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Facilitating EU Food Exports to the USA: A Case Study Analyzing Barriers and Support Strategies

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Abstract

Exporting food products from the European Union (EU) to the United States of America (USA) involves navigating complex regulations and procedural barriers that hinder market access. Italian food businesses (FBs), particularly small and medium-sized enterprises (SMEs), often face difficulties accessing clear guidance, as national procedures are scattered across multiple sources. This paper proposes a structured four-step analytical framework to support EU FBs: product-specific analysis, identification of relevant EU and USA legislation, comparative legislative analysis via concordance tables, and identification of procedures to integrate into the Food Safety Management System. The framework was applied to an Italian medium-sized FB exporting pork-based pasta sauce to the USA. Beyond the specific case study, the proposed framework was designed to be replicable and adaptable to different food products and third-country destinations. As such, it can support both FBs and Competent Authorities in conducting risk-based assessments of regulatory equivalence and export compliance. Results indicated the need for Sanitation Standard Operating Procedures, thermal process validation, direct verification activities, and pre-shipment review. Findings emphasize that operational and procedural barriers disproportionately affect SMEs, highlighting the importance of targeted support to facilitate market access and strengthen certification systems.

Keywords: FSIS; SSOP; HACCP system; pre-shipment review; ministerial circulars

1. Introduction

In an increasingly globalized food system, the export of Italian agri-food products outside the European Union (EU) plays a strategic role not only in terms of economic and reputational value, but also in shaping how national food safety systems interact with international regulatory frameworks [1-3].

Over the years, Italy has progressively consolidated its presence in the global agri-food market, achieving a relevant growth in exports [4]. From 2010 to 2022, there was a steady increase in the value of exported products, with only minimal exceptions [5]. In the second quarter of 2024, agri-food exports increased further, reaching €16.8 billion, representing a growth of 8.2% compared to the same period of the previous year [6]. Despite notable growth in markets such as Australia (+18%) and Japan, where the export value increased by nearly 50% following a slowdown in 2023, these countries are still far from matching the United States of America (USA) as a key destination for Italian agri-food products [7]. Indeed, the USA recorded a +17% increase in imports of Italian agri-food products in the first half of 2024 compared to the same period in 2023 [7].

Exporting food products is a complex activity that requires compliance with numerous guarantees [8-11]. Italian food businesses (FBs), being based in the EU, must comply with the safety and hygiene requirements set forth in Regulations (EC) No 852/2004 and No 853/2004 and subsequent amendments and supplements [12,13]. Article 4 of Regulation (EC) No 852/2004 requires compliance

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with general hygiene requirements, which are supplemented by specific hygiene requirements for food of animal origin [12]. These requirements correspond to what are internationally known as the so-called Prerequisite Programs (PRPs), as defined by the World Health Organization (WHO), the Food and Agriculture Organization of the United Nations (FAO), the Codex Alimentarius and the International Organization for Standardization (ISO). Additionally, Article 5 of Regulation (EC) No 852/2004 requires FBs to establish, implement, and maintain procedures based on the principles of the Hazard Analysis and Critical Control Points (HACCP) system. The HACCP system is internationally recognized as an essential tool for enabling FBs to identify and manage food-related hazards [14]. Together with the principles set out in Regulation (EC) No 178/2002 and subsequent amendments and supplements [15], which include risk analysis, precautionary principle, transparency, the primary responsibility of FBs, and traceability, these form the foundation of the EU Food Safety Management System (FSMS), which all FBs must comply with [16].

In the case of exports, beyond compliance with EU FSMS, FBs must also ensure that their products do not pose risks to animal or plant populations in the destination country [17], while complying with that country's specific safety and hygiene standards [18]. These requirements are defined through negotiations between: i) the Competent Authority (CA) of the exporting and importing country, or ii) the European Commission (EC) and the CA of the importing country [15]. In both cases the process results in an international agreement which, if managed by the EC, is applicable to all Member States [19]. Such agreements are based on international recognized standards, including the food safety standards of the Codex Alimentarius, the animal health standards set out in the Terrestrial Animal Health Code of the World Organization for Animal Health (WOAH), and the provisions of the World Trade Organization's (WTO) Sanitary and Phytosanitary (SPS) Agreement [20]. In fact, although the responsibility for demonstrating equivalence lies with the exporting country, international standards require countries to recognize that different inspection and certification systems can achieve the same level of safety and, therefore, be considered equivalent [21-23]. Compliance with the agreement's requirements is ensured by a health certificate issued by the Member State's CA, which must accompany the exported food [17]. The health certificate specifies the conditions the FB must meet to export to the destination country, and the CA is responsible for verifying compliance before issuing it. However, in many cases, FBs must first be included on lists of authorized establishments, managed either by the importing country's authority or by that of the Member State. Such inclusion, generally subject to the verification of specific requirements by the CA, is a mandatory step before initiating the health certification procedure [8,18].

In Italy, CAs operate within a system of multilevel governance: central, regional, and local [24]. Each level plays a key role in the field of export activities [18,25,26] as illustrated in Figure 1. In this process the Ministry of Health also contributes by issuing internal provisions, typically in the form of circulars. Ministerial circulars are an essential tool for the comprehension and application of legislation, providing instructions and clarifications on the procedures to be followed. These circulars provide guidance to Local Health Units (LHUs) on the interpretation and enforcement of regulations [27]. In the case of export, circulars provide instructions and clarifications to ensure that official veterinarians of LHUs responsible for export certification procedures are properly informed on the verifications they are required to perform in accordance with the specific conditions set by the destination country. Although primarily addressed to CAs, these documents are also transmitted, for knowledge, to trade associations, which in turn make them available to FBs. Indeed, FBs can refer to them as guidance to meet the general and specific requirements established by the destination country.

As mentioned, the primary responsibility for ensuring the safety of exported food products lies with FBs themselves [15,28]. This means FBs must implement, maintain and update their FSMS according to EU legislation, while also demonstrating compliance with the requirements established by international agreements with third countries of destination [18]. However, the procedures that Italian FBs are required to implement for export are not currently consolidated in a single manual or set of guidelines. As a result, FBs must navigate the official website of the Ministry of Health on their

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own or rely on documents that may be provided by trade associations. This fragmentation of information can lead to uncertainty, especially when FBs are faced with interpreting ministerial circulars, which, being primarily intended for the CA, are often highly technical and complex. In addition, health certificates do not always contain sufficiently detailed instructions that effectively guide FBs in implementing the required measures (authors' note). The situation becomes even more complex when considering that such requirements vary not only from one country to another, but also depending on the type of product being exported, making compliance a frequently challenging and burdensome task (authors' note). In this context, especially small and medium-sized enterprises (SMEs) may struggle to adapt their facilities and production processes to meet export requirements, also due to the high costs that such adjustments may involve [29].

Based on these premises, this study, conducted in collaboration with the LHU "Azienda USL Toscana Centro", applied a structured and replicable analytical framework to a real case involving an Italian medium-sized FB intending to export pork-based pasta sauces to the USA. The aim was to identify the concrete procedures and adjustments required within FSMS to comply with USA export requirements. In addition, operational and procedural challenges that may hinder market access, particularly for SMEs, were addressed. By doing so, the study contributes to the practical understanding of regulatory equivalence and offers policy-relevant insights on how to support FBs and CAs in managing export certification processes more effectively. Finally, the study aimed to contribute to the scientific literature on food safety management by proposing a structured analytical framework that can be applied beyond the USA context, supporting the systematic comparison of regulatory requirements between the EU and third countries.

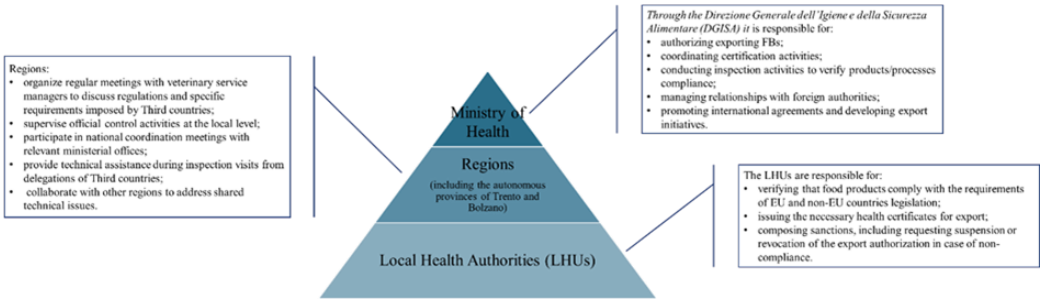

Figure 1. Role of the Italian Competent Authorities in the field of export activities. FBs, food businesses; EU, European Union.

2. Materials and Methods

2.1. Analysis of the Production Plant and the Product to Be Exported

From March to May 2023, several visits were conducted, together with the official veterinarian responsible for export certification procedures of the LHU "Azienda USL Toscana Centro", to a FB approved under Regulation (EC) No 853/2004 for the production of canned foods. Being "approved" means that the FB fully complies with all relevant EU hygiene and safety requirements, including those specific to the production of canned foods. At that time, the FB was managed by approximately 50 employees with an annual revenue of around 20 million euros. Therefore, the FB fell within the definition of a medium-sized enterprise according to European Commission Recommendation 2003/361/EC [30]. The FB was equipped with two distinct and physically separated production lines: one dedicated to sauces and the other to dry products. Specifically, the line dedicated to sauces included the production of pasta sauces made with meat (pork, beef, and game), fish, bivalve mollusks and crustaceans, dairy products, as well as various vegetable-based sauces. In parallel, the other line was dedicated to the production and packaging of dried vegetable products.

In response to FB's request to export meat-based pasta sauces to the USA, the line dedicated to pork-based pasta sauce was identified by the official veterinarian, as among the meat-based products processed at the FB, only pork-based pasta sauce met the eligibility criteria for export to the USA [31].

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2.2. Regulatory Source Collection

To determine the relevant regulatory framework, it was necessary to define the classification of the products according to USA legislation. A summary of the main characteristics of the product intended for export to the USA are provided in Figure 2. Based on these characteristics, the product under study was classified as a "Thermally processed and commercially sterile" (TPCS) meat-based product. Therefore, the Code of Federal Regulations (CFR) and the Food Safety and Inspection Service (FSIS) database were consulted. Specifically, searches were conducted on the FSIS website, as well as through search engines using relevant keywords (USA food legislation, USA food safety, Code of Federal Regulation, FSIS-USDA, FSIS canned food, thermally processed commercially sterile products), to identify the mandatory legislation, guidelines, and other supplementary documents related to both general and specific requirements for the product under study.

As regards the EU legislation, relevant legislative sources concerning general and specific food hygiene and safety requirements were identified through searches on the official EU website (eur-lex.europa.eu) and through targeted search engine queries using keywords (EU food legislation, EU food safety, EU canned food, HACCP EU, EU water quality directive, EU animal by-products regulation). In addition, EU guidance documents were also investigated to ensure a comprehensive understanding of the applicable framework. Finally, ministerial circulars related to USA export requirements were collected. All legislative sources collected refer to the current consolidated versions, which take into account all amendments and supplements made over time, to ensure an up-to-date analysis in line with the applicable regulatory framework.

Product	Description	Picture of the product
Name of the product	Pork-based pasta sauce	
Ingredients	Pork (23%), tomato puree, onion, extra-virgin oil, carrot, white wine, salt corn starch, sugar, garlic, black pepper	
Water activity (Aw)	0.97	
pH	> 4.6	
Heat treatments	Cooked in a brasing pan and sterilized in an autoclave at temperature of 257 °F (125° C) for 35 minutes	
Packaging	Glass jar with screw on metal cap	
Storage conditions	Room temperature	

Figure 2. Analysis of product characteristics intended for export to the USA.

2.3. Comparative Analysis and FSMS Alignment

Firstly, general (PRPs) and specific (HACCP) requirements were identified from the collected legislative sources (both USA and EU). These were then supplemented with the relevant guidance documents covering the different areas of interest. The information was organized into concordance tables, and the tabulated data was compared to highlight differences representing the procedures that the FB must implement in its EU FSMS to comply with USA legislation. Finally, the identified procedures to be implemented were compared with the instructions provided by the pertinent ministerial circulars. Figure 3 visually summarizes the structured four-step based analytical framework used in this study.

To enhance methodological rigor and reduce the risk of researcher bias, the documents collection (USA and EU mandatory legislation, guidelines, and other supplementary documents), data tabulation, and identification of procedures to be implemented were carried out jointly by two researchers. A third researcher then conducted a quality control stage, verifying that all relevant

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documents had been collected and carefully re-reading them to identify any missing sources or overlooked elements. Therefore, this process incorporated data triangulation by involving multiple sources and perspectives. All materials, including the concordance tables, were then submitted to the official veterinarian, who conducted an independent review of both the collected documentation, and the procedures identified, minimizing interpretive bias and increasing methodological robustness. Throughout the process, multiple meetings were held among the team members to iteratively review and validate the findings, ensuring a consistent methodological approach.

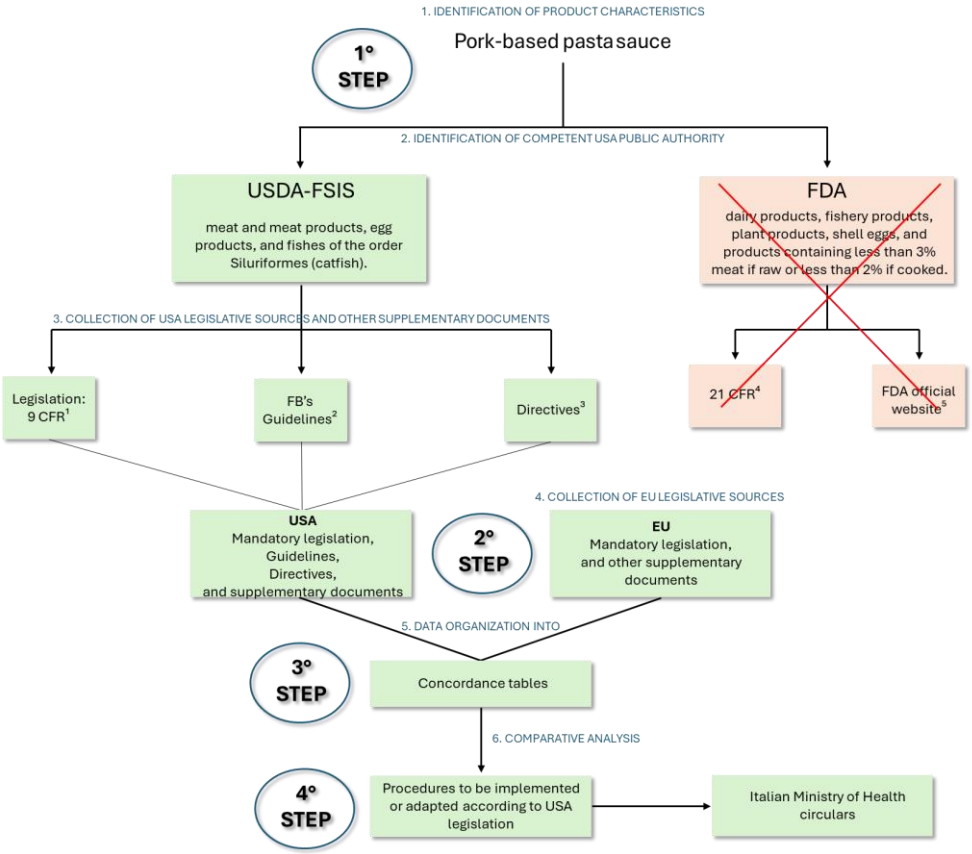

Figure 3. Schematic representation illustrating the four-step based analytical framework used in this study. FSIS, Food Safety and Inspection Service; FDA, Food and Drug Administration; CFR, Code of Federal Regulation; FB, food business; [1] https://www.ecfr.gov/current/title-9 [2] https://www.fsis.usda.gov/policy/fsis-guidelines [3] https://www.fsis.usda.gov/policy/directives-notices-guidelines/fsis-directives [4] https://www.ecfr.gov/current/title-21 [5] https://www.fda.gov/.

3. Results and Discussions

3.1. USA and EU Legislation Collection and Analysis

3.1.1. USA Mandatory Legislation, Guidelines and Other Supplementary Documents

In the USA, the main public authorities responsible for ensuring food safety and hygiene are: i) the Food and Drug Administration (FDA), which operates under the Department of Health and Human Services (DHHS), and ii) the Food Safety and Inspection Service (FSIS), which together with the Animal and Plant Health Inspection Service (APHIS) is part of the United States Department of Agriculture (USDA) [31- 33]. The FDA is responsible for dairy and fishery products, plant-based products, shell eggs, and products containing less than 3% meat if raw or less than 2% if cooked [34]. FSIS, on the other hand, is responsible for meat and meat products, egg products, and fishes of the order Siluriformes [11,35,36]. Based on this, it was determined that the product described in section 2.1 falls under the jurisdiction of FSIS.

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Our analysis identified specific regulations concerning both general and specific requirements for food under FSIS jurisdiction, outlined in Chapter III of Title 9 of the CFR, relating to animals and animal products. Within this chapter, Subchapter E, outlines the regulatory requirements for the inspection of meat, poultry, and egg products. As regards FSIS guidelines, they cover a variety of topics aimed at helping FBs comply with federal regulations [37]. The collected guidelines provide guidance on maintaining adequate hygiene conditions, developing and implementing Sanitation Standard Operating Procedures (SSOPs), applying HACCP principles, and controlling hazards in meat and poultry establishments.

Similarly, several FSIS Directives were collected, which have a different meaning and structure compared to the European ones. In the USA, they provide detailed instructions for federal CA referred to as Inspection Program Personnel (IPP), on how to comply with food safety regulations and policies. They cover a wide range of topics, including inspection procedures, enforcement actions, and the handling of adulterated or misbranded products [37]. Although primarily addressed to the IPP, the content of these directives may also be useful for FBs. The complete list of USA mandatory legislation, guidelines, directives and other supplementary documents considered is reported in Table 1.

Table 1. USA and EU mandatory legislations, guidelines, directives and other supplementary documents collected.

United States of America	
Mandatory legislation	9 CFR part 301 "Terminology; adulteration and misbranding standards". 9 CFR part 314 "Handling and disposal of condemned or other inedible products at official establishments". 9 CFR part 416 "Sanitation". 9 CFR part 417 "Hazard Analysis and Critical Control Point systems". 9 CFR part 431 "Thermally processed, commercially sterile products".
Guidelines	FSIS-GD-1999-0003 "Update - 416.2(g): water supply and water, ice, and solution reuse". FSIS-GD-2016-0003 "Sanitation performance standards compliance guide". FSIS-GD-2018-0005 "Meat and poultry hazard and control guide". FSIS-GD-2020-0008 "Guidebook for the preparation of HACCP plans". FSIS-GD-2020-0009 "A Sanitation Standard Operating Procedure model". FSIS-GD-2021-0010 "HACCP model for Thermally processed, commercially sterile product".
Directives	FSIS Directive 5000.1 (REV8) "Verifying an establishment's food safety system". FSIS Directive 5000.4 (REV 3) "Performing the pre-operational Sanitation Standard Operating Procedures verification task". FSIS Directive 7530.1 (Rev 4) "Handling a process deviation or abnormal container of thermally processed, commercially sterile canned product". FSIS Directive 7530.2 (REV 1) "Verification activities in canning operations that choose to follow the canning regulations".

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Supplementary documents	Microbiology of thermally processed commercially sterile and shelf-stable meat and poultry product (2005). Sanitation Standard Operating Procedures (2019). Thermally processed products FSA tool VS3 (2020). Thermal processing commercially sterile self-paced training course (2021).
European Union	
Mandatory legislation	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs. Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin. Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs. Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation). Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products.
Supplementary documents	2022/C 355/01 Commission Notice on the implementation of food safety management systems covering Good Hygiene Practices and procedures based on the HACCP principles, including the facilitation/flexibility of the implementation in certain food businesses. EFSA Opinion of the Scientific Panel on Biological Hazards on the request from the Commission related to Clostridium spp. in foodstuffs (2005).

3.1.2. EU Mandatory Legislation, Guidelines and Other Supplementary Documents

With regard to the EU, legislative sources concerning both general and specific food hygiene and safety requirements were taken into consideration. General hygiene requirements, including PRPs, as well as specific hygiene rules for food of animal origin, were collected and analyzed. Additionally, relevant legislation on the quality of water intended for human consumption, microbiological criteria for foodstuffs, and health rules applicable to animal by-products and derived products not intended for human consumption were reviewed. Regarding requirements for procedures based on HACCP principles, legislation governing these procedures was considered. Furthermore, regulations establishing the regulatory framework for CAs were also examined. Although these latter are primarily addressed to CAs, they can also provide useful guidance for FBs to ensure compliance with EU legislation.

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During the analysis of EU legislative sources, similarly to the USA context, it was necessary to consider additional documents beyond regulations. For this reason, guidance documents on the implementation of FSMS, with particular focus on good hygiene practices (GHP) and HACCP-based procedures, were examined. Additionally, scientific opinions regarding biological hazards in food were also consulted. The complete list of EU mandatory legislation, guidelines, and other supplementary documents considered is reported in Table 1.

3.2. Ministerial Circulars Collection and Analysis

Being issued by the Italian Ministry of Health, ministerial circulars are positioned at a different level compared to USA and EU regulations. They are, in fact, internal provisions aimed at directing the actions of administrative bodies uniformly [38]. While circulars are not sources of law, they play a fundamental role in the comprehension and application of legislation, serving as a reference point for CAs [27]. Indeed, circulars can serve various functions: some have a regulatory content, outlining procedures and criteria for administrative activities; others are interpretive, providing clarifications on the application of legal provisions; still others are informational, disseminating relevant information for administrative personnel [39]. The ministerial circulars we analyzed perform a dual function, both informational and interpretive, providing practical indications on the application of regulations and clarifying the meaning of certain requirements set by them [39]. As previously mentioned, although these documents are addressed to the CAs, they are also transmitted, for knowledge, to trade associations, which in turn make them available to FBs in the sector. This allows FBs to adopt the information intended for the CAs and apply it to their operational needs. In this way, the circulars issued by the Italian Ministry of Health provide support for FBs in aligning with current export requirements, exerting an indirect external effectiveness [40].

The Italian Ministry of Health, as the CA at central level, has issued several circulars to explain how to implement export requirements to the USA and ensure their uniform application. These circulars, specifically addressing the requirements for inclusion in the USA list, were therefore collected and analyzed. One of these provides clear guidance on how identifying the applicable USA regulations based on the product category, enabling FBs to correctly navigate the regulatory framework [41]. Another focuses on official controls for establishments authorized to export food products to the USA [42]. Its annex can also serve as an operational guide for FBs, providing a translation of relevant USA legislation (9 CFR 416 [43] and 9 CFR 417 [44]) along with interpretative clarifications, practical examples, and compliance criteria [42]. A further circular addresses USA regulation 9 CFR 431 concerning standards for canned products [45]. Furthermore, another circular provides operational guidance for the application process to be included in the list of establishments authorized to export food products to the USA [46]. Finally, other useful ministerial circulars were collected and analyzed to define the measures necessary to obtain the relevant health certificate (Table 2).

Table 2. Italian Ministry of Health circulars collected and analyzed.

Ministerial circulars	
Documents	**Description**
DGISAN 0015006-P-14/04/2016 Export to the United States of America of food of animal origin and food containing products of animal and plant origin (composite products).	The ministerial circular clarifies the responsibilities of the US public authorities (USDA and FDA) for ensuring food safety and hygiene.
DGISAN 0015012-P-14/04/2016 Procedure for registration in the USDA-FSIS list of establishments authorized to export to the United States of America.	It offers detailed instructions on the procedures to follow for inclusion in the list of establishments authorized to export food products to the United States.

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DGISAN 0010140-P-17/03/2017 Official control at establishments on the list of Italian facilities authorized for the export of food products under USDA-FSIS jurisdiction in the USA - REV 1.	It is specific guidance on the methods and responsibilities of official controls at establishments authorized to export to the United States. The objective is to verify the compliance of facilities and products with the requirements established by bilateral agreements between Italy and the USA, ensuring the maintenance of equivalence between US and EU systems.
DGISAN 0040602-24/10/2018 Export to the USA of "thermally processed-commercially sterile" products.	It provides guidance on the official control of products classified as "thermally processed commercially sterile" that are exported to the USA. In addition, it offers useful guidance to Food Business Operators (FBOs) on managing HACCP plans and implementing corrective actions required in case of nonconformities affecting the product, the heat treatment process, or the container.
DGISAN 0010382-24/03/2020 Start of exports to the United States of America of composite products falling within the scope of the USDA and classified as Not Ready to Eat (NRTE) (composite products containing pork-based ingredients).	The circular establishes that the FB must ensure that the raw materials used for products intended for export to the United States come from authorized sources and are accompanied by the necessary health documentation certifying their suitability for export.
DGISAN 0015423-12/04/2022 Clarification on the use of USDA-health certificates for exports to the US of pork and pork products.	The circular provides clarification on the use of USDA health certificates required for exporting pork and pork products to the United States (US C01 + annex E, US-C02, or US-C03).

3.3. Procedures to Be Implemented or Adapted for the Inclusion in the USA List of Authorized Establishments

The comparative analysis of the USA and EU legislation, conducted through concordance tables (Table SM1), allowed us to highlight the main gaps between the two regulatory systems and to identify the procedures to be implemented to align with the USA legislation.

No substantial differences were found regarding the PRPs, except for a different naming and categorization of byproducts. In fact, the definition of "animal byproducts", as outlined in Regulation (EC) No 1069/2009 and further amendments and supplements [47], is not directly comparable with that of the USA legislation (9 CFR 301.2), since in the USA, products intended for human consumption are also included in this category. The EU definition of 'animal byproducts' is, instead, similar to that of "inedible products" defined as "adulterated, uninspected, or not intended for use as human food" [48]. Furthermore, unlike the EU regulatory framework, which classifies animal byproducts according to specific risk levels (category 1, 2 and 3), the USA legislation does not adopt the same categorization but distinguishes them between "condemned" and "other inedible products" [49]. However, despite these differences, byproduct management according to Regulation (EC) No 1069/2009 meets the standards set by USA legislation, as both regulatory frameworks aim to ensure the safe handling, processing, and disposal of animal byproducts.

On the contrary, our analysis showed that the FB must implement new procedures and adapt some of the existing ones. The new procedures to be implemented concern: cleaning and sanitization procedures (SSOPs), while the procedures to be adapted relate to the HACCP system.

At the time of this study, the FB had not yet begun implementing the procedures mentioned above. Therefore, the procedures and recommendations outlined in the following sections should be

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considered as guidelines or suggested steps provided by the CA, to be followed by the FB to enable its inclusion in the list of establishments authorized to export to the USA.

3.4. SSOPs

Concerning cleaning and sanitization procedures, the FB under study must include the SSOPs into its FSMS, as required by 9 CFR 416. SSOPs are written procedures developed and implemented by FBs to prevent direct contamination or adulteration of products and to ensure compliance with quality and safety standards [50-52].These procedures, essential for the effective implementation of HACCP plans specify what to clean and how often, and include monitoring activities, verification, and corrective actions in case of non-compliance [8,51,53,54]. SSOPs are an integral element of the overall daily food handling or processing operation [55]. According to USA legislation (9 CFR 416.11), all FBs must develop, implement, and maintain written SSOPs to prevent both direct and indirect contamination of products. Therefore, FBs wishing to export to the USA, including the one under study, must apply these procedures. SSOPs must be written on paper or in electronic format and carried out regularly and effectively [8,54]. These procedures must be applied systematically and uniformly along the entire production line. According to the USA requirement, the FB was requested to produce SSOPs divided into pre-operational (to be conducted prior to the product processing) and operational (to be conducted during the product processing) phases, both focusing on the effectiveness of cleaning and sanitizing surfaces that have direct, indirect, or no contact with food. In addition, the FB was asked to produce detailed daily records to document the proper implementation of SSOPs. These records should include the date, start and end times, compliance status, any corrective actions taken, and the signature or initials of the trained individual responsible for performing the task [56]. Corrective actions must address the handling of potentially contaminated products (if non-compliances occur during operational activities), which are defined by USA legislation as adulterated products. They must also include restoration of hygienic conditions and the implementation of preventive measures to avoid recurrence. FB was instructed on the fact that records must be kept for at least six months and kept on-site for 48 hours after the procedure. After that period, they may be archived off-site but must be made available to FSIS within 24 hours upon request (9 CFR 416.16 (c)). In the USA, SSOPs are, therefore, a mandatory requirement for FBs, which must develop, implement, and maintain written procedures to ensure food safety and prevent contamination. On the contrary, SSOPs are neither formally required nor mentioned in the EU legislation and therefore are not adopted as specific tools within EU FSMSs. Nevertheless, under Regulations (EC) No 852/2004 and No 853/2004, EU FBs must ensure the effectiveness of cleaning and sanitization procedures through the implementation of a verification plan tailored to the type of processing and the intensity of the production. This plan may include: visual inspections, microbiological sampling and ATP bioluminescence testing of surfaces, equipment and work environments [53,57]. The frequency of sampling and analysis must be justified in light of the FBs historical data, allowing flexibility in the design and application of verification activities [57]. As a result, the implementation of these procedures in the EU is generally less prescriptive compared to the SSOPs defined in 9 CFR Part 416, which represent a more formalized and standardized approach to the same underlying concept. This means that EU FBs intending to export to the USA, including the one under study, are required to implement SSOPs as requested by USA legislation, since the EU system is not considered fully equivalent to the USA system in this specific aspect. This highlights how the requirement to implement SSOPs does not arise from a lack of safety in the EU system, but from the absence of formal equivalence recognition by the USA. This implies a relevant commitment involving both the direct responsibility of FBs, which must develop, apply and document their own SSOPs, and the CA, tasked with verifying the effective implementation of these procedures. In this context, FSIS developed a model to serve as a reference for FBs when drafting their own SSOPs procedures [58]. The FB under study was therefore advised by the CA to use it as a basis for defining its own procedures.

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3.5. HACCP System

The HACCP system is globally recognized as the foundation of effective food safety management in the food industry [59]. It is based on a structured approach consisting of seven principles aimed at identifying, evaluating, and controlling food safety hazards, ensuring that such hazards are prevented, eliminated, or reduced to acceptable levels before the product reaches consumers [60,61]. These principles consist of: 1) hazard analysis; 2) identification of critical control points (CCPs); 3) establishment of critical limits; 4) monitoring procedures; 5) corrective actions; 6) verification procedures; and 7) recordkeeping. They are based on the internationally recognized code of practice established by Codex Alimentarius, which serve as a common reference framework for both the USA and EU [14]. To facilitate their application, internationally recognized standards such as ISO 22000:2018 [62], can provide valuable support in meeting importers' expectations regarding food quality and safety [63].

Despite the existence of a common theoretical framework, our study revealed that some operational and procedural methods for applying these principles differ. According to 9 CFR 417.2(b)(1), FBs are recommended to preliminarily classify their products into one of the nine specific food processing categories as an integral part of HACCP plan implementation (Table SM2). This classification represents a step to ensure that food safety hazards are consistently addressed within the appropriate processing context [64]. Based on our analysis of the product characteristics (Figure 2), it was classified as a "Thermally Processed and Commercially Sterile" (TPCS) product in accordance with 9 CFR 431 [65]. Once classified, the FSIS directly provides a predefined HACCP model for each of the nine food processing categories (Table SM2), which FBs can use as a reference, although its adoption is not mandatory. Regarding TPCS products the reference document is FSIS-GD-2021-0010 [66]. This document provides a concrete example of applying HACCP principles using a representative product for this category. Based on this product, FSIS developed a detailed description of it, a list of the ingredients, a flow diagram of the production process, and a sample hazard analysis. The EU approach is different in respect to the one adopted at the USA level. In fact, there is no EU regulatory provision that foresees specific food processing categories, nor is there a predefined HACCP model for such categories. Thus, it is left to FBs to develop their own HACCP plan, which can make use of sectoral guidelines or general reference documents provided by CAs. The adoption of the USA model therefore represents a pragmatic solution to comply with USA requirements. For this reason, the FB was advised by the CA to adopt the USA model to implement its HACCP plan.

3.5.1. Areas Not Requiring Implementation

Hazard analysis (principle 1), identification of CCPs (principle 2), critical limits (principle 3), monitoring procedures (principle 4) and corrective actions (principle 5)

Regarding hazard analysis (principle 1) and, in particular microbiological hazards, the FSIS guideline "FSIS-GD-2021-0010" emphasizes a key concept outlined in 9 CFR 417.2(b)(3). In fact, according to this provision, "HACCP plans for thermally processed commercially sterile products do not have to address the food safety hazards associated with microbiological contamination if the product is produced in accordance with the requirements of part 431". Anyway, this does not exclude the FB voluntarily including the analysis of microbiological hazards in the HACCP plan. In any case, FSIS offers another guideline concerning the microbiological aspects of TPCS and shelf-stable meat and poultry products [67]. It provides useful details for identifying relevant pathogens in TPCS products, distinguishing them from microorganisms responsible for spoilage, and considering the differences between low-acid products and low-acid acidified products. Low-acid products are defined by 9 CFR 431 as "canned products in which any component has a pH value above 4.6". Since the product under study has a pH greater than 4.6, it fully fits this definition. For these products, FSIS specifies thermal processing standards targeting Clostridium botulinum and Clostridium sporogenes. These standards require a 12-log reduction of C. botulinum spores to ensure public health protection and a 5-log reduction of C. sporogenes spores to achieve commercial sterility. The

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focus on C. sporogenes derives from its greater heat resistance compared to C. botulinum. This makes C. sporogenes a reliable indicator to determine whether a thermal process is rigorous enough to destroy the spores of other microorganisms, including C. botulinum and those that could cause product spoilage [68]. At the EU level instead, all FBs, except primary production, must develop HACCP plans by conducting a hazard analysis to identify those hazards that require elimination or reduction to acceptable levels, based on scientific evidence or the specific experience of the FBs themselves [16]. Furthermore, unlike USA legislation that allows FBs to choose whether to include microbiological hazards in the HACCP plan for TPCS products, EU legislation does not provide such an option. In fact, according to Regulation (EC) No 852/2004, under Article 5, all FBs are required to identify, within their HACCP plan, any hazard, including microbiological hazards, that is reasonably likely to occur, and to assess the relevance of such hazard within the specific context of the production process. Furthermore, EU legislation, specifically Regulation (EC) No 2073/2005 and its further amendments and supplements on microbiological criteria for foodstuffs [69], does not establish safety or hygiene criteria for Clostridium spp. This specific microbiological hazard has instead been considered in an EFSA opinion [67]. It emphasizes the need for sufficient thermal processing to achieve an F_0 value that ensures a 12-log reduction of C. botulinum as required by USA legislation. This "12-log concept" therefore represents a methodological approach shared between the USA and EU systems, aimed at ensuring a relevant reduction of C. botulinum spores from one billion to one spore per thousand units, safeguarding microbiological safety of the product. This is not surprising given that both systems are based on solid historical scientific evidence and harmonized international principles [70,71]. As regards C. sporogenes, the EFSA opinion does not explicitly detail this bacterium as a spoilage target, but it recognizes the importance of eliminating anaerobic spore-forming bacteria to prevent spoilage, aligning with FSIS guideline [67,72]. Therefore, since the FB under study was already applying a thermal treatment capable of ensuring microbiological safety against Clostridium spp., in compliance with EU legislation and, consequently, with the USA microbiological safety standards, no changes were necessary to the thermal treatment applied.

A key step of HACCP system is the identification of CCPs (principle 2) within the production process [60,73]. These are points or phases where control measures can be applied to prevent, eliminate, or reduce hazards to acceptable levels, playing a crucial role in maintaining the overall safety of the food product [59,74]. In this regard a different scheme in determining CCPs has been highlighted between EU and USA. Indeed, while the decision tree proposed by Commission Notice 2022/C 355/01 traces the scheme set by Codex Alimentarius [14], USA guideline (FSIS-GD-2020-0008) presents a scheme that does not completely overlap with it. Both schemes, however, lead to equivalent results; therefore, no changes to the CCPs identified by the FB under study were required. Regarding the establishment of critical limits (principle 3), monitoring procedures (principle 4), and corrective actions (principle 5), no differences were observed between the USA and EU systems that would require substantial changes in the FB's HACCP plan. Therefore, the aforesaid principles were not deeply analyzed in this work.

3.5.2. Areas Requiring Implementation: Verification Procedures (Principle 6) and Recordkeeping (Principle 7)

A more substantial difference emerged concerning the verification procedures (principle 6), in particular as regards the initial validation and ongoing verifications (9 CFR 417.4 (a) (2)). Validation of a control measure is, in fact, the process of "obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling the hazard to achieve a specified outcome"[75]. In the USA, this step is essential for establishing the so-called "process schedule", a written document describing "the thermal process and any specified critical factors for a given canned product required to achieve shelf stability" (9 CFR 431.1). Critical factors are described as "any characteristic, condition or aspect of a product, container, or procedure that affects the adequacy of the process schedule" (9 CFR 431.1). In the case of TPCS products, as the one under study, the relevant critical factors to be considered for the proper application the thermal

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process are explicitly defined in 9 CFR 431.4. Specifically, it affirms that critical factors must be measured, controlled, and recorded by the FB at a specific frequency to ensure they remain within the limits established in the process schedule. Moreover, 9 CFR 431 indicate that the process schedule must be developed by a "processing authority" defined as "a person or organization with expert knowledge of thermal processing requirements for foods in hermetically sealed containers" (9 CFR 431.1) and becomes the primary source for supporting document for the HACCP plan. Therefore, it is essential that the process schedule and the HACCP plan are consistent with each other [76,77]. In EU, the general legislation on food hygiene (Regulation (EC) No 852/2004 and further amendments and supplements) does not provide detailed guidance on the validation of thermal treatments comparable to that set out in the 9 CFR regulations. However, the validation of control measures is recognized as an essential component of HACCP-based procedures, as clarified by the European Commission in its notice (Commission Notice 2022/C 355/01), which highlights that control measures must be validated and "should be supported by detailed procedures and specifications to ensure their effective implementation". Unlike the USA regulatory framework, however, there is no formal requirement in EU for the development of a "process schedule" by a "processing authority," nor is there a legally defined list of critical factors to be monitored, as established in 9 CFR 431.4. Therefore, the FB was requested to validate its thermal process to demonstrate its effectiveness in controlling the identified hazards considering the "critical factors" listed in 9 CFR 431.4. This difference highlights the contrast between the USA's prescriptive regulatory approach, where compliance is ensured through standardized procedures and clearly defined responsibilities, and the EU's outcome-based model, which grants greater autonomy and flexibility to FBs.

As mentioned above, another difference was identified regarding ongoing verifications. Verification is defined as "the application of methods, procedures, tests, and other evaluations, in addition to monitoring, to determine whether a control measure is or has been operating as intended" [14]. Ongoing verifications include, but are not limited to, the calibration of process-monitoring instruments, direct observations of monitoring activities and corrective actions, and the review of records generated and maintained in accordance with 417.5(a)(3). In contrast, monitoring refers to "the act of conducting a planned sequence of observations or measurements of control parameters, to assess whether a control measure is under control" [14]. Thus, while monitoring provides real-time assessment, ongoing verification ensures that the HACCP system is working effectively on a daily basis [59]. Furthermore, the frequency of such verifications must be determined by the FB based on its own risk assessment [64]. However, while the USA legislation provides detailed instructions on how ongoing verifications should be conducted by FBs, as specified above, EU legislation (article 5 of Regulation (EC) No 852/2004) does not detail specific methods. It just requires FBs to "…establish procedures, which shall be carried out regularly, to verify that the implemented measures are working effectively". More specific details have been subsequently provided by the Commission Notice 2022/C 355/01 [16]. However, as a notice, this document is not legally binding, meaning that the adoption of its measures in all their forms is not mandatory, unlike those under 9 CFR 417. Accordingly, in the case of the FB under study, direct observation of monitoring activities was not included in the HACCP plan and, therefore, this represents a point to be implemented in light of 9 CFR 417.4(a)(2)(ii). Specifically, these observations must be carried out by members of the HACCP team or other internal personnel, such as supervisory staff. The FB was also informed by the CA about the possibility of involving external resources or personnel not directly involved in the development or daily management of the HACCP system for ongoing verification activities, to ensure an adequate level of independence, objectivity, and impartiality [59,78].

In the USA, according to 9 CFR 417.5(c), FBs shall implement final verification/recordkeeping (principle 7), commonly referred to as pre-shipment review. The pre-shipment review involves a review of all the records related to each production batch before dispatch [79]. Its purpose is to ensure that all HACCP system requirements have been met, and that the product is free from food safety hazards and other causes of adulteration, making it suitable for commerce [64]. During this review, the responsible in charge by the FB must check the documents associated with the production of the

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batch intended for shipment, verifying that "all critical limits have been met and, if appropriate, corrective actions were taken, including the proper disposition of product" (9 CFR 417.5(c)). According to 9 CFR 417 the review must be dated and signed by someone other than the one who prepared the documents, preferably an individual trained accordingly to 9 CFR 417.7 or by the responsible establishment official. In EU, although FBs are responsible for product safety and compliance through the implementation of an HACCP system that includes control measures and procedures for monitoring, verification and recordkeeping, a mandatory and formally documented final review as a final step before marketing is not required. For this reason, the FB under study was requested to implement the pre-shipment review as part of the verification/recordkeeping procedures established in its HACCP plan. A graphical representation of the areas requiring and not requiring implementation within the HACCP plan is reported in Figure 4.

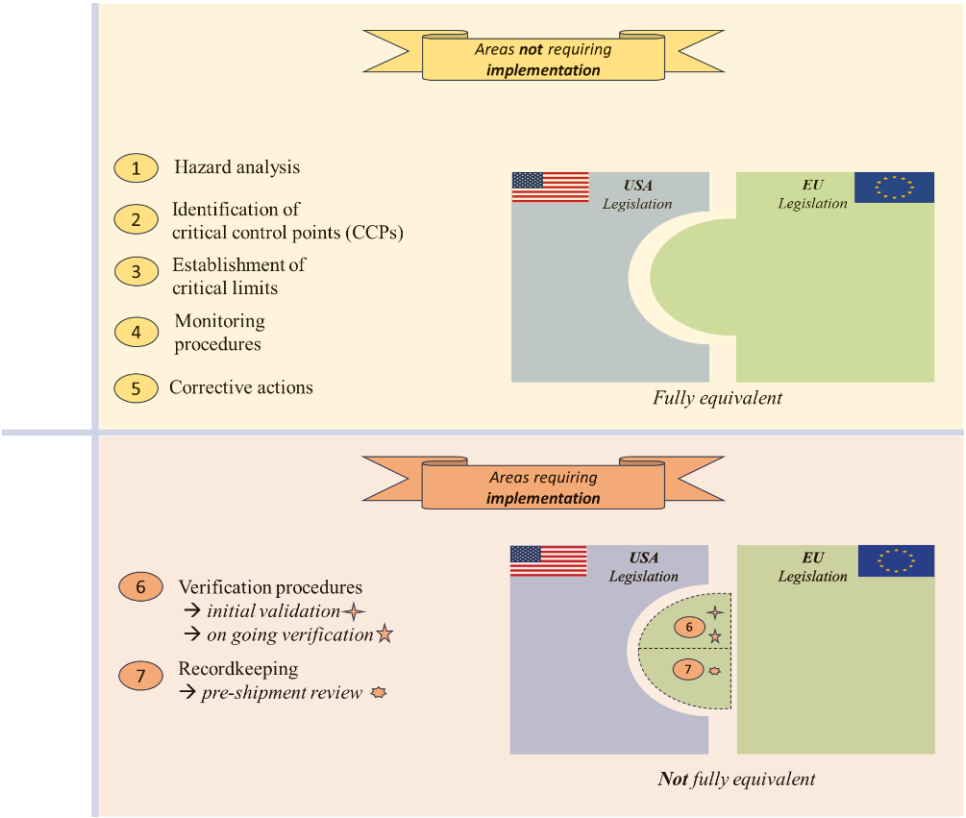

Figure 4. Graphical representation of the areas requiring and not requiring implementation within the HACCP plan.

3.6. Export Authorization Process: Procedural and Operational Barriers and Support Strategies for Small and Medium-Sized Italian Fbs

By integrating regulatory analysis with FSMSs and operational practices, this study addresses a critical gap between regulatory requirements and their practical application. This approach supports a more effective translation of regulatory equivalence into establishment-level food safety management. Overall, the export authorization process for pork-based products to the USA follows a complex and multi-step pathway. In fact, once all the required procedures to align with USA legislation described in sections 3.4 and 3.5 have been addressed, the FB under study must submit a set of documents to the Italian Ministry of Health, through the competent LHU. These documents include the survey record carried out by the LHU itself, based on an on-site verification, attesting compliance with all the aforementioned USA requirements [46]. After submission, the FB must operate for a period of not less than three months following the attested requirements. At the end of this period, the FB is required to validate its FSMS certifying its effective implementation and effectiveness. Following this, the Italian Ministry of Health, through specially designated inspectors,

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conducts an additional on-site verification at the FB to verify the effective implementation of these requirements [46]. If the outcome is favorable, the FB is added to the list of establishments authorized to export to the USA, managed by the Ministry of Health itself [80]. However, being listed is not sufficient to initiate exports. The FB must also comply with specific additional requirements related to the origin and management of pork meat, such as the obligation to source it from establishments that are likewise authorized to export to the USA, and to store and handle it in clearly identified, designated areas that are physically and visually separated, to prevent any commingling with meat or other materials that do not meet USA requirements [81]. The final step consists of obtaining the appropriate health certificate (e.g., US-C01 + Annex E, US-C02, or US-C03). For pork-based pasta sauces, the appropriate health certificate model (US C01 + annex E, US-C02, or US-C03) depends on the origin of the pork raw meat and the sanitary status of the geographic areas where the FBs involved in the production process are located [82], recognized by APHIS as free from Swine Vesicular Disease (9 CFR 94.12 [83]). The entire export authorization process is summarized in Figure 5.

While on the one hand this multi-step process ensures a high level of regulatory oversight and strict alignment with USA requirements, on the other, it adds to an already demanding preliminary phase, which includes the identification and organization of the necessary documentation (e. g. ministerial circulars), as well as the implementation of the FSMS. These activities require a considerable investment in managerial planning, internal reorganization, and procedural compliance, resulting in a relevant burden in terms of both human resources and economic costs [84]. This level of complexity can in itself represent a barrier to market access, with the potential to delay or discourage the entry of new businesses, particularly SMEs, which often have more limited organizational and technical resources than larger ones [85,86].

To this complexity, potential interpretative difficulties related to ministerial circulars may also arise. As previously mentioned, these documents are internal provisions primarily addressed to the CAs [27]. Therefore, although FBs could rely on them as guidelines for implementing USA requirements, they are not originally designed for their direct use. The analysis of ministerial circulars has indeed revealed that, while they provide a general overview of the responsibilities of the main USA public authorities (FSIS, APHIS, and FDA) and of HACCP-based procedures as defined by the Codex Alimentarius [14], they offer more limited guidance on more specific operational aspects, such as SSOPs. In line with this, the study by Antoci et al. [8] identified several non-compliances in the implementation of SSOPs by certain Italian exporting FBs, most notably the absence of a documented list of food-contact surfaces to be monitored and verified. Considering these evidences, it is clear that the complexity of the process and the potential difficulties in interpreting the currently available documentation could, in fact, represent an additional barrier to market access. For these reasons, it would be advisable to provide structured technical and training support tools aimed at FBs, particularly SMEs, in order to reduce the risk that these critical issues could lead to exclusion from international trade.

In this scenario, the crucial role played by the CA, both at central and local levels, supporting FB in fulfilling the requirements for export becomes clear. At the central level, the CA is responsible for issuing ministerial circulars and for defining the technical and regulatory framework necessary to ensure alignment with USA requirements. At the local level, the official veterinarian plays a key role in verifying the effective implementation of such requirements within FBs. Their tasks include carrying out on-site inspections, assessing compliance with the FSMS, and other specific provisions, up to the issuance of the health certificate required for export. This dual responsibility demands not only regulatory expertise but also the ability to apply complex provisions within an operational context. It is therefore essential that official veterinarians receive targeted and continuously updated training on export-related issues. Furthermore, their direct knowledge of the FB they oversee allows them to act not only as inspectors but also as technical interlocutors, addressing any interpretative gaps and guiding FBs in meeting third country requirements, such as those of the USA. Strengthening their technical and regulatory competencies, particularly in the field of export certification, thus represents a key policy lever for improving the overall efficiency and credibility of the export process.

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Their dual role as controllers and facilitators indeed makes them pivotal actors in the implementation of transnational food safety requirements.

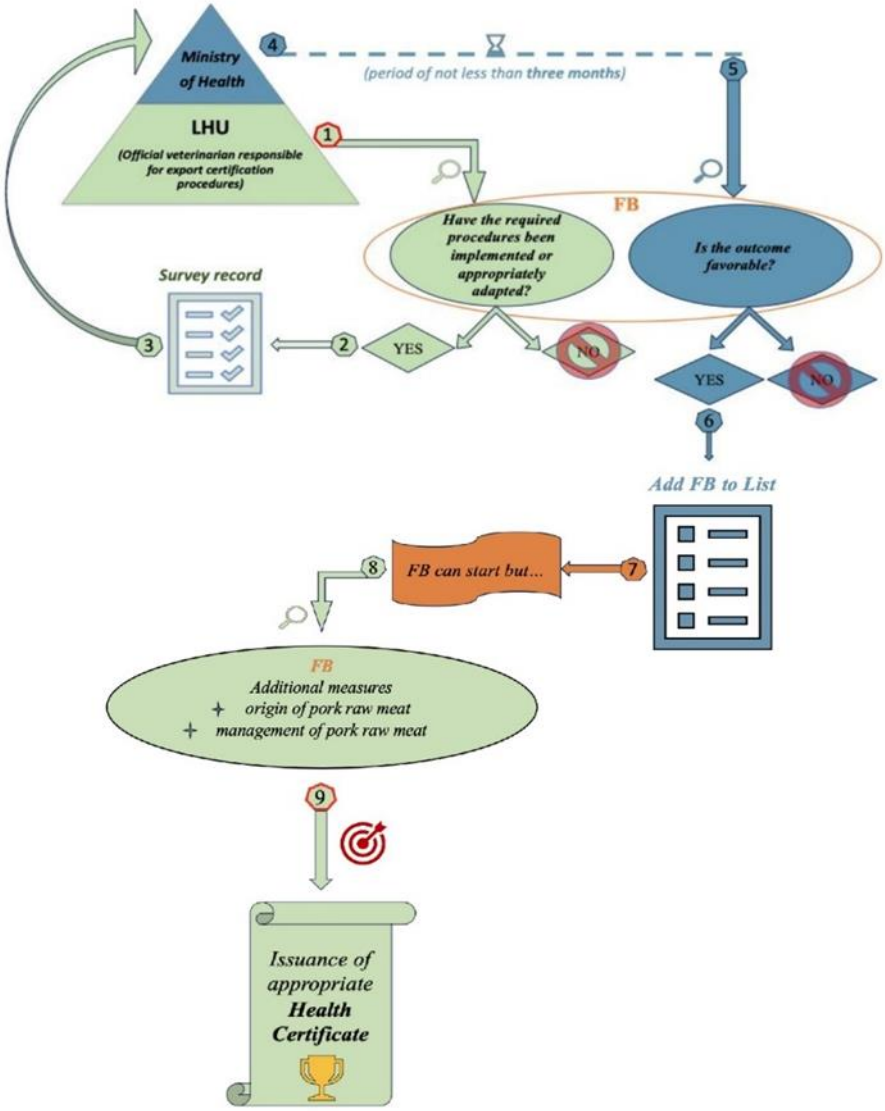

Figure 5. Schematic representation of the entire export authorization process.

4. Conclusions

The analysis of a real case involving a medium-sized Italian FB, conducted through a structured and replicable analytical framework, highlighted the need to comply with specific USA regulatory requirements that go beyond those mandated by EU legislation. In particular, four key areas required implementation: i) application of SSOPs; ii) validation of the thermal process, including all critical factors; iii) direct observation of monitoring and corrective actions as part of ongoing verification; iv) implementation of the pre-shipment review. Beyond technical compliance, the export authorization process includes additional operational requirements and a mandatory preliminary operational period. These steps involve a relevant organizational and economic burden, which may represent a barrier to market access, particularly for SMEs. Based on this, key policy implications emerge: operational support for SMEs, including practical tools, and clearer implementation guidance aligned with USA standards, on the other hand, specialized and ongoing training for official veterinarians, to strengthen their dual role as inspectors and technical facilitators throughout the export process. This case demonstrates that overcoming export barriers is not solely a matter of food safety, but also of

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building a support system that helps businesses translate complex requirements into practical, sustainable, and effective operational measures.

Supplementary Materials: The following supporting information can be downloaded at the website of this paper posted on Preprints.org, Table SM1: Comparative analysis through concordance tables between USA and EU systems; Table SM2: Product categorization according to 9 CFR 417(b)(1).

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Abbreviations

The following abbreviations are used in this manuscript:

APHIS	Animal and Plant Health Inspection Service
CA	Competent Authority
CFR	Code of Federal Regulations
DHHS	Department of Health and Human Services
EC	European Commission
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FBs	Food businesses
FDA	Food and Drug Administration
FSIS	Food Safety and Inspection Service
FSMS	Food Safety Management System
HACCP	Hazard Analysis and Critical Control Points
IPP	Inspection Program Personnel
ISO	International Organization for Standardization
LHU	Local Health Unit
PRPs	Prerequisite Programs
SMEs	Small and medium-sized enterprises
SPS	Sanitary and Phytosanitary
SSOPs	Sanitation Standard Operating Procedures
TPCS	Thermally processed and commercially sterile
USA	United States of America
USDA	United States Department of Agriculture
WHO	World Health Organization
WOAH	World Organization for Animal Health
WTO	World Trade Organization

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