

Italian Journal of Food Safety

https://www.pagepressjournals.org/index.php/ijfs/index

eISSN 2239-7132

<u>Publisher's Disclaimer</u>. E-publishing ahead of print is increasingly important for the rapid dissemination of science. The Early Access service lets users access peer-reviewed articles well before print/regular issue publication, significantly reducing the time it takes for critical findings to reach the research community.

These articles are searchable and citable by their DOI (Digital Object Identifier).

The **Italian Journal of Food Safety** is, therefore, E-publishing PDF files of an early version of manuscripts that have undergone a regular peer review and have been accepted for publication, but have not been through the copyediting, typesetting, pagination, and proofreading processes, which may lead to differences between this version and the final one.

The final version of the manuscript will then appear in a regular issue of the journal.

The E-publishing of this PDF file has been approved by the authors.

Please cite this article as:

Rosamilia A, Benedetti S, Cotugno D, et al. **African swine fever: implications for the Italian pork trade**. *Ital J Food Saf* doi:10.4081/ijfs.2024.12489

Submitted: 21-03-2024 Accepted: 18-04-2024



Note: The publisher is not responsible for the content or functionality of any supporting information supplied by the authors. Any queries should be directed to the corresponding author for the article.

All claims expressed in this article are solely those of the authors and do not necessarily represent those of their affiliated organizations, or those of the publisher, the editors and the reviewers. Any product that may be evaluated in this article or claim that may be made by its manufacturer is not guaranteed or endorsed by the publisher.

African swine fever: implications for the Italian pork trade

Alfonso Rosamilia, ¹ Stefano Benedetti, ² Delia Cotugno, ³ Chiara Guarnieri, ² Viviana Miraglia, ² Andrea Riponi, ² Stefano Capezzuto, ³ Giulia Siragusa, ³ Nicola Santini, ⁴ Marco Pierantoni ³

¹Experimental Zooprophylactic Institute of Lombardy and Emilia-Romagna, Brescia; ²Local Health Authority, Modena; ³Local Health Authority, Parma; ⁴Ministry of Health, Roma, Italy

Correspondence: Alfonso Rosamilia, Experimental Zooprophylactic Institute of Lombardy and Emilia-Romagna, Via Bianchi 9, 25124 Brescia, Italy.

Tel.: +39 0514200011.

E-mail: alfonso.rosamilia@izsler.it

Key words: pork products, official certificate, export, non-EU countries.

Contributions: ARo, MP, conceptualization; ARo, SB, MP, methodology; ARo, DC, CG, VM, ARi, SC, GC, writing - original draft preparation; SB, NS, MP, writing - review and editing. All the authors read and approved the final version of the manuscript and agreed to be accountable for all aspects of the work.

Conflict of interest: the authors declare that they have no competing interests.

Ethics approval and consent to participate: not applicable.

Funding: none.

Availability of data and materials: not applicable.

Acknowledgments: the authors would like to thank Anna Padovani and Gabriele Casadei for their critical reading and comments.

Abstract

In early 2022, the confirmed presence of African swine fever (ASF) circulating in wild boars in mainland Italy and subsequently found in domestic pigs led to several changes regarding the export of pork and pork products to countries outside the European Union (non-EU). The sector suffered the complete and immediate closure of the markets of some countries, often without the measure being communicated in the forms stipulated by international agreements. Indeed, compliance with the current EU regulations does not guarantee the possibility of exporting to non-EU countries. Knowledge of the animal health status requirements of the country (Italy in this case) is essential for food business operators (FBOs) wishing to enter markets outside the EU according to the 'Agreement on the Application of Sanitary and Phytosanitary Measures'. In cases where a sanitary protocol and a model of an official certificate with the importing country exist, the market is officially accessible according to the agreed sanitary requirements. Where no agreement exists, requirements are detailed in the 'import permit' issued to individual FBOs or may be known by directly accessing national regulations through the client/importer. Therefore, the purpose of this work is to outline briefly the conditions imposed by the main non-EU countries for pork products, especially in light of the new epidemiological situation created by the spread of the ASF into a country previously free of the disease.

Introduction

Italy is a global leader in the export of meat products, thanks to the quality and variety produced throughout the country. In 2022, the revenue generated abroad by pork-based products reached \in 1.92 billion, with the primary exported products being boneless hams and 'speck' (45.8%), naturally fermented salami (29.5%), cooked hams (9.4%), 'mortadella', sausages, 'cotechini' and 'zampone' (9.1%) (Ismea, 2022). However, the export of these products is subject to increasingly stringent regulations, both nationally and internationally, aimed at ensuring food safety and quality of exports. Moreover, increasing commitment is required to manage the health restrictions of the meat product market, especially of swine origin, considering the new geopolitical scenario and the epidemiological situation that has been generated with the outbreak of African swine fever (ASF) on the Italian mainland (Giammarioli *et al.*, 2023).

ASF is an infectious disease affecting both feral and domestic pigs and is caused by the ASF virus (ASFV) belonging to the *Asfarviridae* family (Costard *et al.*, 2013). Although humans are not susceptible to infection, ASF is recognized as one of the most significant and feared diseases in pigs for several reasons. Firstly, ASFV is highly contagious and can spread rapidly in pig populations *via* different routes of transmission, including the trade of live animals and animal products, wild animal migration, ticks and fomites (Olesen *et al.*, 2020). It has been demonstrated that the ASFV remains viable for weeks in pork and processed pork products (Mebus *et al.*, 1993; Petrini *et al.*, 2019). Secondly, to date, there is no vaccine against ASFV (Sánchez-Cordón *et al.*, 2018). Thirdly, if a new outbreak of ASF occurs in a previously disease-free area, the disease can have a devastating impact on the swine industry, causing significant economic damage and restrictions in trade and movement (Pavone *et al.*, 2023).

When ASF is confirmed in pigs from a disease-free area, the solutions applied are culling and restrictions on the movement and trade of live pigs and products from that area to limit the spread of the disease to neighboring areas and other countries (European Parliament and Council of the European Union, 2016; European Commission, 2020). These mitigation measures result in economic damage to farmers and food business operators (FBOs). The management and eradication of ASF in disease-free or endemic areas are resource-intensive and costly due to the virus's ability to survive in extreme environmental conditions, the variety of transmission routes, and the potential reservoir population constituted by wild boar (Guberti *et al.*, 2022). The established restriction zones are continuously amended and updated based on the evolution of reported cases in the European Union (EU). These zones are called Type II and III when an ASF outbreak has been reported in a wild

porcine animal or kept porcine animal, respectively, while Type I is called an area with a precise geographical delimitation bordering restricted areas II or III (European Commission, 2023).

However, in the case of an ASF epidemic, measures can be adopted to safeguard some export markets. European regulations list all possible technologies and procedures for inactivating ASFV in pork products from restricted zones (European Commission, 2020). Some of these may be directly considered for the production of certain Italian products, such as 190-day curing for bone-in hams and cooking at 70°C for 30 minutes for cooked products. It should be noted that for certain raw cured hams with 'Protected Designation of Origin' (e.g., Parma Ham and San Daniele Ham), 400-day curing is widely used in the production sector. This has historically allowed such products to enter different non-EU markets, following the provisions of the United States (US) Code of Federal Regulations (CFR). The fact that ASFV had up until recently only been transmitted in countries where the export of pork products does not play a prominent role has only widened the gap in knowledge on the heat resistance of the virus in such matrices. However, the heat treatment that these products undergo is sufficient to inactivate the ASFV and render these products safe. As for cured sausages, according to the standards of the World Organisation for Animal Health (WOAH), these products can be considered a low risk only when the curing period exceeds six months and when, according to Regulation (EU) 2020/687, the area from which the meats originate or the area where the processing plant is located are free from ASFV.

Additionally, the 'Official Controls Regulation' (EU) 2017/625 establishes clear rules for issuing official certificates to accompany goods and animals, extending some principles already found in the EU legislation on the certification of animals and products of animal origin to all agri-food sector goods (European Parliament and Council of the European Union, 2017; Rossi *et al.*, 2020). The certification activity involves any official control aimed at verifying the compliance with the requirements for the export of animals or goods, regardless of their nature. The conditions for issuing an official export certificate include the requirements that the certifier must meet and the methods and sources of acquiring the necessary data, facts, and information for signing the certificate.

Based on the considerations above, it is evident that, if the zones subject to restrictions under Regulation (EU) 2023/594 comprise areas with a higher concentration of pig farms and pork processing facilities, this would result in significant limitations, as far as a complete block in exports, with severe economic and social repercussions. Therefore, it can be useful to provide an update on the current state of affairs regarding the methods implemented for the export of such products to non-EU countries, in order to identify possible alternatives and safeguard this important sector.

Export of pork products to non-EU countries

While upholding the international agreement known as the 'Agreement on the Application of Sanitary and Phytosanitary Measures', which establishes the basic rules for protecting public, animal and plant health in international trade (WTO, 1995), and the provisions outlined in European regulations on the measures to be implemented during ASF outbreaks (European Commission, 2023), there are essentially two principles applicable to the export of pork products to non-EU countries.

The first principle is the health status of the country, as reflected in the WOAH Code (WOAH, 2023), and non-EU countries can adopt one of the following solutions to address this principle in regard to ASF:

- Ban of exports throughout the whole territory of the exporting country due to disease or infection;
- Ban of exports due to disease or infection from geographical areas identified according to the principle of 'zoning or regionalization' according to:
 - i. the European model (European Parliament and Council of the European Union, 2016), or
 - ii. the administrative division, according to model adopted by other countries.

The zones with different animal health statuses require an effective surveillance system and highquality veterinary services at both national and regional levels. It is evident that where the restricted zones specified by Regulation (EU) 2023/594 were to include the areas of a region with a high concentration of farms and processing plants, this would result in substantial limitations, as far as a complet block in exports of meats and processed products to some non-EU countries. The situation is different in the EU, where the commercialization of meats from restricted zones is managed according to the biosecurity conditions on the farms where the animals are housed. This aspect significantly influences the final destination of meats and related products (European Commission, 2023).

Instead, the second principle concerns treatments that inactivate the infectious agent. For ASFV and in relation to the different types of products, non-EU countries refer to the latest edition of the Terrestrial Animal Health Code (WOAH, 2023), or to community legislation, with Regulation (EU) 2020/687 identifying technological treatments applicable to different food matrices (see Table 1 for details) (European Commission, 2020).

In this regard, article 15.1.2 of the WOAH Code defines as 'safe commodities', meaning not subject to any ASF-related conditions, regardless of the ASF status of the exporting country or zone, the following products:

- meat in a hermetically sealed container with a F_0 value of 3 or above;
- gelatine.

Such definition allows the reopening of the market to products such as 'zampone', 'cotechino', canned products like ready-made sauces with swine meat ingredient, or other similar types of products composed with swine meat ingredient subjected to a sterilizing heat treatment once packaged in sealed containers.

Following the principle of cooking, where the capability of the production system and controls to ensure the absence of post-thermal process contamination is recognized, it would be possible to export other types of pork-based products subjected to inactivating heat treatment, even if this treatment does not precede packaging in a sterile container. Article 15.1.23 confirms that the following heat treatments are indeed capable of inactivating the ASFV:

- heat treatment for at least 30 minutes at a minimum temperature of 70 °C, which should be reached throughout the meat;
- any equivalent heat treatment which has been demonstrated to inactivate ASFV in meat.

This authorizes the export of Italian deli products such as cooked ham, and 'mortadella'. Recognition of the inactivating treatments also includes the cured of meats. In particular, Article 15.1.23 of the WOAH code confirms that the ASFV is inactivated if the meat is cured with salt and dried for a minimum of six months ('Dry cured pig meat'). This third step would authorize the export of an additional range of Italian deli products, namely raw hams, especially those cured minimum 400 days. Therefore, a discussion of the conditions set by different non-EU countries and reported in various official certificates, supplemented integrated with information on recent developments in light of the evolving ASF epidemic, would be extensive and somewhat incomplete. Below we report the salient cases, while, in *Supplementary Table 1*, we provide an overview of all non-EU importing countries with the respective measures adopted.

Australia

Regarding pork products, the agreement between the Competent Authorities (CAs) of Italy and Australia has always provided for the export of cured product at least 400 days (e.g., 'culatta', raw ham, and 'speck'), as well as sterilized cooked products, accompanied by their respective specific official certificates. Inclusion on the list for export to Australia is required for all processing plants involved in the production of the exported product and is subject to meeting the additional requirements of the US CFR. For slaughter and cutting plants, possession of recognition under Regulation (EC) 853/2004 is sufficient (European Parliament and Council of the European Union, 2004). Regarding cured products, the ASF-specific requirements in the agreed certificates stipulate that the pigs from which the meats are derived should be born and raised in Italy and must come from farms where no clinical, serological or microbiological symptoms of ASF have been observed in the

three months preceding slaughter. The mandatory minimum cured of 400 days is based on existing agreements between Italian and US CAs - on which Australia relied on almost entirely until 2022 and still follows today - as outlined in US Regulation 9 CFR 94.17 in 1987. This regulation establishes the production processes for inactivating foot-and-mouth disease (FMD), swine vesicular disease (SVD), swine cholera (HC), and ASF. These production processes were validated through studies conducted simultaneously by the Plum Island Animal Disease Center (USA) and the *Istituto Zooprofilattico Sperimentale della Lombardia e Emilia-Romagna* (Italy), which showed that these viruses were inactivated after 170 (FMD), 300 (SVD), 313 (HC), and 399 (ASF) days of cured in every part of the ham (McKercher *et al.*, 1985, 1987). The health requirements established in the official certificates coincide with those required for the issue of 'import permits.' Australian regulations stipulate that such permits can also be issued for different production processes if the Australian government's risk assessment recognizes them as equivalent. Such equivalence has not yet been recognized for cured pork products, given the need to comply with the stringent animal health requirements mentioned above. Following the confirmation of the first outbreak of ASF in mainland Italy, there have been no changes to the existing agreements.

Brazil

The Italian CAs, through a series of Ministry of Health provisions, provided some clarifications, confirming - starting from January 5, 2022 - the suspension of the export of pork and pork-based products with a short-cured period (less than six months). However, it allowed the continuation of exports for pork-based products that undergo one of the recognized treatments for ASFV inactivation (Italian Republic, 2022a, 2022b). Specifically, exports are permitted for cooked pork-based products (undergoing a heat treatment of at least 30 minutes at 70°C or higher throughout the meat or equivalent heat treatment) and cured pork-based products for a minimum period of six months. Therefore, the currently valid official certificate (Mod. BR-CS-21) must specify the type of treatment performed, taking care to delete irrelevant entries (Italian Republic, 2022c). These updates require the certifying veterinarian to verify - in addition to compliance with slaughterhouse and processing plant regulations for export to Brazil - the adoption of the ASFV inactivation treatments and the correct correspondence of the products to be exported with the labeling registration at the Brazilian CAs (European Commission, 2020).

To date, the most exported references manage to meet the requirements introduced by the Ministerial Note n. 1031 of January 14, 2022 – with the only precaution of extending the cured period for porkbased products – are salami, 'coppa', and 'pancetta', which are known for shorter cured periods (Italian Republic, 2022a). However, the adoption and promotion of ASFV inactivating methods in the official certificate will allow the export of pork-based products even in cases not fully meeting the requirement for the meat, meat-based products or offal to come from animals born and raised in a country, zone, or compartment free from ASF, as long as it satisfies the conditions described in the WOAH Code and is recognized by Brazilian CAs (WOAH, 2021).

Canada

The export of food products to Canada is regulated by the trade agreement between EU and Canadian CAs. The Canadian Food Inspection Agency (CFIA) and the European Commission have established more stringent requirements for products of animal origin, specifically for meats and meat-based products, which exporting establishments must adhere to. Establishments interested in exporting meat and meat-based products must be authorized by the Italian CAs applying for inclusion on a list managed by the CFIA and published on the dedicated website. Following bilateral negotiations, an agreement was reached on the official certificate for the export of beef, pork, poultry, and rabbit meat product (Mod. CA01). While the certificates currently negotiated by the EU Commission with Canadian CAs are available on TRACES NT for beef, pork and poultry meat (frozen or refrigerated). After confirming the presence of ASF in Europe and in light of the recognition of regionalization (Italian Republic, 2022a), the official certificate was updated (Mod. CA01 rev4 OMIC) (Italian

Republic, 2022d). Concerning the export of pork and pork-based products to Canada, an additional health certificate was issued, to be attached to the official certification (Italian Republic, 2022e). The new epidemiological conditions required the careful collection of product traceability documentation (e.g., pig farm, raw meat) throughout the production chain, which the FBO must provide to facilitate verification by the certifying veterinarian (Italian Republic, 2022b).

Subsequently, instructions on the use of the ASF Canada supplementary certification ('Additional Certification for Exporting Pork and Pork Products from Italy to Canada: regionalization measures for African Swine Fever ASF') were updated, and references to Regulation (EU) 2021/605 were replaced with those to Regulation (EU) 2023/594 (European Commission, 2021, 2023; Italian Republic, 2024). Considering that Regulation (UE) 2023/594 undergoes frequent updates, it is specified that reference should be made to its 'consolidated' version. The CFIA explicitly clarified that this health certificate must be attached to the final certification only if it concerns products falling into the category of 'uncooked porcine products', such as fresh, refrigerated, or frozen pork, cured pork-based products, and thermally treated pork-based products that do not meet the treatment requirements specified in Annex 2 point 3.1 ('have been heated to maintain an internal temperature at the core of 70 °C or higher for a minimum of 30 minutes'). The same Ministerial Note n. 3551 of February 2, 2024, also includes an attachment (Annex 2, Operational procedures for handling fresh meat and processed products for export to Canada) detailing the requirements for maintaining eligibility for export to Canada at every stage of the pork and pork-based production chain, with the intention of limiting any potential distortion of the required criteria for commercial purposes (Italian Republic, 2024).

Japan

Historically a major importer of Italian food products until January 2022, Japan accepted pork and pork-based products without restrictions on aging or thermal treatment, as long as they were produced in facilities authorized to export such products to Japan, with meat originating from Italy or other countries equally considered free from FMD, Rinderpest, and ASF by Japanese CAs. If imported, raw materials (live animals or fresh meat) had to be transported from the country of origin to Italy accompanied by an official certificate, crossing only countries with an equivalent health qualification, or in closed and sealed containers (Japan Legislation, 2018).

Following the confirmation of the first ASF outbreak in mainland Italy, not recognizing the regionalization of areas subject to ASF restrictions under EU regulations, Japan immediately halted all imports of pork and pork-based products, regardless of the origin of the raw material. Italy was removed from the official list of countries authorized to export such products to Japan effective January 8, 2022, recognizing December 13, 2021 as the last useful packaging date for the clearance of shipments in transit and in customs of swine-origin products (Italian Republic, 2022a, 2022f).

However, the Japanese CAs expressed willingness to initiate negotiations with the Italian CAs to agree on a new health protocol allowing the export of cooked pork-based products subjected to an ASFV-inactivating treatment. The protocol, transmitted in May 2023, outlines the new health requirements that cooked pork-based products must meet to be exported to Japan (Italian Republic, 2023a). The agreement stipulates that while recognition by Italian CAs under Regulation (EC) 853/2004 is sufficient for establishments performing activities before thermal treatment (slaughter, cutting, and any transformation prior to thermal treatment), processing plants carrying out thermal treatment must be authorized by the MAFF (Ministry of Agriculture, Forestry and Fisheries) through on-site inspection by Japanese inspectors. They requested documents and information in advance from the plants seeking export authorization. Among the management and structural requirements, these plants must maintain complete separation between the pre- and post-thermal treatment areas in terms of premises, facilities, equipment and personnel. Although the health protocol requires a physical separation between the two areas, during the visit by MAFF inspectors in September 2023, alternative solutions involving the temporal and management separation of pre- and post-cooking flows were also explored. In February 2024, eligibility for exports of cooked products to Japan was

finally recognized for four out of the five plants visited by MAFF, while evaluations of additional requested documentation continue for the last facility.

Furthemore, the risk assessment process for reopening the Japanese market to cured products is also underway.

People's Republic of China, Mexico and Taiwan

The export of pork products to the People's Republic of China required compliance with specific rules in addition to the registration of the involved production facilities. These rules included separating animals eligible for this market from those with a different health status ('compartmentalization'), the requirement for the slaughter and processing plant to be located within the 'Macroregion of the North', and special storage areas for meats eligible for export to China. With the entry of ASF into mainland Italy, as clarified in the Ministerial Note of January 12, 2022 (Italian Republic, 2022f), China, unlike other non-EU countries, did not recognize the principle of regionalization (application of restrictive measures in the defined infected zone under Regulation (EU) 2021/605). Consequently, the official certificate was no longer endorsable, for both meats and for meat products, confirming the provisions of the Ministerial Note of January 7, 2022 (Italian Republic, 2022g).

A similar situation occurred for Taiwan and Mexico. Specifically, with the Note of January 12, 2022 (Italian Republic, 2022f), the suspension of exports to Taiwan was formalized, removing Italy from the list of disease-free countries as of January 10, 2022. Additionally, the Note of February 28, 2022 (Italian Republic, 2022h), communicated the suspension of pork and derivative product exports to Mexico, effective from January 12, 2022.

Philippines, Singapore and Vietnam

The agreements and health assurances governing exports to the Philippines, Singapore, and Vietnam did not recognize the principle of regionalization according to the EU model. Therefore, from the moment the first cases of ASF were discovered in mainland Italy, exporting pork products to these countries became impossible.

Regarding the Philippines, after the confirmation of the first ASF case, the Philippine CAs immediately imposed an official block on imports of Italian pork products (Department of Agricolture, 2022), reconfirming it again in August 2022 (Philippines Republic, 2022). An intense diplomatic effort ensued, leading to the revocation of the total import ban on pork products from Italy in December 2022. Specifically, the import ban on pork products from Italy was lifted if processed in such a way as to ensure adequate protection against ASFV, as outlined in the Terrestrial Animal Health Code and Annex VII of Regulation (EU) 2020/687. The negotiations also led to the lifting of the temporary ban on the importation of Processed Animal Protein (Italian Republic, 2023b).

Similarly, for exports to Singapore, the arrival of the first ASF cases necessitated the initiation of new negotiations on health assurances and related official certificates. Following the negotiation of a new official certificate that came into effect in March 2022, the Italian CAs provided health assurances enabling not only the continuation of the export of long-cured pork products but also the extension of the range of exportable products to include short-cured meats, previously not allowed. The agreement signed with the Singapore Food Agency expanded the range of exported pork products, including those cured for less than six months of cured, on the condition that the province of origin has been free from ASF for at least three months. If this condition is not met, these products can only be exported if cured for at least six months or subjected to adequate heat treatment to inactivate the ASFV, in accordance with the guidelines of the WOAH (Italian Republic, 2023c).

Similar to the situations in the Philippines and Singapore, ASF outbreaks in Vietnam initially led to a halt in exports due to the restrictions specified on the official certificate, as the concept of regionalization was limited to Sardinia alone. In March 2022, the Italian CAs proposed a new official certificate model to Vietnamese CAs broadening the regionalization concept (Italian Republic, 2022i). The negotiation of the new official certificate has been concluded and the Ministerial Note n.

32468 of August 3, 2023 communicated the launch of the new official certificate, which applies the regionalization requirement but limits the sourcing to pork from pigs born, raised, and slaughtered in Italy (Italian Republic, 2023d).

South Korea

The export of Italian products to South Korea is based on the 2015 agreement on the hygiene and health conditions of processed pork-based products (Italian Republic, 2016). This agreement allows the export of pork-based products cured for at least 400 days, those cooked at a core temperature of 69 °C for 30 minutes or equivalent heat treatment (Mod. ROK-C03), and sterilized products (Mod. ROK-C01). Additionally, the exporting facilities (slaughterhouse, cutting, processing plant, and refrigerated storage) from which the products originate must be approved and listed on the websites of the Ministry of Food and Drug Safety (MFDS) and the Animal and Plant Quarantine Agency (APQA). These CAs require an original copy of the official certification and an attached declaration. With the confirmation of ASF in mainland Italy, Korean CAs have imposed a total block on the importation of Italian pork products from regions ('administrative divisions') containing restricted areas (Italian Republic, 2023e, 2023f). In this regard, the Italian CAs have sought clarification, referring to compliance with regionalization as envisaged in the EU, considering that South Korea has negotiated and shared the principle of equivalence with the European Commission. Since September 2019, South Korea has reported cases of ASF in feral and domestic pigs, giving the country a disease status no different from that of EU Member States (European Commission, 2024). In light of this agreement with the European Commission, there was a proposal to renegotiate the official certification approved by Korean CAs concerning point 'c' on ASFV, aiming to fully implement the principle of equivalent regionalization in Italy, thus applying the export ban only to products from restricted areas and not from the entire territory of the affected regions. However, the Korean Quarantine Policy Division of the Ministry of Agriculture, Food and Rural Affairs (MAFRA) stated that despite the equivalence agreement, the application of regionalization according to EU regulations concerning the movement of batches of fresh meat and meat-based products, including casings, obtained from pigs held in restricted areas, can only begin when Italy obtains approval for the import of 'fresh pork meat', as already awarded to other EU countries. The renegotiation of the official certification with the APQA CA will be possible only following the opening of the market for all pork-based products and not just processed ones. In light of the above, South Korea has confirmed that, by exporting only 'pork products' (processed), Italy can continue to export only from those regions designated as 'ASF-Free zones' (Italian Republic 2023e, 2023f).

United Kingdom

In 2016, following the referendum known as Brexit, the United Kingdom (UK) terminated its membership in the EU and, effectively, all agreements stipulated by the Treaty on the EU. After intense negotiations, the Trade and Cooperation Agreement between the EU and the UK was reached in December 2020, establishing a new framework for collaboration on sanitary and phytosanitary requirements. During the transition period, in collaboration with the European Commission, the UK issued information and clarifications regarding controls and border operations (UK Border Operating Model to 2023) (GOV.UK, 2020). This document outlined the UK government's guiding principles for the functioning of its border controls, which, starting from January 1, 2021, reflected the UK exit from the EU single market. Products subject to Health and Phytosanitary Controls include animal products, fishery products and live bivalve mollusks, high-risk non-animal origin foods and feeds, animal by-products, live animals and germinal products, live aquatic animals for aquaculture and ornamental purposes, equines, and plants. For the movement of all the aforementioned categories, new procedures were implemented, including pre-notification (to be performed on the Import of Products, Animals, Food and Feed System platform, IPAFFS) and official certification with different deadlines based on the product type and its associated high, medium, or low risk according to the Border Target Operating Model (BTOM) (GOV.UK, 2023a).

After several postponements, the British CAs set January 31, 2024 as the deadline for the enforcement of official certification requirements for imports of animal products from the EU, and April 30, 2024 for the introduction of physical, documentary and identity-based risk-based controls on meats, preparations and meat-based products. The collection of all types of official certificates and their update status can be found on the portal of the Department for Environment, Food & Rural Affairs (DEFRA) for consultation (GOV.UK, 2023b). However, the official certificate must be issued through the TRACES NT Platform (various certificates are available for each product type). For the completion of official certificates for pork and pork-based products, the Italian CAs have confirmed that the UK currently applies the principle of 'maintained legislation': the health requirements set for the introduction of animal products into the UK, as stipulated by the official certificates, are deemed equivalent to those for the circulation of the same products within the EU (Italian Republic, 2021). Therefore, concerning ASF, the UK recognizes the regionalization of areas subject to restrictions under EU regulations. Consequently, for the issue of official certification for exports to the UK, the certifying veterinarian does not require additional certificates from upstream competent veterinarians in the supply chain.

United States of America

Despite the presence of ASF in mainland Italy, the United States of America (USA or US) remains the principal non-EU country for the export of key Italian cured meat products (Assica, 2022). Italian plants have been producing references for the US market for over twenty years, expanding further in 2012 following USDA-APHIS recognition of what is known as the 'Macroregion of the North', which enabled the export of not only long-cured pork-based products (minimum 400 days) and pork-based products subjected to specific heat treatment (e.g., cooked hams, 'mortadella') but also short-cured meat products (e.g., salami, 'coppa').

As reiterated in a Ministerial Note (Italian Republic, 2022f), the US recognizes the regionalization provided for by EU regulations on ASF under the primary reference regulation 9 CFR 94.8. This regulation outlines the conditions to be met for the introduction of pork-based products into the US from regions where ASF is present. This legislation emphasizes the need for heat treatments to ensure ASFV inactivation (Annex VII, Regulation (EU) 2020/687), and is applied within the agreed certificate US-C01, specifically in the Annexes on cooked products.

The significant trend in exports of cured pork-based products to the US requires the application of a series of different control regulations. In the case of 'Italian Type Ham' products (e.g., Parma Ham, San Daniele Ham), the minimum 400-day cured required under 9 CFR 94.17 is recognized as virus-inactivating, and is applied under the agreed certificate US-C01, Annex A, B, and G. On the other hand, for short-cured products, the reference regulation is 9 CFR 94.13, which defines more restrictive requirements in terms of animal health. This regulation is applied under the agreed certificates US-C02 and US-C03, which prohibit the export of pork and pork products from areas subject to ASF restrictions under EU regulations (European Commission, 2023). Therefore, given the current continuously evolving epidemiological situation, the need to initiate discussions with US CAs to renegotiate certain points of the official certificates seems increasingly evident.

Conclusions

In this review, we present the key features of the export and official certification of Italian pork products to the major non-EU importing countries. The spread of the ASF epidemic in national and European territories will lead to further restrictions on the export of these products, and eradicating the disease from these areas might not be an immediate goal given its presence in the wild boar population. What is required is a realistic approach that ensures the safety of exportable products for ASF based on a 'production chain' concept and not solely on the health status of the exporting country. This goal could be achieved through the implementation of rigorous biosecurity measures throughout the production chain and by increasing the frequency of official controls for certification purposes (European Parliament and Council of the European Union, 2017). FBOs must provide the

CAs with documentation on the traceability of all stages of the product and collaborate in possible withdrawal or recall procedures resulting from official controls. The European Commission needs to strengthen bilateral relations with non-EU importing countries since the official certificates for some pork-based products require significant revisions and adaptation. Technological processes capable of inactivating the ASFV allow the export of only cooked and long-cured products from restricted zones, while the possibility of exporting all short-cured products remains dubious.

References

- Assica, 2022. Associazione Industriali delle Carni e dei Salumi. Available from: https://www.assica.it/cat_news/dati-economici/#:~:text=Primi%209%20mesi%20del%202022,%25)%20(%2B12%2C3%25). Accessed on: 10/03/2024.
- Costard S, Mur L, Lubroth J, Sanchez-Vizcaino J, Pfeiffer D, 2013. Epidemiology of African swine fever virus. Virus Res 173:191-7.
- Department of Agricolture, 2022. Republic of the Philippines Officer of the Secretary, 31/01/2022. Temporary ban on the importation of domestic and wild pigs and theri products including pork meat, pig skin, processed animal proteins and semen originating from Italy.
- European Commission, 2020. Commission 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. In: Official Journal, L 174/64, 3/06/2020.
- European Commission, 2021. Commission implementing regulation (EU) 2021/605 of 7 April 2021 laying down special control measures for African swine fever. In: Official Journal, L 129/1, 15/04/2021.
- European Commission, 2023. Commission Implementing Regulation (EU) 2023/594 of 16 March 2023 laying down special disease control measures for African swine fever and repealing Implementing Regulation (EU) 2021/605. In: Official Journal, L 79/65, 17/03/2023.
- European Commission, 2024. Trade barriers. Available from: https://trade.ec.europa.eu/access-to-markets/en/barriers/details?barrier_id=12740&sps=true. Accessed on: 10/03/2024.
- European Parliament, Council of the European Union, 2004. 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. In: Official Journal, L 139/55, 30/04/2004.
- European Parliament, Council of the European Union, 2016. 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'). In: Official Journal, L 84/1, 31/03/2016.
- European Parliament, Council of the European Union, 2017. 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, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation)Text with EEA relevance. In: Official Journal, L 95/1, 7/04/2017.

- Giammarioli M, Alessandro D, Cammà C, Masoero L, Torresi C, Marcacci M, Zoppi S, Curini V, Rinaldi A, Rossi E, Casciari C, Pela M, Pellegrini C, Iscaro C, Feliziani F, 2023. Molecular characterization of the first African swine fever virus genotype ii strains identified from mainland Italy, 2022. Pathogens 12:372.
- GOV.UK, 2020. Model health certificates for exports of live animals and animal products to Great Britain. Available at: https://www.gov.uk/government/collections/health-certificates-for-animal-and-animal-product-imports-to-great-britain. Accessed on: 10/03/2024.
- GOV.UK, 2023a. Check import risk categories and related rules for animals and animal products imported from the EU to Great Britain, from 31 January 2024. Available from: https://www.gov.uk/government/publications/risk-categories-for-animal-and-animal-product-imports-to-great-britain. Accessed on: 10/03/2024.
- GOV.UK, 2023b. The Border Target Operating Model: August 2023. Available from: https://www.gov.uk/government/publications/the-border-target-operating-model-august-2023. Accessed on: 10/03/2024.
- Guberti V, Khomenko S, Masiulis M, Kerba S, 2022. African swine fever in wild boar ecology and biosecurity. Available from: https://www.woah.org/app/uploads/2022/07/asf-in-wild-boar-ecology-and-biosecurity-2nd-ed.pdf.
- Ismea, 2022. Carne suina e salumi. Available from: https://www.ismeamercati.it/carni/carne-suina-salumi. Accessed on: 10/03/2024.
- Italian Republic, 2016. Nota del Ministero della Salute 0000383-P-11/01/2016-DGISAN, "Esportazione di prodotti a base di carne suina dall'Italia verso la Corea del Sud. Revisione del certificato veterinario". [Material in Italian].
- Italian Republic, 2021. Nota del Ministero della Salute 0027674-09/07/2021-DGISAN-MDS-P, "Brexit Certificazione sanitaria degli alimenti di origine animale e fonti informative sul luogo di origine delle materie prime". [Material in Italian].
- Italian Republic, 2022a. Nota del Ministero della Salute 0001031-17/01/2022-DGISAN-MDS-P, "Export Paesi Terzi carni e prodotti a base di carne suine rilascio certificazioni sanitarie a seguito della conferma della presenza del virus della Peste suina africana (PSA) nei selvatici in Italia continentale". [Material in Italian].
- Italian Republic, 2022b. Nota del Ministero della Salute 0004800-16/02/2022-DGISAN-MDS-P, "Rilascio certificazioni sanitarie a seguito della conferma della presenza del virus della Peste suina africana (PSA) nei selvatici in Italia continentale Chiarimenti alla Circolare DGSAN n. 1031 del 17 gennaio 2022".
- Italian Republic, 2022c. Nota del Ministero della Salute 0030704-11/07/2022-DGISAN-MDS-P, "Comunicazione delle Autorità Brasiliane n. 2712/2022/CGSF con la quale comunicano che non saranno ritenuti conformi certificati sanitari riportanti parti manoscritte, compresa la cancellazione delle parti da cancellare perché non applicabili". [Material in Italian].
- Italian Republic, 2022d. Nota del Ministero della Salute 0019922-10/05/2022-DGSAN-MDS-P, "Export verso il Canada aggiornamento certificato bilaterale per l'esportazione di prodotti a base di carne". [Material in Italian].
- Italian Republic, 2022e. Nota del Ministero della Salute 0001715-21/01/2022-DGISAN-MDS-P, "Export Canada carni e prodotti a base di carne suina rilascio certificazioni sanitarie a seguito della conferma della presenza del virus della Peste suina africana (PSA) nei selvatici in Italia continentale". [Material in Italian].
- Italian Republic, 2022f. Nota del Ministero della Salute 0000708-12/01/2022-DGISAN-MDS-P, "Export Paesi Terzi Comunicazione conferma Peste suina africana (PSA) nei selvatici in regione Piemonte e Liguria". [Material in Italian].
- Italian Republic, 2022g. Nota del Ministero della Salute 0000239-07/01/2022-DGISAN-MDS-P, "Export Paesi Terzi Comunicazione conferma Peste suina africana (PSA) nei selvatici in regione Piemonte e Liguria". [Material in Italian].

- Italian Republic, 2022h. Nota del Ministero della Salute 0006698-28/02/2022-DGISAN-MDS-P, "Export Paesi Terzi carni e prodotti a base di carne suine rilascio certificazioni sanitarie a seguito della conferma della presenza del virus della Peste suina africana (PSA) nei selvatici in Italia continentale". [Material in Italian].
- Italian Republic, 2022i. Nota del Ministero della Salute 0017668-27/04/2022-DGISAN-MDS-P, "Proposta di un nuovo certificato sanitario per l'esportazione dei prodotti a base di carne suina in Vietnam". [Material in Italian].
- Italian Republic, 2023a. Nota del Ministero della Salute 0020815-17/05/2023-DGISAN-MDS-P, "Riapertura del mercato giapponese alle esportazioni di prodotti a base di carne suina cotti modalità di presentazione delle manifestazioni di interesse da parte degli stabilimenti". [Material in Italian].
- Italian Republic, 2023b. Nota del Ministero della Salute 0002348-25/01/2023-DGISAN-MDS-P, "Filippine Comunicazione revoca blocco export prodotti di origine suina". [Material in Italian].
- Italian Republic, 2023c. Nota del Ministero della Salute 0048509-19/12/2023 DGISAN-MDS-P, "Esportazione di prodotti a base di carne suina a bassa stagionatura a Singapore". [Material in Italian].
- Italian Republic, 2023d. Nota del Ministero della Salute 0032468-03/08/2023-DGISAN-MDS-P, "Nuovo modello di certificato veterinario per l'esportazione di carni suine e prodotti a base di carni suine in Vietnam". [Material in Italian].
- Italian Republic, 2023e. Nota del Ministero della Salute 0028436-10/07/2023-DGISAN-MDS-P, "Aggiornamento restrizioni all'esportazione prodotti a base di carne suina in Corea del Sud". [Material in Italian].
- Italian Republic, 2023f. Nota del Ministero della Salute 0047078-07/12/2023-DGISAN-MDS-P, "Aggiornamento restrizioni all'esportazione prodotti a base di carne suina in Corea del Sud Focolai PSA nella regione Emilia Romagna". [Material in Italian].
- Italian Republic, 2024. Nota del Ministero della Salute 0003551-02/02/2024-DGISAN-MDS-P, "Export Canada carni e prodotti a base di carne suina rilascio certificazioni sanitarie a seguito della conferma della presenza del virus della Peste suina africana (PSA) in Italia continentale Aggiornamenti". [Material in Italian].
- Japan Legislation, 2018. Animal health requirements for meat and viscera derived from cloven hoofed animals and sausages, ham and bacon made from the said meat and viscera as raw materials to be exported to Japan from Italy (excluding Sardinia island). Available from: https://www.maff.go.jp/aqs/hou/require/attach/pdf/sub2-21.pdf. Accessed on: 10/03/2024.
- McKercher PD, Blackwell JH, Murphy R, Callis JJ, Panina GF, Civardi A, Bugnetti M, De Simone F, Scatozza F, 1985. Survival of swine vesicular disease virus in 'Prosciutto di Parma' (Parma Ham). Can Inst Food Sci Technol J 18:163-7.
- McKercher PD, Yedloutschnig RJ, Callis JJ, Murphy R, Panina GF, Civardi A, Bugnetti M, Foni E, Laddomada A, Scarano C, Scatozza F, 1987. Survival of viruses in "prosciutto di Parma" (Parma Ham). Can Inst Food Sci Technol 20:267-72.
- Mebus C, Arias M, Pineda JM, Tapiador J, House C, Sánchez-Vizcaíno JM, 1997. Survival of several porcine viruses in different Spanish dry cured meat products. Food Chem 59:555-9.
- Olesen AS, Belsham GJ, Bruun Rasmussen T, Lohse L, Bødker R, Halasa T, Boklund A, Bøtner A, 2020. Potential routes for indirect transmission of African swine fever virus into domestic pig herds. Transbound Emerg Dis 67:1472-84.
- Pavone S, Iscaro C, Dettori A, Feliziani F, 2023. African swine fever: the state of the art in Italy. Animals 13:2998.
- Petrini S, Feliziani F, Casciari C, Giammarioli M, Torresi C, De Mia GM, 2019. Survival of African swine fever virus (ASFV) in various traditional Italian dry-cured meat products. Prev Vete Med 162:126-30.

- Philippines Republic, 2022. Food and Drug Administration, 25/08/2022. Temporary ban of entry of pork meat products from new indentify countries implicated with African swine fever.
- Rossi A, Rossi G, Rosamilia A, Micheli MR, 2020. Official controls on food safety: competent authority measures. Ital J Food Saf 9:8607.
- Sánchez-Cordón PJ, Montoya M, Reis AL, Dixon LK, 2018. African swine fever: a re-emerging viral disease threatening the global pig industry. Vet J 233:41-8.
- WOAH, 2021. Compartmentalisation guidelines. Available from: https://www.woah.org/app/uploads/2021/10/asf-compartmentalisationguidelines-en.pdf. Accessed on: 10/03/2024.
- WOAH, 2023. Terrestrial Animal Health Code 2023. Available from: https://www.woah.org/en/what-we-do/standards/codes-and-manuals/terrestrial-code-online-access/. Accessed on: 10/03/2024.
- WTO, 1995. Agreement on the application of sanitary and phytosanitary measures. Available from: https://www.wto.org/english/docs_e/legal_e/15-sps.pdf. Accessed on: 10/03/2024.

Online supplementary material:

Supplementary Table 1. Current exports of Italian pork products to non-EU countries following the spread of ASF in mainland Italy.

Table 1. Risk-mitigating treatments for pork products origin from the restricted zones (European Commission, 2020 - Annex VII, Regulation EU 2020/687).

Organs/Tissues	Treatment
Meat	Heat treatment in an hermetically sealed container, to achieve a minimum F_0 (1) value of 3
	Heat treatment to achieve a core temperature of 80°C
	Heat treatment (to meat previously de-boned and defatted) to achieve a core temperature of 70°C for a minimum of 30
	minutes
	In an hermetically sealed container, applying 60 °C for a minimum of 4 hours
	Natural fermentation and maturation for de-boned meat: minimum 9 months, to achieve maximum values of Aw of 0.93 and
	pH of 6
Casings	Natural fermentation for loins: minimum 140 days to achieve maximum values of Aw of 0.93 and pH of 6 (2)
	Natural fermentation for hams: minimum 190 days to achieve maximum values of Aw of 0.93 and pH of 6 (2)
	Salting with sodium chloride (NaCl) either dry or as saturated brine (Aw<0.80), for a continuous period of 30 days or longer
	at an ambient temperature of 20°C or above
	Salting with phosphate supplemented salt 86.5 % NaCl, 10,7 % Na2HPO4 and 2.8 % Na3PO4 either dry or as saturated
	brine (Aw<0.80) for a continuous period of 30 days or longer at an ambient temperature of 20°C or above

⁽¹⁾ F_0 is the calculated killing effect on bacterial spores. An F_0 value of 3 means that the coldest point in the product has been heated sufficiently to achieve the same killing effect as 121° C (250° F) in three minutes with instantaneous heating and chilling.

⁽²⁾ Only for porcine animals.