklist data show that this is the sector with the greatest problems in relation to the economic burden sustained by the spread of animal diseases and is the most relevant in terms of antibiotic consumption and the associated AMR risks in Italy.

Good animal welfare practices and biosecurity measures are therefore crucial to improve the economic sustainability of these activities. Considering also what is happening in other European countries, such as Denmark, Sweden, there is considerable potential for improvements within the Italian pig sector , which can be addressed and given specific focus in the context of this project.

This PhD project is part of international projects and networks on animal health and One Health (OH) economic issues that involve the Department of Agricultural and Food Sciences of the University of Bologna. In particular: the European Project BIOSECURE, the COST Action BETTER – CA20103 – Biosecurity Enhanced Through Training Evaluation and Raising Awareness, and ROADMAP Project – Rethinking of Antimicrobial Decision-systems in the Management of Animal Production. The PhD project had also synergies set with Experimental Zooprophylactic Institute of Lombardy and Emilia Romagna (IZSLER) (https://www.izsler.it) and the network CoEvalAMR (Convergence in evaluation frameworks for integrated surveillance of AMU and AMR (https://guid-ance.fp7-risksur.eu/).

BIOSECURE is a HORIZON Europe FARM2FORK, a four-year research project started in 2023 and supported by the European Union (https://biosecure.eu/about/). The overall aim is to enable decision makers in livestock farming to understand, prioritize and implement evidence-based, cost-effective, and sustainable biosecurity management systems. This PhD project has been part of work package 3 (quantification of biosecurity practices and its impact on infection prevention and economics), and work package 5 (socio-economic impact of BIOSECURE measures beyond the farm level).

The overall aim of the COST Action BETTER is to reduce the risk of infectious disease introduction and spread by improving the implementation of biosecurity measures in animal production systems. This PhD project has been part of working group 3 (methods for evaluation of biosecurity and benefits of its implementation).

ROADMAP is a European Union's Horizon 2020 project, started in 2019 and finished in 2023, the overall aim was to foster transitions towards prudent antimicrobial use (AMU) in animal production in a large variety of contexts.

The international network CoEvalAMR aimed at developing guidance for the evaluation of integrated surveillance for AMU and AMR.

1.2. Research objective and questions

The aim of this PhD thesis is to generate new insights into the economic impact of biosecurity measures, with a particular focus on the costs associated with their implementation in Italian pig farming.

Additionally, the thesis assesses ClassyFarm components that could be further improved to optimize the integrated nature of the system concerning AMU and AMR, considered as indirect indicators of the effectiveness of biosecurity measures implemented in farms.

At this stage, the specific objectives are as follows:

RQ1. Is economic sustainability of biosecurity measures an emerging topic in pig farming research?

To assess the relevance of the topic in current research, the thesis begins with a Systematic Literature Review on the economic sustainability of biosecurity measures in pig farming, while biosecurity has traditionally been studied from an epidemiological and veterinary perspective. This review incorporates a bibliometric and network analysis to: illustrate the publication trends (number of documents and associated citations over time, leading journals, authors and countries contributing to publications, and the most frequently published papers); track the evolution of biosecurity-related concepts (relationships between study components, most common indexed keywords, keywords co-occurrence, and the most examined research areas and themes).

This analysis aims to predict trends, identify research gaps, highlight emerging areas of focus, and shed light on ongoing debates within the academic community, offering a comprehensive understanding of multidisciplinary research efforts on the economic sustainability of biosecurity measures.

RQ2. How does economic sustainability affect biosecurity at farm level?

Following the Systematic Literature Review conducted with RQ1, only articles presenting quantitative data on biosecurity costs are selected to investigate the economic sustainability of biosecurity at the farm level. The papers are grouped based on: supply chain phase, disease, epidemiological study types, economic impact of biosecurity.

The purpose of this analysis is to identify research gaps specifically related to the economic costs of implementing biosecurity in pig farming.

RQ3. What are the potential economic impacts of biosecurity according to a One Health perspective?

Biosecurity, as a key component of the One Health concept, aims to prevent the spread of diseases among humans, animals, plants, and the environment. It takes into account the interconnections between businesses, systems, sectors, market areas and levels, and among different stakeholders.

It therefore becomes necessary to analyze biosecurity in terms of its potential economic impact through a holistic and integrated approach. This represents a challenging task to implement, as it involves multiple entities and demands effective cross-sectoral collaboration to ensure efficient resource allocation.

The study explores the overall framework of relationships and effects stemming from the implementation of biosecurity measures (BSM) across different levels (sector, system, and food-supply-chain level), adopting a theoretical approach. It specifically aims to analyze the economic and systemic consequences of biosecurity practices and their potential impact on the long-term stability and prosperity of local communities and national economies.

It is built on the results of the investigations and reflections carried out in the BIOSECURE Project, to better understand the dynamics that develop between the actors and the supply chain involved and the possible effects on the business balance.

The purpose of an overview of the economic impact of biosecurity is to be able to provide knowledge in order to have a stakeholder engagement and empowerment about the possible negative repercussions that incorrect biosecurity practices in animal farming (especially intensive) would bring. The negative repercussions can translate into economic losses, public health implications. Likewise, knowing this overview can help to protect natural resources, as incentives for investment.

RQ4. How can we categorize and evaluate the costs of biosecurity implementation in pig farming?

Analyzing the costs of biosecurity measures is the first step towards conducting health economic evaluations, which aim to support decision-making processes. Given the scarcity of resources and their multiple potential uses, these evaluations are essential for ensuring the optimal allocation and utilization of available resources. Health economic evaluations in this sense should help us to draw the maximum possible benefit from the health interventions that we carry out with the lowest possible costs. Economic evaluations are critical in the One Health implementation cycle as a tool for decision-making (Drummond *et al.*, 2015). For instance, a government decision maker may wonder what projects or programs to invest in when they have a budget available for One Health initiatives and a particular situation.

Among the threats that prevent the application of biosecurity measures there is certainly a short-term investment that is quite significant for pig farmers to sustain.

The purpose of this research question is to categorize and evaluate costs of biosecurity. Interviews with 13 experts from the pig sector led to a list of variable costs for internal biosecurity measures in intensive pig farms, highlighting the main cost items that businesses must face to ensure animal health and prevent the spread of diseases. These experts, including veterinarians, management technicians, and farmers, contributed with their experience and knowledge of daily farming practices.

RQ5. How can we evaluate the different aspects of the ClassyFarm surveillance system with respect to AMU/AMR from a biosecurity perspective?

Current systems aimed at measuring health risk on farms assume that the implementation of biosecurity measures can provide some effectiveness, but there are not indicators quantifying the real effectiveness of the various biosecurity measures or practices that are recommended. Similarly, the ClassyFarm system quantifies the biosecurity level of a farm based on the implementation of a series of measures or practices. However, it cannot quantify the actual effectiveness of these measures in terms of reducing the risk of infection emergence and disease spread.

Therefore, this research question assesses ClassyFarm components that could be further improved to optimize the integrated nature of the system concerning AMU and AMR, considered as indirect indicators of the effectiveness of biosecurity measures implemented in farms.

The assessment of ClassyFarm lays as a foundation for discussing potential adaptations and improvements in system efficiency and effectiveness. The goal is to enhance the interconnectedness of system components, ensuring a more efficient data collection, processing, and communication framework. This includes evaluating how well the system integrates diverse data sources (e.g., animal health, antimicrobial use, environmental conditions) to provide a comprehensive view of AMR and AMU patterns. In addition, the assessment helps identify gaps or limitations in the system's integration capabilities that may hinder the effective sharing or analysis of data, as well as data consistency across different platforms and among various stakeholders (e.g., farmers, veterinarians, public health authorities). Moreover, an integrated system enhances decision-making and communication. It enables the collection and analysis of more accurate real-time data, offering farmers precise guidance on how to improve AMR and AMU management. This allows for more informed decision-making, prompt identification of animal welfare issues, and reduced risk of disease spread. A more integrated system also improves care quality by quickly detecting problems such as disease outbreaks, inadequate living conditions, or other factors affecting animal health. Next, separate systems may lead to discrepancies in reporting and data interpretation. Evaluating components for greater integration helps ensure consistency across the different parts of the system, resulting in more reliable outcomes. Lastly, the timeliness and responsiveness of actions, a more integrated system enhance the quality of care by promptly detecting issues such as disease outbreaks, inadequate living conditions, or other factors influencing animal health.

To assess and characterize the surveillance capabilities of ClassyFarm regarding AMU and AMR, three evaluation tools are implemented: the Food and Agriculture Organization of the United Nations Progressive Management Pathway for AMR (FAO PMP-AMR), the Network for Evaluation of One Health tool (NEOH http://neoh.onehealthglobal.net), and One Health epidemiological surveillance capacities and capabilities (OH-EpiCap).

1.3. Thesis outline

This thesis describes the research process, providing an overview and synthesizing the results of each individual study into a coherent and consistent argument worthy of critical discussion.

The report is organized as follows:

- The former chapter includes the motivation, aims and objectives, research questions, and initial hypothesis of the PhD project. The section concludes by describing the structure of the study.

- The second chapter includes an introduction to the key topics related to biosecurity measures. Is provided an overview on the definition, the importance of applying preventive measures, as well as the ClassyFarm surveillance system currently in use in Italy, the method for measuring the level of biosecurity within a farm, and also the Italian swine production and the supply chain will be explained.
- The third chapter provides an overview of the material and methodology (a quali-quantitative Systematic Literature Review method), details the data collection process, and presents the results and discussion on the economic sustainability of biosecurity measures, related to RQ1 and RQ2.
- Chapter four addresses RQ3 focusing on the potential economic impact of biosecurity from a One Health perspective. It presents the theoretical approach to the issue, including systems thinking, conceptual framework, theory of change, and cause-and-effect analysis as key theories to investigate and explain the research questions. The chapter also includes the results and discussion.
- Chapter five illustrate in detail the methodology (semi-structured interview method), results, and discussion about the cost categories and cost assessment of biosecurity measures in pig farms, addressing the RQ4.
- The next chapter describes the main findings of RQ5, highlighting the methods used (systems thinking approach, interviews and three assessment tools: the FAO PMP-AMR, the Network for Evaluation of One Health tool, and OH-EpiCap, which have produced semi-quantitative items), results, and discussion on the evaluation of the ClassyFarm surveillance system for AMR and AMU.
- Chapter number seven summarizes the overall conclusion and discussion of the thesis, revealing research limitations, suggesting potential areas for future research, along with recommendations for stakeholders.

In the final section of the thesis is dedicated to the references.

In the present study, both types of methods were used as shown in the research design of the study (Figure 1).

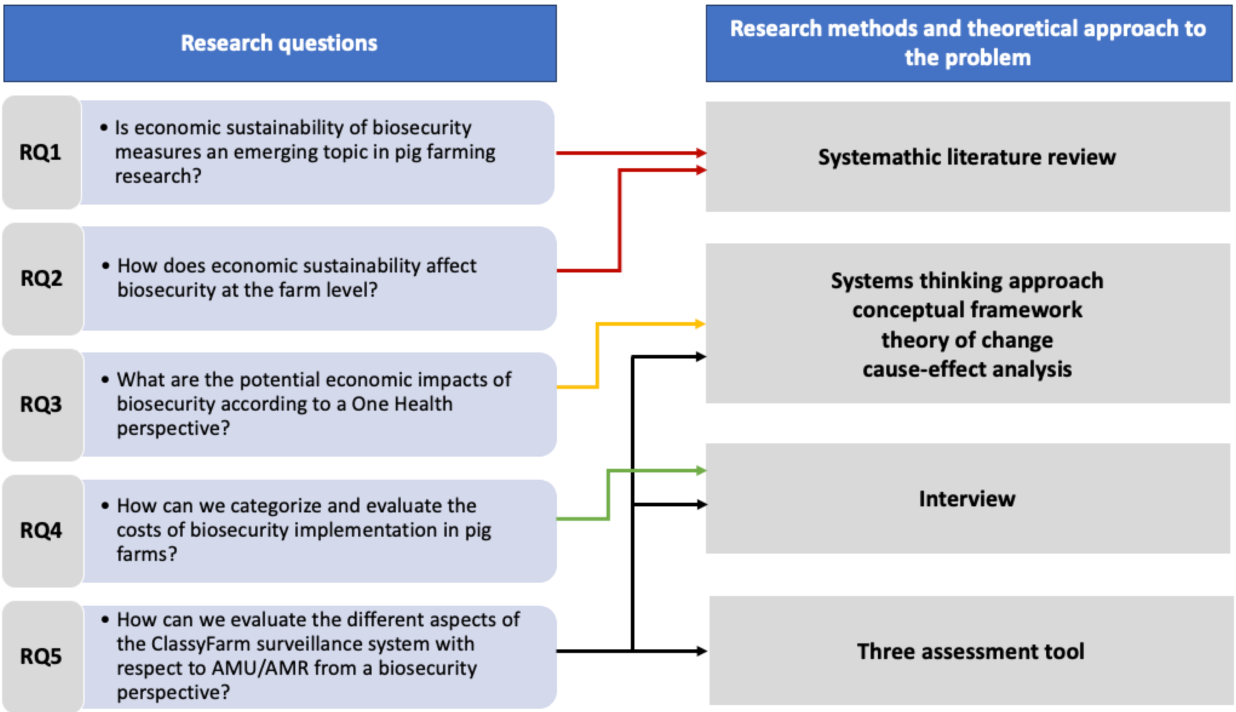

Figure 1. Research design of the study

Figure 2 illustrates the structure of thesis outline:

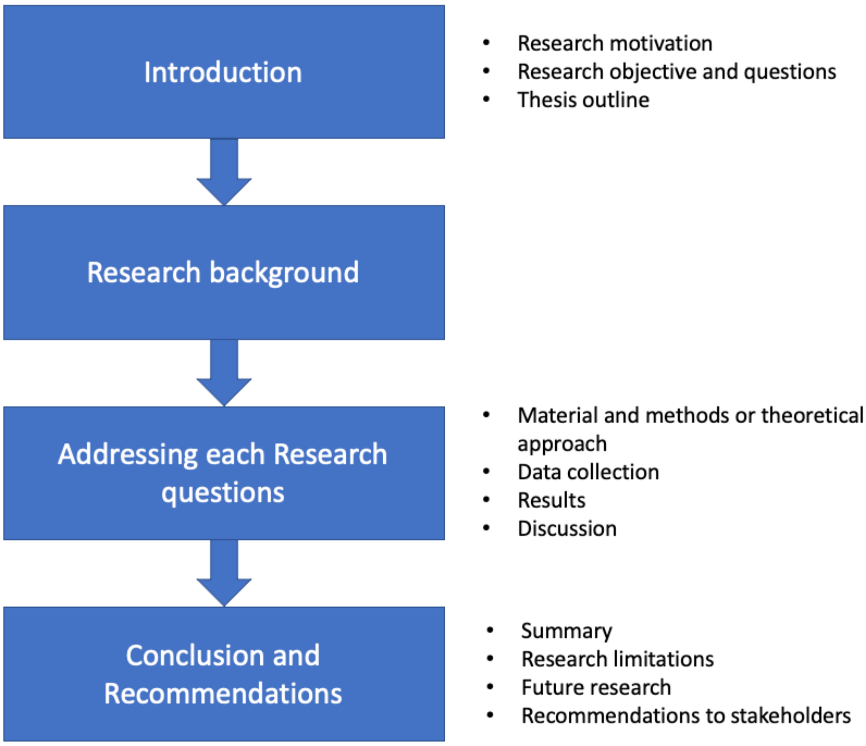

Figure 2. Thesis outline

2. Research background

This section discusses the context of the current research investigation. Central to the investigation are several key topics related to biosecurity measures. First, the definitions of biosecurity will be examined, providing clarity on terms and concepts that underpin the research as well as its applicative importance. The purpose of the ClassyFarm surveillance system currently in use in Italy will also be described and will be explained the method for measuring the level of biosecurity within a farm (Biocheck U-Gent). Lastly, in this paragraph it will talk about Italian swine production and the supply chain. All this to have a deep theoretical introduction to what will then be the following paragraphs.

2.1. Definition of biosecurity

The term "biosecurity" is relatively young, the first citation on PubMed dates back to 1987. Only starting from the 1980s it began to be used in the field of animal health and in the agricultural sector, while originally it referred to the management of biological weapons and bio-terrorism (Renault *et al.*, 2021). It was defined as follows by the U.S. Association of State Departments of Agriculture: "the vital work of strategy, efforts and planning to protect human, animal and environmental health against biological threats".

Today, biosecurity refers to the combination of all the different measures (set of management, practices and physical measures) designed and implemented to reduce the risk of introduction, establishment and spread of disease agents, animal diseases, infections or infestations to, from and within an animal population (Amass, 1999; Saegerman *et al.*, 2024; Shortall *et al.*, 2017).

Food and Agricultural Organization (FAO) has defined biosecurity as "A strategic and integrated approach to analyzing and managing relevant risks to human, animal and plant life and health and associated risks to the environment" (FAO, 2007).

Pathogen is not capable of locomotion and must be carried by something else. Pathogens get into and circulate in the farm through the entry of infected animals, contact with wild animals or pests, movement of infected animals, transit of vehicles or people carrying the pathogens, water, feed, bedding, carcass removal, tools/equipment, waste management etc.

In this regard, biosecurity plays a role of fundamental importance in the surveillance programs of the main diseases. An adequate level of biosecurity can therefore be fundamental to avoid applying eradication and containment actions of a specific infectious disease within the farm.

Biosecurity is based on the prevention and protection against infectious agents. The fundamental principle on which the concept of biosecurity is based is the precautionary principle, that is: do what is needed, when it is not needed. It describes the approach/point of view of biosecurity measures; that is: not managing the emergency, but working on prevention, therefore investing "in peacetime". What is necessary on farms is implement a biosecurity plan based on risk analysis, identifying, and classifying all possible health hazards that pose a threat to the farm. Monitoring to verify that the system works adequately and detect critical points to intervene.

Biosecurity can be divided into two main components: external and internal biosecurity. The first one, includes all measures taken to prevent the introduction of infectious agents into farms as well as the prevention of the spread of pathogens from farms. External biosecurity measures are associated with all actions where there is contact between the farm and the outside world such as structure aspects, organisation of the farm buildings, presence of entrance restriction for animals and people (e.g., hygiene lock, quarantine pen). They also include measures imposed upon others (e.g., restriction of visitors, hygiene of transport vehicles, feed safety). Internal biosecurity consists of a set of measures adopted to prevent the spread of infectious agents within the farm, from one age category to another, or from one production group to another (and also within groups) and between different company structures. Internal measures are strongly linked to farm management and daily practise of animals' carers (e.g., hygienic measures between compartments, working lines, cleaning, and disinfection practices, etc.). Unlike external biosecurity measures, these are much more oriented towards controlling endemic infectious diseases.

Saegerman *et al.*, 2024, have broadened the definition biosecurity measures based on 5 main stages (Figure 3):

1. bio-exclusion: limiting the risk of introduction
2. bio-compartmentation: limiting the spread within the same facility
3. bio-containment: limiting the spread to other animal facilities (inter-herd transmission)
4. bio-prevention: preventing human contamination
5. bio-preservation: preventing environmental bio-contamination.

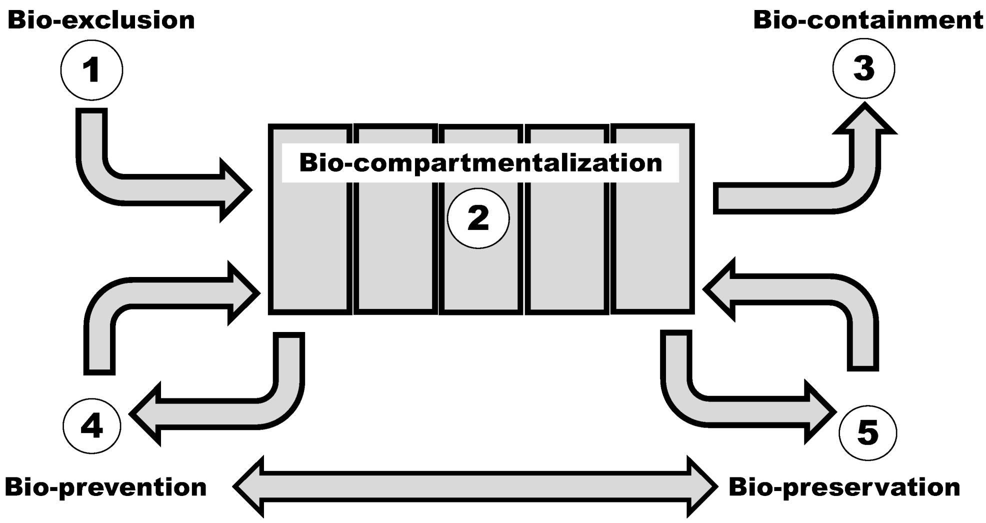

Figure 3. Five stages of biosecurity measures (Saegerman et al.*, 2024)*

The management of internal biosecurity, compared to external biosecurity, is complex and heterogeneous as it requires the evaluation of numerous factors, such as:

- adequate knowledge of the company's state of health
- analysis of the company from the point of view of structure, position, and strategy
- evaluation of the margins for structural-managerial improvement and the cost/benefit ratio of the improvement interventions.

It was only more recently that attention started focusing on internal biosecurity measures (Dewulf and Van Immerseel, 2019). This is probably the result of the intensification of animal production where animal groups have become larger and more vulnerable, and where production efficacy is becoming more critical. Certainly, when designing biosecurity programmes there are some general principles that are of value in all different environments. Examples include the separation of high and low risk animals (i.e., infectious and susceptible animals) or keeping the infection pressure below a level which allows the natural immunity of animals to cope with the infections. However, in order to achieve the highest effectiveness in terms of animal health protection, the epidemiology of pathogens should be carefully considered since it affects target animal species, transmission routes to be primarily controlled, seasonality and level of prevalence within the area where animals are raised.

Several studies have been conducted examining the efficacy of the most applied external and internal biosecurity measures such as distance from neighboring farms (Christensen *et al.*, 1990; Woeste and Grosse Beilage, 2007), the transport of animals (Dee *et al.*, 2004; Otake *et al.*, 2010), people and vehicles as a transportation vector (Amass, Vyverberg, *et al.*, 2000), rodent control (Ospina-Pinto *et al.*, 2017), quarantine, use of semen (Fedorka-Cray *et al.*, 1997; Woeste and Grosse Beilage, 2007); management (Isomura *et al.*, 2018; Lurette *et al.*, 2011), cleaning and disinfections (Amass, Stover, *et al.*, 2000; Dione *et al.*, 2018), personnel working and much of the literature has examined the effectiveness of different vaccination programs and their impact on intensive pig farming (Layton *et al.*, 2017).

The application of good biosecurity measures plays a crucial role in keeping the risk of epidemics and the use of antimicrobials low (Collineau *et al.*, 2017; Laanen *et al.*, 2013; Postma, *et al.*, 2016), improving animal health status with resulting improvements in technical performance, leading to better farm key performance indicators (Laanen *et al.*, 2013), and a raise in farm profitability (Rojo-Gimeno *et al.*, 2016).

Biosecurity is considered as the foundation of all disease control programmes. The aim of combining all biosecurity measures is to prevent both the introduction as well as the spread of infectious agent in a group of animals. As such, it targets reducing the infection pressure exerted upon the animals. It follows that good biosecurity in animal production results in improved animal health and subsequent improvements in technical performances.

A study carried out in Belgium, France, Germany and Sweden found a positive association between the higher level of external biosecurity and the number of weaned piglets per sow per year (Postma, *et al.*, 2016). The results obtained in this study concurred with a study by Dors *et al.*, 2013, that described a higher number of swine born per sow per year and sold per year in herds with a proper level of biosecurity. However, a word of caution is required when interpreting these results as these associations do not prove a direct causal relationship and other potentially related factors such as overall herd management, genetics, feeding etc. may have influenced the observed association.

2.2. The importance of biosecurity

Now that the concept of biosecurity has been understood and what standards it refers to, we need to delve deeper into the reasons why it is important to apply it on farms.

In recent years, the importance of adopting preventive measures in pig farms has gained considerable recognition since in many developed countries, the pig production industry is experiencing a significant trend towards concentration and larger-scale operations, and the spread of a new pathogen can cause catastrophic consequences.

It is precisely for this reason that much of the literature has focused on analyzing the epidemiological aspects of diseases such as Porcine Reproductive Respiratory Syndrome (PRRS), Porcine Epidemic Diarrhea (PED) and African Swine Fever (ASF), as well as the productivity losses and the impact of biosecurity measures on the individual disease (Corzo *et al.*, 2010; Rowlands *et al.*, 2008; Stevenson *et al.*, 2013; Zhou *et al.*, 2018).

Legislation

Biosecurity measures can be implemented at different levels such as country, region, herd or flock and even individual animals. Implementing biosecurity involves providing facilities and adopting behaviour to reduce the risk of infection in all activities involving animal production or animal care.

The severity of the restrictions and precautions necessary to maintain an adequate level of biosecurity may vary depending on the type of company, the health level required, the surrounding epidemiological status as well as the regulatory framework.

In all farms the application of generic biosecurity measures is recommended on a voluntary basis, and it refers to a free choice of the breeder. But there are conditions and situations in which biosecurity measures represent a legal obligation to be applied for a purpose that covers the public safety level, reducing the epidemiological risk health (zoonoses – diseases that can be transmitted from animals to human, therefore food-borne zoonoses, e.g., Salmonellosis) and economic repercussions.

In general terms, the issue of biosecurity is addressed by an EU Regulation 2016/429[2] that gives a definition of biosecurity and assign the responsibility for minimizing the risk of spreading diseases is attributed to the breeder:

- definition of biosecurity: 'biosecurity' means the set of management and physical measures aimed at reducing the risk of introduction, development and spread of diseases to, from or in:

  a) an animal population, or

  b) an establishment, area, compartment, means of transport or any other site, structure, or premises

- responsibility to the breeder: "Biosecurity is one of the main preventive tools available to operators and other persons working with animals to prevent the introduction, development and spread of transmissible animal diseases from and within an animal population" […] "The biosecurity measures adopted should be sufficiently flexible, adapted to the type of production and the species or categories of animals concerned and take into account local circumstances and technical developments." […] "Although biosecurity may require some initial investment, the result of the reduction of animal diseases should constitute a positive incentive for operators".

Regulation (EU) 2016/429 was subsequently supplemented by Delegated Regulation (EU) 2020/687[3] of the European Parliament and of the Council as regards rules for the prevention and control of certain listed diseases, and as regards rules for surveillance, eradication programs and disease-free status for emerging diseases.

Currently, of 26 European countries, only 4 (France, Spain, Italy, and Romania) have a one national biosecurity legislation, and there is more focus on internal compared to external biosecurity measures with a significant correlation.

In Italy, the Decree of 28 June 2022[4] established the biosecurity requirements for establishments that keep pigs. Based on the production orientation, the breeding methods, the maximum capacity of the farm and turnover of animals within it and the risk of contact with wild animals, especially pigs.

The article indicates what the biosecurity measures may be:

a) structural protection measures, which may include: i) fences, roofs, boundary walls and other separation structures such as gates, bars, etc.; ii) stables and possible quarantine rooms; iii) parking and disinfection area for vehicles; iv) filter area; v) structures for loading animals; vi) equipment for washing and disinfecting structures and equipment; vii) a system for the safe storage of animal

[2] Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law'). *Off. J.* 2016, *84*, 1–208.
[3] Delegated Regulation (EU) 2020/687 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council, as regards rules for the prevention and control of certain listed diseases. *Off. J.* 2020, *174*, 64–139.
[4] Decree of 28 June 2022 on the Biosecurity requirements of establishments keeping pigs in Italy.

carcasses and other animal by-products awaiting disposal; viii) structures for the storage of feed and bedding intended for animals; ix) structures for the storage of livestock effluents

b) management measures, including: (i) farm biosecurity plan; (ii) procedures for the entry and exit of animals, products, vehicles and persons into and from the establishment and their registration; (ii) procedures for the use of equipment; (iii) risk-based movement conditions; (iv) conditions for the introduction of animals, feed or other products into the establishment; (v) quarantine, isolation or separation measures for newly introduced or sick animals; (vii) procedures for the washing and disinfection of facilities and equipment, for disinfestation and rodent control.

Antimicrobial use and resistance in farms

Antimicrobial resistance is the ability of one microorganism to resist the action of an antibiotic. Although it is a natural process, overuse and misuse of antimicrobials are drivers of AMR insurgence and spread (OECD, 2022). According to the WHO, this problem today represents one of the greatest threats to public health due to the epidemiological and economic impact of the phenomenon, since the use and the abuse of antibiotic administrations can result in the difficulty of treating pathologies (WHO, 2015).

Most of the antibiotics used in the world at present are consumed to meet the demand for animal proteins in industrial livestock farms, mainly to avoid infections and otherwise unavoidable diseases (Ardakani *et al.*, 2024; Kirchhelle, 2018; Tiseo *et al.*, 2020; Van Boeckel *et al.*, 2015), but also as promoters of growth performances (Dibner and Richards, 2005; Muurinen *et al.*, 2021). Indeed, by 2030, global antimicrobial use across human, terrestrial, and aquatic animal sectors for food production is projected to reach 236,757 tons annually. Of this, human use is expected to account for 48,608 tons, while terrestrial animals used for food production will consume 174,549 tons, and aquatic animals will contribute 13,600 tons. These figures represent 20.5%, 73.7%, and 5.7% of global antimicrobial consumption, respectively (Schar *et al.*, 2020).

Because of AMR, antimicrobials loose effectiveness, and many infections are becoming increasingly difficult or impossible to treat for both human and veterinary medicine. The insurgence and spread of resistant bacteria in farms, both commensal and zoonotic, represents a risk factor for public health in general, but more specifically for animals, farm workers and their families, and may cause farm production losses and inefficiencies (Hickman *et al.*, 2021; Marshall and Levy, 2011; Van Asseldonk *et al.*, 2020).

The repercussions on human health can occur through transfer of resistant bacteria from animals to humans, either by direct contact or through contaminated food along the food-supply chain, or indirectly through more complex cycles of environmental contamination (Innes *et al.*, 2020; Manyi-Loh *et al.*, 2018; Pieri *et al.*, 2020). For this reason, AMR represents a global health challenge that needs an integrated One Health approach (Larsson and Flach, 2022; WHO, 2015).

As antibiotics are mostly administered to animals on a recurring basis, there is an increasing demand for reducing their use in farms. However, the issue is complex, because it is difficult for farmers to implement this reduction without perceiving risks of affecting the economic and operational performance of their business or actually incurring in economic losses (Lhermie *et al.*, 2020, 2020; Van Asseldonk *et al.*, 2020; Visschers *et al.*, 2015).

The strategies for reducing or eliminating antibiotic use in livestock farming present numerous opportunities: vaccines and immune-related products, microbial-derived products, such as probiotic feed additives, innovative drugs, chemicals and enzymes, and phytochemicals (Callaway *et al.*, 2021; Hu and Cowling, 2020; Kumar *et al.*, 2021; Streicher, 2021; Thacker, 2013) but there is not a one-fits-all solution, and antibiotic alternatives need to be integrated within wider strategies of farm animal health management and require, as precondition, high levels of farm animal welfare and biosecurity (Alarcón *et al.*, 2021; Caekebeke *et al.*, 2020; Laanen *et al.*, 2013; Leinonen *et al.*, 2014; Lewerin *et al.*, 2015; Nielsen *et al.*, 2021; Postma *et al.*, 2016; Rodrigues Da Costa *et al.*, 2019; Sasaki *et al.*, 2020; Vissers *et al.*, 2021).

Antimicrobial resistance is a global problem that must be addressed with suitable solutions at the regional, national and international levels, promoting global cooperation (OECD, 2022). Global statistics on veterinary AMU are fragmentary because of the lack of data collection and reporting from many countries (Tiseo *et al.*, 2020; Van Boeckel *et al.*, 2015).

Although Europe is a major consumer, AMU for livestock seems much higher in Asia and in America. According to recent estimations China results by far the highest world consumer followed by Brazil, the USA, Thailand and India, all show increasing trends (Tiseo *et al.*, 2020). The European Union has accumulated a quite long experience on actions against AMR, Italy is among the European countries with the highest levels of veterinary AMU and AMR (European Centre for Disease Prevention and Control (ECDC) *et al.*, 2017) and, like others, has implemented a National Action Plan since 2017 to encourage more prudent AMU and counteract AMR. In the veterinary sector, the plan aims to reduce the use of antimicrobials, with a focus on those of critical importance (Italian Ministry of Health., 2017).

In this way, monitoring and surveillance of AMR is considered a national strategic pillar and is part of the Italian integrated plan to fight AMR, that, among its objectives, includes the reduction of antimicrobial use in farmed animals. The current PNCAR (2022-2025) has broader approach as compared to the previous (first) PNCAR (2017-2020), since it encompasses environmental health besides animal and human health.

This happens with the digitization of veterinary medicines, including electronic prescriptions to track AMU, and through the ClassyFarm (https://www.classyfarm.it) which is one of the main pillars of the PAN. Beyond the national borders ClassyFarm project intends to do can also be implemented and developed in other countries and used as a term of comparison in other parts of the world, to promote farming practices less focused on the consumption of antibiotics.

As already stated, effective biosecurity is the foundation of disease prevention, which can be complemented by additional preventive measures such as vaccination or use of feed additives. If biosecurity and disease prevention are well implemented it is possible to reduce curative treatment of diseased animals to an absolute minimum (Dewulf and Van Immerseel, 2019). If biosecurity is well established, then additional preventive measures will have a greater impact and need for curative treatment can be kept to a minimum. Several studies have recently demonstrated this relationship: Fertner *et al.*, 2015 described that Danish weaner farms using a lower volume of antimicrobials than the national media, had shown similarities relating two important biosecurity measures: separating sections on farms and using all in/all out procedures. Moreover, a significant association was found between disinfection of the loading area, gilt quarantine and adaptation and lower antimicrobial use in French breeder-finishers herds (Lannou, J. *et al.*, 2012). Since swine sector is the most relevant livestock industry for antimicrobial use and connected AMR risks, studies into other species describing the associations between these issues and biosecurity are scarce. However, the results obtained in swine production could be applied to other farms animals.

As is known, the over-use of antimicrobials both in livestock and humans, can lead to the increase of AMR bacterial strains due to the genetic mechanisms underlying the resistance phenomenon. It follows that the implementation of adequate biosecurity measures at farm level is indirectly associated with a reduction of AMR through an improved animal health status and the consequent lower need for veterinary drugs (Ribbens *et al.*, 2008). Non such relationship has been already analysed by several scientific studies: a study by Dohmen *et al.*, 2017 concluded that improved biosecurity, especially the presence of a hygiene lock and pest control by a professional, were associated with a lower likelihood of extended beta-lactamase (ESBL) – *Escherichia coli*-positive farms. Tests for methicillin-resistant Staphylococcus aureus (MRSA) in animals and personnel in dairy herds revealed that a high MRSA prevalence in milk samples was associated with poor hygiene during milking routines (e.g., milkers not wearing gloves) (Locatelli *et al.*, 2017).

Based on the scientific results described above, improving the level of internal and external biosecurity could represent a key strategy towards reducing the use of antimicrobials in animal production and the resulting emergence of AMR.

From ethical point of view to a market expansion

Biosecurity measures play a crucial role in enhancing animal welfare, ensuring the necessary care, reducing suffering, maintaining clean living conditions, minimizing stress and discomfort, creating better living conditions for livestock, and at least reducing drugs consumption.

The positive role of biosecurity on animal welfare and the consequent reduction in drugs consumption allows farmers to obtain quality certifications of animal husbandry process, as well as antibiotic-free or improved animal welfare labels. For a few decades now, the consumer sensitivity/attention towards animal farming conditions have raised from an ethical point of view, and product quality certifications lead to an increasing in consumer confidence.

Previous studies have focused on farmers' attitudes and factors influencing biosecurity decision-making. It is now well known that farmers are hostile to changing their daily routines and adopting biosecurity practices, both from an organizational and economic point of view (Burton *et al.*, 2008; Garforth *et al.*, 2013).

Indeed, it has been widely demonstrated that biosecurity measures bring significant benefits, although adequate application of these practices may require initial investments.

In general, as Berends *et al.*, 2021 suggests, there can be two possible economic scenarios in the case of the establishment of a disease on the farm (Figure 4): in the first, preventive biosecurity measures are not adopted, this would lead to a reduction in farm productivity, with a consequent reduction in revenues and increase in costs for treating sick animals, which in turn would translate into a loss of profits and consequent reduction in investments, a consequent loss of company productivity, so it would create a sort of loop. Instead, in the second case preventive biosecurity measures are adopted, this would reduce mortality, avoiding a loss in farm productivity. The application of biosecurity measures, however, would increase costs, but reduce those incurred to treat sick animals, revenues would remain at least stable, and this would not lead to an exorbitant loss in profits and the consequent possibility of investing in breeding and in the biosecurity measures themselves. The effects of the second scenario, therefore of the application of biosecurity measures, would also have positive effects on the reduction of antimicrobial use and the phenomenon of antimicrobial resistance (Alarcón *et al.*, 2021; Rodrigues Da Costa *et al.*, 2019).

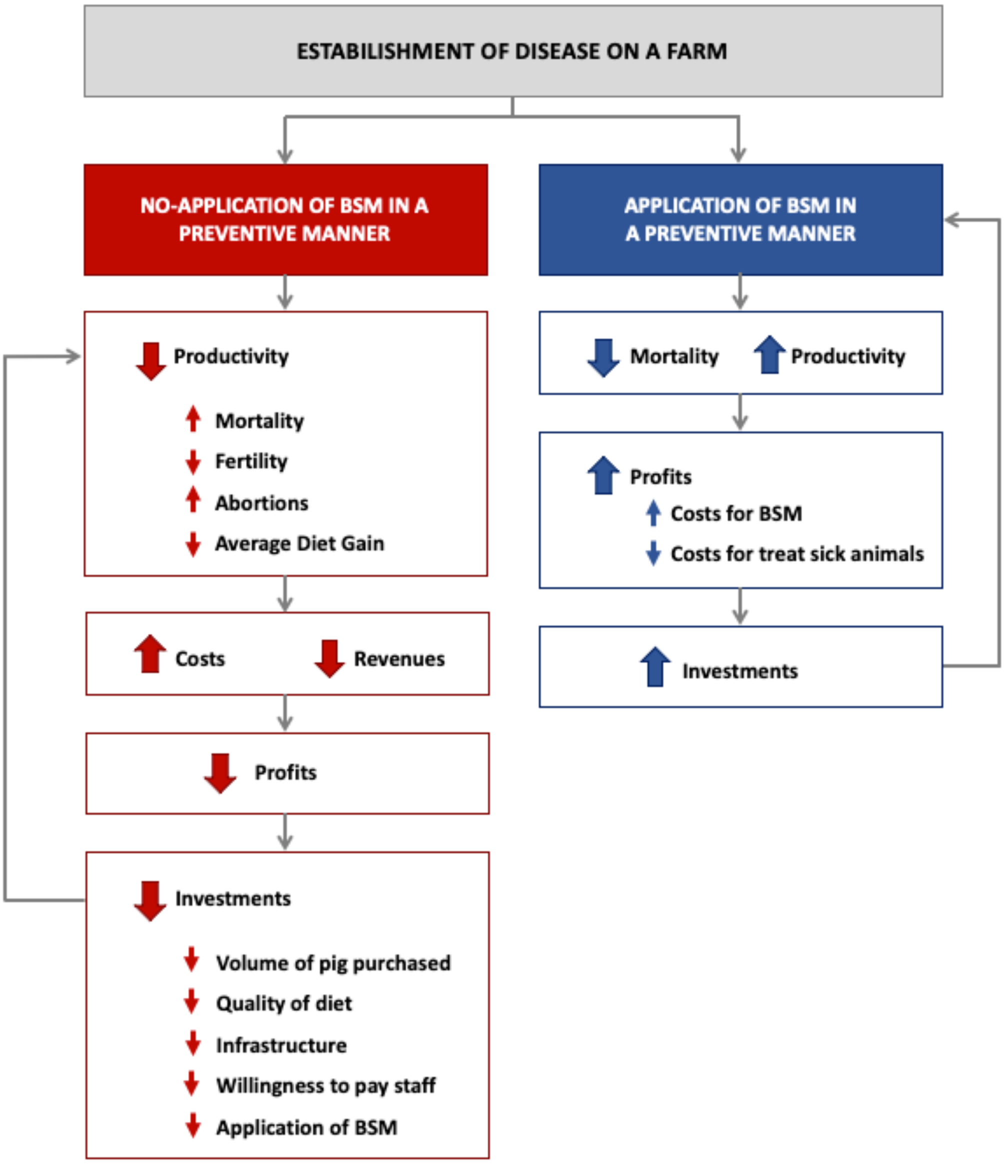

Figure 4. Economic scenarios in the case of the establishment of a disease on the farm

The application of correct biosecurity procedures, in addition to safeguarding the company's animal and productive assets, becomes as a cornerstone for economic stability and success.

There are two ways in which a company can make more profits than its competitors and create a competitive advantage: *Cost advantage* and *Differentiation advantage*. In this way, the investments that biosecurity requires lead to an increase in the value of the company because the conditions for optimizing the management and productivity are guaranteed.

1) Cost advantage: when the firm provides an identical product or service at a lower price, the firm's goal is to become a cost leader. Biosecurity can help to undertake a cost advantage as the attributable advantages can be associated with the search for economies of scale for example through vertical integration. In fact, we speak of economies of scale when an increase in inputs in the production process causes a reduction in the unit cost. Or through the search for economies of learning, and experience related to biosecurity, therefore organizational standards of biosecurity are applied within the farms, and finally a cost advantage linked to lower costs for vaccinations.
2) Differentiation advantage: the company provides a differentiated product or service such that the customer is willing to pay a higher price for the improved product. Differentiation from competitors is achieved when the company provides something unique that has higher value for the customer. Applying higher biosecurity standards may lead to the production of meat certified as "antibiotic free" or produced with stricter biosecurity standards (to be recognizable by consumers they must have a guarantee label).

This way, farms that meet rigorous biosecurity standards can access international markets more easily, as consumers and importing countries are increasingly concerned about animal health and food safety.

2.3. Biocheck U-Gent

Building competitiveness among pig farmers through biosecurity assessments is an effective strategy for enhancing awareness and motivation (Alarcón *et al.*, 2021). The use of scoring systems provides a structured way to evaluate the application of biosecurity measures and encourages farmers to strive for higher scores by improving their practices.

The most common scoring system used is the Biocheck.UGent™ (https://biocheck.ugent.be/en), while others have been developed for specific pathogens (PRRS, Brachyspira hyodysenteriae, Mycoplasma hyopneumoniae) (Allepuz *et al.*, 2018; Holtkamp *et al.*, 2013; Lewerin *et al.*, 2015; Rathkjen PH *et al.*, 2018; Sasaki *et al.*, 2020).

The Biocheck UGent™ is an assessment tool, based on a scoring system used to measure the level of biosecurity in a livestock farming. Developed by Ghent University (UGent) in Belgium, this system is based on a scientific and multidimensional approach to ensure that animals are raised in optimal conditions.

It analyze biosecurity using a risk assessment approach and it has been successfully applied in several EU countries (Filippitzi *et al.*, 2018; Kruse *et al.*, 2020; Postma *et al.*, 2016).

The goal is to evaluate the different aspects of biosecurity on the farm to monitor and improve (critical) biosecurity measures using of a questionnaire. Focused on the common aspects of the transmission of different types of infections but does not on specific animal diseases.

The Biocheck.UGent surveys are used worldwide and in some countries the compilation is mandatory by law for specific animal species, while in other it's an extra-legal legislation (e.g., Belgium, Italy, Spain, Ireland, Finland).

The questionnaire is completed during the farm visit through on-site observation and direct inspection, and biosecurity data are collected by answering the survey questions. The survey can be filled out by the farm veterinarian, owner, worker, farm veterinary advisor, researchers, private veterinarians, or technicians. The interview is preferably addressed to the farm owner or manager.

The results of the questionnaire are automatically analyzed using a unique feature, a scoring method (with an algorithm) based on the weighting of biosecurity measures or a group of measures. The Biocheck.UGent algorithm that determines biosecurity surveys is an independent risk-based scoring system for assessing the level of biosecurity on the farm (Pandolfi *et al.*, 2018).

This algorithm is a weight attributed to all sub-category, is specific to animal species and developed after literature research on pathogens transmission, knowledge of infectious risk and expert opinions on the infection risk through different transmission routes. The scoring system therefore depends on the weight of the question related to the biosecurity measure, and the more the question refers to direct contact with the disease or to the frequency with which a certain infection had the possibility of being transmitted, the more the weight of the score increases (Laanen *et al.*, 2013).

The weights given to the sub-categories are detailed in Table 1, and points are obtained when the biosecurity measure is applied correctly, or not performing a certain action (e.g., not buying breeding pigs). The sum of the points relating to each sub-category is 'weighted' accordingly (Laanen *et al.*, 2013).

To calculate the external or internal biosecurity score, the scores for each of the appropriate sub-categories are totaled to give a score between "0" (total absence of biosecurity) and "98" or "100" (respectively: perfect external and internal biosecurity) (Laanen *et al.*, 2013). The overall score is calculated as the mean of the external and internal biosecurity score (Laanen *et al.*, 2013). The scores for the different sub-categories are then re-calculated to scores between 0 and 98-100 to facilitate their interpretation by the farmers (Laanen *et al.*, 2013).

The Biocheck.UGent questionnaire is composed of all relevant components of biosecurity on pig farms and is subdivided into external and internal biosecurity. Subsequently, all measures that prevent the introduction of pathogens – through blocking the different pathways, breaking the infection cycle, or both – were filtered and grouped into several sub-categories of biosecurity (Gelaude *et al.*, 2014).

The scoring system is separated into two main categories, external and internal biosecurity, and comprises 109 questions on different biosecurity measures (Table 1). The questionnaire has been designed in such a way that the biosecurity management of the pig farm is questioned in detail without having an excessive number of questions. External biosecurity (66 questions) comprises all measures preventing the introduction of off-farm pathogens and is divided into 6 sub-categories, while internal biosecurity (43 questions) includes all measures that aim at preventing the within-herd spread of pathogens and is divided into 6 sub-categories too.

Table 1. Biocheck UGent questions and scoring weight

	N. of questions	Scoring weight
External biosecurity (A-B-C-D-E-F)	66	98
A. Purchase of breeding pigs, piglets, and semen	16	25
B. Transport of animals, removal of carcasses and manure	22	21
C. Feed, water, and equipment supply	7	15
D. Visitors and farmworkers	9	17
E. Vermin and bird control	6	10
F. Location of the farm	6	10
Internal biosecurity (G-H-I-J-K-L)	43	100
G. Disease management	4	10
H. Farrowing and suckling period	8	14
I. Nursery unit	6	14
J. Finishing unit	6	14
K. Measures between compartments, working lines and use of equipment	12	28
L. Cleaning and disinfection	7	20
Total biosecurity	109	198

By completing the questionnaire, a report is provided with the scores on the specific farm for each group of biosecurity measures. The livestock farm is always compared to the average farm in the world (based on all Biocheck.UGent data), and to a comparison with the national average and therefore a benchmark. Table 2 represent a worldwide and Italian overview of the internal and external biosecurity scores for each category of biosecurity measures related to industrial pig farms only. Surveys can be conducted continuously; a farm can be assessed multiple times in the case of training and coaching to monitor progress.

Table 2. Worldwide and Italian biosecurity averages based on all surveys representing the pig indoor herd (https://biocheckgent.com/en/worldwide)

	Worldwide	**Italy**
External biosecurity (A-B-C-D-E-F)	73%	74%
A. Purchase of breeding pigs, piglets, and semen	88%	91%
B. Transport of animals, removal of carcasses and manure	79%	84%
C. Feed, water, and equipment supply	47%	44%
D. Visitors and farmworkers	69%	65%
E. Vermin and bird control	77%	69%
F. Location of the farm	67%	68%
Internal biosecurity (G-H-I-J-K-L)	66%	70%
G. Disease management	73%	84%
H. Farrowing and suckling period	64%	66%
I. Nursery unit	67%	77%
J. Finishing unit	78%	83%
K. Measures between compartments, working lines and use of equipment	55%	56%
L. Cleaning and disinfection	71%	72%
Total biosecurity	70%	72%
Number of completed surveys	24461	423

2.4. The ClassyFarm surveillance system

The biosecurity protocol for pigs is regulated by ministerial decrees and at an international level, unlike that for cattle, which is developed based on international knowledge.

ClassyFarm is a project promoted by the Italian Ministry of Health through the General Directorate of Animal Health and Veterinary Drugs, aimed at developing an integrated system to monitor farms on the risks related to veterinary public health. The project is implemented by the Experimental Zoo-prophylactic Institute of Lombardy and Emilia Romagna (IZSLER) and is part of the Italian Veterinary Information System accessible from the National Veterinary Portal.

ClassyFarm originates from the mandates set by the EU Regulation 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules – repealed by the EU Regulation 2017/625, and the new "Animal Health Law" (EU Regulation 2016/429).

The Italian ClassyFarm checklist was developed in 2007-2008 to assess company risk, in accordance with the ministerial ordinance of 12 April 2008 and the ministerial decree of 1 April 2007.

ClassyFarm is also involved in monitoring the antimicrobial use in animal farming according to the new EU Regulations on veterinary medicines (Reg. 2019/6) and medicated feeds (Reg. 2019/4) coming into force from

January 2022, as well as in the monitoring of antimicrobial resistance in farms (Commission Implementing Decision 2013/652, repealed by 2020/1729).

ClassyFarm covers four main interconnected areas – animal welfare, farm biosecurity, slaughterhouse data, antimicrobials (AMU and AMR). The system evaluates farms' performance and can highlight best practices ad regards biosecurity, management, and farm structure (Holighaus *et al.*, 2023; Ventura *et al.*, 2021), addressing possible interventions for improving animal production, preventing animal diseases, and contrasting AMR spread.

The first version of the ClassyFarm surveillance system was made available to some public (national and local veterinary public health managers) and private stakeholders (farm veterinarians) in December 2017. The system underwent several updates and, in its current version, is also available to other stakeholders such as farmers, certification authorities, companies and supply chain managers.

ClassyFarm is a unit with specific mission and strategy, i.e., providing information to public and private stakeholders by collecting new data and processing existing information, to facilitate decision-making at different level of operation (production, technical advising, and public health management).

The ClassyFarm surveillance system can be described as in the Figure 5 information flows with respect to detection of animal welfare and biosecurity risks. Farm data are provided by:

- public animal health services veterinarians, who collect data on farm control on check list and injuries at the slaughterhouses in official farm controls
- private veterinarians of farmers voluntary participating in ClassyFarm are entered into the system, according to the Decree of the Minister of Health of the 7/12/2017. Private veterinarians collect data on biosecurity, animal welfare, parameters on animal health, nutrition and antimicrobial consumption
- ClassyFarm makes also use of data from the other databases of the National Veterinary Information System (VetInfo; https://www.vetinfo.it/).

Both public animal health service veterinarians and private veterinarians conduct inspections, input data into ClassyFarm, manage programming and coordination, and verify farm activities.

For farms that do not intend to voluntary participate, the ClassyFarm operates evaluations of veterinary public health based only on official control data and data from the National Veterinarian Information System.

Farm data are collected through checklists that are specific for official veterinary controls and the farm self-checking and are also different per animal species and livestock category. All the data available are converted, through scientifically validated coefficients, into numerical indicators measuring the current level of risk of the farm (e.g., AMR us calculated using a national indicator: DDDAit – defined daily dose animal for Italy), combining information from the veterinary prescription required (REV) and the national database of livestock registry (BDN).

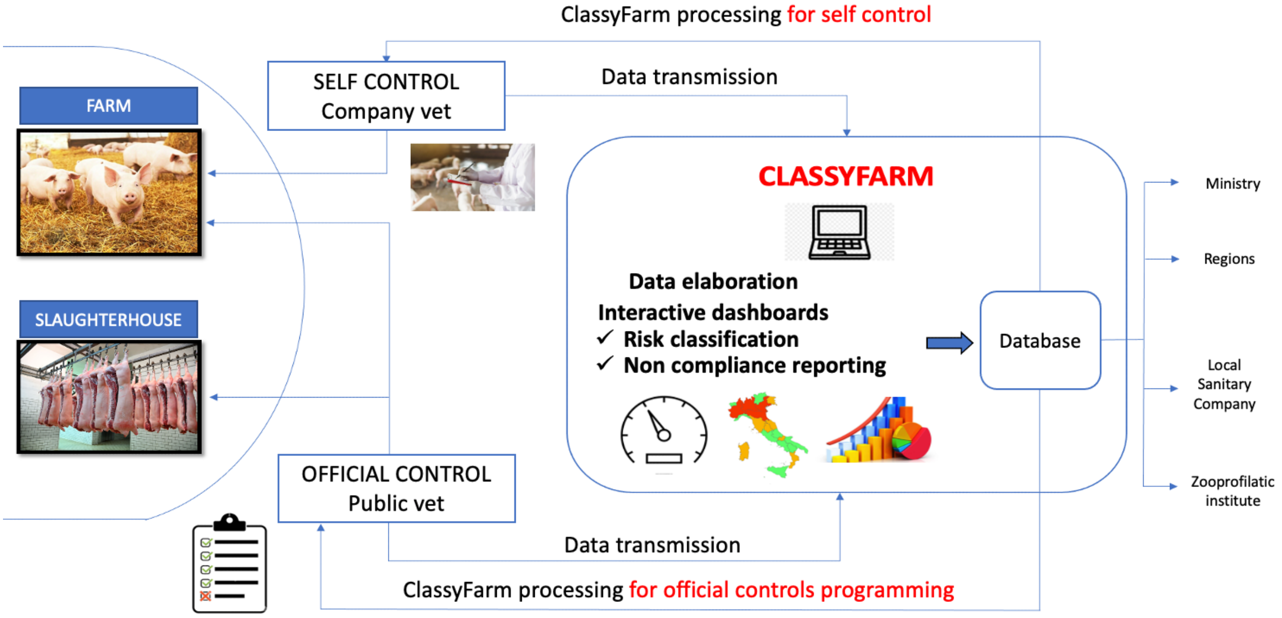

Figure 5. Visual representation of ClassyFarm within the system

The flow chart exemplifies the place and role of ClassyFarm in a system of relationships, which finally impacts public health. In this case, antimicrobial use (AMU) is observed, and some simplification of the system is adopted. The inner frame focuses on the technical process allowing ClassyFarm to comply with its mission (to provide information to public and private actors). Raw information supplied by farmers (here considered as managers of animal production units), duly processed and elaborated, supply the system with the typical ClassyFarm output (information) to the benefit of several units of the system: mainly policy makers and research organizations but also providing feedback to farmers themselves to improve animal health and reduce AMU. At a wider level, reduced AMU can benefit the environment and animal food safety, thus reducing the burden of disease related to antimicrobial resistance (AMR) humans (with related public and private costs).

ClassyFarm can be described as an information hub that integrates data from existing IT systems as well as ad hoc information provided by private and public institutions, including farm veterinarians, public health officials, and government agencies (Figure 6).

ClassyFarm virtual dashboards may show to farmers individual and aggregate information on the levels of farm risk allowing comparisons between each individual farm and its corresponding aggregates in terms of geographical areas, weighted (on heard size) mean, type of animal farming (e.g., fattening pig farms, dairy cow farms). Dashboards are in an advanced testing phase. Registered users can visualize farm data via dashboards created with Microsoft Power BI (Microsoft Corporation, Redmond, WA).

It is intended for public and private stakeholders. Furthermore, the categorization of the level of farm risk allows health authorities to plan more effective targeted controls and savings in the public health budget in terms or financial and human resources.

The role of the Zooprophylactic Institute is to elaborate, validate, update the checklist, and upgrade the manual.

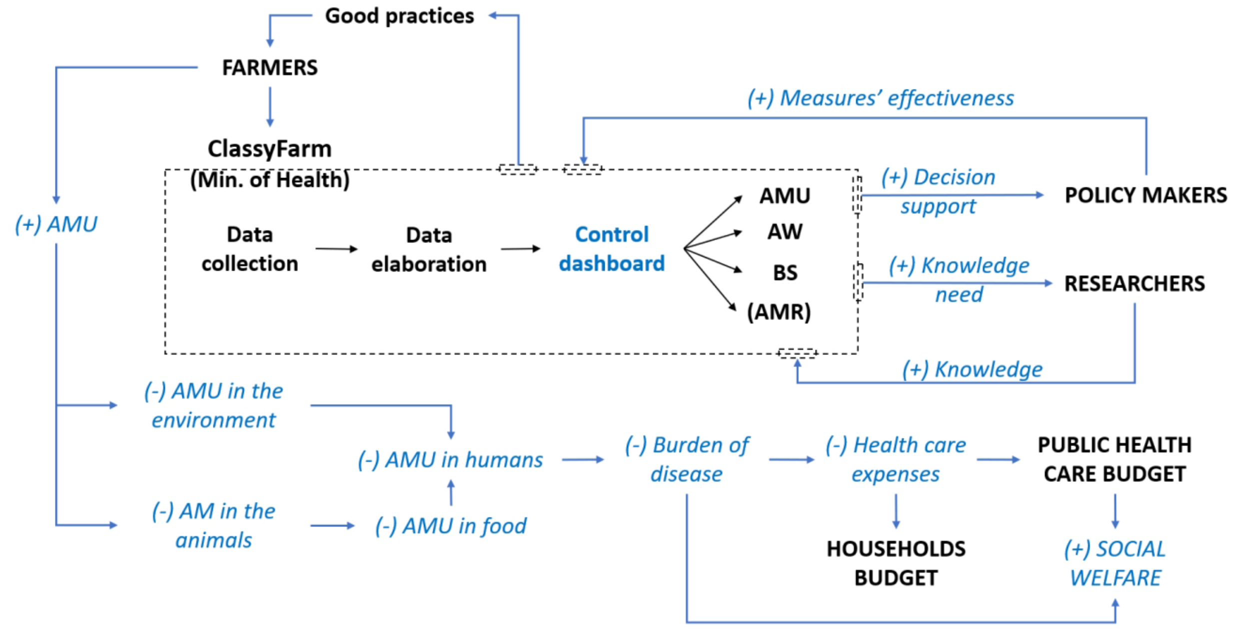

Figure 6. Visual representation of ClassyFarm as system hub

This figure focusing, in this case, the flux of information from and to the context where it operates. Besides the information from animal production, ClassyFarm is fed with data originating from Central and regional administrations and organizations of the public health system, namely VetInfo, IZS, ASL (local units of the National Health System). In turn, ClassyFarm's output is used by most of these organizations to optimize veterinary field controls and prospect general and targeted policy measures, with potential gains of effectiveness and efficiency. This reinforces the idea of ClassyFarm as an information hub placed within a complex health system, though making more complex the economic evaluation. AW: animal welfare; BS: biosecurity AM: antibiotics.

With the advancements of the European legislation on veterinary AMU traceability and AMR surveillance in farms and the food-supply chain, ClassyFarm is expanding its functions and is becoming the main tool for the systematic monitoring of antibiotic consumption in Italian farms, by processing data from the system of electronic veterinary medicine prescriptions already, active in Italy since April 2019 (Law 167/2017), and from the farm registry of farm veterinary treatments that will be mandatory in February 2022 (Legislative Decree 27/2021). Regarding AMR the ClassyFarm collect farm information from the antibiogram tests practiced in farms.

From the data from the ClassyFarm checklists, the swine farming sector presents the largest problems regarding the consumption of antibiotics in Italy. Taking also into account what is happening in other European countries, such as Denmark, Sweden, etc., there are margins for considerable improvements in the Italian swine sector that can be worked on and receive special attention.

The development of ClassyFarm is still ongoing, however, the PNCAR already uses it for monitoring AMU in farms and for veterinary pharmaco-surveillance. Recently, the Italian Ministry of Agriculture decided to use the ClassyFarm indicators to evaluate farm compliance with animal welfare and AMU standards required for the direct payments delivered to farms under the 2023-2027 EU's Common Agricultural Policy (CAP).

2.5. Italian swine production and supply chain

The shift from small, family-run farms to a large-scale pig farming industry had a significant acceleration beginning in the 1950s and 1960s. This period saw the industrialization of agriculture and the introduction of modern technologies, intensive livestock farming practices, and an increase in demand for meat products. In the United States and Europe, the phenomenon was influenced by a variety of factors, including changes in agricultural policies, urbanization, and changing dietary habits. Larger farms became increasingly common beginning in the 1970s and 1980s, thanks in part to globalization.

Biosecurity in livestock farming is a concept that emerged in the 1990s, although practices related to disease prevention in animals have existed much longer. In intensive pig farming began to gain attention in response to several outbreaks of infectious diseases affecting pig livestock. The crisis of African Swine Fever and other pathogens highlighted the importance of preventive measures to protect animal health and ensure food safety. Biosecurity guidelines and regulations developed further in the early 2000s, in response to outbreaks of diseases such as avian flu and ASF, with an increasing awareness on the One Health concept and zoonotic risks.

According to European statistics, Italy is among the countries making the most use of antibiotics in farms compared to the amount of livestock production. In this context, the swine sector, for the presence of many small individual farms scarcely integrated and predominant production of heavy swine destined to designated of origin dry-cured ham, shows non-negligible criticalities but also considerable margins of improvement.

In the past decade, the Regional Administration of Emilia-Romagna made a significant effort by issuing, as the first Region in Italy, in 2018, its Guidelines for the prudent use of antibiotics in swine farming. The Guidelines were also implemented by other Italian regions within the Interregional Coordination of Disease Prevention and Public Health with the approval of the Centre of National Reference for Antibiotic Resistance and the Ministry of Health.

In 2021, nearing the entry into force of the new European regulations on veterinary medicines and medicated feeds and the starting of the new cycle of the Common Agricultural Policy, which included the contrast to antimicrobials resistance in the agri-food supply chain among the priorities of the Farm-to-Fork Strategy.

The Project ROADMAP, in collaboration with the Emilia-Romagna Region, dedicated a Living Lab to the Guidelines, to evaluate their use in farms and possibly improve them with the institutional and private stakeholders that, in part, already participated to the design of the 2018 version.

According to Agricultural and Food Market Services Institute (ISMEA) data, in 2023, pork production will impact agriculture by 6.4% (Statistical National Institute – ISTAT data), and by 4.7% (cured meats) on the food industry (Federalimentare data).

According to data from the National Livestock Registry as of 12/31/2023, there are over 8.1 million pigs in Italy (Table 3), a decreasing trend compared to the previous year (-3.7%). Over 26 thousand farms are registered in Italy, mainly concentrated in the northern regions (Figure 7). Over the last five years, over 6,000 farms have exited the market (-19% between 2019 and 2023), accentuating a concentration process already underway. Lombardy is the main region involved in pig farming, with about half of the national herd located in its territory; followed in importance by Piedmont and Emilia-Romagna, with shares of 16% and 12% respectively.

Table 3. Main characteristics of the Italian swine supply chain

	2019	2020	2021	2022	2023
Pig farms [(1)] (n.)	32.469	31.687	30.228	28.824	26.461
Number of animals [(1)] (000 heads)	8.608	8.791	8.739	8.440	8.130
Slaughtered [(2)] (.000 heads)	11.469	11.214	11.385	10.659	9.884
Import (mln €)	2.395	2.146	2.063	2.592	3.406
Export (mln €)	1.806	1.890	2.125	2.179	2.321
Industry turnover (mln €)	8.160	7.915	8.200	8.470	9.127

[(1)] Excluding wild boars, family farms and zoos (Source: BDN National Zootechnical Registry); [(2)] Excluding wild boars; excluding deaths during transport and slaughter for health reasons (Source: BDN National Zootechnical Registry)

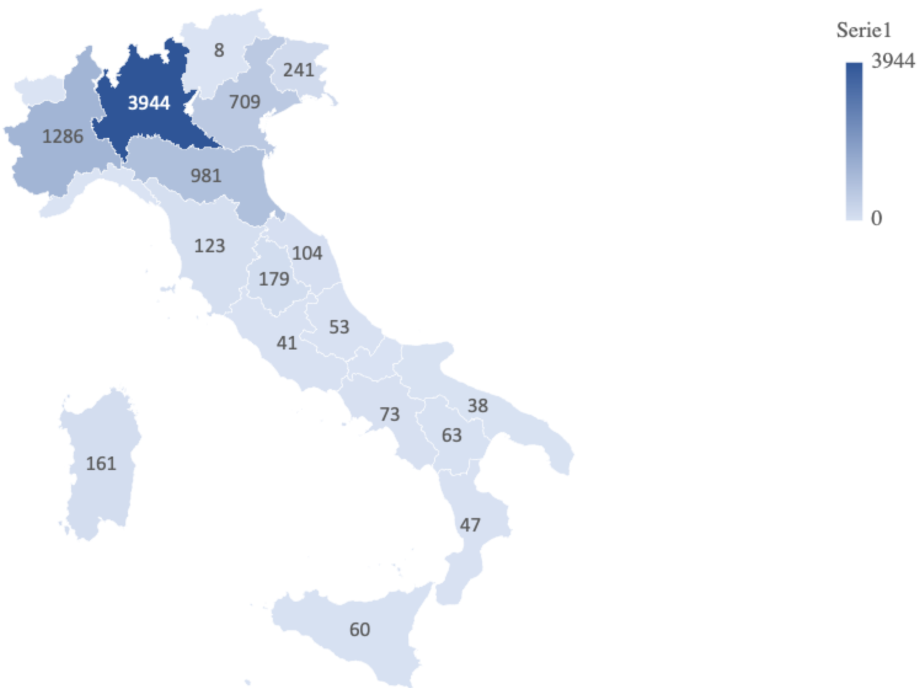

Figure 7. Pig heads in thousand (Ismea processing on National Livestock Registry data as of 12/31/2023)

The pig supply chain is quite long and complex and in detail (Figure 8):

- upstream of the supply chain, there are feed companies (420 companies) with a predominantly industrial connotation and able to meet about half of the demand. The upstream phase is characterized, then, by an increasingly widespread integration downstream with breeding companies, through sharecropping contracts.

- breeding companies are equal to just over 26.4 thousand. Based on the production orientation and production technique, two types of breeding can be distinguished:
   1. open cycle:
      a. reproduction phase: breeding in which boars and sows are kept for reproduction, pig weight <30kg intended for fattening (production area: Lombardy, Piedmont, Emilia-Romagna, and Veneto)
      b. fattening phase: breeding in which there are growing pigs, intended for slaughter or other fattening farms. A distinction is made between "full cycle" fattening, in which pigs are raised from weaning to slaughter, or "weaning" or "leaning" or "finishing" fattening if pigs are raised only for certain growth phases, light pig weight 100-110 kg intended for fresh meat, heavy pig 160-170 kg for the production of hams and cured meats (production area: Lombardy, Emilia-Romagna and Piedmont)
   2. closed cycle: in which all phases are carried out, the pig weighs 110-120 kg intended for fresh meat or cured meats (production area: Central-Southern Italy). The system that provides for an integrated production cycle in which the farms that are part of it are organized into three sites:
      a. site 1 (reproduction)
      b. site 2 (weaning)
      c. site 3 (finishing and fattening)
- the first processing companies are equal to approximately 3,000 units and the larger ones carry out both slaughtering and cutting activities in the strict sense and processing activities; they can be equipped with systems for packaging portions of fresh meat for sale on the shelf or for the preparation of raw or pre-cooked products. Furthermore, many of the slaughterhouses located in Northern Italy have also integrated downstream the seasoning phase of part of the hams that come from their own production lines
- the second processing companies produce 1.14 million tons of cured meats (excluding bresaola) with a turnover of over 9.1 billion euros
- the last link in the supply chain on the domestic market is represented by final distribution, divided between Retail, with the clear prevalence of Modern Distribution, and Ho.re.ca.

The Italian meat production chain is both vertically and horizontally integrated: vertically integrated means that a manufacturing company, by strategic choice, decides to integrate within its own business a greater number of "intermediate steps" that are necessary to obtain the finished product. In the Italian case, the company that supplies animal feed decides to vertically integrate several pig farms, whether they are open-cycle or closed-cycle (reproduction or fattening) and then take them to the slaughterhouses and sell them. With horizontal integration, on the other hand, we mean a series of companies that operate in the same sector united by the same production cycles or processing phases or even production technologies, this is the case of the feed company that does not operate with just one farm, but with several farms.

Furthermore, some breeders decide to stipulate sharecropping contracts where an associative agricultural company is established between the person who has the livestock and the person who must raise it.

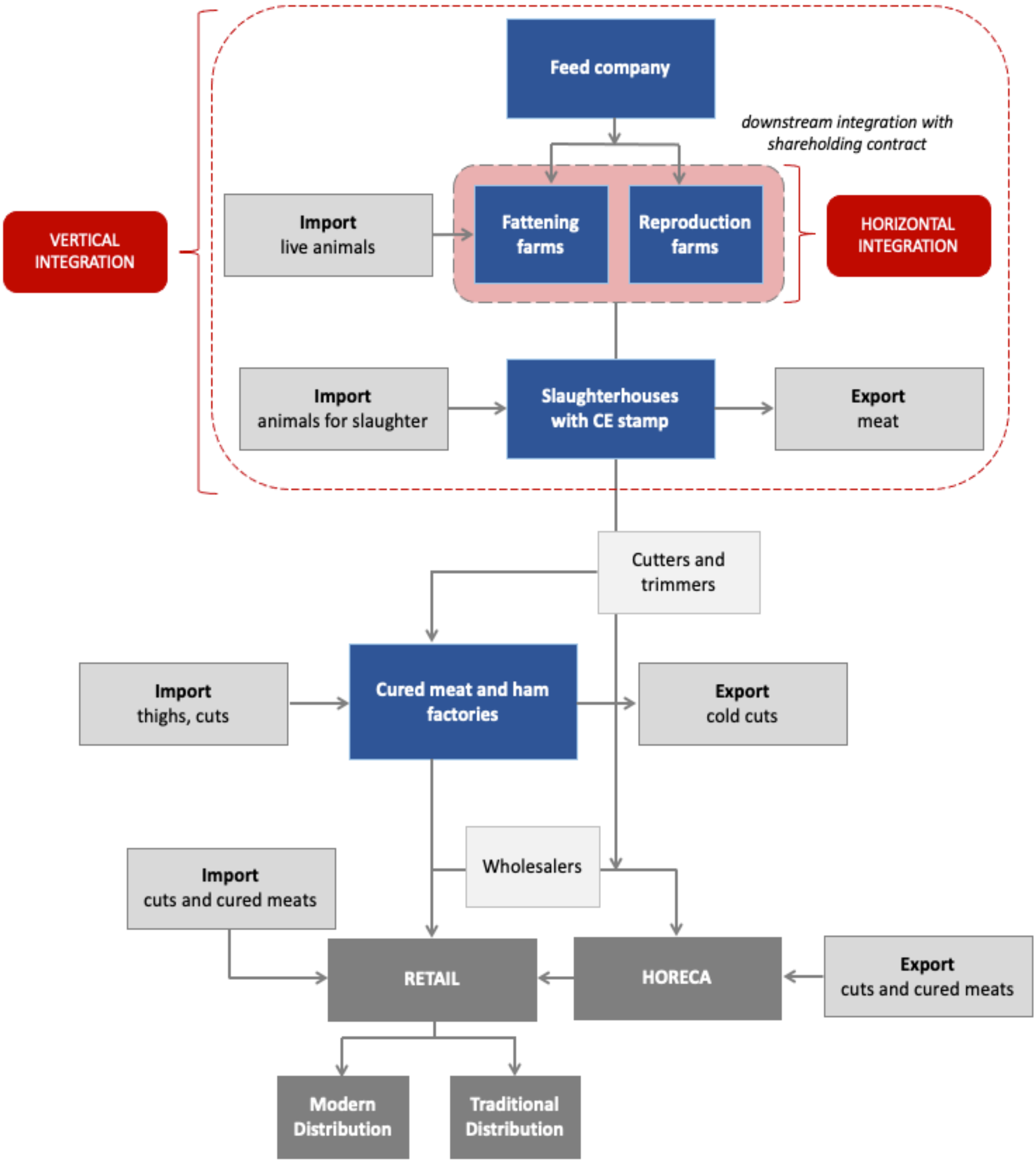

Figure 8. The actors of the swine supply chain in Italy (Ismea Mercati and own processing)

3. Systematic Literature Review on the economic sustainability of biosecurity measures

In this chapter are presented the materials, methods, data collection, results and discussion of the study conducted using an SRL, and is an ongoing publication.

The study addressed the following research questions:

RQ1. Is the economic sustainability of biosecurity measures an emerging topic in pig farming research?

RQ2. How does economic sustainability affect biosecurity at the farm level?

Two primary outcomes were achieved: first, to assess the relevance of the topic in current research, highlight publication trends, and track the evolution of biosecurity-related concepts; and second, to identify research gaps specifically concerning the economic costs of implementing biosecurity in pig farming.

3.1. Materials and methods

Systematic literature review has been widespread since 1980 and is used as a secondary scientific research tool, that is, it is based on data already available. Fink, 2020 provides the following definition: "A literature review is a systematic, explicit, and reproducible design for identifying, evaluating, and interpreting the existing body of recorded documents".

The aim of the SRL is to summarize primary research data through an in-depth analysis and a synthesis of a given topic. It involves gathering data from individual studies, using a wide range of bibliographic sources, with particular emphasis on high-quality references. The process follows a systematic approach that allows to identify, evaluate, and interpret all the relevant evidence, ensuring a complete and rigorous analysis of the scientific problem in question.

Its importance lies in the contribution it can make to the progress of research. According to Mentzer, John T. and Kahn, Kenneth B., 1995, it can summarize past discoveries and outline a historical framework on the topic of study under examination. In this sense, it reproduces a synthesis of the state of the art in the specific disciplinary sector concerned and for the question under examination.

With the use of SRL, it is therefore possible to:

a) map the state of the art: analyze and summarize what has been done in previous studies

b) identify gaps in research: identify areas in which it would be necessary to develop further studies

c) provide suggestions for future research.

The statistical technique called meta-analysis can be combined with SRL, which reproduces a synthesis of the quantitative results presented in individual studies, the objective of which is to support the solidity of scientific evidence. Sometimes scientific communities use the terms SLR and MA as synonymous, while other times it is preferred to identify MA as the quantitative analysis of a SLR.

The methodological approach just described cannot always be easily applied in all research fields due to the different characteristics of scientific questions. The approach varies from others in its transparency, inclusiveness and explanatory and heuristic character (David Tranfield *et al.*, 2003).

For an SLR to be valid, it must be comprehensive, meaning it includes all necessary and appropriate elements to ensure integrity; transparent and reliable, meaning it is clear and free from bias or deception; and reproducible, allowing others to obtain the same results by following the defined criteria (Xiao and Watson, 2019). Therefore, the steps used to select the studies for analysis must be clearly outlined (Seuring and Gold, 2012).

For this reason, compared to other types of literature review methodologies, SRL allows for a more objective overview of research findings and minimizes problems of bias and error, reordering and classifying existing studies, facilitating theory development, and proposing areas for further investigation (Webster, J. and Watson, R. T., 2002).

As specified by Tranfield *et al.*, 2003, the SLR consist of three stages: planning, conducting, reporting e dissemination (Figure 9).

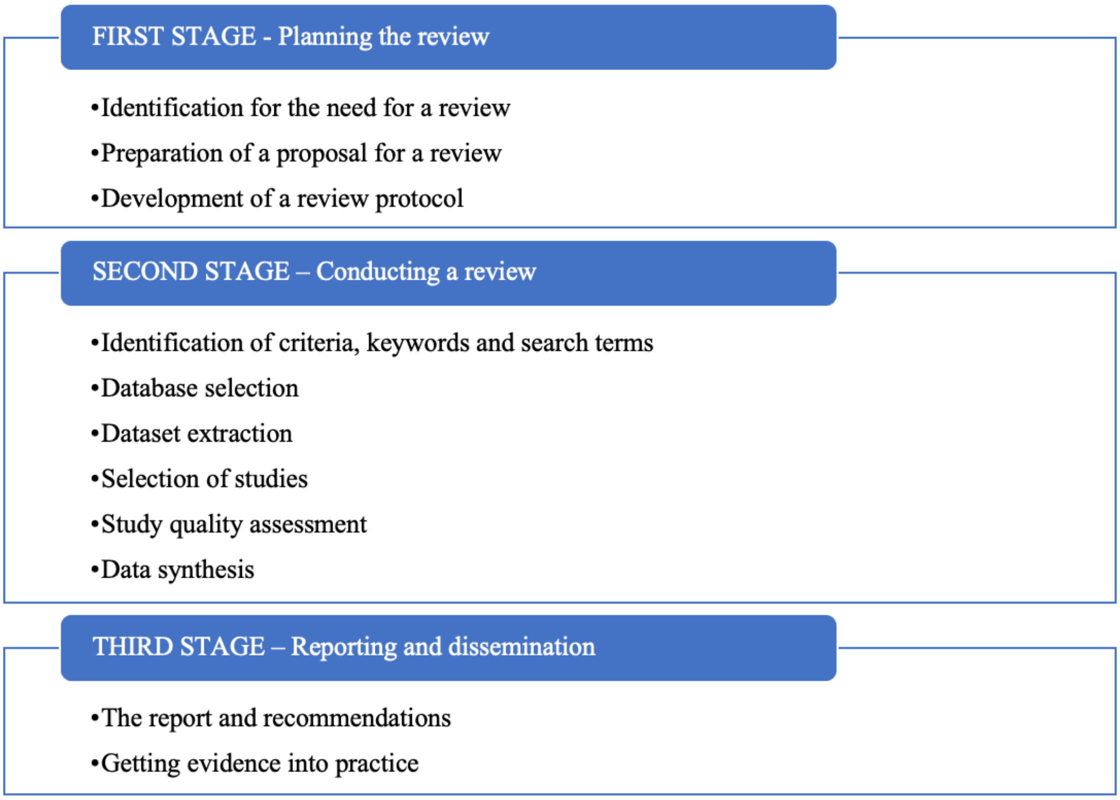

Figure 9. Stages of a systematic review (Tranfield et al., 2003)

The first step in carrying out the literature review involves an initial planning stage, where a panel of experts in the areas of both methodology and theory around a research field is created to identify the need for a review.

This is an iterative process that considers various ways of approaching a research topic, the research topic is chosen, the problem is defined, and research questions are formulated to be explored. This stage then leads to the proposal for a review including a brief parenthesis of the historical theoretical, practical, and methodological debates surrounding the field of study. In the planning phase, a review protocol is also developed, a plan that outlines the key steps to be undertaken during the SLR and includes the study objective, search strategy, and criteria for inclusion and exclusion of studies in the review (Paul and Barari, 2022).

The review process continues with the second phase, that is, conducting the review, in this step it is necessary select the right databases, that must be at least two, to have a comparison between the studies that are sift through. Next step is to identify the keywords and search terms, which are derived from the first phase. To ensure the search can be replicated, it is crucial to define clear inclusion and exclusion criteria. Searches should not be limited to studies listed in bibliographic databases but also include unpublished studies, conference proceedings, patents, and online sources. Systematic reviews use data extraction forms to minimize human error and bias. These forms typically capture key information such as the study title, author, publication details, as well as study characteristics and specific details (e.g., methods and outcomes). Data extraction forms serve as historical records and data repositories on which the analysis is performed.

At this point the database extracts and incorporates into the review only those studies that meet the inclusion criteria. The study selection process continues using the PRISMA approach, which incorporates other sub-phases described in Figure 10.

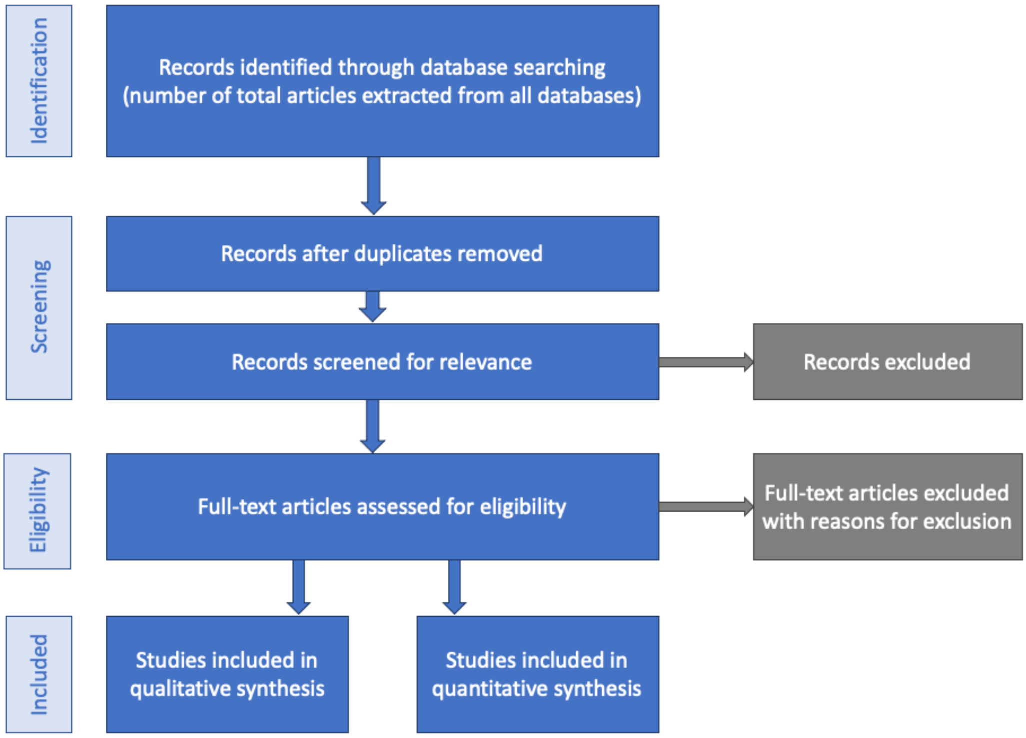

Figure 10. The PRISMA flow diagram, depicting the flow of information through the different phases of a systematic review

The use of PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analyses) allows a better evaluation of the quality of the study and guarantees transparency in the selection process in a systematic review. In fact, in case of exclusion of studies, the motivation is always accompanied.

Finally, data synthesis is the last stage of conducting the review, which includes methods to summarize, integrate and cumulate the results of different studies on a topic or with respect to the research question that was formulated during the first stage (Mulrow, C. D., 1994). In this space may reside the meta-analysis, which is an approach to synthesis, which allows to pool the data of individual studies, leaving room for an increase in statistical consistency and more precise estimates (Glass, G. V., 1976). In any case, it is unlikely that the meta-analysis is appropriate for every field of research because few are the studies that address the same research question and that measure the phenomenon in the same way. Instead, meta-synthesis does not simply synthesize closely comparable studies, but builds interpretations, reveals similarities and differences in concepts, methods, and other ideas around a target experience (Noblit, G.W. and Hare, R.D., 1988; Sandelowski, M. *et al.*, 1997). The stage of reporting and dissemination aims at using systematic reviews as the *recommendations* provided by research to inform the decisions of practitioners. Since decision-makers are likely to rely on personal experience and skills rather than use exclusively the results of systematic reviews, turning the latter into guidelines for practice represents a challenge (Bero, L. and Rennie, D., 1995; Rosenberg, W. and Donald, A., 1995). Improving the translation of research evidence into practice is not easy because the relationships between research, knowledge, policy and practice are always likely to remain loose, shifting and contingent (Nutley, S. M. and H. T. O. Davies, 2002).

To address RQ1 and RQ2, the current study employs a three-step methodological approach: first, a bibliometric analysis that uses quantitative methods to map and evaluate research topics, publication trends, and leading journals; second, a network analysis to explore research themes, keywords patterns, and cluster; and in conclusion, a content analysis to summarize and identify key themes in literature, while also to highlighting research gaps, in line with Fahimnia *et al.*, 2015 and Qaiser *et al.*, 2017.

The present review has been performed adapting the guidelines proposed by Tranfield *et al.*, 2003 and synthesize the state of the art, identifying gaps in the analyzed field (Figure 11).

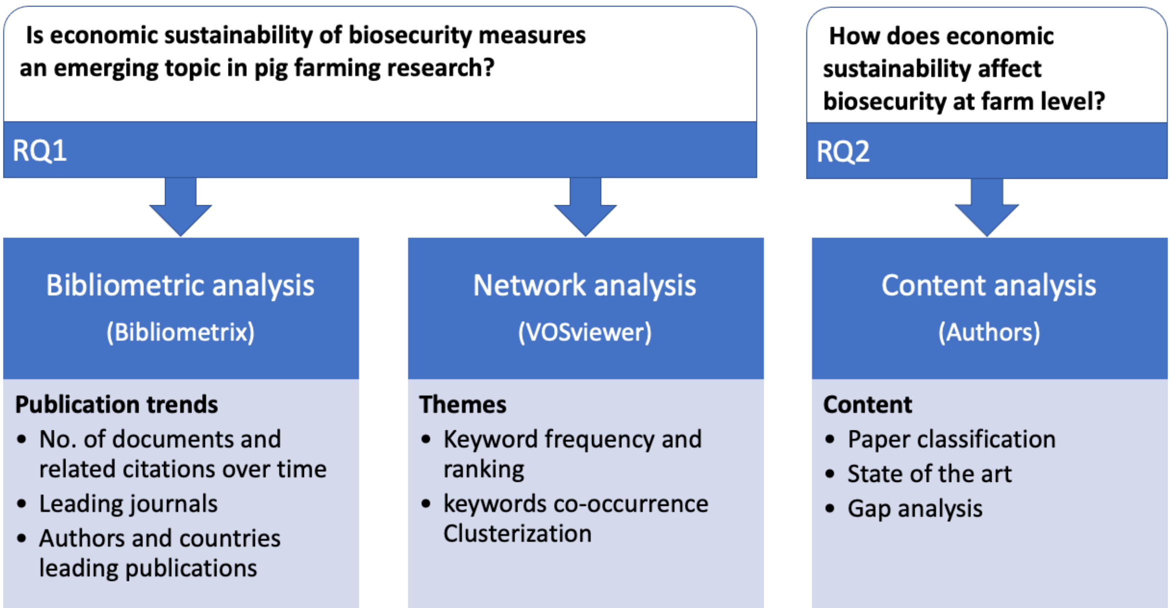

Figure 11. Research design and methodological framework for the SLR

3.2. Data collection

In this study, the PRISMA methodology and guidelines were applied to select relevant papers through a systematic process of identification, screening, eligibility, and inclusion evaluation (Agnusdei and Coluccia, 2022). The articles included in the review were published between 1995 and 2023, despite the relatively recent emergence of the concept of biosecurity. Document extraction was conducted using Scopus, and then collected in an Excel format.

During the identification phase, three distinct groups of keywords were used. Group A encompasses the keywords related to animal species, Group B included keywords from the economic research field, and Group C consisted of biosecurity-related terms (Table 4). The three groups of keywords were combined using the Boolean operator "AND", while within each group, the keywords were linked using the Boolean operator "OR" to account for variations and synonyms within each category.

Table 4. Identification and grouping of keywords

Group A – Animal species	Group B - Economic	Group C
pig	economic	biosecurity
swine	loss	biocheck
porcine	impact	
	cost	
	benefit	
	budget	
	investment	
	management	

The database query was conducted on November 22, 2023. Documents were filtered based on subject area, language, and source types, following the search protocol outlined in Table 5.

Table 5. Search protocols for databases

Subject area	Veterinary Agricultural and Biological Sciences Immunology and Microbiology Medicine Biochemistry, Genetics and Molecular Biology Multidisciplinary Environmental Science Social Sciences Engineering Chemical Engineering Pharmacology, Toxicology and Pharmaceutics Economics, Econometrics and Finance Earth and Planetary Sciences Business, Management and Accounting
Language	English
Source types	Journal Conference proceedings

The extracted data included citation details (e.g., authors, documents title, affiliations, publication year, and citation count), along with abstracts and indexed keywords.

Duplicate documents, those with incomplete information, or those deemed irrelevant to the topic were excluded from the final dataset. A total of 586 documents were ultimately selected for analysis. All eligible documents were included in the sample for the bibliometric and network analyses, while a separate selection process was conducted for the content analysis. Three authors independently and thoroughly reviewed all the documents to avoid reading bias and selected the articles that each of them considered to be included in the content analysis. Subsequently, after a critical appraisal of the selected articles, an agreement was reached between all the authors regarding the inclusion/exclusion of the papers. As a result, 25 studies were identified as directly related to the economic aspects and cost analyses of biosecurity in the swine supply chain and considered for the content analysis (Figure 12).

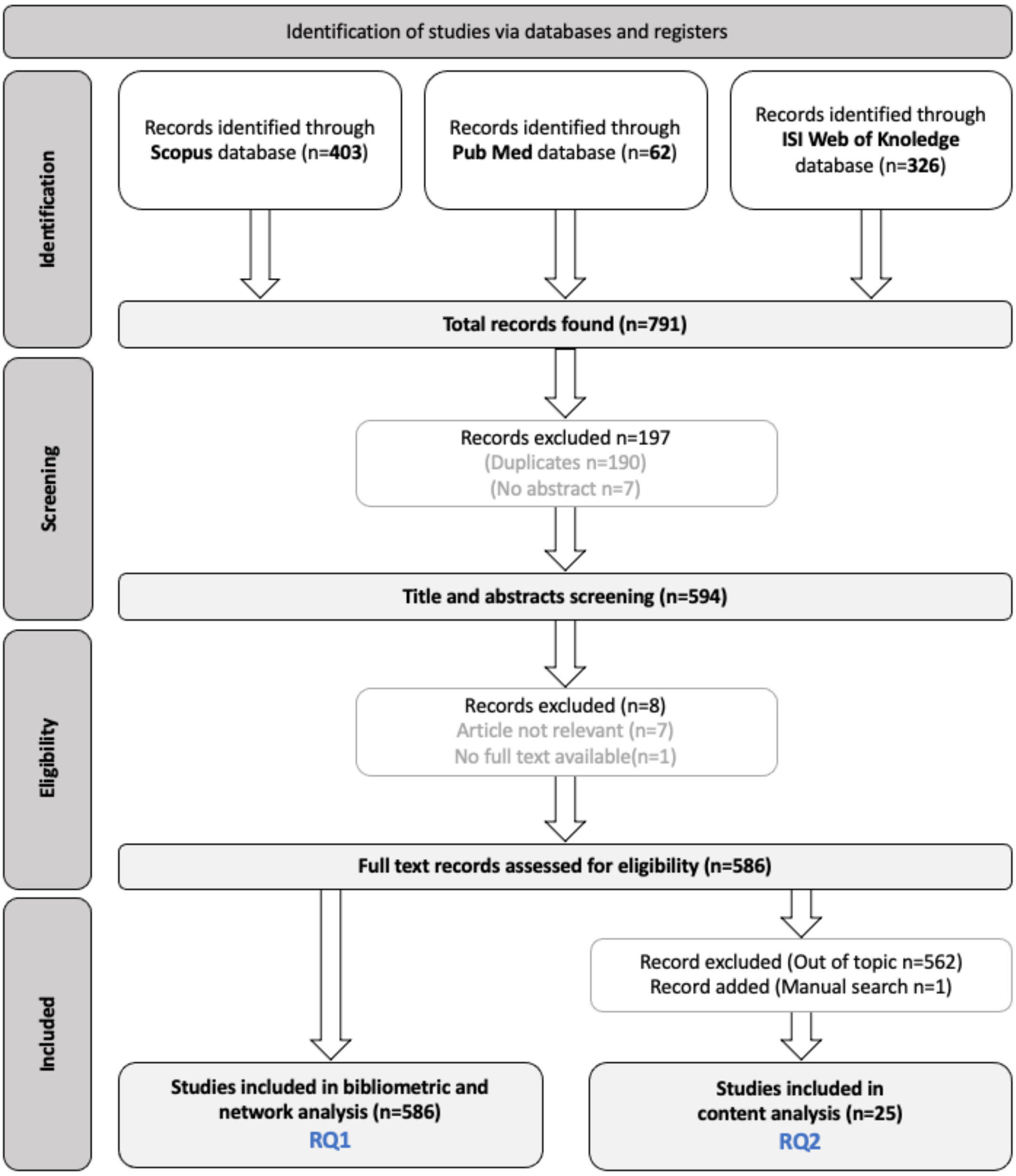

Figure 12. Selection of studies to be included in the systematic review

To address RQ1, a bibliometric and network analysis were conducted, while RQ2 was answered through content analysis (Figure 11).

For the bibliometric analysis, documents obtained from Scopus in .csv format were imported into R software and transformed into a bibliographic data frame. The analysis included assessing annual scientific production, annual percentage growth, average citations per year, document types, most prolific authors, prominent journals, and top countries for citations and document count.

The network analysis was performed by using VOSviewer 1.6.14 software. For this aim, the most relevant index keywords were identified, in order to define the documents associated with a topic. The network analysis consists of a keyword co-occurrence analysis, that show graphically the link between each keyword.

Specifically, the full counting method – which assigns equal weight to each co-occurrence – was used to conduct the co-occurrence analysis of the index keywords. The number of documents in which two index keywords occur together was used to determine the relatedness of the keywords.

13,548 total index keywords were chosen, and off-topic keywords were eliminated. The keywords with at least 10 occurrences were included. The network visualization of 192 keywords extracted, showed the weight of the keywords as represented by the circle's dimension, the relationship between two words as shown by the lines (thicker lines indicate stronger word connections), and the research clusters to which the index keywords belong as indicated by the various colors (Waltman *et al.*, 2010). According to Eck and Waltman, 2009; Waltman *et al.*, 2010, the layout was constructed by normalizing the strength of the links between the elements using the association strength method.

For the content analysis, four criteria were identified to classify the documents to investigate the economics sustainability of biosecurity at farm level: (i) supply chain phase, (ii) disease, (iii) epidemiological study types, (iv) economic impact of biosecurity.

Based on the supply chain phase criterion, documents were attributed to the following categories:

- *farrow-to-finish*, referring to studies that considers biosecurity aspects in the entire life cycle of swine production, from breeding and farrowing to finishing and market readiness
- *farrow-to-wean*, referring to studies that consider biosecurity aspects focus on breeding and farrowing, producing piglets that are then weaned and sold to other producers for further growth and finishing
- *finisher*, referring to studies that consider biosecurity aspects from the post-weaning stage to market weight, optimizing the swine growth and health for meat production.

The diseases criterion refers to the illness of swine considered in the studies. This classification criterion is relevant, because the economics aspects of biosecurity may vary depending on different disease that require different measure to prevent and manage. The identified diseases are:

- African Swine Fever (ASF)

- AMU-AMR
- Campylobacter infection
- Classical rabies
- Classical Swine Fever (CSF)
- General animal health status
- Porcine Epidemic Diarrhea Virus (PEDV)
- Porcine Reproductive and Respiratory Syndrome (PRRS)
- Foot and Mouth Disease (FMD)
- Post-weaning Multi-systemic Wasting Syndrome (PMWS)
- Porcine Circovirus type 2 Subclinical Infection (PCV2SI)
- Salmonella
- Toxoplasmosis.

The documents were organized also according to the epidemiological study types:

- case-control studies that investigate associations between individuals with a specific condition (cases) and those without it (controls) by analyzing past exposures, often used for rare disease
- cross-sectional studies that collect data at a single point in time to provide a snapshot of a population, evaluating the prevalence of a condition or exposure and identifying correlations between variables
- case-studies that analyze individual cases, groups, or situations, offering detailed information to gain comprehensive insights
- modeling and simulation studies that use of mathematical, statistical, or computational models to simulate complex phenomena and predict outcomes based on different variables
- reviews that make systematic evaluations of existing research on a specific topic, summarizing evidence and identifying gaps or new directions
- surveys as a tool for gathering data through direct questions to a sample population, aimed at understanding opinions, behaviors, or trends within a given group.

Finally, the documents were categorized according to the economic impact of biosecurity measures assessed:

- economic impact of biosecurity structural measures and procedures
- economic impact of biosecurity based on geographic region.

Each document was reviewed and classified to according to the four criteria abovementioned.

3.3. Results

The bibliometric analysis reveals the results of the annual scientific production in the field (Figure 13) showing a notable increase in published documents, particularly over the last five years. Table 6 summarizes the key bibliometric results. Findings indicate that the economic aspects of biosecurity within the swine supply chain are gaining increasing attention, with growing interest from both researchers and practitioners.

The extracted and analyzed sample consists of 586 documents. 2679 authors contribute to publish the documents in 193 different journals. The average citation level per document is equal to 20.75 and average annual publications growth rate is equal to 13.89% for the years from 1995 to 2023. The first study within research field was published in 1995 and in the following years, until 2007, the number of published documents was very low, with a maximum of 4 documents per year. From 2008 to 2019 there has been a constant increase in the number of published documents. In 2022 it has been registered a peak, with 99 published documents and an increase of 55% compared to the previous year. Also, for 2023 it is confirmed the growing interest trend to the field.

Table 6. Main results of bibliometric analysis

Main information data	
Documents	586
Sources (Journals)	193
Keywords Plus (ID)	3548
Author's keywords (DE)	1511
Timespan	1995 - 2023
Average citations per document	20.75
Authors	2679
Author appearances	3609
Documents per author	0.223
Co-Authors per document	6.04
International co-authorship	34.95%
Annual percentual growth rate	13.89%

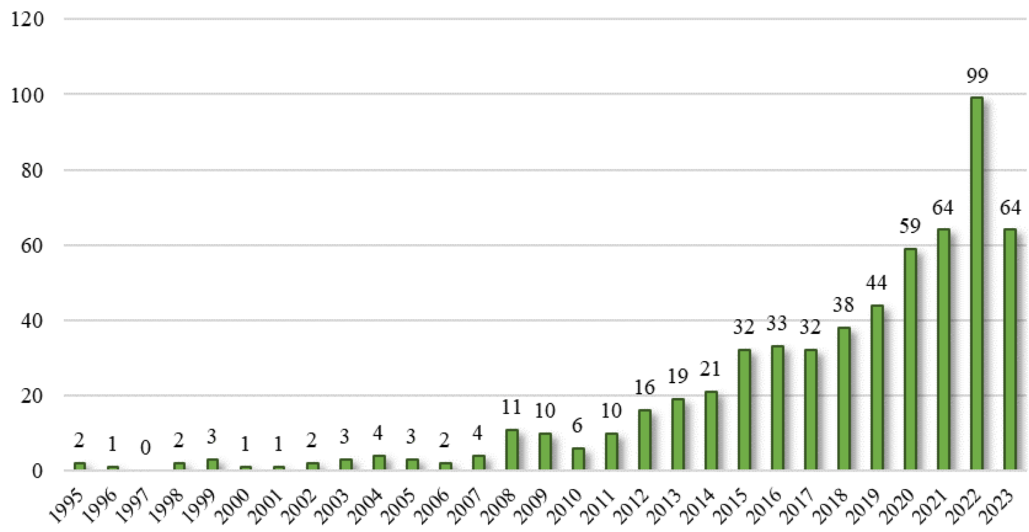

Figure 13. Annual trend in the number of publications

The top ten leading journals in terms of published documents are shown in Table 7. All the listed journals focus on veterinary medicine and animal health related topics. Preventive Veterinary Medicine is the journal in which the most documents are published (83), followed by Frontiers in Veterinary Medicine (43) and Transboundary and Emerging Diseases (36). The abovementioned journals focus on animal disease prevention strategies and explore interspecies transmission risks. Porcine Health Management (26) specializes in porcine health. There is not a specific journal specialized on economics aspects of animal biosecurity and this factor underlines that the topic is not yet fully explored and investigated.

Table 7. Leading journal for number of published documents

Journal	Publisher	No. documents	Quartile	Impact Factor
Preventive Veterinary Medicine	Elsevier	83	Q1	2.6
Frontiers in Veterinary Science	Frontiers	43	Q1	3.2
Transboundary and Emerging Diseases	Wiley	36	Q1	4.5
Porcine Health Management	Springer	26	Q1	3.6
Animals	MDPI	18	Q1	3.0
Plos One	PLOS	15	Q1	-
Pathogens	MDPI	13	Q2	3.7
BMC Veterinary Research	Springer	12	Q1	2.9
Veterinary Microbiology	Elsevier	11	Q1	3.3
Journal of Swine Health and Production	AASV	10	Q3	-

The journals quality is not very high, in fact the Impact Factor (IF) (referred to year 2022) never exceed 4.5, even if the majority of journals are positioned in the first quartile (Q1) highlighting their relevance.

Table 8 presents the top seven authors with the highest document output (at least 10 published documents) in the analyzed research field, along with their productivity assessed by the H-index.

The H-index, an author-level metric, gauges both the productivity and citation impact of publications by considering the ordered list of the researcher's most cited papers and the number of citations received in other works (Garousi and Fernandes, 2017; Simoes and Crespo, 2020).

Table 8. Top authors for number of published documents in the field

Author	Affiliation	Publications on the topic	H-index
Dewulf J.	Universiteit Gent (Belgium)	24	62
Maes D.	Universiteit Gent (Belgium)	14	54
Postma M.	Universiteit Gent (Belgium)	13	20
Chenais E.	Statens Veterinärmedicinska anstalt (Sweden)	10	16
Poljak Z.	Ontario Veterinary College (Canada)	10	24
Sjölund M.	Statens Veterinärmedicinska anstalt (Sweden)	10	17
Stärk K.D.C.	Royal Veterinary College University of London (United Kingdom)	10	44

In Table 9 are listed the most productive countries in terms of published documents in the field of research. Authors affiliated with United States universities represent an outlier with 106 documents. In fact, the biosecurity standards in United States are very high (Moore *et al.*, 2008). Then, Australia, United Kingdom and Belgium register a relevant number of published documents.

Table 9 also provides information on the count of published documents authored exclusively by individuals from a single country (Single Country Publications) or by authors from different countries (Multiple Country Publications). Sweden is the country with the highest percentage of inter-country collaboration (60%), followed by Belgium (43.4%).

Table 9. Top 10 most productive countries based on the number of published documents and citations

Country	**No. documents**	**Single country publication (SCP)**	**Multiple country publications (MCP)**	**MCP ratio**
United States	106	73	33	33.1%
Australia	31	21	10	32.3%
United Kingdom	31	19	12	38.7%
Belgium	30	17	13	43.4%
China	25	21	4	16.0%
Italy	24	17	7	29.2%
Canada	21	17	4	19.0%
France	21	16	5	23.8%
Sweden	20	8	12	60.0%
Spain	17	12	5	29.4%

The network analysis was performed on 192 keywords extracted from the documents. The frequency of index keywords was tallied to generate a ranking, and the results are presented in Table 10. Among the top ten Keywords-Plus (ID), "Animal" emerged as the most recurrent keyword, appearing 327 times. Notably, several keywords in this ranking are associated with swine, such as "Pig," "Swine," "Swine disease," "African swine fever," and "Pig farming." This underscores the significance of the context related to the transmission of diseases within the pig sector.

Table 10. Top 10 most frequent index keywords in the analyzed research field

Articles keywords-plus (ID)	**Articles**
Animal	327
Pig	306
Swine	293
Swine disease	186
Animal husbandry	159
Biosecurity	140
African Swine Fever	126
Risk factor	125
Epidemic	107
Pig farming	89

Figure 14 depicts a network visualization showing the co-occurrence of keywords from 1995 to 2023. The analysis considered keywords that appeared together in a minimum of ten documents. The closeness and thickness of the lines connecting two keywords convey the frequency of their co-occurrence, while the size of a node reflects the frequency of its occurrence as a keyword (Donthu *et al.*, 2021; Strozzi *et al.*, 2017).

The network analysis points out four clusters of connected topics: swine health and virology (red cluster), public health and food safety (green cluster), animal disease management (blue cluster), epidemiology and disease studies (yellow cluster).

The red cluster, named “swine health and virology” (60 items), refers to studies focused on veterinary virology and swine health. The keywords in this cluster refer to various aspects, including virus identification, diagnosis, genetics, immunology, and swine diseases. "Virus detection", "virology", "virus infection", "virus transmission" indicate the centrality of viruses in the research field.

The green cluster, named “Biosecurity and socioeconomic impact in swine farming” (55 items), refers to studies that emphasizes the role of biosecurity in safeguarding food safety and preventing contamination in swine products. The presence of "socioeconomics" and "agricultural worker" highlights the economic and social aspects of swine farming, suggesting an interdependence between disease management, biosecurity, and the economic well-being of farmers and industry operators.

The blue cluster, named “animal disease management” (52 items), refers to studies concerning on management aspects of animal diseases. Key terms such as "Suidae," "animal husbandry," "infection control," "disease outbreaks," and "attitude to health" indicate a connection between swine disease management, infection control, and the operators' approach to animal health.

The yellow cluster highlighted in yellow is named “epidemiology and disease studies” (25 items), refers to centered on the epidemiology of animal diseases, with particular attention to infections such as "salmonella", and "swine disease". The keywords in this cluster focus on understanding the spread of swine diseases, identifying risk factors, and analyzing prevalence through epidemiological and diagnostic approaches. This information is crucial for evaluating the economic impact of biosecurity in pig farming, directly influencing livestock health and pork production.

In general, each cluster seems to be centered on a specific aspect of animal health, from scientific research and virology to disease management, agricultural administration, and epidemiology.

Observing the overlay visualization of keyword co-occurrence in Figure 15, it emerges a high concentration of published documents in the last five years. Furthermore, animal biosecurity has emerged as a key issue due to the heightened awareness of health, environmental, and economic risks associated with animal diseases, especially in a context of increasing globalization and interconnection between economies.

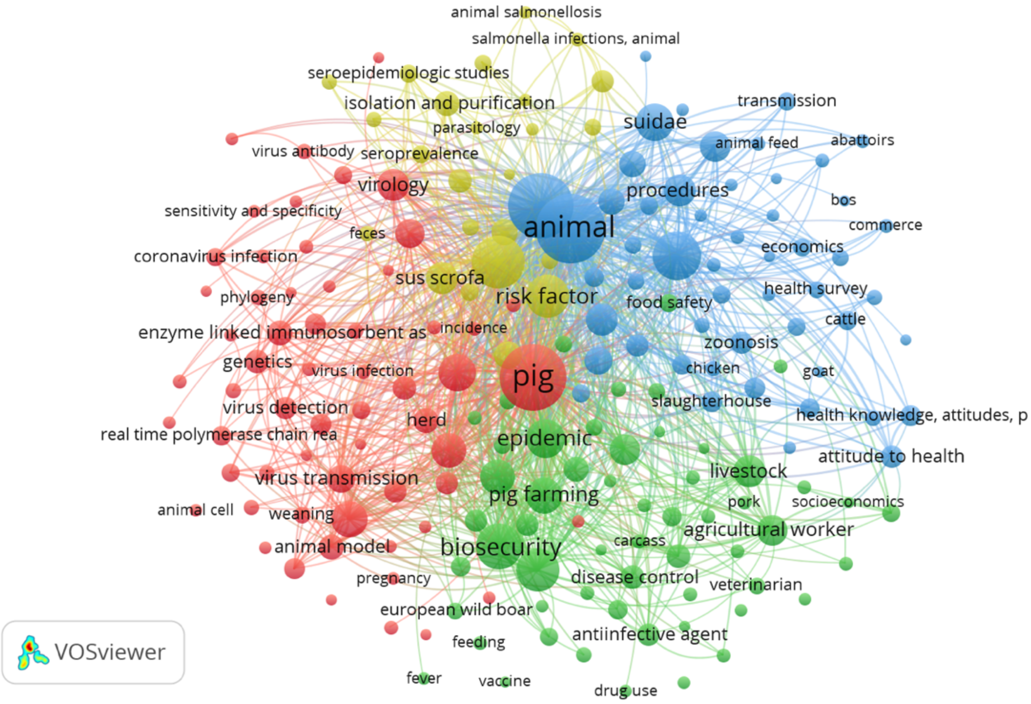

Figure 14. Network visualization of keyword co-occurrence analysis

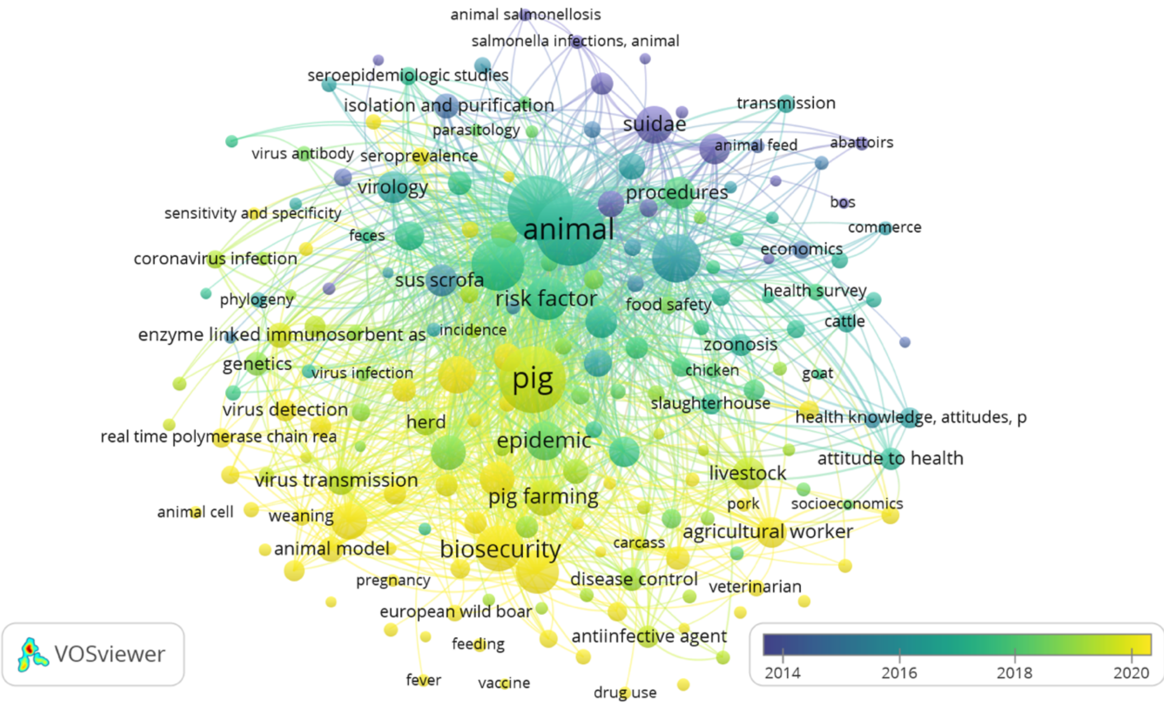

Figure 15. Overlay visualization of keyword co-occurrence analysis

A total of 25 papers were selected for the content analysis, and a classification system was developed to summarize and identify key themes in the literature. These papers were chosen for their presentation of quantitative data on the economic aspects and cost analyses of biosecurity.

The papers were grouped based on supply chain segment, study design, disease type, biosecurity structural measures and procedures, and geographic region. These groups have been adopted to divide the results into the following subsections and to present them in a way that reflects the relevant characteristics of the research field and highlights the contributions of the economic aspects of biosecurity.

For the supply chain classification (
Figure 16), three categories emerged: farrow-to-finish, farrow-to-weaning, and finisher. Among the selected papers, 78% focused on the farrow-to-finish category, 13% on farrow-to-weaning, and 9% on finisher operations. The higher percentage of studies on farrow-to-finish operations reflects the fact that farms covering all stages of pig growth are more common.

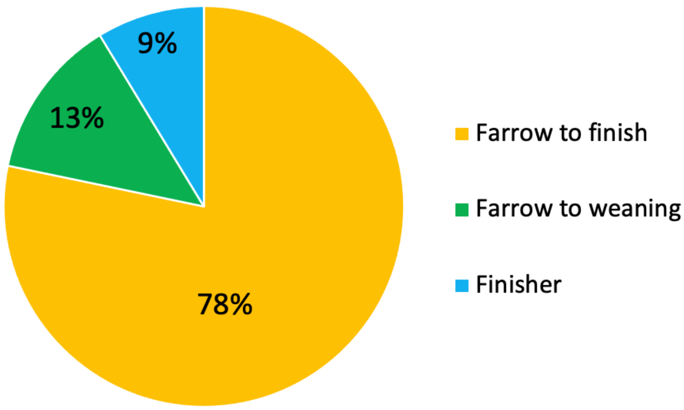

Figure 16. Classification of the papers based on supply chain

Regarding study design, 33% of the papers employed a cross-sectional approach, 29% conducted case studies, 21% used modeling and simulation, and 8% applied a case-control design. Review and survey papers each represented 4% of the sample (Figure 17).

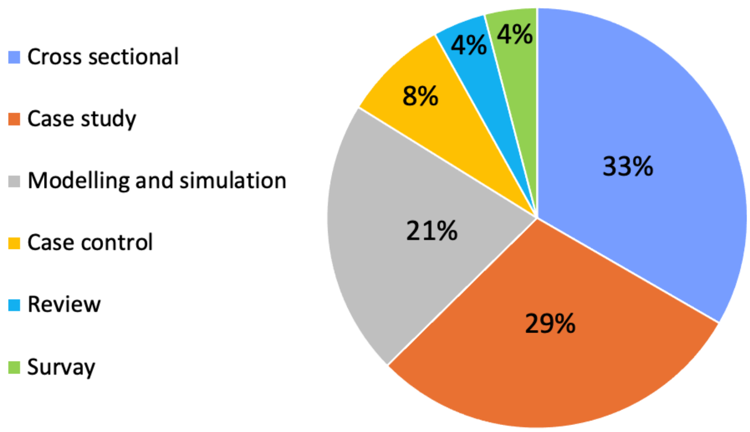

Figure 17. Classification of the papers based on the study type

In terms of disease focus, Figure 18 illustrates the classification of studies that dealt with the economics and costs of biosecurity measures according to the type of disease found on the farm during data collection. In one article it was possible to observe the presence of even more than one disease in the herd. The 22% of papers addressed ASF, followed by PRRS (15%), general animal health (15%), CSF (11%), PEDV (11%), and Salmonella and Campylobacter infections (7%). Only 4% of papers concentrated on AMR, FMD, Toxoplasmosis, Porcine Circovirus Type 2 Subclinical Infection, and Post-Weaning Multi-Systemic Wasting Syndrome. These data can be attributed to the fact that since the trend of publications has been increasing for some decades, at the same time ASF and PRRS have been studied, which are the most recently spread viral diseases in pig farms.

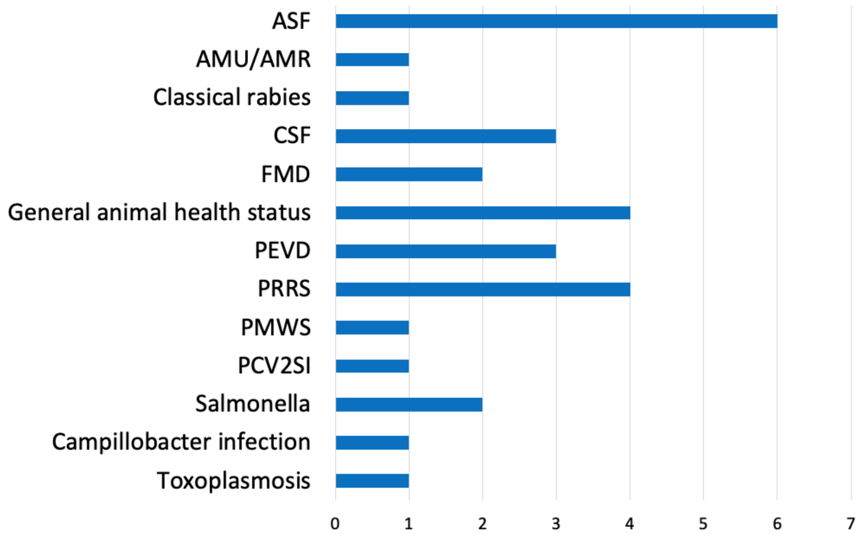

Figure 18. Classification of the papers based on disease

The papers examining the economics and costs of biosecurity measures (Figure 19) primarily focused on those associated with internal biosecurity procedures, which accounted for 60% of the studies. These were followed by the costs of external biosecurity procedures (33%), by the costs of structural measures for internal biosecurity (5%) and by the costs of structural measures for external biosecurity (2%). Studies that addressed structural biosecurity measures analyzed the costs related to fences (external biosecurity), water access and control, and air filtration system (internal biosecurity).

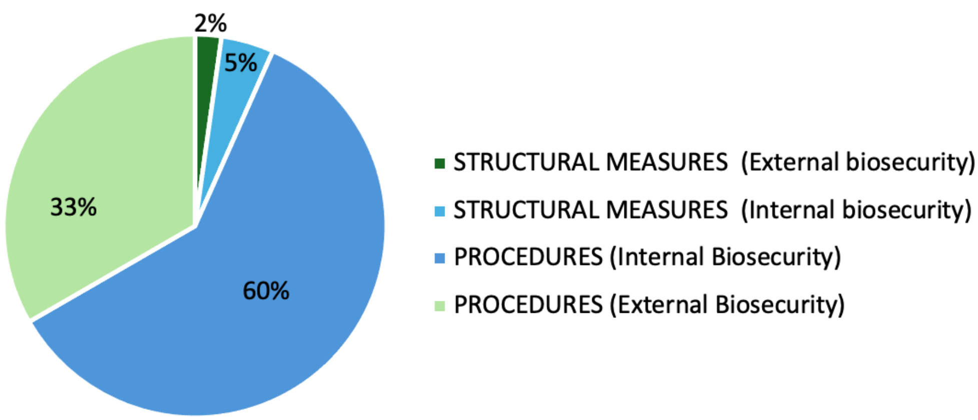

Figure 19. Studies focused on structural measures and procedures (internal and external biosecurity)

The procedures with reported cost data were further subcategorized, revealing a total of 42 measures across different procedure subcategories (Figure 20). Disease management presented the highest number of measures per subcategory (12), followed by smaller, more uniform numbers in other categories.

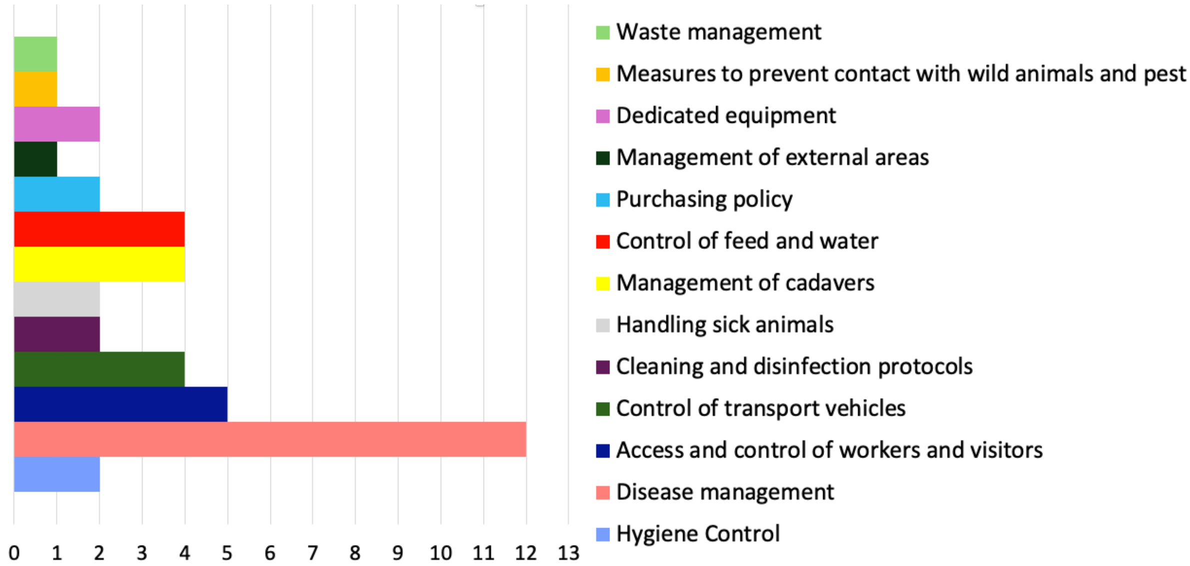

Figure 20. Number of measures per procedure subcategory

As shown in Figure 21, the number of studies addressing each procedure subcategory varied. Disease management was covered in 15 studies, followed by hygiene control (12 studies) and access and control of workers and visitors (12 studies). Other frequently analyzed measures included control of transport vehicles (8 studies), management of cadavers (7 studies), and handling sick animals (7 studies), with fewer studies on other biosecurity procedures. The higher frequency of cost analyses for disease management, hygiene control, access control for workers and visitors, and transport vehicle controls suggests that these procedures are considered particularly critical in biosecurity. In particular, access control for workers and visitors, along with transport vehicle controls, are biosecurity measures that pose a significant risk of introducing contamination from external sources. Meanwhile, disease management and hygiene controls are essential for preventing the spread of disease within the farm.

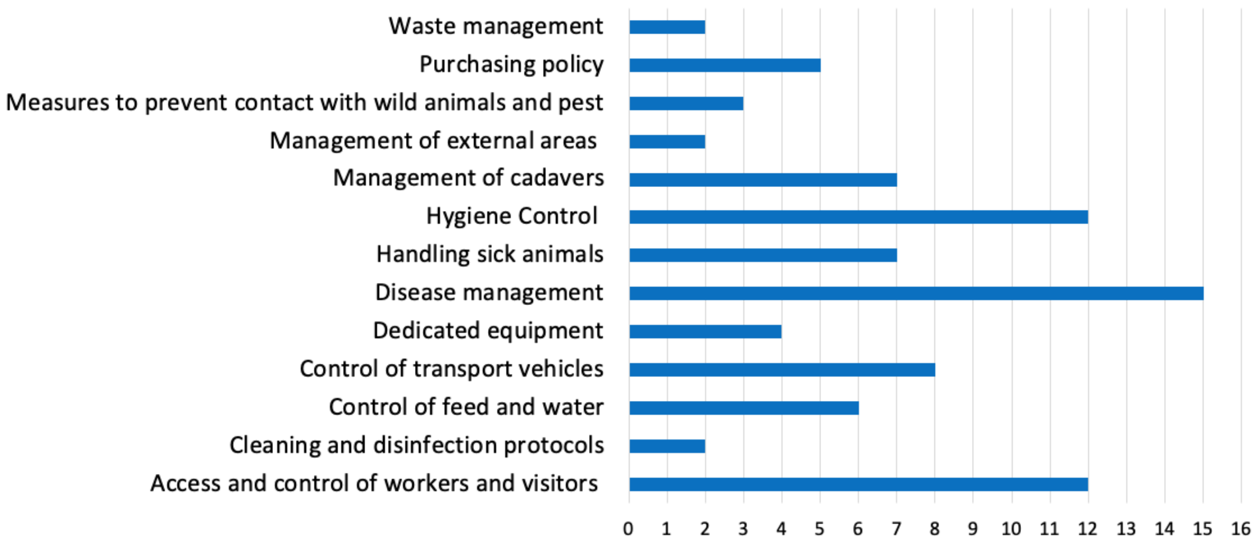

Figure 21. Number of studies per procedure subcategory

Finally, the papers were categorized by geographic region: 63% of studies were conducted in Europe, 16% in the Americas, 11% in Africa, and 11% in Asia (Figure 22).

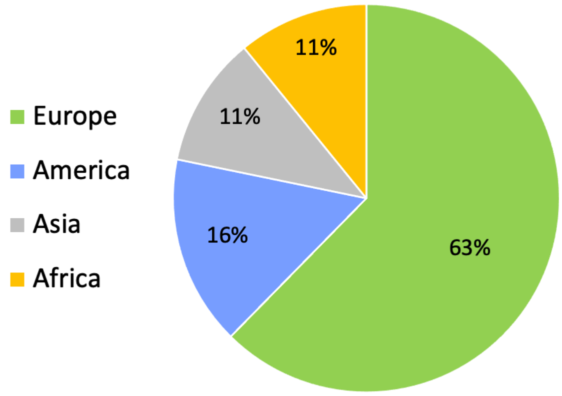

Figure 22. Classification of the papers based on geographic region

Based on general industry knowledge and available literature, we can make some general observations about the potential costs and benefits of biosecurity. In Europe, biosecurity measures, while essential, can increase operational costs; however, these expenses are often lower than the potential losses from outbreaks like ASF. Studies across Europe illustrate the diverse costs associated with biosecurity implementation. In the Netherlands, enhanced biosecurity can raise costs by €1.1 million to €2.5 million (Suijkerbuijk *et al.*, 2019), while in Spain, biosecurity on outdoor pig farms with an average number of 501 pigs per farm incurs around €14,780 per farm (Jiménez-Ruiz *et al.*, 2022). In Belgium, a cost-accounting analysis showed a median increase of €3.96 per sow annually for tailored biosecurity advice, yet improvements in internal biosecurity often lead to only modest cost increases (Rojo-Gimeno *et al.*, 2016). For example, a German study reported just a 2% rise in total costs with improved internal biosecurity and management practices (Nathues *et al.*, 2018). In the United Kingdom, instituting a visitor policy incurs minimal costs, though the construction of isolation hospital pens can be significant, estimated at €157.96 (*1 £ = 1,19 €*) per pig space (Alarcon *et al.*, 2013). The Danish finisher pig industry experienced considerable costs from mandatory fecal sampling, totaling about €1.5 million, while the cost of each round for the farmer is only 350 to 470 € (Baptista *et al.*, 2009).

Conversely, the economic charges of disease outbreaks can be far greater. For instance, the ASF outbreak in Romania led to direct costs estimated at €502,967,500 (Ladoşi *et al.*, 2023), and a single ASF outbreak in Bulgaria can result in economic losses of around €230,000 (*1 BGN = 0.51€*) (Ivanova and Ivanova, 2019). In Serbia, compensation costs for an ASF-affected sow or boar are €350, while control measures on a 2,000-square-meter farm with five fatteners can cost about €1,000 (Polaček *et al.*, 2021). Evaluations of four disease outbreak scenarios in Serbia revealed associated costs for cleaning, disinfection, euthanasia, compensation, carcass disposal, vaccination, and surveillance ranging from €143,430 to €367,110 (Stanojevic *et al.*, 2015). Belgium's experience underscores how biosecurity improvements can positively impact both economic and health outcomes. In a cost-accounting analysis, an increase of €3.96 per sow per year in biosecurity costs from tailored advice was offset by a €2.68 reduction in antibiotic costs and by an increase of €39.21 in enterprise profit per sow per year. This demonstrates how reducing antibiotic usage and enhancing herd management can yield both cost savings and profitability (Rojo-Gimeno *et al.*, 2016).

The analysis of papers from the Americas underscores the substantial economic impact of PEDV on the swine industry. Implementing air filtration systems, an effective preventative measure against PEDV and other respiratory diseases, can be costly, averaging $150 to $200 per sow (or $450,000 to $600,000 for a 3,000-sow herd) (Alonso *et al.*, 2013). However, the potential losses from a single PEDV outbreak are often far more severe. For example, in Mexico, a PEDV outbreak can lead to significant losses primarily due to piglet mortality and reproductive challenges, with eradication costs potentially exceeding $800,000 per herd (Garrido-Mantilla *et al.*, 2022). Similarly, in Canada, an outbreak can result in annual losses of approximately $300,000 for a 700-sow farm. Strategic biosecurity interventions, such as front-loading gilts with infected material, have shown to significantly reduce these financial losses (Weng *et al.*, 2016).

In Asia, the swine industry faces substantial economic challenges from diseases such as PRRS, FMD, and PEDV.

In Cambodia, a PRRS outbreak can lead to annual losses averaging $425.14 per smallholder farmer ($494.33, $387.61, and $393.48 per year for a two-sow breeder, a five-pig fattener, and a single-sow, three-pig farrow-to-finish/breeder, respectively) (Zhang *et al.*, 2017). However, adopting both biosecurity and vaccination strategy will be 100% effective against the risk of infection with PRRS and will provide total prevention of weight loss and death. Vietnam provides further insight into the impact of disease on various farm sizes. Large-scale farms experience the highest losses due to PRRS, with a 41% reduction in gross margin (approximately $18,846). Fattening farms incur a 38% loss ($7,014), while smallholder farms face the most significant proportional loss, at 63% of their gross margin ($2,350). The total cost of PRRS was estimated at $7722, $2673, and $1470 for large farm, fattening farm, and smallholder, respectively (Pham *et al.*, 2017).

In Africa, implementing robust biosecurity measures is essential to protect the swine industry from devastating diseases like ASF. In Uganda, farmers need to invest only $0.72 (*1 Ug Shs = 0,00027 US$*) per week per grower to establish basic biosecurity practices (Ouma *et al.*, 2018). In Nigeria, the annual cost of comprehensive biosecurity measures can reach $9,232.62 per farm (a 122-sow farrow-to-finish pig farm). However, the benefits significantly outweigh these costs, as preventing a single ASF outbreak can save farmers up to $910,836 annually (Fasina *et al.*, 2012).

3.4. Discussion

Studies examining the economic implications of improving animal welfare and biosecurity remain relatively rare. However, the trend in related publications has increased significantly in recent years, especially over the past five years, indicating a growing interest among researchers in this area. From 1995 to 2023, the average annual growth rate of publications was 13.89%, with a notable peak in 2022, when 99 papers were published – representing a 55% increase compared to the previous year. The 2023 data, however, shows a decline in publications, likely due to partial data collection, as the extraction was conducted in November and did not account for the full year.

Despite the emerging interest in biosecurity, there remains a significant gap in specialized journals focusing on the economic aspects of animal biosecurity. This suggests that the economic dimension of biosecurity is still underexplored, presenting an opportunity for further research. Many of the relevant studies have been published in journals focused on veterinary medicine, animal health, and animal diseases, highlighting that the economic aspects of biosecurity require further investigation. Additionally, the growing trend of intercontinental collaboration among authors reflects a more global approach to addressing the challenges and opportunities in biosecurity research.

These analyses provide valuable insights for farmers, researchers, and policymakers, emphasizing the critical intersection of scientific research, agricultural practices, and regulatory frameworks. The study confirms that the economic aspects of biosecurity remain an underdeveloped area of research. While significant attention has been given to virus detection, transmission control, and general health management, it is clear that farmers need strategic biosecurity practices to effectively manage these risks.

Although biosecurity, animal health, welfare, and performance have been extensively studied individually, there is a clear gap in research that integrates these elements. A holistic approach could uncover the interconnections between these areas. It is essential to tailor biosecurity measures to specific risks, available resources, and the socioeconomic conditions that vary from one country or region to another.

The economic aspects and cost analyses of biosecurity measures in pig farming, as discussed in the analysis of 25 selected papers, highlight several key findings. The farrow-to-finish segment was the most commonly studied, suggesting that farmers in this segment prioritize controlling the entire production process for cost optimization through economies of scale. Disease outbreaks can lead to significant economic losses, often far exceeding the costs of implementing biosecurity measures. For example, ASF outbreaks in Europe have been shown to cause millions of euros in losses, far more than the biosecurity costs required to prevent such outbreaks. Measures such as hygiene protocols, disease management, and access control for workers and visitors were highlighted as key cost drivers. These procedures are essential to prevent disease spread within the farm and limit external contamination. For instance, visitor policies and transport vehicle controls are critical in preventing external contamination.

The conclusions drawn from the analysis of the economic impact of disease outbreaks on the swine industry clearly indicate that, although biosecurity measures can lead to higher operational costs, their long-term benefits often far outweigh these expenses. The economic losses resulting from disease outbreaks, such as those caused by ASF (African Swine Fever) and other illnesses, are far more severe than the costs associated with implementing preventive measures.

The economic impact of disease outbreaks on the swine industry is substantial, with costs varying across regions and disease types. Unfortunately, due to the limited data available in the analyzed papers, it was not possible to conduct a comprehensive analysis of the specific costs and losses associated with biosecurity measures and disease outbreaks in each region. However, the geographic region with the highest biosecurity costs seems to be Europe, particularly in countries like the Netherlands and Belgium, which require significant investments to adopt preventive measures. In the Netherlands, for example, improving biosecurity practices can lead to cost increases ranging from €1.1 million to €2.5 million, mainly to prevent devastating outbreaks like ASF (African Swine Fever). In general, while Europe has the highest biosecurity costs, the North American region (particularly Canada and the United States) closely follows, with costs related to the installation of air filtration systems, which, although expensive, help reduce economic losses from diseases like PEDV (Porcine Epidemic Diarrhea Virus).

The economic analysis also underscores the high costs of disease outbreaks, which often far exceed the initial costs of implementing biosecurity measures. While biosecurity investments may increase operational expenses in the short term, the long-term cost savings – both in terms of preventing disease outbreaks and increasing profitability – and disease prevention they offer make them a sound financial strategy for safeguarding the swine industry. Key biosecurity measures, especially those focused on disease management, hygiene, and access control, are critical for both economic and health outcomes in pig farming.

A limitation of this study is the relatively small number of studies included in the analysis, which may reflect the fact that the field of biosecurity, particularly from an economic perspective, is still in its early stages. This trend is evident in the bibliometric analysis, which shows a recent increase in publications on this subject. Additionally, the study's results are influenced by the initial search query, particularly the choice of keywords.

Another limitation pertains to the number of articles included in the content analysis. Only 25 out of 586 studies were analyzed, as the focus was specifically on those that provided data related to the costs of biosecurity measures. However, the selection of these 25 studies was carried out independently by three different researchers, followed by a briefing session with additional experts to compare and validate the results, ensuring a rigorous and objective selection process.

A notable gap in the literature remains regarding the economic aspects of biosecurity in intensive pig farming. This highlights the need for a more comprehensive understanding of how to optimize spending, both in terms of activity levels and specific biosecurity measures (Kompas *et al.*, 2015).

Ensuring the sustainability of biosecurity measures is crucial, both from an economic and social perspective. A comprehensive approach to biosecurity in swine farms must take into account the economic aspects as well. It is essential to adapt biosecurity measures to specific risks, resources, and socioeconomic conditions that differ across countries and regions.

To address this research gap, future studies should focus on quantifying the economic impacts of biosecurity practices in intensive pig farming. This research should aim to identify best practices, assess potential returns on investment, and determine the most cost-effective strategies for leveraging biosecurity to enhance overall farm profitability and sustainability.

Based on the findings of this study, the costs associated with structural adjustments have been insufficiently explored in the literature; in contrast, several studies have primarily focused on business practices. Future research should prioritize examining how the operational efficiency of facilities influences the costs of implementing biosecurity measures. This is a crucial area for the development of effective and sustainable biosecurity policies and practices. Indeed, when facilities are designed to optimize biosecurity management and minimize contamination risks, the overall costs are likely to decrease, as the incidence of diseases or epidemics requiring additional containment measures is reduced.

Additionally, future studies should pay particular attention to the biosecurity costs faced by small-scale farms. While these farms may not have high production volumes, they are often highly vulnerable to infection and contagion risks, which could have catastrophic consequences not only for the individual farms but also for the broader agricultural and livestock sectors.

Finally, through the use of Biocheck assessments, it would be possible to identify the most at-risk farms from a biosecurity perspective, enabling targeted support in the form of subsidies, low-interest loans, or tax incentives to help farmers cover the initial costs of implementing biosecurity measures.

4. Potential economic impact of biosecurity from a One Health perspective: a theoretical approach

This chapter addressed the third research question:

RQ3. What are the potential economic impacts of biosecurity according to a One Health perspective?

Based on theory of the systems thinking approach, conceptual framework, theory of change and cause-effect analysis, is presented an investigation and explanation of the potential economic impact from the application of biosecurity measures in pig farming from a One Health perspective, according to a theoretical approach.

The goal is to investigate the economic impact effects of biosecurity practices and their potential consequences on the short and long term. This study is an ongoing publication.

4.1. Theoretical approach to the problem

This analysis is a qualitative conceptual framework developed in the context of the ongoing European HE Project BIOSECURE to evaluate the economic sustainability of biosecurity measures, strategies, and policies designed by the Project.

The need of a holistic One Health approach (Häsler *et al.*, 2018, 2024; Zinsstag *et al.*, 2021) relates to the fact that many of the challenges we face today cannot be fully understood or addressed from a single disciplinary perspective. We currently observe increasingly complex and interconnected social phenomena.

Researchers need a multidisciplinary approach that allows them to integrate insights from various fields such as sociology, economics, environmental studies, among others. A more holistic understanding of the complexities involved can be sought by taking the key points and different methodologies of different disciplines.

Qualitative methods are well-suited for exploring the general nature of these phenomena, allowing for more nuanced insights, in contrast to quantitative methods, which aim to measure and quantify experiences. In general, “qualitative studies ultimately aim to describe and explain a pattern of relationships, which can only be done with a set of conceptually specified categories” (Jabareen, 2009).

Employing qualitative methods increases understanding of social phenomena and improves the ability to address the multifaceted challenges of contemporary society by creating informed solutions that consider multiple influences and contexts.

It has been thought about how to represent a complex system such as health studies in a One Health perspective. Systems thinking (Whitehead *et al.*, 2015) applied to health-related studies refers to a conceptual framework, that consider the knowledge generated by the study of complex systems in multiple disciplines and to include all the components that have an impact on health and their dynamic interactions over time (Chughtai and Blanchet, 2017).

Often in research, a theory cannot sufficiently address all the issues or frame the problem that needs to be solved.

Systems thinking applied to health studies refers to a conceptual framework, which considers the knowledge generated by the study of complex systems across multiple disciplines and includes all components that impact health and their dynamic interactions over time (Chughtai and Blanchet, 2017). A systems thinking built on existing theories and models on which the study is based, aim to investigate the causes and interdependencies of a given phenomenon in a general way and visualize the result through the support of a graph and through the brainstorming of subject matter experts. There can be negative consequences of a particular effect that is observed and that the study tries to overcome through the involvement of stakeholders.

"Conceptual framework is as a network of interlinked concepts that together provide a comprehensive understanding of a phenomenon or phenomena" (Jabareen, 2009). It helps to investigate reality in a holistic way and connect all aspects of an analysis together.

The aim of conceptual framework is to create, identify, and link a phenomenon's major concepts, which together constitute its theoretical framework. The nucleus of this methodology lies the interplay among induction, derivation of concepts from data, and deduction aimed at hypothesizing the relationship between concepts.

The conceptual framework can be used to guide all aspects of research such as questions, variables, analysis, and integration. Using concepts, relevant literature, and models relevant to the problem, the framework helps guide the researcher to make more critical evaluations (Shannon-Baker, 2022).

The conceptual framework is a graphic or written product that illustrate, either visualizing or in narrative form, the main things of which it is essentially composed:

1. key variables, concepts, and constructs: therefore, themes or elements central to the research, where each concept plays an integral role (Miles and Huberman, 1994)
2. relationships between variables: where it is illustrated how these variables are interconnected and their relationship
3. contextual factors: environmental, social, or organizational factors must also be considered
4. theoretical foundation: it is based on existing theories
5. assumptions and hypotheses: expectations can be described with respect to the relationships between variables.

A conceptual framework provides understanding and interpretation of intention (Levering, 2002) to social reality and is non-deterministic in nature and therefore it does not allow us to predict an outcome. It can be developed from different sources of data as a qualitative analysis, consist of many discipline-oriented theories generates from multidisciplinary bodies of knowledge and systematic synthesis.

Advantages of conceptual analysis lie in:

a) flexibility: conceptual terms are flexible rather than rigid theoretical variables and causal relations

b) capacity for modification: it can be reconceptualized and modified according to the evolution of the phenomenon in question or because of new data and texts that were not available at the time the framework was first developed. This is consistent with the basic premise that social phenomena are evolutionary and not static

c) structured understanding: conceptual frameworks aim to help to understand complex phenomena rather than to predict them

d) supporting communication: researcher's individual experiences and beliefs, also known as the worldview of inquiry (DeCuir-Gunby and Schutz, 2017), will guide the direction of the proposal.

Nevertheless, conceptual framework analysis has its limitations, the fact that different researchers may have different conceptions of the same phenomenon and may create different "planes" and conceptual frameworks, and possible difficulties finding suitable texts and data.

Theory of change is a graphical representation of sequential chains of events and form the basis of causal chain analysis (Wirtz, 2007). It describes in detail how and why a change is expected to occur in a given context, highlighting the causal relationships between the activities undertaken and the objectives achieved. Its main characteristic is that it must be guided by consultation with key stakeholders. The aim is to be able to provide solutions to complex problems and challenges, it helps to reflect on the many causes of development challenges and how they influence each other.

The key steps to developing a theory of change are (Mayne, 2017):

a) it should be developed in a consultative manner to reflect the understanding of all relevant stakeholders, facilitating communication between various actors involved in the project, making explicit the links between activities and expected outcomes. Stakeholders should also question the dynamics of change, clearly define their strategies, and evaluate the effectiveness of their actions

b) it should be grounded in, tested with, and revised based on robust evidence at all stages

c) it should support continuous learning and improvement from program design to closure.

The main components of a theory of change include:

1. final objectives: the desired impacts or conditions that are to be achieved
2. intermediate outcomes: the expected short- and medium-term changes that will lead to the final objectives being achieved
3. assumptions: the assumptions on which the model is based, describing the conditions necessary for activities to lead to the desired results
4. success indicators: measures used to monitor and evaluate progress towards objectives.

In 1960s the expert Japanese Kaoru Ishikawa developed the cause-effect analysis, a visual tool used for problem-solving and root cause analysis.

The purposes of a cause-effect analysis are: (i) to identify the causes of the problem being researched by finding the underlying causes, (ii) to facilitate communication and collaboration of the team seeking the solution to the problem, the graph in this helps brainstorming, (iii) to illustrate the connections between variables and how they contribute to the problem (Ishikawa, 1996). It is a more structured approach than other tools used for brainstorming.

The research of the cause-effect analysis is typically constructed starting from the issue that needs to be solved, that has to be written in the head of the graphic sheet into a box. Then the causes of the problem are discussed among stakeholders through brainstorming sessions and written in the graph.

The study investigates the aspect about:

- the farm level: the focus is on food production
- system level: the interaction between different elements of food production, such as natural resources, technologies and agricultural practices
- sector level: the economic and social dynamics that influence the entire food sector are analyzed, such as agricultural policies and market trends
- the food supply chain: the process by which food originating from a farm is consumed. The processes encompass production, processing, distribution, consumption, and disposal.

4.2. Results

The economic impact of the application of biosecurity measures in pig farms in Italy is complex and multifactorial, biosecurity measures can be costly for farmers. The economic sustainability of such measures is therefore crucial and can guide policy makers to allocate resources in order to support farmers and at the same time improve the level of biosecurity (Berends *et al.*, 2021).

Taking a multidisciplinary and systems view of the issue under discussion, several further direct and indirect effects arising from the implementation of biosecurity measures at farm level can be analysed. Just to name a few, recent research and field experiments have shown that improvement in biosecurity status is economically beneficial for farmers (net of the necessary investment costs) thanks to a better state of health of the animals and subsequent improvements in technical performances.

The Figure 23 analyses in detail the effects of the application of biosecurity measures in livestock farming according to a One Health perspective: a method for interpreting and managing health problems based on the principle that the health of humans, animals, plants, and ecosystems in general is strictly interconnected, for thus a multidisciplinary, intersectoral and coordinated method is required (Häsler *et al.*, 2018, 2024; Zinsstag *et al.*, 2021).

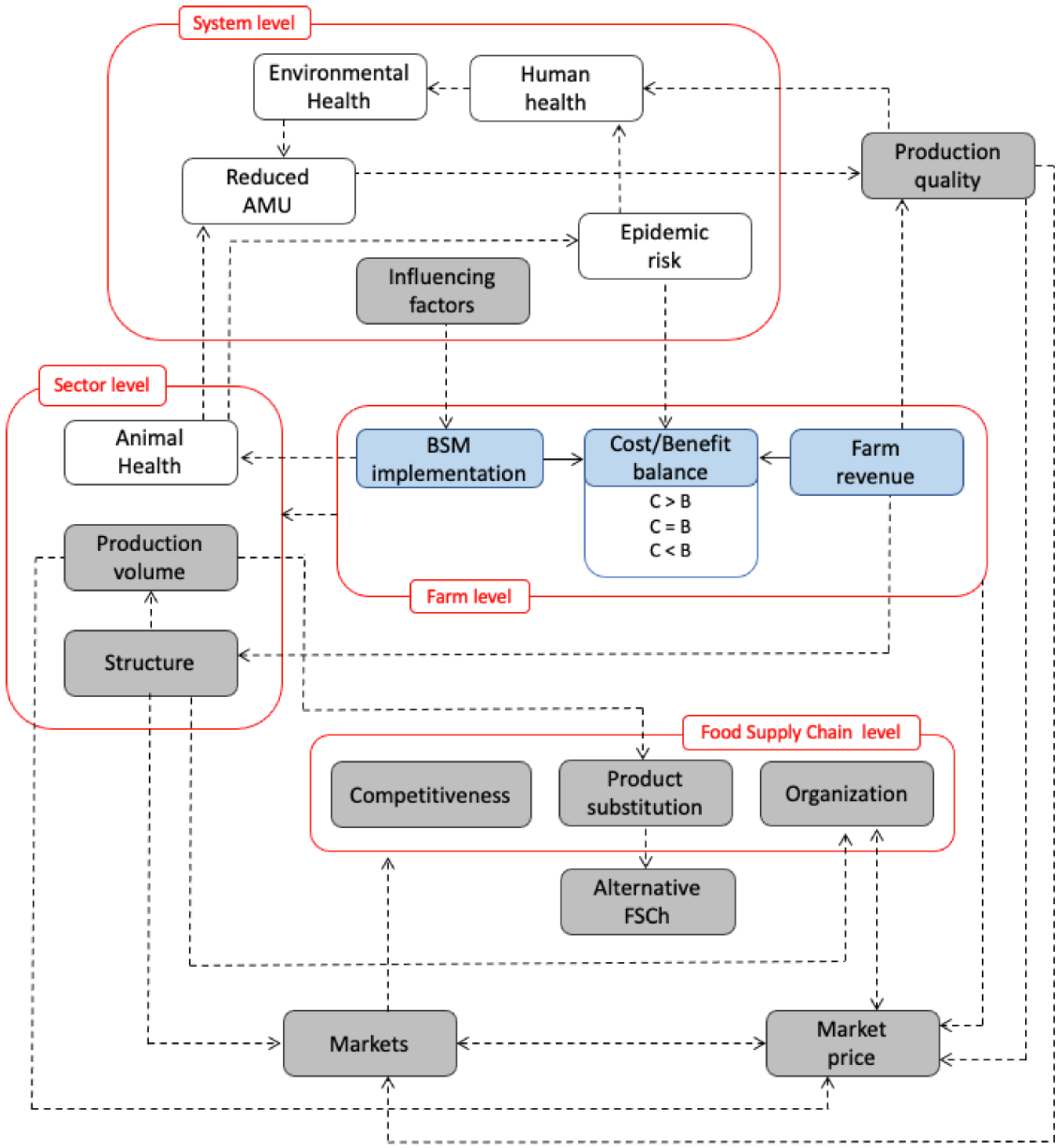

Figure 23. Outline of the relationships and impacts of the implementation of biosecurity measures (BSM) at different levels

Starting from the factors that can influence the implementation of the biosecurity measure, these may vary depending on the context. The key inputs for any economic evaluation are evidence on the effects of alternative courses of action (Drummond *et al.*, 2015). Certainly, the application of biosecurity measures may depend on the rules and regulations in force in a country or in a specific geographical area, in this case national or even international laws may determine which measures must be adopted, to what extent and how they must be applied and verified by the competent authorities.

Likewise, stakeholders involved play a key role in ensuring the understanding and correct implementation of preventive measures, this also concerns training programs for farmers, operators, veterinarians, zootechnicians and all those involved in the food chain. In fact, the habits, routines, and cultural and generational practices of breeders often influence the adoption of such practices.

For this reason, a system based on monitoring and evaluation system can be effective to encourage the improvement and adaptation of prevention strategies. Through access to advanced technologies, the implementation and management of biosecurity can be made easier, making it less costly through the availability of funding and economic resources that come from an active administration of public funds. At the same time the spread of certain pathologies can be influenced by environmental and climatic factors or even by the movement of animals and people themselves.

BSM implementation is the starting point of a series of economic effects at farm level and in the system. The core of the diagram focuses on the application of biosecurity measures, from this central point, possible effects on the business balance are listed. Costs and benefits are then evaluated and the case that can emerge are:

- C=B in this scenario, the implementation of biosecurity measures does not result in any significant advantages or disadvantages for the company’s balance sheet. The economic impact of the measures taken is therefore neutral, indicating that the costs incurred for biosecurity are balanced by the benefits derived from disease prevention and the improvement of overall health conditions. In this case, biosecurity measures are considered a necessary expense but do not lead to a direct economic gain.
- C<B: In this case, there is an economic benefit for the company implementing biosecurity measures. The initial implementation costs are lower than the benefits achieved, which can result from increased productivity, reduced losses due to diseases, and improvements in product quality. In this scenario, the investment in biosecurity is not only justified but could also help improve the company's economic sustainability, strengthening market competitiveness and reducing risks related to animal health.
- C>B: This scenario represents a situation in which the costs incurred for the implementation of biosecurity measures exceed the benefits obtained. In other words, the company incurs an economic loss due to the investment in measures that do not result in sufficient returns, in terms of cost savings or productivity increases. In this case, the company may face financial difficulties, with the risk of becoming economically marginalized, especially if the biosecurity measures are not applied efficiently or if they do not meet the company's specific needs.

Since the fixed and variable costs of biosecurity directly affect the overall cost structure of the business, it is essential to analyze how these costs can determine the competitiveness and economic sustainability of the pig farming enterprise.

Fixed costs, such as initial investments in biosecurity structures and necessary equipment, remain constant regardless of the number of animals raised, while variable costs, including expenses for materials, labor, and maintenance related to animal health management, increase in proportion to the number of animals present on the farm.

The analysis of average and marginal cost curves, in relation to the total cost function (Figure 24), is crucial for understanding how the balance between fixed and variable costs can influence the competitiveness of the business.

Specifically, if total costs exceed benefits (C > B), companies may face an economic difficulty, where the high investment in biosecurity measures does not generate sufficient returns in terms of productivity or cost savings. In this context, an effective solution to preserve the economic margin is the adoption of economies of scale.

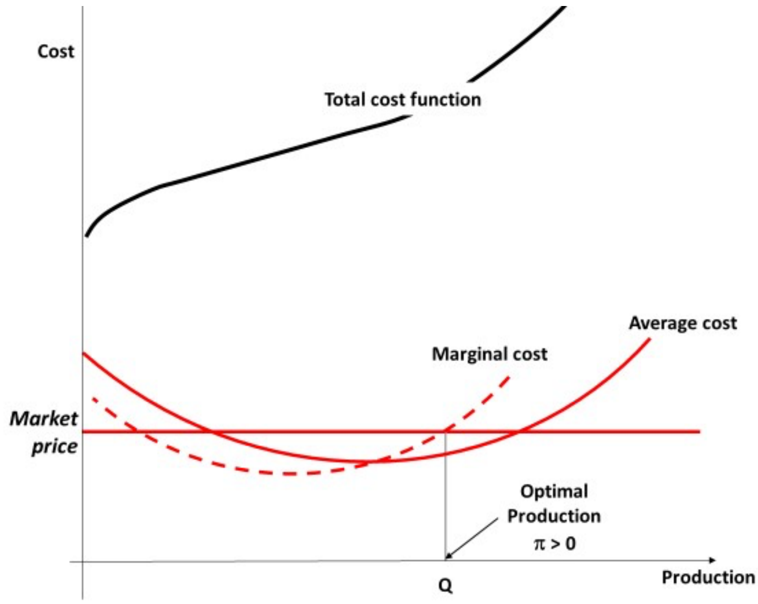

Figure 24. Cost-function of biosecurity measure

Economies of scale, as illustrated in Figure 26 and Figure 25, occur when the business manages to reduce the unit average cost by increasing production, that is, by increasing the number of animals raised. By increasing production scale, fixed costs are distributed over a larger base, reducing their impact per unit of product. Additionally, increasing the number of animals allows for greater efficiency in managing variable costs, as resources (such as personnel, equipment, and biosecurity materials) can be utilized more efficiently on a larger scale.

However, the implementation of economies of scale must be carefully evaluated, as an excessive increase in the number of animals could also bring challenges in terms of health management, disease spread risks, and environmental impacts.

For this reason, it is crucial for pig farming businesses to find a balance between expanding production and maintaining high standards of biosecurity and animal welfare.

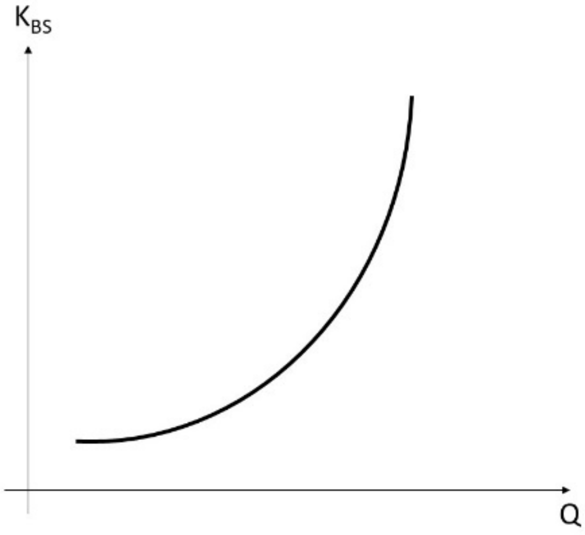

Figure 26. Biosecurity measure function sensitiveness to scale economies

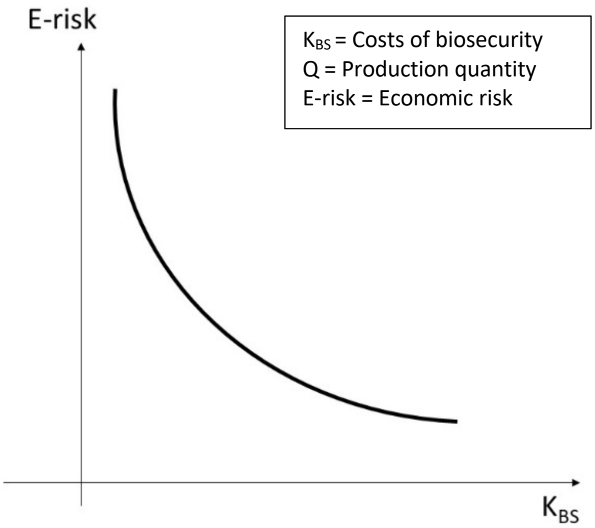

Figure 25. Cost effectiveness function of BSM in relation to the epidemic risk reduction

At the farm level, the revenue generated is affected by the balance of costs and benefits of BSM implementation, influencing investments, profitability, and economic sustainability. The application of the measures initially requires a financial investment in fixed costs (structures), and recurring variable costs (equipment, regular maintenance and operational costs as cleaning and disinfection, vaccinations, treatments, and labor costs increasing due to additional biosecurity protocols).

At the same time there is a decreasing in cost for medicines incurred to treat sick animals, revenues would remain at least stable, and this would not lead to an exorbitant loss in profits and the consequent possibility of investing in breeding and in the biosecurity measures themselves (Alarcón *et al.*, 2021; Rodrigues Da Costa *et al.*, 2019). The benefits can result in improved technical performance of the herd, including reduced mortality, fewer abortions, lower incidence of anorexia, increased fertility, and higher average weight gain. This leads to better overall animal health and enhanced productivity for the company.

This results in an increase in company profitability, the profits of which can be invested in biosecurity, creating a continuous loop. If biosecurity measures were applied continuously and consistently by all farms, there would also be positive impacts at system and sector level.

In this context, at the system level, the positive outcomes would include a reduced risk of epidemics, as well as a decrease in health hazards from contagion between farms. Fewer disease outbreaks in a region would lead to a reduction in interventions by public veterinary services (ASL). As a result, economic losses for businesses due to livestock eradication measures would also be avoided (Figure 25). Other benefits include improvements in human health, as the risk of zoonotic diseases is reduced, along with a decrease in antibiotic use, which helps mitigate the risk of antimicrobial resistance. Proper waste management and reduced use of antibiotics contribute to better environmental health. In terms of public health, official veterinary controls on farms would be reduced, with a consequent decrement in public medical costs.

The application of biosecurity measures in the short term also has long-term repercussions (Figure 27). In fact, it could result in a decreasing of transmission of diseases between farms, with the consequent mitigation of the epidemic risk. In the long term would also lead to a reduction in losses in the sector. Although there may be no immediate profit for the farmer, the decrease in epidemic risk ultimately leads to a positive long-term outcome. As the risk of farm losses due to epidemics declines, the individual costs for each farm are reduced. Therefore, implementing biosecurity measures on a large scale is beneficial for everyone, creating a collective advantage in the long run.

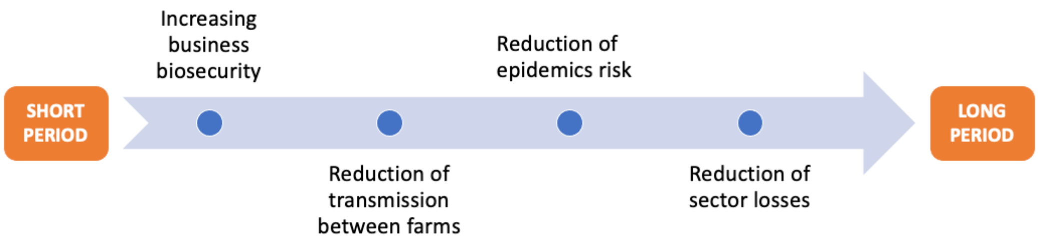

Figure 27. Epidemiological effects and business feedback

At the sector level, the widespread implementation of biosecurity measures across farms would result in better overall animal health. This would, in turn, reduce the use of antimicrobials, creating positive effects on both environmental and human health. Simultaneously, preventing deaths and abortions at the farm level would increase overall production volume, which is crucial in the event of rising market demand. This would encourage farms to expand in terms of size, type, and specialization, potentially leading to a long-term shift in the structure of the sector.

In case of a significant impact on production, the downstream food industry could experience a shortage of supply and a price increase. Assuming that animal production can be considered a commodity (with generic quality standards), supplier substitution could occur (e.g., the processing industry would import a similar product from other production areas) and the competitiveness of the consumer supply system would be affected to some extent. In case of "cost neutrality" of the BSM implementation, no effects should arise on this side.

The positive role of biosecurity on animal welfare and the consequent reduction in drugs and antimicrobial consumption added a new element related the company's ability to access higher product quality (that influence also the market prices) allowing farmers to obtain quality product certifications of animal husbandry process, as well as antibiotic-free or improved animal welfare labels. Indeed, for a few decades now, the consumer sensitivity/attention towards animal farming conditions have raised from an ethical point of view, and product quality certifications lead to an increasing in consumer confidence.

The reduction of official controls has the effect of greater freedom of movement for animals. This aspect together with the certifications allows the producer to have access to markets outside the EU and to be able to reach that part of consumers who have needs linked to a greater sensitivity towards the conditions in which the animals are raised as well as new trade opportunities.

The application of biosecurity measures would also have repercussions at the food supply chain level, so there could be improvements in the competitiveness of the pig industry by ensuring higher quality and safer products or having the ability to substitute products or adapt production in response to market demands (product substitution).

The increase in competitiveness within the pig farming sector, although it may lead to economic benefits for larger companies, also raises significant social and economic issues. In fact, the growing need to adopt biosecurity measures to ensure the sustainability and health safety of farms could lead to a natural selection that favors larger players at the expense of small businesses. Small farms, which often cannot afford the initial costs of implementing biosecurity measures, may find themselves struggling and ultimately forced to close or significantly reduce their production capacity. This phenomenon would accelerate the concentration of businesses within the sector, resulting in fewer companies remaining operational, but with production becoming more concentrated in the hands of a few.

As a result, while the reduction in the number of small farms could initially reduce the sector's overall production capacity, the increase in the size of remaining farms could lead to a growth in total production due to economies of scale. Larger companies, in fact, could benefit from lower unit costs for biosecurity measures due to their ability to manage resources and equipment on a larger scale, thus improving their competitiveness in the market.

However, this process is not without implications for the local supply chain. The change in market structure could lead to growing dependence on larger companies, which may turn to external suppliers, possibly international ones, for resources, materials, or even specialized labor. In this scenario, the local supply chain could lose competitiveness, as it would be unable to produce the necessary goods and services at competitive prices compared to foreign suppliers. Moreover, the reduction in the number of small producers could decrease the sector's diversity, negatively impacting the overall resilience of the supply chain, especially in times of economic or health crises.

The effects of biosecurity measures (BSM) on the food supply chain are primarily determined by the impact these measures have on the production sector, particularly animal production. When the impact of BSM is significant, the downstream food industry may face supply shortages and price increases. This scenario is especially relevant when considering animal production as a commodity with generic quality standards, without specific differentiations. In such a case, the supply chain might have to face supplier substitution. For example, if a local producer fails to meet new biosecurity requirements, food processing companies may turn to external suppliers, including international ones, to avoid supply disruptions. This dynamic could undermine the competitiveness of the traditional supply system, risking market disruption, increasing reliance on external sources of supply, and reducing local self-sufficiency, which would have a negative economic impact both for local companies and consumers, who might face higher prices due to distortions in trade flows.

If, on the other hand, the implementation of BSM proves to be "cost-neutral," meaning it does not generate significant increases in production costs, the negative effects on the supply system could be minimized, allowing stability in supply and price dynamics.

Moving to the demand side, it is essential to understand that the demand for animal products at the farm or sector level is not an independent demand, but a derived demand. This means that the demand for meat is influenced by the overall demand for finished products in the market.

The introduction or strengthening of quality standards, which also includes biosecurity measures, inevitably leads to a reorganization of the food supply chain. Supply chain operators, in fact, seek to adopt an organizational model that ensures constant product flows while maintaining certified quality standards. The quality-oriented food supply chain (FSCh) model aims to ensure not only food safety but also a constant and traceable production.

A well-structured, quality oriented FSCh model contributes to strong integration both horizontally, among producers, and vertically, between producers, food processors, and distributors. In particular, the certified quality of products becomes a determining factor in selecting suppliers, as consumers and food industry operators are increasingly focused on high standards that ensure safety and traceability.

Vertical integration can lead to greater efficiency, reducing transaction costs and improving the ability to respond to market demand fluctuations. However, this tighter interconnection may also affect the final product price, as more integrated processes tend to reduce cost variability through economies of scale, but at the same time, could lead to centralization of power in the hands of a few major players in the supply chain. This could result in higher prices if these players control a significant portion of the value chain.

Therefore, the implementation of biosecurity measures creates an opportunity for the affirmation of distinctive quality attributes, which can improve the competitiveness of the supply chain. If biosecurity measures are perceived as an added value by consumers, they could facilitate the entry of new players into the food supply chain or encourage existing ones to improve their quality standards. However, it is important to reflect on how much biosecurity can become a recognizable quality attribute for consumers, i.e., how it can differentiate animal products in the market from other non-certified productions.

In this context, the organization of the supply chain and consumer perception play a key role in identifying and creating more sustainable and competitive business models. The final consumer demand, in fact, is reflected throughout the food supply chain, conveyed by distributors and food processors, who must be able to respond efficiently and consistently to market needs.

Focusing on the economic effects, it is important to analyze how policy scenarios and biosecurity measures can influence the structure of the sector and production. Following a cost/benefit analysis, if the implementation of BSM has negative effects, such as increased costs for farms, farm income may decrease, leading to changes in sector structure, with a potential reduction in production and employment opportunities. On the other hand, if sector production were to decrease due to supply difficulties, the food processing industry might adopt a supplier substitution strategy, seeking to negotiate with new producers or alternative supply chains. In this case, the food supply chain could undergo restructuring in response to changes in production volumes and price dynamics, potentially leading to new negotiation models between the various players.

Some of these effects may manifest in the short term, such as changes in production volumes or farm income, while others may emerge in the medium-to-long term, such as farm adaptation to new economies of scale or the introduction of more efficient processes.

4.3. Discussion

By providing a comprehensive overview of the economic impact of biosecurity, the aim is to equip stakeholders with the knowledge necessary for making informed decisions and engaging actively. This will help raise awareness of the potential negative effects arising from inadequate biosecurity practices in animal farming, particularly in intensive systems. These consequences may include economic losses and public health issues. Furthermore, this overview can play a crucial role in protecting natural resources and promoting investment.

Biosecurity is not only a matter of environmental and health protection, but also has significant economic implications that can affect the long-term stability and prosperity of communities and national economies. It must be considered as concrete management and physical measures aimed at reducing the risk of diseases (prevention of entry and control of the circulation of diseases) in the farm or in the territory but also as a strategic and holistic approach to risk management.

While implementing and maintaining biosecurity measures may initially raise fixed and variable costs, the long-term advantages – such as reduced health risks, enhanced productivity, access to premium markets, and overall sustainability – can far outweigh these expenses. These positive effects on the farm's economic balance can lead to higher profitability, which can then be reinvested into further biosecurity measures, creating a continuous cycle of growth and improvement.

The economic sustainability of BSM depends largely on the ability to manage costs, access funding, and implement economies of scale effectively. Large-scale farms may benefit more from economies of scale, reducing unit costs and improving competitiveness. However, for smaller farms, the financial burden of implementing biosecurity measures could lead to marginalization or closures, exacerbating sector concentration. From a broader perspective, the implementation of biosecurity measures can also positively impact public health by reducing zoonotic diseases, lowering antimicrobial use, and minimizing the environmental impact of livestock farming.

The implementation of biosecurity measures not only has immediate effects on production but can also trigger a series of complex changes at the market level, going far beyond mere compliance with health regulations. These effects can influence not only product prices but also access to markets and the ability of the food supply chain to adapt to health or economic challenges. The issue of competitiveness in local supply chains remains central, as integration with other economic players, sometimes international, could reduce the ability of national supply chains to maintain a competitive position.

While field experiments demonstrate positive effects, comprehensive, long-term data on the precise economic benefits of biosecurity measures remain scarce. The variability of costs and benefits across different farm contexts – depending on farm size, management practices, and the geographical area – complicates generalization. Additionally, while direct economic benefits in terms of reduced disease and improved productivity are evident, indirect effects, such as changes in supply chain dynamics, are harder to quantify. These indirect effects include how changes in biosecurity standards may alter competitiveness, local market conditions, and the structure of the farming sector.

Furthermore, the research does not extensively explore the role of cultural factors, the adoption of technology, and training in the effective implementation of biosecurity measures, despite their crucial importance in farm management. There is also limited attention given to the socio-economic consequences of biosecurity measures, especially regarding the displacement of small-scale farms and the increasing concentration of production in larger companies.

Future research could focus on longitudinal studies on economic impact. Long-term studies that track the economic effects of biosecurity measures over time would provide more robust data. These studies should assess how the initial costs of biosecurity investment compare with long-term gains in productivity, health outcomes, and profitability. Moreover, research into the long-term benefits to public health – especially regarding antimicrobial resistance, zoonoses, and environmental health – could further justify investments in biosecurity. Research should also investigate the economic impact of biosecurity measures across a broader range of farm types (e.g., small vs. large farms) and geographic regions. This would help identify specific factors that influence the cost-effectiveness of biosecurity investments and provide insights on how small farms could be supported. There is a need to further explore how biosecurity measures affect the food supply chain, particularly in terms of supply shortages, product substitution, and the shifting balance between local and international suppliers. Analyzing the market effects of widespread biosecurity implementation could yield important insights into how producers and processors adapt to these changes. Research should examine the social and economic consequences of farm concentration resulting from biosecurity measures. This would include analyzing the risks of market dominance by larger companies, the loss of small farms, and the impact on rural economies. Finally, research into policy interventions, such as subsidies or support mechanisms for smaller farms, would be crucial for ensuring that the benefits of biosecurity measures are equitable across the sector. Studies on policy efficiency and the impact of financial support on farm resilience could inform better-targeted regulations and resource allocation.

5. Cost categories and cost assessment of biosecurity measures in pig farms

In this chapter are presented the methodology, the results, and discussions on the fourth research question:

RQ4: **How can we categorize and evaluate the costs of biosecurity implementation in pig farms?**

The purpose is understanding the relevance of various cost categories that can help improve resource allocation, budgeting, and prioritizing areas for training or improvement in farm operations. Identifying where organizational best practices apply can further improve efficiency and effectiveness in managing livestock health and productivity.

This study is part of the ongoing European HE Project BIOSECURE, a four-year research project started in 2023 and supported by the European Union, therefore no conclusive results have been reported.

5.1. Methodology

The interview is a qualitative research whose origins date back to 1800s (Moser and Korstjens, 2017). The interview is a way to gain a deeper understanding of people's experiences, knowledge, behavior, and processes when there is an interest in other individuals' professional knowledge (Seidman, 2006).

The interview is a tool that must be well designed, which requires a series of phases to be built as shown in Figure 28.

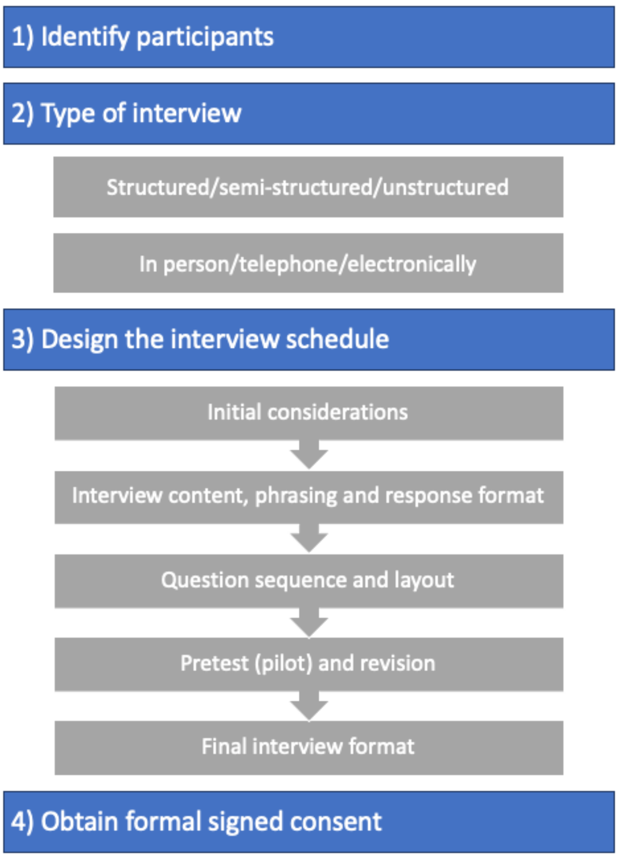

Figure 28. Stages of planning an interview (Roopa and Rani, 2012)

First, is important to identify the right interviewees, for the interviewer is fundamental how to select the participants (e.g., randomly or through a self-selection), how open they can be to questions, and the questions to ask them must be relevant to their field of expertise. And it is also important that participants were informed that the data collected is anonymous.

The next step is individuate the right types of interviewing styles to choose from (Alsaawi, 2014; Wilson, 2012):

a. structured interviews: involve asking the same set of questions to all participant, frequently is used in conducting surveys, the weak point is that is quite limiting

b. semi-structured interviews: it allows for greater flexibility during the interview, in fact there are a series of guiding questions that are asked by the interviewer that keep the focus on the topic

c. unstructured interviews: the interview is completely free like a conversation, the positive aspects is that is flexible and unrestricted, but also has limitations, indeed comparing data between interviews becomes more difficult.

Interviews can be conducted in person, (where it can be seen see facial expressions and body language), but also over the telephone, or electronically using applications and programs. These last two types are cost effective, as no travel is involved, and may provide a certain level of comfort to participants (Beck, S. E. and Manuel, K., 2008).

Other important things to do before the interview starts are design a schedule in case of structured and semi-structured interviews and have the opportunity to try it a few times, because once the participant has been interviewed, he/she can no longer be interviewed. In this way the interview can be divided into five steps (Alsaawi, 2014) :

1. introduction: there is an introduction of the two parties, therefore of the interviewee and the interviewer in order to break the ice, and also a description of the aim of the interview
2. warm-up: start with easy questions to ease the situation from the beginning
3. main body: the interviewer focuses on the main topic of the study
4. cool-off: again, simple questions which will conclude the interview
5. closure: the interviewer thanks the interviewee for his/her valuable contribution.

Some suggestions for the interview can be referred to the pace to be maintained during the interview, giving adequate time for each question and answer, at last it is of fundamental importance to record the interview especially in case of semi-structured and unstructured ones, because currently note-taking is not enough (Wilson, 2012).

In this study, a research method based on semi-structured interviews was developed, allowing for the collection of both qualitative and quantitative data in a flexible and detailed manner. Additionally, a specific questionnaire was administered to categorize the costs of internal biosecurity measures, as outlined by the Biocheck.UGent checklist (see at Table 1).

To identify the cost categories and associated expenses, thirteen interviews were conducted with industry specialists between May 3rd and August 9th, 2023, in order to gain a comprehensive and accurate understanding of the practices currently in use. Three zootechnicians, two breeders, and eight veterinarians were interviewed (Table 11), all of whom are professionals with extensive experience in the pig farming sector. These interviews allowed for the collection technical and economic information on the application of biosecurity measures in pig farms.

The interviewees were selected using a snowball sampling method, which proved particularly effective for reaching individuals within a specific network of professionals, such as veterinarians and breeders. During each interview, participants were asked if they knew other colleagues or professionals in the field who might be interested in participating in the research or who had relevant expertise on the topic. This approach allowed the sample to be gradually expanded, thanks to the suggestions made by the participants themselves, creating a network of contacts that would otherwise have been difficult to establish through more traditional selection methods.

The professional activities of the interviewees were primarily located in the regions of Veneto, Emilia-Romagna, and Lombardy, areas that represent the heart of Italian pig production. The responses obtained, therefore, reflect the experience of professionals working in a highly industrialized context focused on the production of pork at both the national and international levels. On average, the respondents have nearly 20 years of experience in pig farms, a figure that attests to the strength of their professional training and their long careers in an ever-evolving sector, where managing regulations, technologies, and resources is crucial to ensure the efficiency and quality of production.

The questions were structured differently based on each interviewee's professional role in order to gather more specific and relevant information for each operational area. In particular:

- veterinarians were asked questions from a practical-technical perspective, primarily focusing on compliance with current regulations, the adoption of biosecurity measures, and the management of animal health. Their responses provided valuable insights into daily procedures for monitoring and managing animal health, as well as the sector's ability to adapt to constantly evolving regulations, especially concerning health safety and animal welfare.
- zootechnicians were asked questions related to operational activities within the farms, exploring their role in the technical and productive management of pig farms. Their responses covered aspects related to animal nutrition, the management of farm facilities, and the use of resources.
- breeders were asked questions focused on the overall management of the farm, with particular attention to economic planning and costs. Their responses highlighted the daily challenges of managing a farming operation, including issues related to investments, workforce management, and balancing economic needs with the health and welfare of the animals.

This division of questions allowed for a comprehensive and multidimensional view of the practices in use within pig farms, considering the different professional roles and areas of expertise.

Table 11. Sociodemographic characteristics of interviewees

ID	Occupation	Sex	Basic information	Age	Years of experience	Region	Number of animals under control
1	Veterinarian	M	Practitioner	40	15 years, 10 years for Ministry of Health	Lombardy	20.000 sows
2	Veterinarian	M	Practitioner	-	21	Emilia-Romagna	15,500 pigs in full cycle and 13,000 pigs in another farm
3	Veterinarian	M	ASL Vet	62	31	Emilia-Romagna	-
4	Veterinarian	M	Company Vet	-	-	Lombardia e Veneto	10.000 sows, 100,000 weaned and 100,000 finishing
5	Veterinarian	M	Company Vet	-	36	Lombardy	A farm of 1.00 sows and one from 12,000 antibiotic-free sows
6	Veterinarian	M	Academic	-	-	Veneto	90-120 animals, experimental breeding (finishing)
7	Veterinarian	M	ASL Vet	32	1 and half	Emilia-Romagna	-
8	Veterinarian	M	Academic	-	-	Veneto	90-120 animals, experimental breeding (finishing)
9	Zootechnician	M	Agricultural expert	-	18 with sows	-	1800 sow farm and site two, piglets and weaning (open cycle)
10	Zootechnician	M	Veterinary technician	40	10 with supply chain companies	-	120,000 fattening pigs and 7,000 pigs (from weaning)
11	Zootechnician	F	Ph.D. Student	26	1	Veneto	90-110 pigs (finishing)
12	Breeder	M	Site 1-2-3	57	32	Emilia-Romagna	15.500 swines
13	Breeder	F	Site 1 - 2	54	24	Lombardy	2.500 sows, 70,000 piglets a year

5.2. Results

The data gathered through the interviews are presented in Table 12, Table 13, Table 14, Table 15, where both technical and economic aspects have been integrated, providing a comprehensive overview of the effectiveness and sustainability of internal biosecurity measures.

Table 12 shows whether internal biosecurity measures have cost categories:

- Internal biosecurity sub-categories: as demonstrated in Table 1, the first column corresponds to the subcategories delineated in the UGent checklist
- Cost categories: operating costs (working hours, operating cost for veterinarians, breeders and technical operator); materials and equipment consumption (include consumables such as needles, disposable gloves, disinfectant, cleaners and other equipment); structural costs (facilities, fences, nets, gates etc.); staff training (training courses or updates); external services (serology, disposal of carcasses); organizational costs (organization of the workflow); and implementation of good practices (implementation of protocols).

The table indicates "yes" if the sub-categories have a certain cost category, or "no" if the cost categories are not present in the sub-categories.

The table is a useful tool for understanding how resources are allocated with specifics on how each area impacts the overall economic balance. It also provides a comprehensive view of the operational costs and resources needed to effectively implement internal biosecurity.

Table 12. Cost category of internal biosecurity

Internal biosecurity sub-categories	**Cost categories**						
	Operating	Material and equipment	Structural	Training	External services	Organiza-tional	Good Practices
Disease management	yes	yes	yes	yes	no	no	no
Farrowing and suckling period	yes	yes	yes	yes	no	yes	no
Nursery unit	yes	no	yes	no	no	no	no
Finishing unit	yes	yes	yes	no	no	no	no
Measures between compartments, working lines and use of equipment	yes	yes	yes	yes	yes	yes	yes
Cleaning and disinfection	yes	yes	yes	yes	no	no	no

It is interesting to note that, although each sub-categories of biosecurity involves a combination of operational, material, and structural costs, the area that includes measures between compartments, work lines, and equipment use is the only one that impacts all cost categories. This indicates that the biosecurity measures implemented to separate compartments, work lines, and equipment use require a comprehensive financial commitment across various fronts.

At this point, a matrix was created (Table 13) which summarizes the costs associated with the sub-categories of internal biosecurity.

From an economic point of view, all the cost can be categorized according to the classical distinction among fixed and variable cost. Variable costs are easier to identify because they depend on the number of workers, working hours, and the number of animals in the farm. On the contrary, fixed costs are more difficult to calculate in a standard way that is adaptable for each company, precisely because each farm has a different structural condition from another.

Fixed costs are expenses that remain relatively stable over time, regardless of the number of animals or production levels. Such costs are crucial, as they ensure the basic structures and practices necessary to operate in compliance with biosecurity regulations:

- Structures**:** Fixed costs include all the necessary structures for internal biosecurity. For example, the sick room and the cold room for carcasses (if required, possibly rented) are integral parts of the farm's health management. The sick room is essential for isolating sick animals and preventing the spread of infections, while the cold room for carcasses is necessary for the safe storage of carcasses in case of mortality, reducing the risk of contamination. These costs, primarily related to structural adjustments, represent initial investment items that, once incurred, do not vary significantly.

  Additionally, there are costs related to the structural adjustments necessary to comply with biosecurity regulations. Such interventions, like the construction of fences, disinfection systems, and ventilation systems, are needed to maintain a controlled and safe environment.

- Training**:** Another example of fixed costs is the periodic biosecurity training courses, which are organized every 3-4 years for the operators. These courses, while being a constant expense, do not depend on the number of animals but on the need to update the staff on new regulations and safety practices. Training costs are thus divided into macro areas, such as health management, infectious disease management, and the use of protective equipment.
- Laboratory Analysis: Laboratory tests, generally performed in the case of an infectious epidemic, are another fixed cost, though less frequent than other items. These tests are necessary to monitor the health of animals but are not performed regularly, unless there is an epidemiological risk. The analyses include serological tests, fecal examinations, and other investigations to detect infections or diseases.
- Equipment: in this case the equipment does not depend on the number of animals present in the farm, for example, the boots and professional clothes depend on the number of workers, but they are used

for many years. The same thing for the guns and knives, they are disinfected but they always remain the same. The knives are changed or sharpened in case they no longer cut.

Variable costs, on the other hand, are linked to dynamic factors such as the number of animals in the farm, daily operations, and the frequency of biosecurity activities, they directly vary with the intensity of farming operations:

- Carcass Disposal Managing: animal death is another aspect that involves variable costs, such as the disposal of carcasses (for example, through incineration or other legal procedures). These costs are closely related to the management of extraordinary situations, such as epidemics or high mortality rates, and depend on the number of dead animals.
- Sanitary materials: The majority of variable costs are associated with the purchase and use of sanitary materials, which are necessary to keep the animals healthy and safe. Common sanitary materials include:
    - Vaccines to prevent infectious diseases
    - Personal protective equipment (PPE), such as suits, gloves, boots, to ensure the safety of operators and prevent cross-contamination between animals
    - Surgical instruments, syringes, needles, and other veterinary tools used for vaccinations and treatments.

  The purchase of these materials is variable and depends on the number of animals treated, the frequency of vaccinations, and the specific needs of the farm.
- Additives and supplements: Feed additives and supplements, if given to animals to improve their health or to address specific needs, also fall under variable costs. For example, if a farm decides to enrich the animals' diet with additives to improve growth or disease resistance, these costs will be directly tied to the amount of feed purchased.
- Cleaning and disinfection: Washing and disinfecting the facilities are daily, repetitive tasks that generate variable costs. Detergents, disinfectants, and the labor time required to clean and disinfect housing areas and other sanitary facilities (such as the infirmary and farrowing areas) are important variable costs, which depend on the size of the farm and the frequency of operations.
- Workload: The workload for biosecurity operations is also a variable cost. These costs include labor hours for staff responsible for cleaning, disinfecting, washing animals, and administering sanitary treatments. These costs are related to the number of workers, working hours, and the amount of work required.

Table 13. Matrix of sub-categories of internal biosecurity and cost categories

Internal biosecurity sub-categories	Cost categories								
	Fixed costs				Variable costs				
	Structures	**Training**	**Lab. Analysis**	**Equipment**	**Consultancy**	**External operators**	**Sanitary materials**	**Products**	**Labor**
Disease management	Infirmary box	Biosecurity course	Serology		Company veterinarian or pharma-ceutical business for vaccination protocol	Disposal of carcasses	Vaccines	Additives/ supplements	Administra-tion of vaccines
	Cold room			Felling equipment (pistol, knife…)	Supplement nutritionist				Killing and moving carcasses
					Vet ASL: score at the slaughter-house				
					Company Vet: samples for serology				
					Company vet for euthanasia with drugs				
Farrowing and suckling period	Washing area	Biosecurity course		Basin			PPE	Cleaners	Sow washing
				Castration box			Scalpel	Disinfectants for vet equipment	
				Sow washing equipment					
Nursery unit	Adequacy of the structures								
Finishing unit	Adequacy of the structures							Detergents	Cleaning and disinfection of the housing area after each cycle
								Disinfectants	
Measures between compartments working lines and use of equipment	Adequacy of the structures	Biosecurity course		Professional clothing	Quality Consultant for drafting a hygienic operating procedure	Sanitary material disposal	Syringes	Detergents	Cleaning and disinfection of panels for moving pigs at the end of the cycle
				Boots			Needles	Disinfectants	
				Trays				Disinfectants for footwear tray	
				Equipment set for managing animals of different ages					
Cleaning and disinfection	Adequacy of the structures	Biosecurity course	Swab analysis	Trays			Surface swabs	Disinfectants for footwear tray	Performing swabs
				Boot washing machine			PPE	Detergents	Cleaning and disinfection of the housing area after each cycle
								Disinfectants	Cleaning and disinfection of aisles and loading areas

Through the interviews, a list of variable costs for internal biosecurity measures has been identified (Table 14). The highest variable costs include Cleaning and Disinfecting Environments (€4,000 per year): Ensuring that animal housing and related facilities are cleaned and disinfected regularly incurs a considerable cost, which is necessary to maintain a safe and hygienic environment for the animals.

The least expensive variable costs include needles (€1.00 per 100 animals): the purchase of needles, necessary for vaccination or other medical procedures, is a relatively low-cost item when spread across many animals.

Table 14. Internal biosecurity variable costs

VARIABLE COSTS	Costs	Unit of measure
Cost for vaccinations (labor and materials)	143,00 €	1 vaccination/100 swine
Cost of scores	200,00 €	1 score to slaughter
Cost of disposal of carcasses	9,00 €	1 carcass disposal for average weight
Cost of killing sick animals (materials)	35,00 €	1 slaughter by euthanasia
Cost for washing sows before farrowing	20,00 €	-
Cost of detergents for washing animals	16,00 €	100 swine
Cost of disinfectant for veterinary equipment	2,50 €	100 swine
PPE cost	2,50 €	100 swine
Hand cleaner costs	220,00 €	Per year
Costs for cleaners and disinfectants for animals	160,00 €	Per year / 100 sows
Cost of syringes (Availability of syringes in an adequate number for the age groups present on the farm. How many syringes per sow, per litter, per number of growing or fattening pigs present?)	50,00 €	100 swine
Cost of needles (Availability of needles in an adequate number for the age groups present in the farm. How many needles per sow, per litter, per number of growing or fattening pigs present?)	1,00 €	100 swine
Cost of a tampon	120,00 €	10 tampons
Cost for the analysis of a swab	22,00 €	
Costs for cleaners and disinfectants for buildings	320,00 €	Per year per 100 sows
Cost of footwear disinfection trays (1 tray per house)	20,00 €	1
Disinfectant cost for trays	10,00 €	Per Lt

Table 15 present the fixed costs, but cost data are available for structures, as the interviewees were unaware of the associated expenses.

The highest fixed costs presented include Professional Clothing (€6,800 per year): The purchase and maintenance of professional clothing is a significant expenditure. This category likely includes specialized workwear for farm staff to prevent the transmission of diseases between different areas of the farm and protect workers from potential hazards.

Table 15. List of internal biosecurity fixed costs

FIXED COSTS	Costs	Unit costs
Cost of a cold room for carcasses (for death animals)	1.000,00 €	Annual rental
Cost of retractor for piglet castration	115,00 €	1
Cost for professional clothing	6.800,00 €	Per year
Cost of a tray = €20; Tray capacity = 12-20 litres; 1 tray/sector	20,00 €	1
Cost of boots (availability of a pair of boots/sector/employee working in that sector; included in the overall cost of workwear (C91)?)	70,00 €	1
Average cost of a set of equipment for managing animals of different ages (by sector)	200,00 €	Average per year
Cost of a biosecurity training course	200,00€	2/3 years
Cost of a sick bay		
Structural costs for washing sows before farrowing		
Costs of AI/AO in weaning		
Cost of an adequate sanitary barrier		
Costs of the AI/AO for the fattening sector		
Costs of the AI/AO: Fixed costs incurred by the farmer (losses) during the sanitation gap?		
Cost for the presence of a changing room for changing clothes between the different sectors		

5.3. Discussion

Studies investigating the economic aspect of improving animal welfare and biosecurity are still quite rare, mainly due to the difficulty of collecting reliable and representative data in such a complex sector. Most available studies are based on analyses of small herd samples, which often do not reflect the reality of large-scale operations or consider the variability of practices across different business models.

In this study, the results of 13 interviews conducted with industry professionals were reported, which led to the definition of a list of variable costs associated with internal biosecurity measures in intensive pig farms. However, these data may not be sufficiently representative of the entire sector. In fact, a larger and more diverse sample of interviews would be necessary, including perspectives from farmers of different business sizes, as well as from pigsty builders and specialized technicians, in order to obtain a more complete and accurate understanding of the costs and practices applied.

The primary expenses stem from professional clothing, cleaning, and disinfecting, followed by the costs associated with maintaining animal health through vaccinations, equipment, and ongoing biosecurity structure.

The results lead to the consideration that a significant portion of the costs necessary for the proper implementation of biosecurity in pig farms is closely related to the improvement of farm structures. The size and quality of the structures are, in fact, key factors in ensuring the effectiveness of biosecurity measures, as inadequate management of spaces and equipment can promote the spread of diseases, reduce productivity, and compromise animal health.

Among the results of the study, costs of structures are missing, which should not be considered essential for the analysis, as in the case of pig farming, these facilities are generally built from scratch, already adhering to predefined biosecurity standards. This means that the design and implementation of the structures are based on established parameters, ensuring compliance with regulations and good biosecurity practices. Therefore, while structural costs are relevant to overall management, they do not represent a determining variable for this specific analysis. What is of greater importance are the operational practices and daily management applied within the farm. In fact, it is the adoption of correct biosecurity practices – such as strict control of health conditions, management of animal flows, and disease monitoring – that directly impacts the costs of biosecurity measures and plays a crucial role in the success and sustainability of the farm.

In this context, the characteristics of the Italian pig sector present a significant challenge. The market is still dominated by small individual producers, many of whom are nearing retirement age and manage farms with outdated costs of structures that are unable to fully meet modern biosecurity standards. These farms, while still playing a relevant role in the supply of pork, often lack the necessary resources to invest in modernization or to bear the financial burden of upgrading their facilities.

The presence of these small-scale operations, which function within a highly fragmented sector, makes it difficult to expect rapid or significant changes in the short term. The process of adapting to new regulations and biosecurity standards requires not only a substantial initial investment but also a cultural and operational shift on the part of farmers, which must necessarily be accompanied by an improvement in technical and managerial skills. The current situation, therefore, suggests that the general improvement of biosecurity at the national level cannot be separated from a generational shift in the sector, bringing new ideas, methods, and the capacity to adopt innovative technologies. However, for this change to take place, it is crucial that significant incentives be introduced by agricultural policy. These incentives could include funding for the restructuring of facilities, tax breaks, grants for the purchase of advanced technologies, and increased training for farmers.

Moreover, the improvement of biosecurity should not be limited to the upgrading of physical structures alone but should also focus on the adoption of more modern management practices, the digitalization of business operations, and the implementation of advanced disease monitoring and control systems. Only an integrated approach, which includes both structural renewal and innovation in operational practices, will allow for the achievement of an adequate level of biosecurity to ensure the health of animals and the long-term sustainability of the sector.

6. Evaluation of the ClassyFarm surveillance system on efficacy biosecurity indirect indicator

In this chapter address the following research question:

RQ5. How can we evaluate the different aspects of the ClassyFarm surveillance system with respect to AMU/AMR from a biosecurity perspective?

Methods, results and discussion are presented in order to assess ClassyFarm components that could be further improved to optimize the integrated nature of the system concerning AMU and AMR, considered as indirect indicators of the effectiveness of biosecurity measures implemented in farms. Three evaluation tools are used for the assessment: the Food and Agriculture Organization of the United Nations Progressive Management Pathway for AMR (FAO PMP-AMR), the Network for Evaluation of One Health tool (NEOH http://neoh.onehealthglobal.net), and One Health epidemiological surveillance capacities and capabilities (OH-EpiCap).

This assessment is part of the study on "Evaluation of ClassyFarm, the Italian integrated surveillance system of livestock farms, in the context of antimicrobial use and antimicrobial resistance" (Tomassone *et al.*, 2024).

6.1. Materials and methods

Existing systems for assessing livestock health risks operate on the assumption that biosecurity measures are inherently effective to some degree, yet there are no indicators that truly measure the effectiveness of the recommended biosecurity practices. In the same vein, the ClassyFarm system gauges a farm's biosecurity level by tracking the implementation of various measures or practices. However, it cannot assess how effectively these measures reduce the risk of infection outbreaks or disease transmission.

By monitoring the use of antimicrobials, it is possible to obtain indirect information about the effectiveness of the biosecurity measures implemented. In fact, a high and frequent use of antibiotics can be a symptom of inadequate animal health management and insufficient biosecurity. On the contrary, if biosecurity measures were effective, a reduction in the need to use antimicrobials should be observed, since infections occur less frequently. In this sense, AMU serves as a reflection, acting as an indirect index of the effectiveness of the biosecurity measures implemented in farming.

In pig farming operations, antimicrobials should only be used when absolutely necessary, such as for treating specific infections, and always under the supervision of a veterinarian. If antibiotics are used excessively or routinely, it may suggest that key preventive measures – like controlling infectious diseases, managing quarantine areas effectively, and maintaining strict hygiene – are not being properly implemented. In these situations, ongoing monitoring and accurate record-keeping of antimicrobial treatments are essential for evaluating the success of biosecurity strategies. An increase in antibiotic use may highlight the need to reassess and enhance biosecurity practices, with a focus on improving sanitation and preventing disease outbreaks.

ClassyFarm was analyzed as a processing unit, functioning as an institution or organization that allocates resources to achieve its mission – processing and providing information. This perspective is rooted in traditional concepts of technical-economic and business organization, which enable the description of a production process. In the context of AMU/AMR, ClassyFarm collects raw data from other system databases for further analysis and presents the results to users through its business intelligence dashboards. Currently, ClassyFarm estimates AMU in pig, poultry, and ruminant (cattle, buffalo, goat, and sheep) farms, with future plans to include other livestock species. It provides nationwide coverage, with farms automatically included in the system. A national indicator (DDDAit – defined daily dose for Italy) calculate AMU, and it also combine data from REV (Electronic Veterinary Prescription) and BDN (National Database of Livestock Registry). Farm benchmarking is performed by comparing its AMU against the median and weighted mean (based on herd size) of farms of the same production type (e.g., fattening pig farms, dairy cow farms).

Three different evaluation tools were used to evaluate ClassyFarm: the FAO Progressive Management Pathway for AMR (FAO PMP-AMR), the Network for Evaluation of One Health (NEOH http://neoh.onehealthglobal.net) tool, and OH-EpiCap. The evaluations with FAO-PMP and NEOH tools were conducted through interviews (see 5.1. Methodology) with key informants. The evaluations took place twice: in autumn 2019 and summer 2022, to assess changes over time in ClassyFarm's functionality, implementation progress (FAO-PMP), and its One Health approach (OH-ness) as measured by NEOH.

A systems thinking approach (see 4.1. Theoretical approach to the problem) was adopted to describe the role of ClassyFarm from an intersectoral perspective. The internal expert discussions, along with the existing knowledge from past and ongoing projects such as Cost Action BETTER, BIOSECURE, and CoEvalAMR, informed our systems thinking exercise. This contributed to a broader framework for understanding the role of biosecurity, both before and after the implementation of the ClassyFarm surveillance system.

Interviewees were selected through purposive sampling, targeting participants who could provide relevant, comprehensive, and diverse insights into the research questions (Tong *et al.*, 2007). A total of 16 participants were selected, including representatives from the ClassyFarm management team (n=3), farm veterinarians (n=2), veterinarians from the National Health System (n=4), farmers and livestock industry operators (n=4), and academics/experts in AMR/AMU (n=3). In-person meetings were organized, each interview lasting approximately one and a half hours, and responses were recorded through written notes. The questions posed were based on the set embedded in each evaluation tool. The assessors reviewed the responses, reached a consensus on the answers provided by the interviewees, and entered the scores into the respective Excel spreadsheets.

The OH-EpiCap evaluation was conducted in 2022, initially based on the knowledge of the assessors, acquired through previous evaluations using NEOH and FAO-PMP. Subsequently, two virtual meetings, each lasting one hour, were held with three members of the ClassyFarm management team. During these sessions, a consensus was reached on the shared answer options for each question, and notes were taken to justify the responses provided. The aim of this evaluation was to reassess the OH-ness of the system using a faster, more user-friendly tool that incorporates an "impact" dimension, facilitating discussions on the evaluation outcomes and potential adaptations.

The three tools differ in their evaluation objectives, analytical depth, and the time and training resources needed to carry out the evaluation. However, each tool collects distinct information that can serve as a foundation for discussing potential adaptations and improvements to ClassyFarm. The first PMP-AMR, developed by FAO, offers guidance to countries for developing and implementing their multi-sector One Health National Action Plans (NAP) on AMR using a step-by-step approach (FAO, 2019). Since the questions are designed to analyze a One Health NAP, not all of them were directly relevant for evaluating the ClassyFarm surveillance system, which primarily focuses on the animal production sector. However, we used the tool for self-assessment to evaluate progress in achieving the optimal and sustainable use of antimicrobials. The tool is structured around four key focus areas: awareness, evidence, governance, and practices. For each area, it outlines specific activities, achievements, and key performance indicators (KPIs). The evaluators score activities and indicators based on their relevance in a spreadsheet, which automatically generates the results in a dashboard. We used a beta version of the tool, provided by FAO upon request. The evaluators score activities and indicators based on their relevance in a spreadsheet, which automatically generates the results in a dashboard. We used a beta version of the tool, provided by FAO upon request. The second, NEOH tool, was developed within the framework of the EU COST Action TD1404 "Network for the Evaluation of One Health" (NEOH) to provide science-based guidance for evaluating One Health and other integrated health approaches. It evaluates the extent to which the six dimensions of knowledge integration – systems thinking, planning, transdisciplinary collaboration, sharing, learning, and systemic organization – are implemented in a given One Health initiative. The scores assigned to qualitative and semi-quantitative items are entered into a spreadsheet to evaluate the degree of One Health implementation or "OH-ness." An OH index and OH ratio are automatically calculated and displayed in spider diagrams, highlighting the distribution of scores. The operational aspects, located in the upper-left of the diagonal, are contrasted with the infrastructure in the lower-right. Each axis is scaled to cover a range of values between 0 and 1. As a result, the graph not only illustrates the degree of integration but also demonstrates the balance between operations and supporting resources through its symmetry along the diagonal, numerically represented as the OHR. The tool is freely available (Rüegg *et al.*, 2018). The third, OH-EpiCap tool, was created by the MATRIX consortium, with funding from the One Health European Joint Program, to standardize the characterization of epidemiological surveillance activities in national surveillance systems. (Tegegne *et al.*, 2023). It was designed to characterize, assess, and monitor One Health epidemiological surveillance capacities and capabilities across three dimensions: organization, operational activities, and the impact of the surveillance system. A beta version of this tool was used for the evaluation. It is an interactive web application that allows users to complete the questionnaire by assigning scores from 1 (indicating a low degree of OH-ness) to 4 (indicating a high degree). Answers are automatically analyzed, and the results are displayed as radar charts and lollipop plots. The tool is freely available at: (https://freddietafreeth.shinyapps.io/OH-EpiCap/).

6.2. Results

Evaluation through the PMP-AMR tool

The dashboard displays the scores assigned to overall activities and key performance indicators across the four focus areas of the tool, as shown in Table 16.

Table 16. Percentage of achievement considering the overall activities and key performance indicators in the four focus areas of the FAO PMP-AMR evaluation tool, applied to ClassyFarm system in 2019 and 2022

		2019		2022	
Focus area	**Stage**	**Overall %**	**KPI %**	**Overall %**	**KPI %**
Awareness	1 – assessing awareness	25	50	25	50
	2 – limited or small-scale AMR awareness	25	0	100	100
	3 – nationwide awareness of AMR in some sectors	60	60	100	100
	4 – nationwide awareness of AMR in all sectors	0	0	0	0
Evidence	1 – system development	83	80	100	100
	2 – focus AMU and AMR surveillance	40	40	100	100
	3 – nationwide AMU and AMR surveillance in some sectors	63	60	100	100
	4 – nationwide AMU and AMR surveillance in all sectors	60	60	80	80
Governance	1 – establish a governance mechanism	63	0	100	100
	2 – situational analysis and assessment	71	67	71	67
	3 – strategic and operational planning	100	100	100	100
	4 – national 'One Health' action plan implementation and review	100	100	100	100
Practice	1 – regional promotion of Good Practices	50	67	100	100
	2 – national promotion of Good Practices	50	67	83	100
	3 – national implementation of Good Practices	71	67	86	83
	4 – national implementation of 'One Health' good practices	17	0	17	0

The "awareness" focus area refers to the progress made in raising awareness and enhancing understanding of AMR through communication, education, and training initiatives. Stage 1 (assessing awareness) remained unchanged between 2019 and 2022, as the initial activity (identifying stakeholders) had already been completed in 2019. The other activities, such as awareness assessment and inventorying existing training opportunities, were not included in the surveillance system. Stage 2 (limited or small-scale AMR awareness) showed improvement, as the design of campaigns targeting key stakeholders and veterinary professionals began in 2019 and was completed by 2022. By 2019, core curricula had already been reviewed to ensure that AMR/AMU topics were included in dedicated courses for both undergraduate and graduate veterinary students. All activities planned for Stage 3 (nationwide awareness of AMR in certain sectors) were successfully carried out and completed in the animal science sector by 2022. Regarding Stage 4 (nationwide awareness of AMR across all sectors), slight improvements were made by 2022, although these were not reflected in the dashboard percentage or KPI. Training courses promoting successful alternatives to AMU were implemented for food professionals, but not for agricultural students. Annual reports on the evolution of AMU and AMR incidence, based on surveillance and monitoring data, are available for animals and humans, but not yet for the environmental sector. As with Stage 1, awareness campaigns were not included in the surveillance system.

The "evidence" focus area refers to the surveillance and monitoring of AMR and AMU, which serve as the foundation for driving action. Regarding Stage 1 (system development), the implementation of surveillance plans and laboratory capacity was completed by 2019. By 2022, the routes and flows of antimicrobial use and sales had also been mapped, thanks to the adoption of the REV by the Veterinary Public Health Sector. As a result, Stage 2 (focused on AMU and AMR surveillance) activities, including the implementation of surveillance for antimicrobial residues in animal products for food consumption and the enhancement of laboratory capacity for AMR and residue surveillance, were completed by 2019. In 2022, data collection and reporting on AMU, antimicrobial sales, and small-scale AMR surveillance in animal products were also completed. All Stage 3 (nationwide AMU and AMR surveillance in certain sectors) activities and achievements were considered completed in 2022. In 2019, however, some activities were still in progress, including end-user benchmarking, reporting on antimicrobial sales by class, and national-scale AMR surveillance in animal products. Stage 4 (Nationwide AMU and AMR surveillance across all sectors) actions were completed in 2022, with the exception of the plant production sector.

The “governance” focus area refers to political commitment, policy development, and regulatory frameworks that provide the necessary capacity and resources to address AMR. It achieved strong results as early as 2019. Stage 1 (establishing a governance mechanism) saw further improvement with the introduction of the new PNCAR 2022–2025, which involved representatives from both the Ministry of Agriculture and the Ministry of Ecological Transition. We did not observe significant progress in Stage 2 (situational analysis and assessment), as data on AMR burden in the plant and environmental sectors have yet to be provided and reviewed by key stakeholders. Additionally, the assessment of stakeholders' behavior regarding AMR drivers remains incomplete. Activities in Stage 3 (strategic and operational planning) and Stage 4 (National “One Health” action plan implementation and review) were considered already completed as of 2019.

The “practice” focus area emphasizes the development of good practices within food and agriculture systems to reduce drug use and prevent the spread of AMR. Among these good practices, biosecurity measures are included. Our evaluation shows progress over time, particularly in the first three stages. In Stage 1 (Regional Promotion of Good Practices), national activities related to AMU regulation and overall antimicrobial good practices were fully implemented in 2019, while small-scale initiatives supporting prudent AMU were completed in 2022. In Stage 2 (National Promotion of Good Practices), most activities were completed by 2022, except for legislation and guidelines regulating the prudent use of animal waste as fertilizers for plant-based food. Efforts such as the development of national good practices for prudent AMU in priority animal production sectors, and initiatives to promote prudent AMU on livestock farms, were finalized in 2022. Stage 3 (National Implementation of Good Practices) activities were considered complete in 2022, except for the benchmarking of veterinary professionals, which is not included in the system. Lastly, Stage 4 (National Implementation of “One Health” Good Practices) activities have been implemented in the animal production sector, but not in other agricultural sectors. Coaching programs for livestock production professionals aimed at changing behavior regarding AMR and AMU began in 2022.

In conclusion, the FAO PMP-AMR has made significant strides in raising awareness about AMR, particularly through campaigns targeting key stakeholders and veterinarians, as well as promoting good practices within food and agricultural systems. The advancement of good practices, such as biosecurity measures for prudent AMU, has been notable. National campaigns aimed at regulating AMU and reducing antimicrobial use in food and agriculture systems have achieved considerable success, particularly within the animal production sector.

Improvements have been made in the assessment of AMR at the national level in some sectors, but awareness across all sectors is still limited. The progress made in AMU/AMR surveillance and the establishment of governance mechanisms is evident. The governance system has been strengthened with the introduction of the PNCAR 2022-2025, but progress in situational analysis and stakeholder behavior assessment remains partial. Strategic planning and the implementation of the national "One Health" action plan were completed in 2019. Good practices, including biosecurity interventions, have been successfully promoted to reduce antimicrobial use in food and agricultural systems. Many activities were completed by 2022, but the regulation of prudent use of animal waste as fertilizers is still under development. However, the evaluation also underscores the persistence of important gaps, particularly in the environmental sector.

Evaluation through the NEOH tool

The average scores of OH aspects (Table 17) indicate an uneven balance between operations and infrastructures of the surveillance system, as shown in the spider diagram from both the 2019 and 2022 evaluations (Figure 29). The components of "thinking" and "systemic organization" have seen a slight improvement over time.

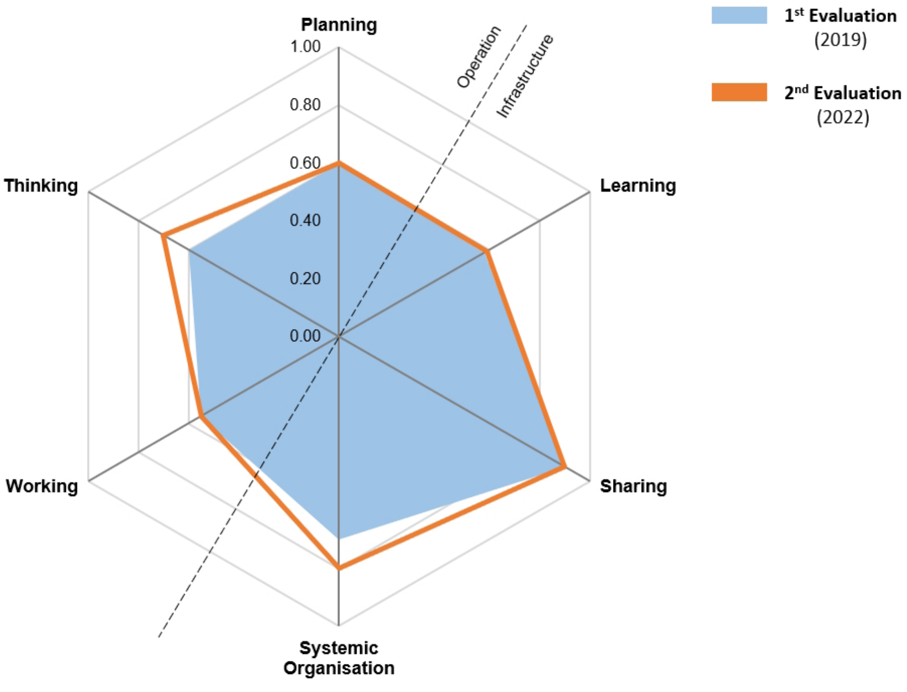

Figure 29. Spider diagrams illustrating the degree of One Health implementation and the balance between the operational and the supporting mean values of ClassyFarm surveillance on AMU/AMR in 2019 (light blue shade) and in 2022 (orange line). The diagrams are generated by the NEOH spreadsheet (Rüegg et al.*, 2018).*

Table 17. Scores attributed to operational and infrastructural dimensions of ClassyFarm with NEOH tool (in 2019 and 2022)

	Thinking	Planning	Working	Learning	Sharing	Systemic organization
1st evaluation (2019)	0.60	0.60	0.55	0.58	0.90	0.70
2nd evaluation (2022)	0.70	0.60	0.55	0.59	0.90	0.80

Regarding OH thinking, several dimensions and scales were identified as key elements within the initiative. The surveillance system is closely tied to both national and EU regulations on AMU/AMR, with ClassyFarm playing a crucial role in the PNCAR. The time scale is significant as the system has evolved over time, initially focusing on monitoring welfare and biosecurity on farms and progressively adopting a more integrated approach. Additionally, the range of livestock species included, and the number of participating farms has expanded. The economic dimension is also essential, encompassing investments and cost-benefit considerations for farmers. Socio-ecological systems related to animal health and production, with impacts on human and environmental health, are considered. In the second evaluation, a higher score for OH thinking was achieved, reflecting the system's growing attention to the environmental pillar.

In terms of OH planning, although the initiative mainly focuses on animal health, its core principle is OH-oriented: addressing AMR in animals to also safeguard human and environmental health. Veterinarians and other key actors in the animal and food production chain play a central role in this process. At the outset, the initiative involved only a limited number of stakeholders, particularly from regions with intensive livestock production systems. These stakeholders contributed to the planning and adjustments of ClassyFarm across its various stages. While the time and budget allocated for self-assessment and the pursuit of its objectives are generally sufficient, there remains a concern regarding the adequacy of human resources.

Regarding OH operations, the initiative incorporates a moderate diversity of disciplines (animal science, biology, computer science, public health), methods (epidemiological data collection, diagnostics, computational models), and actors (including the non-scientific community). However, the level of integration and collaboration among these elements remains limited.

As regards OH sharing, optimal scores are related to data/information quality and storage. Internal mechanisms for sharing information and awareness are better than external mechanisms; indeed, more resources are needed, especially in terms of personnel, for sharing. Results are shared between groups, though privilege of access to data is restricted to certain categories. Institutional memory and resilience to change obtained the highest score.

The OH learning demonstrates a reasonable level of cooperation among stakeholders at various levels of the initiative. Stakeholder engagement and awareness have contributed to the adaptive learning of the health system. However, at the organizational level, generative learning is infrequent, as the information collected seldom results in changes to core principles or objectives.

Regarding systemic organization, teamwork is strong, with effective cooperation both within and between working groups, as well as between regional teams and the national ClassyFarm coordinating team, which demonstrates strong leadership. While the initiative primarily focuses on animal health and production, the

OH challenge is not sufficiently addressed, and the scientific and developmental innovations provided mainly pertain to the animal sector. Over time, team collaboration and coordination have improved, leading to a higher score for systemic organization in the second evaluation.

The NEOH assessment allowed us to gain a deeper understanding of the system in which ClassyFarm operates. It revealed an imbalance between the operations and infrastructure of the surveillance system, highlighting that integration and collaboration between disciplines is still limited, with the system remaining livestock-focused. While internal data sharing is present, external sharing was insufficient and more resources were needed, particularly in terms of staff. Additionally, while stakeholder engagement and collaboration has improved, generative learning remains relatively low. On a positive note, the NEOH assessment also identified some progress within the system, particularly in terms of compliance, timeliness and completeness (such as the inclusion of new animal categories/species).

Evaluation through the OH-EpiCap tool

The ClassyFarm system received a sub-optimal score across the three dimensions identified by the OH-EpiCap tool, with an EpiCap Index of 50%, and no targets demonstrating strong adherence to One Health principles. The average evaluation score of ClassyFarm for all questions in each target area covered by the OH-EpiCap tool is presented in Figure 30, while the radar charts for the three specific tool dimensions can be found in Figure 31.

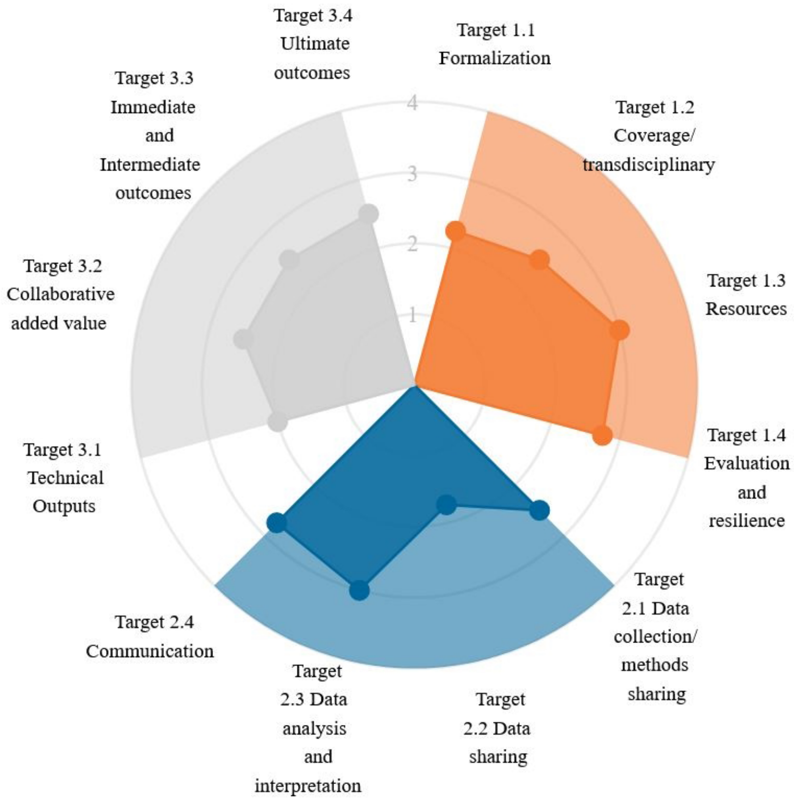

Figure 30. Average scores of ClassyFarm in the target areas covered by the OH-EpiCap tool, segmented into three dimensions (1 = organization, 2 = operational activities, 3 = impact). The radar chart was generated in the EpiCap web application (https://freddietafreeth.shinyapps.io/OH-EpiCap/).

(A - organization)

(B – operational activities)

(C – impact)

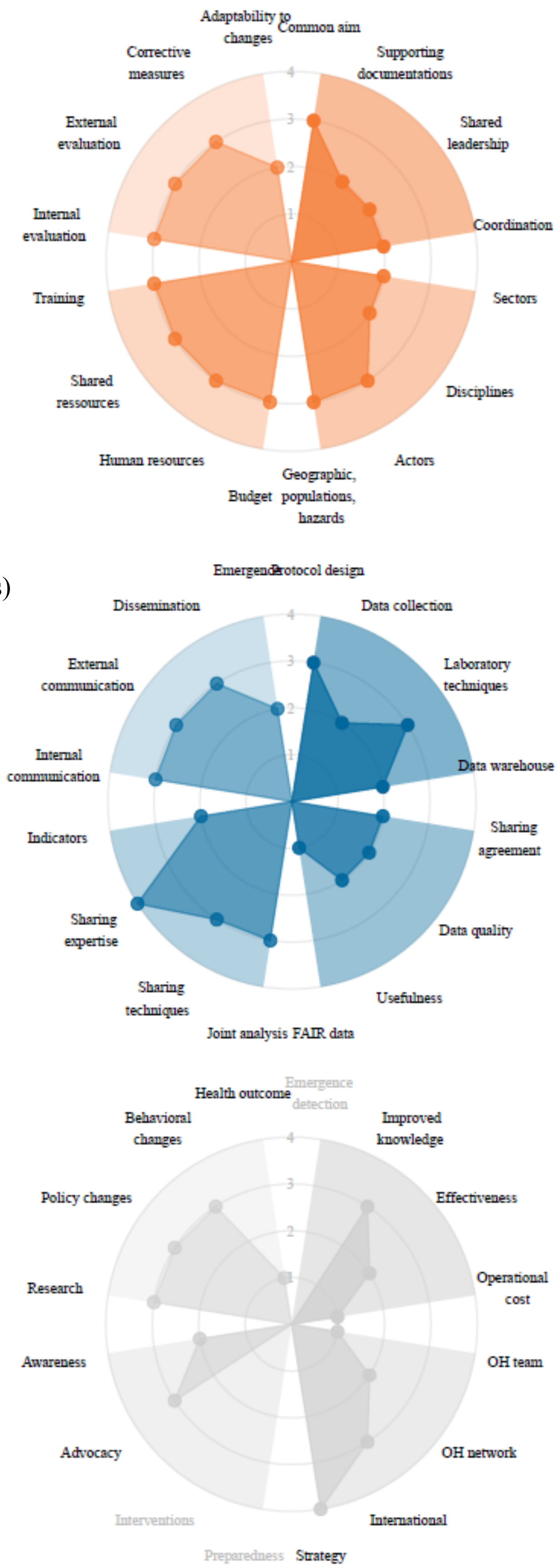

Figure 31. Scores attributed to the indicators of the "organization" (A), "operational activities" (B) and "impact" (C) dimensions of the OH-EpiCap tool, based on the evaluation of ClassyFarm system. The radar charts were generated in the EpiCap web application (https://freddietafreeth.shinyapps.io/OH-EpiCap/).

Dimension 1 (A – Organisation) addresses various aspects related to the organisation of the OH surveillance system, including formalisation, coverage, resources, evaluation, and resilience. This dimension received a score of 54%, with 10 out of 16 indicators scoring "3" and the remaining indicators scoring "2" (Figure 31). The goal of the ClassyFarm system was shaped by the expectations of both private and public stakeholders in the animal health and livestock production sectors. However, since veterinary public health in Italy falls under the Ministry of Health, ClassyFarm is primarily overseen by this Ministry. Recently, the Ministry of Agriculture has also become involved in the governance, given ClassyFarm's role in the allocation of a portion of the CAP funds. Coordination activities are well defined, although they have not yet been shared across sectors; however, a progression toward more integrated coordination at various levels of surveillance is anticipated. Regarding the transdisciplinarity of the AMR surveillance system, as mentioned, the animal health and production sectors are the most prominent within ClassyFarm. Nonetheless, the environmental sector has begun to take a more active role, with initiatives such as the study of AMR genes in farming and agricultural environments, wastewater, and freshwater. The human health sector is indirectly linked to the public health implications of the agriculture and livestock production system. In addition to traditional life sciences, several other disciplines relevant to AMR surveillance, such as economics and social sciences, are being integrated. While most categories of relevant actors are included, the general public remains underrepresented in the surveillance system. Hitziger *et al.*, 2021, also report low citizen participation in OH initiatives, highlighting the need for efforts to address this gap. Regarding resources, EpiCap evaluates budget, human resources, shared materials and equipment, and training. While the allocated budget is considered sustainable, it is not sufficient, and the same applies to human resources. Raw data are shared upon request within the Ministry of Health at both national and regional levels. ClassyFarm experts participate in ad hoc meetings at the Ministries of Health and Agriculture. Training related to ClassyFarm is deemed appropriate, but insufficient, and it does not specifically focus on the OH approach. Regarding the evaluation and resilience of the surveillance system, internal evaluations (e.g., data checks and validations, software testing, stress tests) are conducted, but they are neither regular nor systematic, limiting the ability to fully monitor the system. External evaluation was carried out within the CoEvalAMR project, utilizing various evaluation tools (NEOH, FAO-PMP, OH-EpiCap), as discussed in this paper. Some corrective measures recommended by stakeholders have already been implemented; however, stakeholder feedback remains irregular and needs to be more structured and consistent for improvement. Regarding the evaluation and resilience of the surveillance system, internal evaluations (such as data checks and validations, software testing, and stress tests) are performed, but they are neither consistent nor systematic, which limits comprehensive monitoring of the system. An external evaluation was conducted within the CoEvalAMR project, using various evaluation tools (NEOH, FAO-PMP, OH-EpiCap), as outlined in this paper. Some corrective actions recommended by stakeholders have already been implemented; however, stakeholder feedback remains inconsistent and would benefit from a more structured and systematic approach. Additional corrective measures, such as the revision and introduction of new interactive dashboards, suggested by the evaluators, have been implemented. The system demonstrates the ability to adjust and improve its functioning, adapting to changes in coverage, organization, and new activities. However, the pace of these changes is hindered by bureaucratic processes and the fragmented nature of the Italian health system, which, although centralized in policy, is managed at the local and regional level (Italy is divided into 20 administrative regions).

Dimension 2 (B – Operational activities) addresses various aspects of OH integration in operational activities, including data collection, methods, data sharing, analysis, interpretation, and communication. Overall, this dimension scored 50%. One indicator, "sharing expertise," demonstrated strong adherence to OH principles, while the "FAIR data" indicator (encompassing Findability, Accessibility, Interoperability, and Reusability principles) was identified as an area in need of improvement (Figure 31). Surveillance protocols are developed through collaboration among stakeholders from various sectors, with the environmental sector recently being included to monitor residues in wastewater from urban areas, animal husbandry, and agro-industry. Most laboratory techniques for AMR detection and procedures are standardized within the national veterinary laboratory network, a process initiated by ClassyFarm. While data collection for surveillance has primarily been focused within the animal health and production sectors, efforts are now underway to expand data collection to include the environmental sector as well. Data collected are stored in a central repository accessible via the ClassyFarm dashboard. Data-sharing agreements are in place between stakeholders within sectors. While data quality is evaluated, it is not yet done systematically. Currently, data sharing is limited within the animal health and production sectors, but the system is progressing towards integrating data sharing with the environmental and human health sectors. So far, the data partially meet the FAIR principles, and improvements are needed. Joint data analyses and sharing of techniques, such as statistical analyses and visualization procedures, are planned across the animal and human sectors. Scientific expertise is shared across all sectors, with this indicator demonstrating good adherence to OH principles according to OH-EpiCap. Internal and external communication channels are fairly well established, involving stakeholders from various sectors who, on occasion, collaborate to disseminate information to decision-makers. However, communication could be further improved, such as by publishing annual reports on aggregated results and creating materials aimed at a broader audience, like infographics and dissemination videos. Information regarding the suspicion or detection of emerging AMR agents is primarily shared among actors within the animal sector.

Dimension 3 (C – Impact) focuses on the effectiveness of the OH surveillance system, evaluating targets such as technical outputs, collaborative added value, and immediate, intermediate, and long-term outcomes. This dimension scored 46%. The indicator “strategy” showed good alignment with OH principles. However, the indicators that would benefit most from improvement include “operational cost”, “OH team”, and “health outcome”. Questions related to emergence detection, interventions, and preparedness were deemed not applicable to our AMR surveillance context. (Figure 31). ClassyFarm has contributed to an improved understanding of the epidemiological situation of AMR in livestock, but outreach efforts to the general public remain limited. While the overall effectiveness of the surveillance system is being assessed, further improvements may take time to manifest, given the complexity of AMR. An evaluation of the operational costs associated with surveillance activities in the animal health sector is currently underway. A multidisciplinary team is in place, though its composition is not fully OH-oriented, as establishing an OH team was not a primary goal of ClassyFarm. The surveillance system has strengthened the network of stakeholders, which predominantly includes individuals from the animal health and production sectors (public health officers, veterinarians, producers, farmers, etc.). ClassyFarm also maintains effective international collaboration with animal health and production experts involved in biosecurity, such as those at Biocheck.UGent. Currently, international collaboration in AMR surveillance is mainly limited to research projects. While extensive advocacy activities are carried out within the system and involve multiple stakeholders, their effectiveness still requires evaluation. Through the surveillance system, awareness has improved among stakeholders in the animal health and production sectors, but better communication is needed to engage all relevant stakeholders. Multi-sectoral research collaborations have been initiated among actors from various sectors, particularly with the human health sector. Some changes in national AMR surveillance policy have been driven by the outputs from the animal sector surveillance. For instance, the new PNCAR now includes the agriculture and environmental sectors alongside human and animal health. In terms of behavioral changes, new attitudes and practices aimed at reducing AMR-related risks have been observed among animal breeders, veterinarians, and other professionals in the animal production system. However, further interventions and activities are necessary to reinforce these behavioral changes and to extend their impact on the general public. The outcomes of surveillance on population health have not been evaluated yet, and more time is required to take this step. However, this evaluation will be challenging due to the lack of a benchmark.

OH-EpiCap facilitated the assessment of the degree of One Health integration in surveillance systems. Although the assessment was not particularly in-depth, it was efficient and helped identify gaps, providing an opportunity to discuss potential measures for system improvement (Moura, Collineau, *et al.*, 2023). The assessment revealed suboptimal One Health scores, without a clear adherence to OH principles, as ClassyFarm focuses mainly on livestock. The average system assessment score across the different target areas was relatively low, especially in the "Impact" dimension, which only scored 46%. However, it highlighted progress in terms of organization and operational activities, with scores of 54% and 50% respectively, as well as greater transdisciplinarity in AMR, with increasing involvement of the environmental sector. Although efforts to raise awareness among the general public were limited. Furthermore, multi-sector collaborations were initiated, especially with the human health sector. The evaluation showed that the system is evolving, but there is still room for improvement in resource allocation, data sharing and communication.

6.3. Discussion

ClassyFarm was developed primarily for livestock surveillance, so it focuses on animal health and production, and has an effective international collaboration with animal health/production experts involved in biosecurity (e.g. Biocheck.UGent).

Given its focus, ClassyFarm cannot fully integrate animal-human-environment surveillance on AMU/AMR, nor incorporate biosecurity directly within its framework. However, all three tools agree that the "One Health" aspect of ClassyFarm can be significantly improved. For instance, the system already has an AMU/AMR database that could be expanded within a broader framework, encompassing the human sector, while surveillance of the environmental component could be better integrated into the system. Regarding the environmental pillar, all three tools acknowledge that it is the weakest element in the integrated AMR surveillance programs in Denmark and Norway (Moura, Borck Høg, *et al.*, 2023; Norström *et al.*, 2023).

Both programs demonstrated strong adherence to One Health principles when assessed using the OH-EpiCap tool. They were specifically designed to monitor AMR in both the veterinary and human sectors and have been operational for over 20 years. In contrast, integrated approaches to AMR in Italy are relatively recent. ClassyFarm has made significant progress in promoting the integration of AMU and AMR data within the animal sector, as evidenced by the development of new methods, tools, standardized SOPs, and collaborative projects through surveillance components. Additionally, there has been a notable increase in awareness among professionals regarding the global significance of AMR and AMU. This shift has resulted in behavioral changes and the adoption of good practices by stakeholders, specifically aimed at reducing antimicrobial use through biosecurity measures. Finally, there is an encouraging decline in the use of critical priority antimicrobials (HPCIA) in Italian livestock, including colistin and third- and fourth-generation cephalosporins (European Medicines Agency, 2022). However, it is challenging to determine whether all of these advancements can be solely attributed to the integrated surveillance system itself, as they may also be influenced by the official controls implemented within ClassyFarm and the economic incentives for farms that reduce AMU.

The evaluation of surveillance impacts is still a challenge (Aenishaenslin *et al.*, 2021). Some Authors identified possible indicators of the performance of integrated surveillance systems for AMU/AMR: Bennani *et al.*, 2021 cite the capacity of the system to produce information and use it, and to provide a OH response to AMR threats. However, it is still unclear how to measure these indicators, also due to the lack of benchmarks. Some studies have evaluated the economic impact of OH surveillance (Queenan *et al.*, 2016).

Regarding costs, the ClassyFarm case study presents a particular complexity: while the cost of the system itself is relatively straightforward to evaluate, assessing the value of the information that ClassyFarm extracts from other public health system databases is more challenging. This is because the information serves multiple purposes within the broader health system. As a result, a more detailed evaluation of the cost conceptual framework is needed. The evaluation tools adopted in our study have different characteristics as regards the evaluation objectives, depth of analysis, and time/training resources to perform the evaluation (Sandberg *et al.*, 2021). No tool can cover all evaluation aspects comprehensively, and in a user-friendly manner (Alban *et al.*, 2023).

All three methods proved valuable in analyzing the operationalization of surveillance, with a particular focus on One Health (OH) implementation. PMP-AMR specifically evaluated the surveillance process, concentrating on AMR and biosecurity. NEOH, on the other hand, emphasized a systemic understanding of OH activities and the theory of change. Meanwhile, OH-EpiCap focused on the operational aspects and outcomes of surveillance. Each tool provided distinct insights, highlighting the strengths and weaknesses of ClassyFarm, and served as a foundation for discussing potential adaptations and improvements to enhance the system's efficacy and effectiveness.

In summary, this research not only makes a significant contribution to the theoretical landscape but also provides valuable insights for practitioners, researchers, and stakeholders, while outlining potential directions for future research. For instance, future studies could focus on key aspects to further enhance the ClassyFarm surveillance system and strengthen the One Health approach. Research could explore strategies for improving external data sharing, particularly across borders, to foster greater transparency, coordination, and collaboration in AMU/AMR surveillance. Additionally, investigations into optimal resource allocation models could ensure adequate human and financial support for all aspects of the OH approach, with a particular emphasis on data sharing and external collaborations. Long-term studies examining the real impact of the ClassyFarm surveillance system on AMU/AMR trends across different livestock species and regions could provide crucial insights into its effectiveness and highlight areas for improvement.

7. Conclusions and recommendations

In this final section are summarized study results and limitations, and suggestions for future research, at least are considered recommendations for policy makers.

7.1. Summary of results

The objective of this research was to provide new insights into the economic impact of biosecurity measures, with a particular focus on the costs associated with their implementation in Italian pig farming. Additionally, the thesis assessed the components of the ClassyFarm system that could be further refined to improve its integrated approach to monitoring AMU and AMR, which act as indirect indicators of the effectiveness of biosecurity measures on farms.

To do this, both qualitative and quantitative methods were adopted in the current research study:

- The Systematic Literature Review helped to answer the first two research questions with the support of bibliometric, network and content analysis. In-depth knowledge about the economic aspects of biosecurity in research was provided, and trends, gaps and potential future research opportunities were identified. The articles analyzed were selected through the guideline of the PRISMA diagram.
- The systems thinking approach, incorporating conceptual framework analysis, theory of change, and cause-effect analysis, identified the potential economic impacts of implementing biosecurity measures from a One Health perspective, adopting a theoretical approach to the problem. The approach taken into consideration concerns a general overall context where the business, system, sector and food supply chain aspects are seen as a single large dimension. The systems thinking approach was also used to respond the fifth research question. The role of ClassyFarm survaillance system according to a cross-sectoral vision was depiscted, and it was also evaluated with the support of the three assessment tools: the FAO PMP-AMR, the Network for Evaluation of One Health tool, and OH-EpiCap.
- The semi-structured interview method was used to answer research questions number three and five. For the third research question, a questionnaire was submitted to 13 Italian experts in the pig sector (veterinarians, breeders and zootechnicians) to identifying the costs of the biosecurity measures indicated by the Biocheck.UGent^{TM} checklist. While in the fifth research question total of 16 participants were selected for the interview.

The overall contribution is shown below:

RQ1: Is economic sustainability of biosecurity measures an emerging topic in pig farming research?

The analyses conducted provide tangible implications for farmers, researchers, and policy makers, highlighting the crucial interaction between scientific research, agricultural practices and regulatory frameworks.

It has founded that the economic aspect of biosecurity is a relatively young field of research. In the literature there is a strong interest in virus detection, transmission control and general health management, therefore farmers need strategic biosecurity practices. Although biosecurity, health, animal welfare and performance have been well explored separately, an integrated approach to study their interconnections is lacking.

Studies on the economic implications of improving animal welfare and biosecurity are still rare, but interest is increasing, with an average annual growth rate of 13.89% from 1995 to 2023. In 2022, there was a significant peak in publications, but in 2023, a decline was recorded due to partial data collection. Despite the growing interest, there is a lack of sufficient literature on the economic aspects of animal biosecurity, suggesting a research opportunity. Many studies are published in veterinary medicine journals, indicating that the economic aspects need further investigation.

RQ2: How does economic sustainability affect biosecurity at farm level?

The studies analyzed highlight that disease outbreaks, such as ASF (African Swine Fever), cause enormous economic losses, far exceeding the costs of the biosecurity measures required. Key measures such as hygiene, disease management, and access control are essential to prevent the spread of diseases. Although biosecurity measures involve high operational costs, the long-term benefits, such as preventing outbreaks and increasing profitability, often outweigh these costs. In Europe, biosecurity costs are the highest, followed by North America. It is essential to adapt biosecurity measures to address specific risks, available resources and socioeconomic conditions that vary from country to region.

RQ3: What are the potential economic impacts of biosecurity according to a One Health perspective?

The overview highlights the economic significance of biosecurity in animal farming, emphasizing its role in mitigating risks and fostering long-term sustainability. While implementing biosecurity measures may initially increase costs, the long-term benefits – such as reduced health risks, improved productivity, and market access – often outweigh these expenses, contributing to higher profitability. However, the financial burden on smaller farms could lead to marginalization or closure, increasing sector concentration. Large farms may benefit more from economies of scale, improving competitiveness.

Biosecurity has broader impacts beyond production, influencing market dynamics, competitiveness, and local supply chains. It can enhance public health by reducing zoonotic diseases and antimicrobial use. Despite positive effects, data on the precise economic benefits remain limited, and indirect impacts – like market competitiveness and supply chain shifts – are harder to quantify. Cultural factors, technology adoption, and training also play crucial roles in successful implementation but are not sufficiently addressed in research.

RQ4. How can we categorize and evaluate the costs of biosecurity implementation in pig farms?

Studies investigating the economic aspect of improving animal welfare and biosecurity are still quite rare and are generally based on the analysis of small herd samples. The results of 13 interviews led to some reports. In particular, the area involving measures between compartments, work lines, and equipment use is the only one that impacts all cost categories, highlighting the need for a comprehensive financial investment across multiple fronts. The interviews also led to the definition of a list of variable and fixed costs associated with internal biosecurity measures in intensive pig farms. The variable costs show significant expenses such as cleaning and disinfection of environments (€4,000 per year) and low-cost items like needles (€1.00 per 100 animals). Fixed costs include professional clothing (€6,800 per year) and structural costs like the cold room for carcasses (€1,000 annual rental). However, some data on fixed costs related to structures were absent, as the interviewees were unaware of these expenses. At least, the primary expenses stem from professional clothing, cleaning, and disinfecting, followed by the costs associated with maintaining animal health through vaccinations, equipment, and ongoing biosecurity structure.

Among the results of the study, costs of structures are missing, which should not be considered essential for the analysis, as in the case of pig farming, these facilities are generally built from scratch, already adhering to predefined biosecurity standards.

RQ5. How can we evaluate the different aspects of the ClassyFarm surveillance system with respect to AMU/AMR from a biosecurity perspective?

Although ClassyFarm has a limited degree of One Health (OH) implementation, the evaluation reveals that the system has gradually evolved from a primarily biosecurity and welfare surveillance system into a more integrated OH approach. A transdisciplinary nature is emerging, with increasing involvement from the environmental sector. However, there remains room for improvement in areas such as resource allocation, data sharing, and communication. Beyond the structural evaluation, the effectiveness of surveillance systems should also be assessed from a cost-effectiveness perspective, taking into account their broader system impacts. In recent years, significant progress has been made in Italy regarding AMU/AMR awareness and reductions in AMU. This suggests that biosecurity practices have been enhanced and successfully implemented on farms. However, it remains challenging to determine the precise role of ClassyFarm in driving these changes.

7.2. Research limitations of the thesis

This PhD thesis is not free from limitations that must be taken into consideration when contents are interpreted, as they could affect the generalizability of the results.

Firstly, the results are strongly dependent on the initial search query and in particular on the keywords chosen, which may have limited the scope of the research. As a result, the comprehensiveness of the included studies may have been impacted. This limitation is evident in the relatively low number of studies collected during the early stages of the research. This can be attributed to the fact that the field of biosecurity, especially from an economic perspective, is still emerging. This is further supported by the publication trends identified in the bibliometric analysis, which show a recent increase in interest in this area of study.

It has been selected a limited number of studies analyzed in the content analysis, only 25 out of 586 studies, primarily focusing on those that provided data related to biosecurity costs. While the selection process was rigorous, the small sample size may not fully represent the broader field of biosecurity research. The content analysis highlights regional disparities in biosecurity costs, particularly in Europe and North America, but lacks a detailed geographic and disease-specific analysis due to limited data. This restricts the ability to generalize the findings to all regions or diseases.

Secondly, indirect economic effects, such as changes in supply chain dynamics, competitiveness, and local market conditions, are difficult to quantify and were not extensively explored in the study. These effects could be significant in understanding the full economic impact of biosecurity measures. The research did not delve deeply into the role of cultural factors, technology adoption, and training in the effective implementation of biosecurity measures. These elements are crucial in farm management but were not thoroughly examined in the study. There is limited attention given to the socio-economic impacts of biosecurity measures, especially the displacement of small-scale farms and the increasing concentration of production in larger companies. This could exacerbate inequalities and further marginalize smaller farms, leading to sector concentration. The research did not account for the wide variability in the implementation and effectiveness of biosecurity measures across different farm types and geographic regions.

Thirdly, interviews were conducted with 13 industry professionals, which helped identify the variable costs associated with internal biosecurity measures. However, this sample may not fully represent the sector as a whole. To gain a more comprehensive understanding, a larger and more diverse sample would be necessary, incorporating feedback from farmers of different business scales, as well as input from pigsty builders and specialized technicians. This would provide a completer and more accurate picture of the sector's practices and challenges. The study does not include costs for new technologies and structures, as these latter are typically built from the outset to meet biosecurity standards. However, in the case of adapting existing structures to new regulations, a substantial initial investment would be required, along with cultural changes and improvements in technical and managerial skills. Some data have been examined, but a longer period is certainly needed to study all these aspects, but the current research has only had a period of three years, also remembering the context in which this PhD project is part: the BIOSECURE HORIZON Europe FARM2FORK, a four-year research project started in 2023.

Fourth, although ClassyFarm is primarily focused on animal health and production surveillance, it does not fully integrate animal-human-environment (OH) surveillance for antimicrobial use (AMU) and antimicrobial resistance (AMR), and especially does not precisely provide information on how biosecurity has contributed to reducing antibiotic use in livestock. Despite ClassyFarm’s progress in promoting integration within the animal sector, there is room for further improvement, particularly in integrating environmental monitoring and expanding the system's OH-ness. ClassyFarm has contributed by promoting the integration of AMU and AMR data within the animal sector. However, it is difficult to attribute progress directly to the system, as improvements could also stem from official controls, economic benefits of reduced AMU, and effective management of biosecurity practices. Although there are indicators to measure system performance, such as the ability to provide an OH response to AMR threats, their practical measurement is uncertain due to the lack of benchmarks. Furthermore, the study used several evaluation tools, each with strengths and limitations.

While these tools helped analyze various aspects of OH implementation, no single method can comprehensively cover all evaluation aspects.

7.3. Research quality

To ensure that the research results obtained are significant and applicable, the quality of the research, both qualitative and quantitative, must be judged. In particular, four requirements must be met to judge the quality of a study (Halldórsson and Aastrup, 2003; Karlsson, 2016): construct validity, internal validity, external validity and reliability.

In the context of this study that adopts both qualitative and quantitative methods, it is necessary to analyze whether the requirements just mentioned have been adequately met by the research process. Below are the subsections that explain how these aspects have been addressed, in order to ensure quality, reliability and ethics in the research, usable by scholars and practitioners.

Construct validity

Construct validity is fundamental in the field of research and data analysis, as its importance lies in ensuring that the measurements and definitions adopted in studies are adequate and meaningful for the topic under examination. Providing operational definitions is essential to clearly outline the concepts and variables to be studied, ensuring the correct interpretation and use of the results. This also involves distinguishing boundaries and relationships with other topics, as well as demonstrating that the chosen definitions accurately reflect the phenomenon being analyzed. This means testing and verifying that what is being examined corresponds to the reality of the construct (Yin, R. K., 2013)

In the introduction of the thesis, a description of the scope was presented, along with definitions and explanations. In this research study, a clear logical flow has been emphasized, allowing readers to easily follow the reasoning and draw conclusions from the data input and analysis. As far as possible, the study provides documentary evidence regarding the information deduced at each stage of the research, the decisions made, and the motivations behind them, thus contributing to the transparency and reproducibility of the study.

Internal validity

Internal validity is essential to give credibility to the results of a quantitative study and can be improved by using various methodological techniques, including theoretical replication and the use of rigorous experimental designs. When hypotheses are formulated based on previous studies, and the obtained results are then compared with these expectations, the risks of interpretative conflicts can be reduced. The expected results were formulated based on the scientific literature before conducting data collection and analysis, and only after the empirical results were compared with expectations and discussed. However, while internal validity can be considered an evaluation criterion in exploratory and causal studies, other research methodologies, such as qualitative or descriptive research, like systematic literature reviews, do not require the same rigidity in terms of internal validity (Karlsson, 2016). In these cases, the focus might be on understanding phenomena where causal relationships may be less detailed and non-linear.

External validity

External validity is essential to give meaning and utility to research conclusions, so that the findings can be extended to different contexts. It concerns the possibility of applying the conclusions obtained in the specific context of the study beyond the sample examined, extending the results to broader situations (Cook, T. D. *et al.*, 1979). It is necessary to ask whether the conditions and characteristics of the sample used can be representative of a different context to evaluate the external validity of a study. Being able to describe in detail aspects such as sample selection, the context of the intervention and the type of measurement observed allows readers to understand how the conclusions of the study can be replicated in other scenarios.

As highlighted by Yin, R. K., 2013, however, the peculiarities of each case can often complicate the generalization of the conclusions. In fact, the work that researchers must do is also to isolate the particular elements from the general ones, to try to formulate results that can reproduce a broader reality. When it comes to generalizing the result, it is possible to subsequently return to consider the individual specific case studies considering how they can be inserted within the overall framework.

Reliability

Reliability in research means ensuring that a study can be replicated and results can be reproduced (Karlsson, 2016). The inclusion of a well-detailed research design and precise methodological guidelines offers the possibility of following the same approach and obtaining similar results to future research.

Including the contribution of multiple researchers in the study process and during data analysis helps to reduce subjectivity and individual bias, and also enriches the analytical process thanks to the vision of different perspectives and skills. In this way, the results are also more acceptable and the credibility of the conclusions increases.

To ensure reliability, the current study included a research design and methodology guidelines, also for each attached document, making it possible to replicate all analyses.

7.4. Future research and follow-up activities

While substantial research has been conducted on the costs and benefits of specific eradication and containment programs (Gohin and Rault, 2013; Hauser and McCarthy, 2009; Thompson and Tebbens, 2007), there remains a notable gap in literature regarding the economic aspects of biosecurity in intensive pig farming. This highlights the need for a more comprehensive understanding of how to optimize expenditure both in terms of activity levels and different biosecurity measures (Kompas *et al.*, 2015).

In this sense, researchers who are currently involved in animal biosecurity studies should start to consider also the economic side, especially when doing field research. A cost-benefit analysis could present a new opportunity to explore the field of biosecurity at sector level (swine, chickens, cows etc.), and this is what we are currently trying to do within the European HE Project BIOSECURE. The next steps of this research are the definition of the structural costs for internal biosecurity, the total costs for external biosecurity and the economic benefits for farmers. The results of the research conducted also suggest a growing interest in biosecurity for health, welfare and performance of intensive pig farming, studies have highlighted that these topics have been well explored separately, but that an integrated approach to study their interconnections is lacking. A holistic approach could reveal their interrelationships.

Future studies should focus on the economic impacts of biosecurity practices in intensive pig farming, particularly regarding best practices, returns on investment, and economic strategies to improve farm profitability and sustainability. In particular, small farms, which are vulnerable to infection risks, should be given attention, with targeted support for the adoption of biosecurity measures, and further exploration of the sustainability of these measures from both economic and social perspectives, especially in varying socioeconomic contexts. There is also a need to focus on the strategic decision at both a corporate and political level, research on the economic aspects of biosecurity should focus on both microeconomic and systemic issues, since biosecurity applied at a corporate level also has consequences at an epidemic and territorial level, production system, including economic performance of agricultural companies. In this regard, future research should focus on longitudinal studies to assess the long-term economic impacts, comparing initial costs with long-term benefits. They should also examine the effects of biosecurity in relation to potential economic impacts on different types of farms, food supply chains, and geographic regions. Furthermore, research should explore the socio-economic consequences of biosecurity, including the displacement of small farms, the concentration of production, and the impact on rural economies. Intervention policies, such as subsidies or support mechanisms for small farms, should be investigated to ensure equitable benefits across the sector.

The evaluation conducted in the most recent study highlighted the considerable progress made by ClassyFarm. This development began with a minimal biosecurity and welfare surveillance system and has evolved into a more integrated approach, emphasizing the system's role in ensuring animal welfare and biosecurity within the One Health framework. Given this progress, we anticipate that future evaluation scores will reflect this trend and show improvements. Regular reassessments, at least using OH-EpiCap, will allow for the systematic detection of these improvements and help identify areas still requiring attention. Lastly, future evaluations that encompass the entire NAP and involve stakeholders from various health sectors could prove particularly valuable in fostering cross-disciplinary collaboration and strengthening the One Health aspect of AMR/AMU surveillance.

The studies that investigate economic aspect of improving animal welfare and biosecurity are still quite rare and in general are based on the analysis of restricted farm samples. Future research can focus on the use of data from the thousands of swine farms monitored by ClassyFarm to set a farm clustering based on indicators available from both the ClassyFarm and the Veterinary Information System will enhance the capacity of evaluating the economic sustainability of farm improvements in animal welfare and biosecurity. Furthermore, in the perspective of ClassyFarm, that intends to be a tool supporting farmers' decisions on such matters, the opportunity to set a basis to provide economic information could open relevant developments.

The establishment of interrelations between the ClassyFarm metrics and economic values may also open new perspectives in terms of evaluation methods comparing the cost-effectiveness of alternative strategies to upgrade animal welfare and biosecurity in farms. This can apply at the farmer level (e.g., by comparing the cost-effectiveness for animal welfare and/or biosecurity of an intervention on the farms facilities vs a specific training for farm worker) and at the level of policy makers' decisions as well (e.g., to choose the most effective option between different types of incentives aimed at improving animal welfare and/or biosecurity in the farms of a given region).

In summary, this research not only contributes significantly to the theoretical landscape, but also offers concrete insights for practitioners, researchers and stakeholders while highlighting directions for future research.

7.4. Recommendations

Biosecurity policies must integrate economic incentives and structural support measures to promote the adoption of more sustainable and safe farming practices. A key priority must be the allocation of adequate resources, such as direct farm support in the form of payments that encourage good management practices and the structural upgrading of farms. These payments should be aimed not only at improving daily practices but also at implementing modern and safe infrastructures to facilitate the implementation of biosecurity practices.

Another useful tool could be intensifying incentives for the upgrading of existing structures, with particular attention to older farms that require structural interventions to meet new health and safety standards. Early retirement incentives could also serve as a support measure to encourage generational renewal in farms, enabling a transition to more modern and effective practices.

Moreover, the improvement of biosecurity should not focus solely on upgrading physical structures but also on the adoption of modern management practices, digitization, and advanced disease monitoring systems. For these changes to occur, significant political incentives will be necessary, such as funding for restructuring, tax breaks, and increased training to support farmers in adopting innovative technologies and practices.

Additionally, it would be essential to encourage investment in the renewal of structures and the introduction of new technologies that can enhance biosecurity. Rural development policies could finance such investments, supporting not only farmers but also supply chains, such as agricultural cooperatives that build processing plants, with the goal of promoting sustainability and the safety of agri-food production.

The direct payment system should continue to finance agricultural practices but with greater emphasis on biosecurity practices that protect the environment and animal health. A fundamental step would be to condition direct payments on the adoption of monitoring systems such as ClassyFarm, which should also be extended to environmental health risks and wildlife. In particular, African Swine Fever represents a threat to farms, and strengthening surveillance in this area, along with the inclusion of environmental risks, can help reduce contamination risks.

Biosecurity surveillance should be strengthened, as has already been done for antibiotic use and animal health. Direct indicators could be created to establish clear cause-and-effect relationships between the practices adopted and the reduction of health risks, to be used for farm monitoring. Such indicators should be developed and validated through research, particularly to collect practical data that highlights the connection between farms with good biosecurity standards and those without.

Furthermore, the creation of general biosecurity guidelines, applicable at national and European levels, should be promoted. The guidelines should follow established examples, such as FAO's GMP for AMR, to develop a global and standardized biosecurity framework that all countries can reference. This institutional building process will be crucial in increasing the effectiveness of biosecurity at a global level, ensuring that adopted measures align with international standards.

Finally, strengthening the training and awareness of farmers, veterinarians, and the general public regarding biosecurity, through research activities, awareness campaigns, and training, is essential to ensure full and correct implementation of policies. Awareness, combined with the introduction of targeted financial incentives, will allow for better adaptation of agricultural producers to biosecurity regulations and ensure the sustainability and competitiveness of the sector in the long term.

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