



Animal and Plant Health Inspection Service
U.S. DEPARTMENT OF AGRICULTURE

APHIS evaluation of Toscana and Umbria, Italy for swine vesicular disease

Veterinary Services
November 2022

Table of Contents

Table of Contents	2
Section 1: Executive Summary	4
Section 2: Introduction	5
Section 3: Hazard Identification	9
Section 4: Entry Assessment	12
Section 5: Risk Estimation	46
References	47

Abbreviations

APHIS	Animal and Plant Health Inspection Service
BIP	border inspection post
BDN	National Livestock Database (referred to as the <i>Banca Dati Nazionale</i>)
CERVES	Centre of Reference for Vesicular Diseases
CFR	United States Code of Federal Regulations
CSF	classical swine fever
EC	European Commission
ELISA	enzyme-linked immunosorbent assay
EU	European Union
ISS	<i>Istituto Superiore di Sanita</i>
IZS	<i>Istituti Zooprofilattici Sperimentali</i>
MOH	Ministry of Health
PCR	polymerase chain reaction
SVD	swine vesicular disease
VNT	virus neutralization test
WOAH	World Organisation for Animal Health (formally <i>Office International des Epizooties</i> - OIE)

Section 1: Executive Summary

The Animal and Plant Health Inspection Service (APHIS) currently includes the Regions of Toscana (henceforth in this document referred to as Tuscany) and Umbria in the portion of Italy it considers to be affected with swine vesicular disease (SVD) [1]. As such, APHIS restricts the importation of live swine, fresh pork, and pork products from the region.

Since 1999, APHIS has conducted multiple SVD evaluations in Italy, which led to progressive expansion of the region of Italy that APHIS recognizes as free of SVD [2, 3]. During this time, there have been several significant events affecting Italy's SVD status. Italy reported 702 SVD outbreaks from 1995 through 2015, primarily in southern Italy, although in 2006-2007 and 2009 there were spikes in outbreaks reported in central and northern Italy [4]. There were also significant changes to Italy's veterinary infrastructure and animal health laws and regulations [3].

In December 2015, APHIS received a request from the government of Italy for recognition of the SVD status of Tuscany. APHIS conducted a site visit in Tuscany in May 2016 [5]. In April 2017, APHIS received documentation supporting the SVD evaluation of Umbria and subsequently conducted a site visit to Umbria in October 2017 [6]. Since the technical site visits, APHIS received additional information from Italy in support of the evaluation of these two regions [4].

This document describes APHIS' evaluation of the SVD status of Tuscany and Umbria. Supporting documentation reviewed for this risk analysis came from the national government of Italy and the regional governments of Tuscany and Umbria; reports published by the European Commission (EC); observations made by APHIS technical teams during site visits in May 2016 and October 2017; peer-reviewed articles; data from the World Organisation for Animal Health (WOAH, formally *Office International des Epizooties* - OIE); and other technical sources.

This risk analysis was conducted according to WOAH guidelines for import risk analysis [7]. The hazard under consideration is the SVD virus. The risk analysis is considered by APHIS in its decision whether and under what conditions to accept the importation of live swine,¹ fresh pork, and pork products from the Regions of Tuscany and Umbria, Italy [8].

APHIS concludes from the entry assessment that SVD does not exist in Tuscany and Umbria. Furthermore, APHIS considers that Italy possesses the detection capabilities, reporting and traceability systems, and emergency response systems necessary to respond to any reintroduction of SVD; to identify and remove exposed or potentially infected live swine, contaminated fresh pork, and contaminated pork products from the export market channel; and to comply with the certification requirements that APHIS intends to impose for exports to the United States from Tuscany and Umbria. For these reasons, APHIS concludes that the likelihood of importing SVD-infected live swine, contaminated fresh pork, and contaminated pork products from Tuscany and Umbria would be negligible. Thus, the risk of introducing SVD via swine commodities from Italy is negligible.

¹ Since Italy is included in the APHIS-defined EU CSF region, live swine imports are restricted to breeding swine.

Section 2: Introduction

Italy is organized into twenty-one political units, nineteen regions and two autonomous provinces,² which are further subdivided into provinces. The Regions of Toscana (henceforth in this document referred to as Tuscany) and Umbria are in central Italy (see Figure 1).

Tuscany is the largest region in central Italy, incorporating 22,987 square kilometers, and has a population of approximately 3,750,511 [9]. It borders the Regions of Liguria, Emilia-Romagna, Marche, Umbria, and Lazio, and has a coastline along the Mediterranean Sea to the west. Tuscany is divided into 10 provinces, with 279 municipalities. Florence is the regional capital (see Figure 2).

Umbria is in central Italy and borders Tuscany on the west, Marche on the east, and Lazio on the south. It lacks a sea coastline and is a hilly, mountainous region comprised of 8,464 square kilometers with a population of approximately 894,762 [10]. Umbria is divided into two provinces, with 92 municipalities. Perugia is the regional capital (see Figure 2).

History

The Animal and Plant Health Inspection Service (APHIS) currently includes Tuscany and Umbria in the portion of Italy it considers to be affected with swine vesicular disease (SVD) [1]. As such, APHIS restricts the importation of live swine, fresh pork, and pork products from the region.

Since 1999, APHIS has conducted multiple SVD evaluations in Italy [2, 3]. During this time there have been several significant events affecting Italy's SVD status. Italy reported 702 SVD outbreaks from 1995 through 2015, primarily in southern Italy, although in 2006-2007 and 2009 there were spikes in outbreaks reported in central and northern Italy [4]. There were also significant changes to Italy's veterinary infrastructure and animal health laws and regulations [3].

Based on these evaluations, APHIS recognized a macro region in northern Italy as free of SVD. In 2003, APHIS recognized the Regions of Friuli, Liguria, Marche, and Valle d'Aosta [11], and later in 2013, the Regions of Lombardia, Emilia-Romagna, Veneto, Piemonte, and the autonomous provinces of Trento and Bolzano [12].

In December 2015, APHIS received a request from the government of Italy for recognition of the SVD status of Tuscany. After reviewing the documentation submitted with the request, personnel from APHIS visited Tuscany in May 2016 [5]. The team met with Italian officials from the Italian Ministry of Health and from the Government of Tuscany. At the conclusion of the site visit to Tuscany, Italian officials indicated Italy's intention to expand its request to include SVD status recognition of Umbria. In April 2017, APHIS received documentation supporting the evaluation of Umbria and subsequently conducted a site visit to Umbria in October 2017 [6]. Since the technical site visits, APHIS received additional information from Italy in support of the evaluation of these two regions [4]. This document describes APHIS' evaluation of the

² The Provinces of Trento and Bolzano act independently with authority like that of a region.

information received and gathered, its observations, and the resulting conclusions about the SVD status of Tuscany and Umbria.



Source: USDA, APHIS, VS, CEAH

Figure 1: Map of Italy



Figure 2: Map of Tuscany and Umbria

Documentation

Supporting documentation reviewed for this risk analysis came from the Government of Italy, Ministry of Health; reports published by the European Commission (EC); observations made by APHIS technical teams during site visits in May 2016 and October 2017; peer-reviewed articles;

and data from the World Organisation for Animal Health (WOAH , formally *Office International des Epizooties* - OIE) and other technical sources.

Methodology

This risk analysis was conducted according to WOAH guidelines and therefore includes a hazard identification section, an entry assessment, and a risk estimate [7]. The hazard under consideration is the SVD virus. The risk analysis is considered by APHIS in its decision whether and under what conditions to accept the importation of live swine,³ fresh pork, and pork products from the Regions of Tuscany and Umbria, Italy [8].

³ Since Italy is included in the APHIS-defined European CSF region, live swine imports are restricted to breeding swine.

Section 3: Hazard Identification

The WOAHA lists animal diseases that are considered primary hazards associated with trade of animals and animal products [13]. Although previously listed, the WOAHA discontinued listing SVD in 2015 [14]. However, APHIS considers the SVD virus to be a potential hazard associated with trade of live swine and swine products, and through regulations APHIS mitigates the risk of SVD introduction into the United States [1]. As a foreign animal disease of concern, APHIS conducts an import risk analysis to evaluate the hazard of SVD introduction prior to initiating trade of susceptible animal commodities. SVD, once endemic in much of Europe, in recent years had sporadic distribution with the last cases being reported in southern Italy in 2015 [4, 14]. It had also been reported in parts of Asia where the last outbreak occurred in China in 1999 [15]. SVD has never been reported in the United States [14].

Causative agent

SVD virus is a member of the viral family *Picornoviridae*, genus *Enterovirus*. One serotype and several strains have been identified [15-19]. SVD virus isolates have been classified into at least four distinct groups, with two groups containing older isolates, and two groups containing more recent isolates.

Host range

Swine (domestic and wild pigs) are the only natural hosts of SVD virus [16, 20, 21]. Serological evidence suggests that it is unlikely that wild boar serve as reservoir hosts in Europe [3, 15, 22]. Infections have been reported in humans working with SVD virus in the laboratory and in experimental mice, but these species are not significant in the epidemiology of the disease [15, 20, 21, 23].

Morbidity and mortality

The primary significance of SVD is its clinical similarity to foot and mouth disease (FMD) [15, 20]. Clinical signs include fever, sudden lameness, and vesicles with subsequent erosions along the lips, tongue, snout, feet, and teats [16, 20]. Signs can range from absent to mild to severe, depending on virus strain, route of infection, age of the animal, and husbandry. Morbidity rates may be low throughout an entire herd, but high in certain pens. Clinical recovery usually occurs within 2 to 3 weeks [15, 16, 20, 21]. Production losses are not severe, and SVD essentially causes no mortality [15, 16, 24]. Persistence of SVD virus infection is rare [21, 25]. Some strains of SVD virus produce only mild clinical symptoms in animals or animals are asymptomatic and detected only through laboratory testing [20, 21].

Incubation period

The incubation period for SVD virus is generally 2 to 7 days but can be longer if the infecting dose is small [16, 20, 21]. Large amounts of virus can be present in nasal and oral secretions and feces up to 2 days prior to the appearance of clinical signs [15, 16].

Sources of virus and transmission

SVD virus can be present in most tissues, secretions, and excretions of infected animals, including oral and nasal secretions, blood, feces, semen, epithelial cells, tonsils, myocardium, brain stem, lymph nodes, skeletal muscle, cardiac muscle, salivary glands, adipose tissue, tongue, central nervous system [15, 17, 21, 26, 27]. SVD virus has also been detected in zona pellucida-intact embryos that were exposed to SVD virus and subsequently washed [28]. Blood and feces of sick animals, as well as epithelium from vesicles and vesicular fluid, are good sources of SVD virus. The period of highest shedding occurs during the first week after infection [15, 16]. The virus can be detected in the blood 2 days after exposure and subsequently in most other tissues and semen [16, 17, 27, 29]. Although SVD virus does not appear to have a tropism for skeletal muscle cells, it is viable and infectious in meat for long periods of time [15, 16, 30]. Persistent infection is rare, but persistence of some strains in tissue for up to 100 days and fecal shedding for more than 4 months has been reported [16, 17, 21, 25].

Spread of SVD is most often attributed to movement of infected animals, or contaminated feces or equipment [16, 24, 31]. SVD is highly contagious, and spreads rapidly by direct contact with infected animals and by environmental contamination [17]. SVD virus is transmitted mainly through contact with infected swine or their excrement and through feeding of contaminated meat to swine [21]. Spread through contact with an environment contaminated with SVD virus has been shown to occur as easily as spread through direct inoculation or contact with infected swine. Airborne spread is not a major feature of SVD virus transmission. Attempts to experimentally demonstrate SVD virus transmission to sows through artificial insemination have been unsuccessful [32]. Similarly, attempts to experimentally demonstrate SVD virus transmission through embryo transfer from infected sows to recipient animals have been unsuccessful [28]. No vaccine for SVD is commercially available [15, 16].

High environmental stability is a key feature in the epidemiology of SVD. The SVD virus enters the body via broken skin, mucus membranes, or ingestion. After initial introduction into a herd, the disease spreads due to contact of susceptible pigs with infected pigs and feces [15-17, 21, 30].

Inactivation and survival

SVD virus is very stable in the environment. It is highly resistant to desiccation and freezing, and can survive for up to 11 months at -20°C to 12°C [17]. It is stable at pH 2.5-12 [15-17], and is therefore unlikely to be destroyed by the decrease in muscle pH that accompanies carcass maturation. SVD virus is also resistant to fermentation and smoking processes, and may remain in ham for 180 days, dried sausage for more than a year, and processed intestinal casings for more than 2 years [16, 20, 26]. The virus is resistant to many common disinfectants [17]. Inactivation can be achieved by heating at 60°C for 10 minutes [17]. Apparent thermal inactivation of SVD virus in meat can be achieved by (1) heating at 56°C for 1 hour [16]; (2) heating at 60°C for 10 minutes [17]; or (3) heating to at least 69°C [33, 34].

Vaccination

Vaccines against SVD are not available [20].

Laboratory Diagnostics

Serologic (antibody detection) tests can be used to confirm clinical cases of SVD and detect subclinical infections. Since many cases of SVD are subclinical, the disease is often first suspected based on positive results on serologic tests performed for surveillance or export certification. Specific antibody to SVD can be identified using ELISA or the microneutralization test, a type of virus neutralization test (VNT), which is the definitive test for antibody detection [20]. The VNT is the WOAHA-recommended test for use in international trade. Up to 0.1 percent of uninfected pigs can exhibit a false positive serological test for SVD. Reactivity is transient and can be differentiated from infected pigs by resampling of the positive animal and its herd mates.

Polymerase chain reaction (PCR) and ELISA are suitable screening tests for SVD antigen detection; however, virus isolation is the preferred antigen detection test and should be used for confirmation at a reference laboratory when a positive PCR or ELISA result occurs in the absence of clinical signs, without positive antibody results, or in situation not directly related to a verified outbreak.

In the presence of clinical signs, demonstration of SVD viral antigen in lesion material or vesicular fluid via ELISA is sufficient to make a diagnosis of SVD [20]. More sensitive tests such as reverse transcriptase PCR or viral isolation in porcine cell cultures may be needed if the test results are negative or inconclusive. Demonstration of SVD viral antigen by ELISA or viral RNA by RT-PCR from inoculated cultures that develop a cytopathic effect is sufficient to confirm the diagnosis.

Section 4: Entry Assessment

An entry assessment describes the biological pathway(s) necessary for an importation activity to introduce pathogenic agents into a particular environment and estimates the probability of that introduction [7]. This entry assessment addresses the factors described under *Title 9 of the Code of Federal Regulations Part 92* (9 CFR 92) for evaluation of the animal health status of a region [8]. Risk factors and issues of concern, which may directly or indirectly affect the risk estimate, are identified during this process.

4.1. Scope of the evaluation

APHIS evaluates the Regions of Tuscany and Umbria, Italy in this assessment of the SVD virus risk for importation of live swine, fresh pork, and pork products from this region.

4.2. Veterinary control and oversight

Organization of veterinary services

The Italian veterinary services operate under the coordination and supervision of the Ministry of Health (MOH) and are comprised of several entities that interact with each other at the central, regional, and local levels (see Figure 3) [9, 10]. Approximately 6,000 official veterinarians (veterinarians employed by the government) are assigned to positions throughout the Italian veterinary services [35]. APHIS conducted two sites visits for this evaluation, Tuscany (May 2016) and Umbria (October 2017) [5, 6]. During these visits the APHIS teams toured offices and facilities of Italy's central, regional, and local veterinary authorities to interview personnel, observe procedures and activities, review records, verify information provided by the competent authority, and collected additional data. The APHIS teams were briefed on the organization of the central, regional, and local veterinary authorities and their respective roles and responsibilities, including SVD disease control and surveillance activities.

The team found a good working relationship throughout the various levels and branches of the MOH, with legal authority sufficient to carry out the critical aspects of swine disease prevention, monitoring, and control. There is excellent cooperation and communication between local and regional level officials and national MOH officials with clear division of roles and responsibilities. Similarly, the team observed close relationships between swine producers and the regional health agency veterinarians. All central, regional, and local personnel that the site visit team interviewed were competent, knowledgeable, professional, and transparent [5, 6].

Ministry of Health

- International relations
- European Union relations
- Guidance, policy, and coordination of the Regions

Regional Governments

- Relations with MOH and other Regions
- Instruction and coordination of activities of Local Health Units
- Audit and supervision of the Local Health Units

Local Health Units

- Conduct official activities and inspections related to animal health, animal welfare, food of animal origin, and feed, including official checks and daily inspections of plants approved to export

Source: Ministry of Health [9, 10]

Figure 3: Italian veterinary services – levels and authorities

Central authority

The MOH is the central authority of the Italian government responsible for public health, animal health, food hygiene and safety, feed safety and animal welfare. The MOH is composed of a General Secretariat and 12 Directorates-General. The three Directorates involved with animal health, veterinary medicine, food safety, and veterinary public health are: Directorate-General for Animal Health and Veterinary Medical Products (DGSAF); Directorate-General for Hygiene, Food Safety and Nutrition (DGISAN); and Directorate-General for Collegial Bodies for Health Protection (DGOCTS) [9, 10, 35].

Italy's chief veterinary officer (CVO) is the head of DGSAF and reports directly to the Minister of Health. DGSAF is responsible for national programs for the eradication of animal diseases; controls on the importation of animals, food of animal origin, animal products, and animal feed; animal welfare on farms; and authorization for the manufacture, importation, and distribution of veterinary medicinal products. DGSAF coordinates all SVD surveillance and control activities

throughout Italy. The APHIS team met with Italy's CVO to share information and discuss findings during site visits to Tuscany (2016) and Umbria (2017).

DGISAN is responsible for the health and safety of food production and marketing; control plans of the food chain and operational guidelines for official controls on imported food; hygiene and safety of food for export; rapid response to disease or contamination spread in food, feed, or animal by-products; nutrition labeling and education; safety of food technology, genetically modified organisms, and food and feed additives; and plant protection products. DGISAN conducts investigations, audits, and inspections in its areas of responsibilities.

DGOCTS is the national contact point for the European Food Safety Authority and is responsible for the physical, chemical, and biological risk assessment for food safety in cooperation with the Committee of Consumers and Producers Associations and DGISAN.

Central authority field offices

The MOH has the authority and the responsibility to operate local offices controlling the import, intra-community trade, and export to third countries of animals, food of animal origin and animal feed. For these commodities, the MOH operates 24 border inspection posts (BIPs), which are responsible for import control, and 9 Veterinary Offices for Compliance with Community Requirements, which are responsible for intra-community Union trade surveillance [35].

Laboratory services

The *Istituti Zooprofilattici Sperimentali* (IZS) are veterinary public health institutes which provide a network of public laboratories at the national and regional level. There are 10 IZS with 90 field diagnostic units at the provincial level [36]. Each IZS serves one or more regions. The IZS are subject to control and supervision by the regions and coordination by the MOH. The most important tasks of the IZS are:

- Diagnosis of animal and zoonotic diseases
- Epidemiological surveillance in animal health, animal production and food of animal origin
- Research on animal health and welfare, infectious animal diseases, zoonoses, food and feed safety
- Training of specialized animal health veterinarians and animal health technicians
- Support and assistance in the animal disease control and eradication and with development of improvements in animal production

Each IZS serves as a national reference laboratory of one or more animal diseases or for food safety issues and some have been designated as Food and Agriculture Organization of the United Nations, WOA, or World Health Organization reference laboratories. The IZS at Brescia is the *Istituto Zooprofilattico Sperimentale della Lombardia e dell'Emilia* (IZSLER). Operating within IZSLER is Italy's national reference laboratory for vesicular diseases, the Centre of Reference for Vesicular Diseases (CERVES). An APHIS team visited the IZS at Brescia during a site visit in 2010 and did not identify any concerns related to the laboratory network. In its 2012 risk assessment, APHIS concluded that the laboratory consistently conformed to EC and international

standards on swine diseases, and that the laboratory capacity was adequate and capable of meeting the diagnostic needs should an outbreak of SVD occur [3]. During the 2016 and 2017 site visits to Tuscany and Umbria, the APHIS teams were accompanied by technical experts from the IZS at Brescia and the IZS regional laboratories (the Zooprofilaxis Experimental Institute of Lazio and Tuscany and the Institute Zooprofilactic Experimental of Umbria and Marche) and received updated briefings on SVD surveillance in Italy. Based on the favorable observations of previous site visits, the APHIS teams concluded it was unnecessary to revisit the laboratory [5, 6].

The National Health Institute (*Istituto Superiore di Sanita*) (ISS) is the leading technical and scientific public body of the Italian National Health Services. The ISS supervises the laboratories of the Italian National Health Service engaged in food safety. Its activities include public health research, control, training, and consultation. An important activity of ISS, which is carried out on behalf of the MOH or the regions, is inspection and quality control of food products and packaging. The ISS includes the European Union Reference laboratories for *Escheria coli*; for parasites (in particular *Trichinella*) and for the residues [35].

Regional veterinary authorities

The Italian Constitution provides that the national and regional governments share responsibility for health in general, including animal health, food and feed safety and animal welfare. Where these authorities overlap, the national and regional governments share legislative authority. However, related administrative powers are delegated to the regional governments. The national authority transposes EC directives and decisions for the whole country and these are then legislatively adopted by individual regions. However, the MOH maintains the authority and responsibility for international commerce of animals and animal products, setting and developing necessary import and export controls. This responsibility includes the management of all BIPs. The MOH also serves to provide national coordination, guidance, and inspection of establishments in relation to export to other countries. The MOH has the authority to audit regional control activities [35, 37, 38].

Italy is subdivided regionally into 19 regions and 2 autonomous provinces each having the responsibility for planning, implementing, and verifying controls within their respective territory. Although there is some regional variation in the internal structure, responsibility for animal health, food and feed safety and animal welfare is assigned to the Regional Veterinary Services (RVS) which normally are part of the Regional Public Health Services (RPHS). While the RPHS functions to provide oversight and coordination, implementation of controls is done by local employed officials [9, 10].

During the 2016 site visit, officials of the RVS of Tuscany briefed the APHIS team on the organization, training, and function of the regional veterinary authorities. Tuscan officials described the regional training plan for official veterinarians, animal health technicians, and animal care professionals which was developed in collaboration with University of Pisa and included EU-sanctioned coursework. The RVS officials explained that Italy's national budget is proportionally divided among regional governments, adding that the budget of Tuscany's RVS

represents approximately 5% of the total regional budget. It was also mentioned that the EU provides funding for animal disease emergency response activities in the event of disease outbreaks [5].

An APHIS team also met with officials of MOH and the Region of Umbria at the RVS headquarters in Perugia in 2017. During those meetings, the APHIS team received briefings on the overall epidemiological situation of SVD in Italy, organization of Umbria's RVS, and Umbria's SVD control program and surveillance data from 2014–2017. Umbrian officials explained that the Prevention, Veterinary Public Health, and Food Safety Service was the competent regional authority in the Region of Umbria responsible for animal health. A description was given of the two main regional acts which provide the authority for the regional health services, namely, Regional Law No. 11 (9 April 2015) and Regional Law No. 2 (1 February 2005). The region employed a number of veterinarians, technicians, and administrative support personnel [6].

Local veterinary authorities

The Local Health Units (*Aziende Sanitarie Locali* – ASLs) are public bodies responsible at the local level for the organization and management of all public health services. The ASLs have a high degree of managerial, administrative, financial, and technical autonomy. There are 123 ASLs in Italy. Within the ASL, the Local Veterinary Services (LVS) is a division of the Department of Prevention. The LVS are responsible for animal health, animal welfare, food of animal origin, and animal feed. Most inspectors in the LVS are veterinarians [35].

During the 2016 site visit, the APHIS team learned that a major reorganization of regional health services in Tuscany had recently occurred which were expected to increase efficiency and lower costs. Twelve ASLs were reduced to three, one each in Sienna, Pisa, and Firenze [5]. The APHIS team was advised that similar reorganizations were underway in other Italian Regions as well. In 2017, Umbria was comprised of 92 municipalities that were organized into two ASLs [6]. Each ASL included a local veterinary services office (LVS) responsible for animal health, food hygiene of animal origins, and animal welfare, feedstuffs, and medicinal products.

During both site visits the APHIS team noted that LVS veterinarians frequently visit farms and slaughterhouses whenever there is unloading of animals or vaccinations. The APHIS team learned that private veterinarians are occasionally contracted by the LVS to perform official functions, so to avoid any conflicts of interest these private veterinarians are required to sign a statement that they do not work privately within the region. Training of official veterinarians is conducted by the RVS [5, 6].

Oversight

The EC monitors Member States' implementation of EC regulations on food and feed safety, animal health, animal welfare, plant health, and in certain areas of human health protection [39]. The Directorate-General for Health and Food Safety conducts periodic audits in accordance with the general provisions of EC legislation (Articles 116, 117 and 119 of Regulation (European Union [EU]) 2017/625 of the European Parliament and of the European Council) [40]. These

audit reports contain recommendations to assist the competent authorities of audited Member States to rectify any identified shortcomings. The EC verifies actions to the report's recommendations either administratively or through subsequent audits. In cases where the non-compliances are sufficiently serious, the EC has the authority to take stronger actions, including legal action, restrictions, or bans on movement of goods or animals.

In addition, Member States are required by Regulation (EU) 2017/625 (Article 6) to conduct internal audits of animal health activities and to take appropriate measures considering the results of those audits [40]. These audits are to be transparent and subject to independent scrutiny. In Italy, the internal audit system follows its descending hierarchy with the MOH conducting audits of the RVSs, which in turn audit the ASLs [35]. These audits are comprised of a system audit of the overall management structure of the RVS, and at least four sectoral audits looking vertically at the implementation of controls. Member States are also required by Regulation (EU) 2017/625 (Article 113) to submit an annual report to the EC describing the performance of its official animal health control activities.

In addition, the EC and Member States monitor the disease situation throughout the EU through the EC Standing Committee on Plants, Animals, Food and Feed, Animal Health, and Welfare. At the monthly committee meetings, Member States provide situational updates whenever there are occurrences of animal disease or ongoing disease eradication programs in a Member State [41].

Legal authority

Animal health control measures in Italy are required to follow EC regulations that are applicable throughout the EU. The provisions of the EC regulations must be incorporated into Italy's legal framework. Currently, the EC regulations are contained in the EU Regulation 2016/429 (the Animal Health Law) and multiple associated delegated and implementing regulations that became effective April 21, 2021 [42]. Previously, the EC's animal health regulations were contained in multiple legal documents, commonly known as commission decisions, directives, and regulations, which were harmonized throughout the EU.

Prior to implementation of the new Animal Health Law, the EU addressed SVD control measures through both general animal health regulations and disease specific regulations. The previous general animal health regulations were replaced by the new Animal Health Law in April 2021, which continues to enforce many of the same measures. The specific SVD regulations were repealed on March 20, 2019, when the EC, with concurrence of Italy, concluded that these regulations were obsolete, as SVD no longer existed in Italy or elsewhere in the EU [43].

In this evaluation, APHIS considers the impact of SVD control measures enforced in Italy from November 5, 2005 through March 20, 2019, the period when the EU and Italy actively conducted

an SVD eradication and monitoring program, the general animal health measures that were previously in force, and those currently effective under the new Animal Health Law [42-49].

General animal health measures

Previously, Council Directive 82/894/EEC (December 1982) stipulated that SVD was a notifiable disease in accordance with provisions for the notification of animal diseases within the EU, meaning that it was incumbent upon each Member State to notify the EC and other Member States upon confirmation of a new primary case of SVD [50]. Under the new Animal Health Law that went into effect April 21, 2021, the EC ceased to classify SVD as a disease of concern, which means Member States are no longer obligated to conduct surveillance for SVD [42, 51].⁴

Under the previous animal health framework, Council Directive 92/119/EEC (December 1992) established general emergency response measures that were to be applied whenever a disease outbreak occurred in a Member State [52]. While most of the measures were general and applicable for outbreaks of various animal diseases, some measures were targeted for specific animal diseases, such as SVD. Directive 92/119/EEC was repealed on April 21, 2021, upon implementation of the new Animal Health Law, which carries over most of the general measures from Directive 92/119/EEC, but none of the specific measures for SVD described below [42].

Standards for laboratory diagnostic procedures, sampling methods and criteria for the evaluation of the results of laboratory tests for the confirmation and differential diagnosis of SVD were set out in Commission Decision 2000/428/EC (July 2000) [53]. This decision also recognized the Institute for Animal Health in Pirbright, England as the EC reference laboratory for SVD. Transposition of these EC requirements into Italian law was principally made through Republic Presidential Decree no. 362, May 17, 1996, and Ministerial Order of March 28, 2007. Under the new Animal Health Law, the EC no longer requires Member States to conduct SVD surveillance, so Decision 2000/428/EC was effectively repealed on April 21, 2021, by Commission Delegated Regulation (EU) 2020/689 [54].

Specific EU measures for SVD control in Italy

Except for three single outbreaks in Portugal (2003, 2004, and 2007), Italy is the only EU Member State to experience SVD outbreaks in recent years [55, 56]. Historically, SVD had been persisting within limited regions of Italy giving rise to sporadic outbreaks elsewhere in the country. These limited regions were located in southern Italy where swine production consisted primarily as numerous small farms, usually raising 1-3 pigs for self-consumption [56]. SVD virus is particularly stable in the environment and is often characterized as a “pen disease”. These small farms obtained pigs through dealers, and the transport by dealers has been implicated in the spread of SVD.

Following a significant rise in SVD outbreaks in 2002-2004, the EC issued Decision 2005/779/EC in November 2005 addressing specific SVD control measures to be applied in Italy [44]. This regulation provided the framework for Italy’s SVD eradication and monitoring

⁴ In 2015 the WOA removed SVD from its list of diseases of concern and ceased collecting SVD data from member countries [12]. As of 2015, EU Member States are not required to report detection of SVD to the WOA.

program and included provisions to regionalize Italy for SVD, recognition of SVD-status of individual holdings, surveillance, movement controls, and communication between Italy and the EC and other Member States. The provisions were intended to mitigate SVD spread to the free areas of Italy or to other Member States and are described in more detail in the next section.

This decision was amended multiple times since originally adopted, strengthening certain provisions, and revising the lists of regions recognized as being SVD-free and not SVD-free, and was eventually repealed on March 20, 2019, when the EC concurred with Italy that SVD was no longer present in Italy [43-49].

Italy transposed Decision 2005/779/EC into Italian law with the issuance of Ministerial Order dated April 12, 2008, Sanitary Measures for the Eradication of Swine Vesicular Disease and Surveillance of Classical Swine Fever [57]. That Ministerial Order exceeded the requirements of Decision 2005/779/EC in several significant ways, which are described in the next section.

Traceability measures

The legal authority establishing the regulations for swine traceability has been maintained through a series of laws and regulations over the last thirty years. EC measures regarding the identification and registration of swine were laid down in Council Directive 92/102/EEC (November 1992), which was amended several times and eventually replaced by Council Directive 2008/71/EC (July 2008). Directive 2008/71/EC was eventually replaced with the Animal Health Law in April 2021 [9, 10, 42, 58, 59]. Italy transposed and clarified the requirements of Directive 92/102/EEC as amended in Ministerial Order dated April 12, 2008, Identification and Registration System of holdings, pigs, and their movements, and incorporated the changes made in 2008 through the Legislative Decree 26 October 2010 No. 200: Implementation of Directive 2008/71/EC relating to identification and registration of swine [9, 10]. Italy's identification and registration system for swine are described in Section 4.4.

Discussion

During site visits to Tuscany (May 2016) and Umbria (October 2017), as well as a previous site visit to northern Italy (December 2010), the APHIS team focused its attention on matters related to the authority, organization, and infrastructure of the veterinary services in Italy. APHIS focused on these factors since identifying several concerns in a 2007 site visit that were related to gaps in the authority, organization, and infrastructure of the Italian veterinary services [3]. APHIS concludes that the concerns identified in 2007 have been fully addressed by Tuscany and Umbria, as it similarly concluded for the regions evaluated in 2012.

APHIS observed that the Ministerial Order of April 12, 2008, harmonized the SVD control framework in Tuscany and Umbria with those in the previously evaluated regions in northern Italy. Specifically, the lines of authority between the national, regional (or provincial), and local authorities appeared to more clearly defined. Communication chains between these entities operated efficiently, especially regarding real-time integration of local, regional, and national

databases. The holding registry system provides the necessary support to conduct traceability activities by official veterinary authorities.

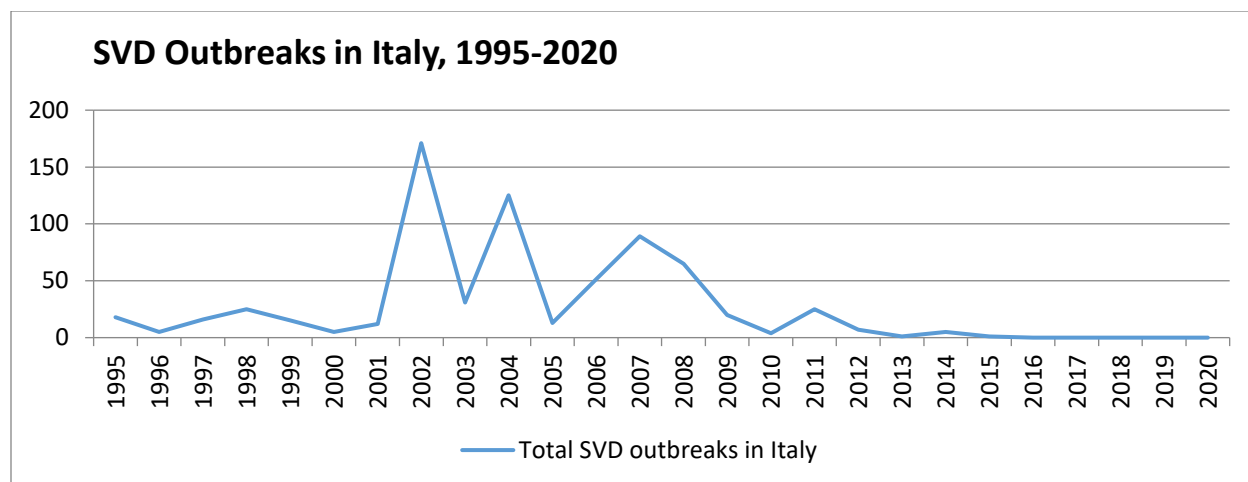
APHIS concludes that Tuscany and Umbria have fully competent veterinary infrastructure, in conjunction with the MOH and other Italian agencies, and the necessary legal authorities to conduct the necessary animal health control activities to address the risk of SVD and to prevent the spread to third countries through the exportation of live swine, fresh pork, and pork products.

4.3. Disease history and vaccination practices

Disease history

SVD was first observed in Italy in 1966 when it appeared clinically as a suspicion of foot and mouth disease (FMD) [16]. Despite its similar clinical presentation, the SVD virus was found to have distinct biological, physical, and chemical differences from other swine vesicular viruses. SVD became a reportable disease in Italy in 1973, and from 1995 through 2019, Italy conducted SVD eradication and monitoring activities [43, 44]. SVD proved to be persistent and difficult to eradicate in certain areas of Italy giving rise to sporadic outbreaks elsewhere in the country. SVD was not found to be very contagious and presented little to no clinical symptoms, making rapid detection more difficult and resulting in more extensive spread. Historically, movement of swine through dealer premises had been linked to the spread of SVD. Detection was achieved primarily as the result of Italy's active surveillance program, and the disease was eventually brought under control with implementation of specific control measures, as described below.

During the period from 1995-2015, numerous SVD outbreaks occurred in Italy, most notably in southern Italy, although significant spread to northern Italy occurred during outbreak events in 2002, 2006-2007, and 2008 (see Figure 4). During the site visits to Tuscany and Umbria, the APHIS teams were briefed on the history of SVD disease control and surveillance in the two regions. SVD last occurred in Tuscany in 2008 and in Umbria in 2009 [5, 6, 14]. MOH officials also noted that the last outbreak of SVD in Italy occurred in 2015 in Calabria in southern Italy, and the last seropositive pig was detected in 2017 [4, 10, 55, 56].



Source: Ministry of Health, CERVES, WOH [9, 10, 14, 36]

Figure 4: SVD outbreaks in Italy, 1995-2020

Following a significant rise in SVD outbreaks in 2002-2004, the EC issued Decision 2005/779/EC in November 2005 addressing specific SVD control measures to be applied in Italy and created lists of regions recognized as either being SVD-free or not SVD-free[44].

Key provisions of Decision 2005/779/EC were:

- **Recognition of regions:** established two lists of regions in Italy, SVD-free regions and not SVD-free regions. When first adopted in December 2005, the EC considered four regions in Italy to not be SVD-free. The decision was subsequently amended multiple times, including several amendments to these two lists, culminating when all of Italy was deemed to be SVD-free. The last two regions in Italy listed as not SVD-free were the Regions of Campania and Calabria.
- **Suspension of the recognition of provinces in a region recognized as SVD-free:** established the requirement and process for suspending and subsequently regaining the free status of a region or province (a subunit of a region) that had been listed as being SVD-free. A suspended province needed to complete the steps to regain its status within 6 months or the recognition would have been revoked.
- **SVD-free accreditation of individual holdings:** provided the criteria for obtaining, maintaining, and suspending accreditation of individual holdings as SVD-free in both SVD-free and not SVD-free regions.
- **Surveillance:** established the requirements for surveillance in both SVD-free and not SVD-free regions. Requirements were specified, for each list of regions, the type and frequency of testing for holdings with breeding pigs and assembly centers to detect a 5% SVD prevalence with a 95% confidence interval. SVD surveillance activity is described in more detail in Section 4.6.
- **Movement controls for swine:** established measures restricting the movement of swine both within Italy and between Italy and other Member States. Movement of swine from a

holding not recognized as SVD-free was prohibited, including movement to a slaughterhouse. However, Article 8 allowed swine from accredited SVD-free holdings within not SVD-free regions to move to SVD-free regions under certain conditions, including movement restrictions on the destination herd in which movement is prohibited until completion of mandatory testing of the herd at least 28 days after receiving swine from regions not SVD-free. Movement of swine from regions not SVD-free to other EU Member States was prohibited regardless of the SVD-accreditation status of the holding of origin. Swine were not permitted to move from assembly centers (dealer premises) until obtaining negative results on SVD samples, and that shipment of swine must have been sampled and negative test results obtained prior to movement from the holding of origin to a slaughterhouse.

- **Communication to the EC and the Member States:** Italy was obligated to report every six months through the EC Standing Committee on the Food Chain and Animal Health any relevant information on its SVD situation.

Italy issued the Ministerial Order transposing Decision 2005/779/EC into Italian law [57], it exceeded the requirements of Decision 2005/779/EC in several significant ways:

- **Criteria for recognition of regions:** Article 3 of the Ministerial Order defined criteria for a region to be recognized as SVD-free, whereas Decision 2005/779/EC lists SVD-free and not SVD-free regions. For recognition to have been granted by the Ministry of Health, Italy required that: all swine holdings in the region are accredited as SVD-free holdings and that all SVD control activities as set forth in the national SVD eradication and monitoring plan were to have been carried out in the previous year.
- **Dealer premises:** To address an identified risk of SVD spread, Italy restricted the movement of swine from dealer premises to allow only movements directly to slaughter. Furthermore, animals were not permitted to be kept on a dealer premises for more than 30 days. Culled, unthrifty, underweight, or diseased pigs were prohibited from being sold through dealer premises. Dealer premises were required to have been emptied every 30 days to allow for a period of cleaning and disinfection. Transport vehicles were required to have been washed and sanitized after each shipment and records verifying cleaning and disinfection were to have been maintained for one year. Minimum standards were set for biosecurity, sanitation, and traceability records. Compliance with these measures must have been verified by local veterinary authorities as a pre-requisite for maintaining the holding registration.
- **Singleton reactors:** Article 11 defined a singleton reactor as being suspected when a single seropositive case occurs with the following conditions: (1) the absence of clinical symptoms of SVD in the holding's animals, (2) no history of SVD on the holding, and (3) no epidemiological correlation of the holding or seropositive animal with an outbreak of SVD or another seropositive animal. A singleton reactor would have been confirmed when there was no seroconversion of other swine on the holding and there was no increase in the antibody titer of the seropositive animal.
- **Slaughter of seropositive swine:** Article 12 stipulated that seropositive animals, including singleton reactors, must have been slaughtered within 72 hours of being so ordered by the local veterinary authorities. Seropositive animals must have been

transported and slaughtered separately without commingling with other swine, the head and viscera must have been destroyed, and the meat must only have been sold for the domestic market. The transport and slaughter were to have been conducted under the supervision of the local veterinary authorities.

- **Communications:** Article 14 described the required notifications and procedures by which local, regional, and national veterinary authorities were to have been notified of any serological or virological finding of SVD.
- **Biosecurity checklist:** The annex to the Ministerial Order included a biosecurity checklist which described minimum standards and procedures for biosecurity on swine holdings and a list of approved disinfectants efficacious against SVD. Italy has continually enhanced its national animal health database system to include an interactive module that allows producers to characterize their production according to risk and to assess and track progress with implementation of appropriate biosecurity protocols, specific for their facilities [36].

Soon after Decision 2005/779/EC was issued, Italy experienced a sharp rise in the number of SVD outbreaks detected. The outbreaks occurred in both northern and central/southern parts of the country. Slight distinctions were found between the viruses circulating in the two areas, leading EC and Italian officials to conclude that two separate epidemics were occurring, one in the northern Regions of Lombardia and Veneto and the other in the central/southern Regions of Lazio, Molise, and Calabria. Tuscany reported two outbreaks in 2008, while Umbria reported 30 outbreaks in 2008 and one outbreak in 2009, all epidemiologically linked to outbreaks in other regions during these epidemics [14].

The occurrence of outbreaks in the central/southern region was not unexpected, as pockets of SVD virus persisted in some parts of the area. The central/southern part of Italy was not a major swine production area, with few large commercial swine production facilities. Most swine in this region were raised for domestic consumption rather than production of pork and pork products for intra-community trade or export. Some traditional practices associated with the domestic market carry a higher risk for spreading SVD and may have resulted in the persistence of SVD in this region. Movement of swine through dealer premises was the practice most often implicated because of the likelihood of direct contact with infected swine or indirect contact with the feces of infected swine from contaminated holding pens or transport vehicles.

The epidemic in the north was significant because it occurred in the highest density swine production area of Italy characterized by numerous large commercial swine facilities. Much of the commercial production in this region operated within the vertically integrated pork consortium enterprises, such as the *Consorzio del Prosciutto di Parma*. Most of Italy's intra-community trade and export of pork and pork products derived from swine produced and processed in this region. The northern Italy area had been recognized as SVD-free for some time and was distant to the regions of Italy where SVD persisted. The disease presented sub-clinically and was detected during routine SVD surveillance at the slaughterhouse. The financial impact due to the loss in production and export markets was significant. Regional and local authorities worked closely with the swine production industry to respond to the epidemic. This alliance

between government and industry resulted in major advances in the development of effective control measures to combat SVD in Italy. The lessons learned during these epidemics resulted in several amendments to Decision 2005/779/EC to incorporate enhancements to SVD control measures regarding on farm biosecurity, movement through dealer premises, and enhanced active SVD surveillance standards [44, 48, 49]. The EC repealed Decision 2005/779/EC on Mar. 20, 2019, after Italy demonstrated that SVD was no longer present in Italy [43].

Vaccination

Vaccines against SVD are not available [20]. Therefore, vaccination is not practiced in Italy, including Tuscany and Umbria, and is not a risk factor for SVD release in Italy.

Discussion

The SVD epidemics of 2006-2007 provide an interesting case study to understand the epidemiology of SVD in Italy and the development of the measures employed to bring the epidemics under control.

Both northern and central/southern epidemics shared several important characteristics. Primarily, the disease presented as sub-clinical infections. Extensive secondary spread involved dealer visits to multiple farms and movement of animals. Detection in both epidemics resulted from Italy's active SVD surveillance program.

Regional differences in the characteristics and practices of swine production in Italy impacted the epidemiology of the epidemics. Enhancements to the SVD eradication and monitoring program benefitted disease control activities throughout Italy, including in Tuscany and Umbria. This was particularly important regarding measures applied to curtail risky practices associated with dealer premises.

In 2010, APHIS observed that efforts by Italy to restrict swine movements through dealer premises, such as limiting the movement of swine from dealer premises exclusively to slaughterhouses, significantly reduced SVD spread. Historically, dealer premises had been implicated in high rate of SVD transmission to other swine holdings. APHIS concluded that these measures also played a role in eliminating SVD from Tuscany and Umbria. APHIS was made aware that these measures have also resulted in a reduction of the number of dealer premises operating in Tuscany and Umbria. At the time of the site visit in 2016, only one dealer premises remained in Tuscany, and by 2017 only two remained in Umbria [5, 6].

Active participation by the major commercial pork industry, which was heavily impacted by the disease, significantly influenced the priority given to swine disease control by local and regional authorities as evidenced by the resource allocation and enforcement activities. Likewise, the interests of the commercial swine industry contributed to the swine producers' perceived value of compliance with control measures. The combined efforts of the EU, the MOH, regional and local Italian authorities, the commercial pork industry, and swine producers led to successful elimination of SVD in Tuscany and Umbria, as well as the success of the SVD eradication and monitoring program throughout Italy.

4.4. Livestock demographics and traceability

Swine Production in Italy

Italy's commercial swine production area is centered in the northcentral part of the country, principally in Lombardia, Piemonte, Emilia-Romagna, and Veneto (see Table 1). Umbria and Tuscany also contribute significantly to the swine production of this area.

Table 1: Swine population of Italy by region, as of December 2020

Region or Province	No. of swine holdings	Pig population
Lombardia	8,382	4,407,955
Piemonte	3,001	1,277,081
Emilia-Romagna	3,793	1,120,567
Veneto	9,474	684,025
Friuli Venezia Giulia	1,864	245,457
Umbria	4,637	204,019
Sardegna	14,267	190,425
Tuscany	5,159	119,854
Marche	7,987	117,417
Campania	17,124	90,505
Basilicata	7,400	75,076
Abruzzo	13,390	74,567
Sicily	2,036	73,095
Calabria	13,759	47,774
Lazio	13,356	41,846
Puglia	1,048	39,530
Molise	5,358	21,502
Bolzano	5,408	8,793
Trento	617	5,580
Liguria	551	1,087
Valle D'Aosta	111	76
TOTAL	138,722	8,846,231

Data Source: Ministry of Health [36]

In Italy, swine are reared under two very different production systems, commercial production, and private production for personal consumption [3].

Commercial swine are raised through a highly developed, professional system of production, organized, and tightly managed by producer consortiums and associations. This commercial production chain operates primarily in northern Italy. About seventy percent of pork produced in Italy is destined for commercial markets, primarily by two well-known brands *Prosciutto di Parma* and *Prosciutto di San Daniele* [3]. This vertically integrated production chain tends to involve larger holdings with privately certified control systems that require adherence to standards for good animal disease control, biosecurity, and record keeping. Over the past three decades, the Italian commercial swine industry has evolved into a multi-site production system,

necessitating numerous movements of pigs between facilities for farrowing, fattening, and slaughter. Nearly every pig in this commercial market chain is moved more than once.

The remaining thirty percent of pigs are raised on small, often family-owned operations where pigs are raised either for the domestic market or for personal consumption. Most pigs raised in southern Italy are raised under this system of production. This system is characterized by small number but frequent transport of swine. Typically, piglets raised for personal consumption are purchased in the spring from multiple small breeding operations by dealers who then sell them to individuals and families who fatten them for slaughter in December.

Historically, farms with a high number of animal movements on/off the farm had been epidemiologically linked to SVD outbreaks. Thus, certain restrictions were put in place via Ministerial Order dated April 12, 2008 to mitigate the risk of introduction and spread of SVD on dealer premises and high turnover farms (HTO farms) [57]. During the site visits, Italian officials provided a detailed description of the distinctions between the dealer premises and HTO farms [5, 6]. Both dealer premises and HTO farms must be registered and assigned a unique alphanumeric holding code (identification code), the same as for commercial swine holdings. They are also required to document all animal movements using electronic certificates and are subject to the same truck cleaning and disinfection protocols.

At dealer premises, pigs stay less than 30 days. The premises must be emptied every 30 days, cleaned, and disinfected. These premises are tested each month (blood and feces) for SVD. Dealer premises move small numbers of pigs and sell their pigs to households (backyard), small farms (holdings with 2 or more pigs must register as a “farm holding”), butchers, and retail specialty shops (such as those that prepare roasted pork). Pigs from dealer premises are slaughtered for domestic consumption only. In comparison, HTO farms are permitted to have pigs on the farm for more than 30 days. The pigs are fattened on HTO farms (not on dealer premises). In general, HTO farms are larger than dealer premises, and HTO farms move larger groups/lots of pigs. Typically, lots are sold in multiple sub-lots based on weight for the desired final pork product.

Italy imports a significant number of live swine from EU Member States, such as the Netherlands, Denmark, France, Spain, Germany, and Belgium. Italy imports very few live pigs from third countries; in some years, there are no third country imports. In 2020, Italy imported nearly 892,000 tons of pork, mainly from the EU Member States, Germany, Spain, the Netherlands, Denmark, and France, and very little from third countries [60].

Italy exported over 89,500 tons of pork products, mainly ham and sausage in 2020. Italy exported primarily to other EU Member States (45%) and to Asian countries (44%), especially to China and Japan. Italy also exported a very small number of breeding swine to Germany, the Netherlands, and France [60].

Swine Production in Tuscany and Umbria

Tuscany and Umbria combined account for more than two percent of Italy’s total swine population; these regions rank sixth and eighth respectively among all regions of Italy in swine

production. At the end of 2020, MOH reported Umbria having a swine population of 204,019 and Tuscany having a swine population of 119,854 (see Table 1 above) [36].

At the beginning of this evaluation (October 31, 2015), Tuscany reported a total of 7,194 swine holdings, of which 1,432 were commercial holdings, and 5,762 were classified as backyard holdings (raising pigs for personal consumption) and other non-commercial holdings [9]. The commercial holdings included 731 fattening farms, 392 open-cycle reproduction holdings, 308 closed-cycle reproduction holdings, and 1 unclassified reproduction holding. Tuscany also reported 5 dealer premises, 2 assembly centers, and 1 boar semen collection center. By the time of the site visit in 2016, Tuscany officials reported that only one dealer premises remained in operation[5].

By the end of 2016, Umbria reported a total of 3,673 swine holdings of which 925 were commercial holdings and 2,748 were classified as backyard holdings (raising pigs for personal consumption) and other non-commercial holdings [10]. The commercial holdings included 515 fattening farms, 277 open-cycle reproduction holdings, and 133 closed-cycle reproduction holdings. Umbria also reported 3 dealer premises, 1 assembly center, and no boar semen collection centers. By the time of the site visit in 2017, Umbria officials reported that only two dealer premises remained in operation[6].

To understand the pattern of swine movement, APHIS looked at MOH movement data for a 12-month period for Tuscany (Nov. 2014 – Oct. 2015) and Umbria (Jan. – Dec. 2016) [9, 10]. During the 12-month period, Tuscany reported the birth of 48,878 pigs; receiving 152,209 pigs from other regions of Italy; receiving 22,037 pigs from other EU Member States; and no imports from third countries. During that time, Tuscany moved 147,305 pigs to other Italian regions; slaughtered 152,022 pigs; exported 24 pigs to third countries; and did not move any pigs to other EU Member States. Tuscany also recorded on-farm mortality of 4,510 and 191 stolen pigs.

Similarly, during a 12-month period, Umbria reported the birth of 252,834 pigs; receiving 400,022 pigs from other regions of Italy; receiving 115,128 pigs from other EU Member States; and no imports from third countries. During that time, Umbria moved 547,773 pigs to other Italian regions; slaughtered 224,830 pigs; and did not export any pigs to third countries or move pigs to other EU Member States. Umbria also recorded on-farm mortality of 57,767 and 16 stolen pigs.

As described in previous APHIS evaluations, feeder pigs born in northern Italy are transported to fattening operations in other regions including Tuscany and Umbria. Fattened swine are then transported back from those regions for slaughtering and processing at the large capacity plants mainly located in Lombardia and Emilia-Romagna [3]. The backyard-reared swine tend to be slaughtered locally, either at home or in small municipal plants, and used for self-consumption or the domestic market.

Animal identification and registration

In Italy, all swine holdings where animals are held, kept, or handled, including those keeping animals outdoors, whether on a temporary basis or longer, are required to be registered.

Registered holdings are assigned a unique identification number, which is a 10-digit alphanumeric code, using IT as the country code for Italy, a 3-digit municipality code of the holding, 2-digits to identify the Province, and 3-digits for the number assigned to the holding in the municipality. The person responsible for the holding must apply for registration within 20 days from the start of operations. Holdings are registered by the local veterinary service and the registration information is entered into the National Livestock Database (referred to as the *Banca Dati Nazionale* – BDN) which is maintained by the MOH [9, 10, 37, 38].

The BDN maintains a record of swine holding registrations, including their unique identification number, address, geospatial coordinates, name, and address of the person responsible for the animals, type of production unit and capacity, the herd's health status, and a record of all swine movements onto and off the holding. The database is a web-based application which can be accessed by national, regional, and local authorities. The regions and autonomous provinces integrate BDN in real time within their own databases [36].

Any keeper of swine is required to keep a register stating the number of pigs present on the holding. This register shall include an up-to-date record of all movements, indicating the number of swine entering and leaving, origin or destination, and the date of each movement [9, 10].

Pigs are identified by either a tattoo on the left ear or outer thigh or any auricular marking on the right ear, which identifies the holding of origin (i.e., country code and holding identification number). Pigs must be marked within 70 day of birth or earlier if the animal leaves the holding. If the identification mark becomes illegible or is lost, a new one must be affixed and recorded in the holding register and matched to the previous identification mark [9, 10].

A movement document, referred to as Model IV (also referred to as “Form 4”), is required for all movements and subject to authorization by the regional veterinary services. Model IV records detailed information on the holding of origin and destination, identification of the animals, means of transport, animal health status, the departure and arrival dates, the number of animals being moved, and the number of the transport document and/or health certificate [9, 10]. To increase the efficiency of traceability and to guarantee the authenticity of the documents accompanying the animals, Ministerial Decree of 28th June 2016 established that Model IV must be prepared and transmitted only in electronic format by using a dedicated function in the BDN [36]. The requirement for electronic submission for Model IV has been compulsory throughout Italy since September 2, 2017. This process provides for real-time traceability of pig movements throughout the country, and the data integrates with the other information systems available to the MOH, including those used for disease control activities on holdings and epidemiological investigations. This information is held on the database for three years.

The BDN also collects information from slaughterhouses. For each group of swine slaughtered, the database records: date of slaughter, the number of animals slaughtered, the identification number of the holding of departure, the commercial categorization of the herd, and for breeding animals, the sex of the animal slaughtered. Additionally, for swine originating from outside of Italy, the database identifies the country of origin, health certificate information, and if from a third country, the date and location of inspection carried out at a BIP [9, 10, 36].

Annually, Italy audits compliance with the identification and registration system requirements by examining the records for at least 1% of all swine holdings. Penalties may be assessed for non-compliances [5, 6].

Farm biosecurity enhancement program

During the 2017 site visit, the APHIS team was given an overview of the BioFaBen database system that was in the process of being implemented [6]. The objective of BioFaBen is to provide a national, harmonized approach to food safety, biosecurity, and animal welfare. The system was developed and piloted from 2013-2016.

In 2017, the system was implemented in the Region of Lombardia and piloted in 6 other regions. In 2018, the system was implemented across all regions of Italy beginning with Campania and Calabria. As of January 2018, the system became accessible. Personnel were trained initially at the national and regional level, later extended to local health officials, and eventually to farm level personnel.

BioFaBen is organized into two main levels. The area level offers access to all sections in the system and is given to the MOH and regional personnel. The farm or company level limits access to view information on an individual farm. Vertically integrated production systems though would have access to view all farms, whether owned or contract, within their swine production group. The APHIS team was given a presentation of the system from the area level. The sections in the system include animal welfare, biosecurity, and drug use. For biosecurity, it was explained that premises would be evaluated by the LVS veterinarian on a yearly basis (more frequently if corrective issues arise). For each section, a premises is scored according to the section parameters or criteria (checklist) and given an overall rating by section.

At the farm level, the producer would be able to view their actual score and their standing in comparison with regional/national averages. At the area level, greater access and detail would be available to officials to identify “below average” and “above average farms” and to understand why premises are falling below the regional/national average. Corrective measures could then be assigned to “below average” farms and the premises would be re-evaluated later. Through BioFaBen, producers would be able to identify which biosecurity measures need attention to improve their score and overall standing. Officials would be able to target low scoring premises for more frequent inspections and diagnostic sampling, and since producers would incur additional costs for these activities, then an incentive would be created for the producer to improve on-farm biosecurity. Additionally, better standing within BioFaBen would ensure better market access.

It was explained to the APHIS team that as an extreme measure, the MOH had downgraded farms that were not compliant with minimum standards or parameters (such as labeling the premises as backyard farm, thus, prohibiting their animals from accessing commercial market chains) [6]. This process was used in the Regions of Campania and Calabria to enforce biosecurity standards and movement restrictions in the SVD campaign in those regions. This approach has also been used for other diseases (such as TB) when accreditation was being sought.

Site visit observations

During the two site visits, APHIS teams visited several swine production premises (including commercial farrowing and finishing swine holdings, a dealer premises, and two high turnover farms). The teams also visited commercial slaughterhouses and pork processing plants [5, 6]. The teams examined records and interviewed personnel.

While visiting the commercial swine production holdings, APHIS teams were briefed on the farm production/marketing practices, and biosecurity procedures. The teams also reviewed farm registers, movement documents (both paper documents and electronic Model IV records), movement procedures, truck cleaning and disinfection (C&D) records, and the visitor log. The team found that the records to be complete and in compliance with Italian and EU regulations in force at the time of the visit.

During site visits to the dealer premises and HTO farms, APHIS teams reviewed farm registers, visitor logs, and Model IV movement certificate records. APHIS teams verified that the Model IV certificates recorded movements on and off premises, as well as truck C&D processes. For the dealer premises, the operator explained that all incoming pigs were sourced from commercial farms in SVD-free regions and were only sold directly to butchers as meat or to individual households for self-consumption. Pigs from dealer premises do not enter commercial markets or export market channels. The operator explained that dealer premises are sampled monthly for SVD surveillance, and that the LVS veterinarian visits the premises weekly to conduct clinical checks and diagnostic sampling.

Although not considered to be as risky for SVD spread as dealer premises, HTO farms are considered to be a higher risk category than other commercial swine holdings due to the increased number of animal movements. Swine produced on HTO farms may enter commercial markets. Both HTO farms visited by APHIS received piglets from Denmark which were fattened before being sent to slaughter. Sampling for SVD on the HTO farms was carried out 6-7 times per year. Blood and feces samples were taken by an official veterinarian at 30-40 days intervals for both serological and virological SVD testing.

At the slaughter plants, the team interviewed plant managers and official veterinarians assigned to the plant. The team observed the unloading of pigs, ante-mortem inspection, and document verification by an official veterinarian. The team observed the C&D of an animal transport vehicle. The official veterinarian explained that normally the driver is responsible for the C&D of his own truck, which is conducted at a designated washing station at the plant. The team was told that if pigs are received from areas restricted due to animal disease outbreaks, then the C&D process is verified by veterinary inspection. Employees receive training in C&D procedures used for the plant facilities and transport vehicles. A plant employee is responsible for preparing the disinfectant.

Plant managers explained the process and showed the APHIS teams the standard operating procedures (SOPs) for cleaning pens. During normal times (that is when there are no enhanced security measures implemented in response to animal disease outbreaks in the area), the pens are washed daily with pressurized water and disinfected weekly with Virkon, and the whole building

is washed weekly. The plant managers explained that the SOPs stipulate extraordinary procedures be implemented during times of animal disease outbreaks, which include daily washing and disinfection of the pens and building, leaving the disinfectant on surfaces for 24-hour contact.

Plant managers explained that meat derived from pigs originating from restricted areas would be stamped with a special seal (the stamp has an “X” over the plant number) in accordance with EU directives in force at the time of the visit. Such meat would only be destined for local trade (i.e., not for export or intracommunity trade) unless it is heat treated to inactivate the virus per the EU directive. The team was shown an example of the stamp used to identify meat derived from restricted areas, and the SOPs for the shipping of meat from restricted areas. The SOP specifies that notice must be received 24-hours prior to arrival; and that an official veterinarian must be present at unloading. Furthermore, these animals must arrive at the end of the morning slaughter to ensure that these pigs are slaughtered last to avoid commingling; that offal and heads must be destroyed; and the meat derived from these animals will be stamped with the restricted seal, placed in a separate refrigeration unit, and be transported separately from non-restricted meat.

The plant managers explained and showed the team the plan of how waste is handled. Wastewater is treated on site by a wastewater purification plant that reduces the level of nitrogen and phosphorus before being discharged into an adjacent canal. Solid fecal waste is held in a tank on site and later removed for disposal by a third-party contractor who picks up the tank on Saturdays when the slaughter line is not operating. Transporting the tank avoids spillage of waste residue on the ground. Slaughter trimmings are picked up by an authorized firm to be incinerated.

The official veterinarians assigned to the plant showed the team examples of the Model IV transport certificate and a health certificate signed by the veterinarian in charge of the farm. They explained that the information on these documents may be verified by cross referencing them with the data previously entered into the national database. They explained that they usually conduct random checks several times per farm per year.

It was explained to the team that before pigs originating from SVD-free farms located in SVD affected areas can be moved, an official veterinarian employed by the local health unit must carry out a clinical examination of the pigs and sign a health certificate. The local health unit authorities enter this information into the national database. Access to this information is controlled; so, slaughterhouse personnel only have access to read the data in the national database that they need to verify compliance of applicable animal health controls for animals that the plant receives. Farm owners are allowed to only modify data in the national database in regard to births, deaths, and animal movements for their farm. Only official veterinary authorities can enter information into the national database regarding official SVD accreditation. The farm owner sends one copy of the Model IV to the local health unit within 7 days of arrival of new pigs on the farm.

Official veterinarians assigned to the slaughterhouse conduct ante-mortem inspection of animals as they are being unloaded from the transport vehicles, or soon thereafter. Animals suspected of

being injured or ill would be diverted to a pen where they undergo further examination to detect signs of infectious disease, including measuring their temperature and inspection of their mouth and hooves to exclude signs of vesicular diseases. These animals were held until either being sent to slaughter or destroyed (no live pigs may leave the slaughterhouse once they arrive). If signs of vesicular disease are observed, then all the animals in the lot would be isolated and tested for SVD and FMD before being slaughtered at the end of the day (thereby being the last animals slaughtered before the cleaning and sanitizing of the process line). The pens and chutes would be cleaned and disinfected after the animals were slaughtered. The resultant carcasses are held separately in refrigeration until lab results are obtained. In the event of positive test results, both official veterinarians assigned to the plant and the local health unit authority for the farm of origin would initiate an epidemiological investigation.

Discussion

Tuscany and Umbria are located at the southern edge of Italy's major swine production area in northern Italy. While their swine populations are not as large as the regions to the north, Tuscany and Umbria contribute significantly to Italy's overall swine production, especially in comparison to regions to the south.

Most swine raised in Italy are produced in a vertically integrated system for which producers are required to adhere to a highly developed system of internal industry controls for the maintenance of animal health. The Italian pork consortiums provide stringent oversight of the producers, slaughterhouses, and processing plants to ensure compliance with their standards. Often the consortium standards for biosecurity exceed those required by Italian national law. Since participation in the consortium is advantageous to the producers to market swine, the producers have a strong incentive to comply with industry and government animal health controls. Italy's successes in controlling SVD were largely due to the close cooperation between the swine industry consortiums and national, regional, and local veterinary officials.

The number of swine movements associated with the multi-site production system does increase the potential for inadvertent spread of disease if the disease agent is present. However, Italy's biosecurity requirements, especially regarding the cleaning and disinfection of swine transport vehicles, mitigates this risk. Additionally, Italy's SVD active and passive surveillance program during the period when the SVD virus was active in the country provided early detection of disease and a systematic method to identify SVD-free regions and SVD-free holdings. The specific controls imposed on movements through dealer premises greatly reduced the risk of transmission through this pathway, as well as the decline in the number of dealer premises operating in Italy.

Italy requires that all swine are identified, all holdings to be registered, and all movements recorded into the national swine health database. Slaughterhouses track the animals as they are slaughtered, and the production and processing facilities can track products as they move through the production line. These processes support the ability to trace pork and pork products as it moves from the holding through the market channel. The pork production plants visited by APHIS were able to demonstrate this capacity. This traceability capability gives APHIS

confidence that MOH can identify and remove any potentially infected pork and pork products from the export market chain if SVD were detected.

Overall, the APHIS site visit team observed that farm, veterinary, and slaughterhouse/processing plant personnel were knowledgeable about SVD, biosecurity measures, movement requirements, truck C&D, disease surveillance, farm procedures and protocols, and emergency procedures for suspected foreign animal diseases. There appears to be satisfactory collaboration and cooperation between the LVS veterinarian, farm veterinarian, producers, and slaughterhouse/processing plant personnel. Biosecurity measures and record-keeping appear to be adequately implemented and followed. Overall, the team found that oversight measures for dealer premises appeared to adequately address their level of risk of potential to spread SVD.

4.5. Epidemiological separation from potential sources of infection

Disease status of adjacent regions

Since 2005, SVD has only been confirmed in Italy except for a single outbreak detected in Portugal in 2007 [14, 55]. Italy shares land borders in the north with France, Switzerland, Austria, and Slovenia. Except for Switzerland, all bordering countries are EU Member States. The remainder of Italy is surrounded by the Mediterranean and Adriatic Seas. APHIS does not consider there to be a risk of SVD release in Italy from adjacent regions.

Within Italy, APHIS currently recognizes as SVD-free the Italian Regions of Emilia-Romagna, Friuli, Liguria, Lombardia, Marche, Piemonte, Valle d'Aosta, and Veneto, and the Autonomous Provinces of Trento and Bolzano [61]. These regions are located to the north and east of Tuscany and Umbria. APHIS has not evaluated the regions of Italy to the south of Tuscany and Umbria, nor the Island of Sardinia [3]. The last outbreak of SVD in Italy occurred in 2015 in the Region of Calabria in southern Italy [38].

Import Controls

In 2016, the APHIS team visited the BIP at the Port of Livorno, Tuscany. The BIP director provided a very informative overview presentation to the APHIS team [5]. She explained the difference between a BIP and a veterinary office for intracommunity trade (UVAC). BIPs operate under the Italian Ministry of Health and are subject to supervision by the Directorate-General for Health and Food Safety of the European Commission. In accordance with EU legislation, BIPs monitor the import of animals, food of animal origin, and feedstuffs for consumption by animals (animal feed) into Italy or into the other EU Member States from third countries. UVACs are responsible for checking commodities imported from other EU Member States. At the time of the site visit, Italy was the only EU Member State with offices to check commodities (animals, food of animal origin and animal feed) received from elsewhere in the EU. BIPs are separate entities from UVACs.

Italy operated 17 UVACs throughout the country in cooperation with regional and local health units [5]. The UVACs also worked with veterinary authorities in other Member States to resolve

non-compliance issues and to consult on technical and legal issues related to food and animal feed.

In 2016, there were 23 BIPs in Italy, 2 located in Tuscany—the Livorno port and Pisa airport [5]. There were no BIPs in Umbria [10]. The official controls included at least a systematic documentary check, identity check, and a physical check if appropriate. There was a memorandum of understanding establishing cooperative relationships between BIP and Italian customs officials. EU regulation (Regulation 450/2008) formalized this cooperation by creating a “one-stop-shop” approach to ease the burden on shippers. Shippers could obtain information regarding import and export procedures through a single website, interact with BIP and customs officials at a single window at ports of entry, and receive joint BIP/customs inspections. Information was shared between the TRACES (BIP) and AIDA (Customs) databases.

The BIP director described 2015 data that showed that 9,536 consignments were handled by the Livorno and Pisa BIPs which in total weighed approximately 250,000 metric tons [5]. The commodities received through these BIPs were animal products, including both products intended for human consumption and products not for human consumption, as well as animal feed (derived from both animal and plant origins). All consignments (100%) received documentary and identity checks. Approximately 5% of these consignments were subject to laboratory testing and 39% had physical checks. The main problems found upon inspection include labeling errors, contamination (such as with mercury and nitrofluorenes), absence of required health certifications, and containing products ineligible for entry into the EU.

The APHIS team was informed that BIP and Customs officials conduct random checks of passenger belongings to enhance compliance with applicable EU legislation regarding items that passengers may bring with them into the EU. Prohibited items such as meat and dairy products would be seized and destroyed. The Director showed to the APHIS team an exceptionally well-made video that was shown to passengers at Pisa airport baggage claim to reinforce the message “when in doubt, leave it out.”

The BIP director explained that officials of the local health unit provide control of animal product exports [5]. Animal products intended for export would be initially checked by official veterinarians assigned to the plant where they are processed, and subsequently verified at the port of embarkation by a customs official (non-veterinary official). The director noted the need to maintain awareness by Customs officials to animal health risks and cited the observation of increased level of interceptions after BIP officials provide periodic training for customs officials.

Domestic Movement Controls

From 2005-2019, the EU imposed restrictions on routine movement of swine to control the spread of SVD within Italy. These routine movement restrictions, imposed by EC Decision 2005/779/EC, were in addition to emergency movement restrictions imposed during a response

to SVD outbreaks (described in Section 4.8). Italy transposed these restrictions into Italian law by the April 2008 Ministerial Order [44, 57].

Under these measures, movement of swine from a holding that was not accredited as SVD-free was prohibited, including movement to a slaughterhouse. This restriction was imposed until the holding was recognized as SVD-free. This measure mitigated the risk of pork, derived from pigs originating from holdings not accredited as SVD-free, from entering the commercial pork production market.

Movement of pork and pork products within Italy and between Italy and other Member States was not restricted based on SVD control measures per se, except in two situations. Pork produced from SVD-seropositive pigs, including singleton reactors, could only be distributed locally (restricted by April 2008 Ministerial Order). Secondly, pork and pork products produced from swine originating and slaughtered within protection and surveillance zones established around outbreaks of SVD could not be marketed to other Member States nor to third countries unless treated in a manner to inactivate the SVD virus.

Movement of swine from regions not SVD-free was prohibited except in the following situation. Article 8 of Decision 2005/779/EC allowed swine from accredited SVD-free holdings within regions not SVD-free to move to SVD-free regions under certain strict conditions which mitigated the risk of SVD spread. Those conditions included provisions that the holding of origin had to be accredited SVD-free for at least two years without interruption and had, for 60 days prior to movement, not been located in a protection or surveillance zone established because of an outbreak of SVD. Additional conditions for this type of movement addressed sourcing of pigs on the holding of origin; sampling and serological testing on both the holdings of origin and destination; transport under seal; advance notification of movements; and proper cleaning and disinfection of transport vehicles.

From 2008-2014, Tuscany received 28 shipments with a total of 8,405 pigs from regions not SVD-free (averaging 4 shipments per year, each with 300 pigs) [9]. During a similar period, 2008-2016, Umbria received 14 shipments with a total of 5,822 pigs from regions not SVD-free (averaging 2 shipments per year, each with 416 pigs) [10]. For both Tuscany and Umbria, all shipments originated from Campania, and for Tuscany, over 80% of the shipments were exclusively between one accredited SVD-free holding in Campania to one accredited SVD-free holding in Tuscany.

A movement document, referred to as Model IV, was required for all swine movements and subject to authorization by the regional veterinary services. Model IV records detailed information on the holding of origin and destination, identification of the animals, means of transport and animal health status. Information captured on Model IV was entered into the national swine health database.

Historically, movement of swine through dealer premises had been linked to the spread of SVD in Italy [3]. In response, specific regulations were imposed on dealer premises (also referred to as “assembly centers”) to reduce this risk. Swine were only permitted to move from dealer premises directly to slaughterhouses. Before such movements could occur, the holding was sampled, both

serologically and virologically, and negative results obtained before the swine could move from the dealer premises to the slaughterhouse. Fortunately, Tuscany and Umbria have only a small number of dealer premises in operation [5, 6].

Seropositive pigs, including singleton reactors, were required to be slaughtered within 72 hours of notification by the local veterinary authorities. The slaughter was conducted within the region in which the holding of origin was located. Seropositive animals were transported and slaughtered separately without commingling with other swine, the head and viscera were destroyed, and the meat could only be used for the domestic market. The transport and slaughter were conducted under the supervision of the local veterinary authorities.

Since the repeal of EC Decision 2005/779/EC on March 20, 2019, the EC no longer imposed SVD-related movement restrictions within Italy, as it considers Italy to be SVD-free [43].

Intracommunity Trade

From 2005-2019, the movement of swine from Italy to other Member States was allowed only if the animals originated from accredited SVD-free holdings located in SVD-free regions. Movement of swine from regions not SVD-free to other EC Member States was prohibited regardless of the SVD-accreditation status of the holding of origin.

For swine movements that were permitted, the EC required health certificates, in compliance with Council Directive 64/432/EEC, Article 5(1), to accompany these shipments. These health certificates were required to have an endorsement stating that the animals listed on the certificate met the SVD health protections in accordance with Commission Decision 2005/779/EC [44].

Movement of pork or pork products to other Member States or third countries was not restricted based on EC or Italian SVD control measures except as described in the previous subsection.

Discussion

During the last fourteen years, SVD occurred only in Italy and nowhere else in the world. Furthermore, SVD has not been reported anywhere in Italy since 2015. Tuscany and Umbria are not adjacent to any regions where SVD is known to exist. Likewise, imports from third countries and trade from other EU Member States pose little risk for SVD introduction.

APHIS has previously assessed the external movement controls for the EU in its evaluations of the classical swine fever (CSF) status of various EU Member States. For those evaluations, APHIS visited and analyzed the EC controls on the movement of swine, fresh pork, and pork products into the EU from third countries, as well as movement controls and processes for intra-community trade of these commodities between Member States. APHIS concluded that the BIPs with third countries consistently conformed to EC standards, regardless of the country of location. APHIS did not identify any significant concerns related to the BIPs. APHIS was also satisfied with the management and function of movement controls between Member States. The APHIS team observed that the BIP visited in Tuscany operated as efficiently and effectively as the previously evaluated BIPs in other EU Member States. For these reasons, plus the fact that

SVD has not been detected outside Italy since 2007, APHIS considers introduction of SVD into Italy through importation of pork or pork products to be unlikely.

An important component of Italy's approach to reduce spread of SVD within Italy was to control movement of swine from areas of higher risk to areas of lower risk. This was accomplished by restricting swine movement from holdings that were not accredited as being SVD-free and from areas around SVD outbreaks. With these movement controls, Italy was able to reduce or prevent SVD spread within Italy, to other Member States, and to third countries.

The system of movement controls implemented by Italy had multiple verification checks and balances built into the process which allowed veterinary authorities to manage compliance. These included holding registers, movement documents, vehicle cleaning and disinfection certificates, the national database, and slaughterhouse registers.

4.6. Surveillance practices

Italy's surveillance program was essential to control SVD and prevent further outbreaks. Italy achieved its goal through incremental regionalization, separating areas free of SVD from those where the disease was present. Because SVD cases increasingly presented with sub-clinical infections, Italy relied on robust active surveillance, in conjunction with the movement controls described in the previous section, to achieve the separation of SVD-free from SVD-affected areas and holdings. Passive surveillance, also a critical component of the strategy, was supported by required notification of SVD suspicion and the visibility and engagement of local veterinary authorities.

Italy's SVD active surveillance plan was designed in consideration of risk based on a holding's production characteristics (i.e., breeding vs. fattening, open vs. closed systems) and on the risk associated with the frequency of swine movements to and from the holding. Only commercial herds and dealer premises were included in the SVD surveillance program. Backyard herds were not included as their production was for personal consumption. The surveillance scheme that was utilized, at the time of APHIS' visits to Tuscany and Umbria, is summarized in Table 2. Italy revised the scheme as necessary as part of its national SVD control plan [9, 10]. Technical experts from the IZS at Brescia and the IZS regional laboratories accompanied the APHIS teams during the 2016 and 2017 site visits, and provided briefings on SVD surveillance activities in Italy [5, 6].

Table 2: Italy – national SVD active surveillance program scheme, as of October 2017

	Breeding (closed cycle) holdings	Breeding (open cycle) holdings	Fattening holdings	High risk holdings (dealer premises, assembly center, or high turnover)
SVD-Free Region	all holdings serological testing every 12 months only breeding pigs P: 10%; CI 95%*	all holdings serological testing every 6 months only breeding pigs P: 10%; CI 95%*	representative sample of up to 300 holdings serological testing every 6 months fattening pigs P: 5%; CI 95%*	all holdings serological and virological testing monthly all pigs P: 5%; CI 95%*
Region Not SVD-Free	all holdings serological testing every 12 months only breeding pigs P: 10%; CI 95%*	all holdings serological testing every 6 months only breeding pigs P: 10%; CI 95%*	all holdings serological testing every 6 months fattening pigs P: 5%; CI 95%*	all holdings serological and virological testing monthly all pigs P: 5%; CI 95%*

* Sampling shall be carried out on a number of pigs sufficient to detect the specified prevalence (P) of either 5 or 10% with a confidence interval (CI) of 95%
Source: Ministry of Health [9, 10]

Surveillance conducted on high-risk holdings, such as dealer premises, assembly centers, and holdings with a high turnover of animals, sampling was conducted monthly with both serology and virology testing. The virological samples were environmental samples of pig feces collected from the animal holding pens. Swine on these holdings were not allowed to be moved until the negative test results were received.

For SVD antibody detection, Italy utilized ELISA for screening tests, VNT for confirmation, and IgG/IgM ELISA for viral characterization. For SVD virus detection, CERVES utilized PCR for screening, virus isolation for confirmation and virus sequencing for molecular epidemiology. CERVES developed the WOA reference SVD tests for ELISA and PCR. Serological samples from Tuscany were processed at the IZS regional laboratory in Rome, and the IZS regional laboratory in Perugia processed all serological samples for Umbria. CERVES provided SVD test kits to the IZS regional laboratories. CERVES in Brescia conducted confirmatory testing and SVD virological diagnostics for all samples collected in Italy [9, 10].

In each of the nine years from 2011-2019, Italy tested on average over 16,500 holdings and sampled 380,000 pigs through its SVD active surveillance program (see Tables 3 and 4). Italy

reported its last SVD outbreak in Italy in 2015. SVD active surveillance data for Tuscany and Umbria are summarized in Tables 5 and 6, respectively.

Table 3: Italy – national SVD active surveillance data, holdings tested 2011-2019

Regions recognized by APHIS as SVD- free	2011	2012	2013	2014	2015	2016	2017	2018	2019
No. of regions	3	3	10	10	10	10	10	10	10
No. of tested holdings	245	237	4,106	3,685	3,942	3,620	3,610	3,438	3,464
No. of confirmed positive holdings	0	0	0	0	0	0	0	0	0
No. of SVD outbreaks	0	0	0	0	0	0	0	0	0
Regions considered by APHIS to be SVD-affected	2011	2012	2013	2014	2015	2016	2017	2018	2019
No. of regions	18	18	11	11	11	11	11	11	11
No. of tested holdings	14,181	20,531	20,578	15,025	12,606	10,394	10,307	11,571	9,698
No. of confirmed positive holdings	90	31	12	8	18	3	1	0	0
No. of SVD outbreaks	25	7	1	5	1	0	0	0	0

Data Source: CERVES [4, 36]

Table 4: Italy – national SVD active surveillance data, samples tested 2011-2019

Year	Competitive ELISA screening tests (antibody detection)	VNT, confirmatory tests (antibody detection)	Isotyping ELISA IgG (antibody detection)	Isotyping ELISA IgM (antibody detection)	PCR (virus detection)	Virus isolation test (virus detection)
2011	379,216	1,157	1,118	1,118	2,527	99
2012	411,806	895	917	917	2,463	11
2013	435,629	370	356	356	2,398	12
2014	419,385	431	367	367	2,438	0
2015	402,549	587	552	552	2,532	0
2016	377,854	449	486	486	2,139	0
2017	349,137	637	636	636	2,209	0
2018	329,338	683	704	704	2,519	0
2019	321,581	453	447	447	1,595	0

Data Source: CERVES [4, 36]

Table 5: Tuscany – SVD active surveillance in commercial farms during 2012-2014

Year	Fattening holdings tested	Fattening pigs sampled	Breeding holdings tested	Breeding pigs sampled	Total holdings tested	Total pigs sampled
2012	438	7,583	1,108	7,068	1,546	14,651
2013	426	8,037	1,072	7,052	1,498	15,089
2014	373	6,880	970	6,262	1,343	13,142

Data Source: CERVES [9]

Table 6: Umbria – SVD active surveillance in commercial farms during 2014-2016

Year	Fattening holdings tested	Fattening pigs sampled	Breeding holdings tested	Breeding pigs sampled	Total holdings tested	Total pigs sampled
2014	291	10,239	415	3,717	706	13,956
2015	323	10,373	385	3,719	708	14,092
2016	154	9,607	361	3,212	515	12,819

Data Source: CERVES [10]

In 2019, when the EU recognized all of Italy as free of SVD, it eliminated its requirement that Italy have an SVD surveillance program [43]. Italy continued its SVD surveillance into 2020, reducing the frequency of serological testing on breeding and fattening farms from six-month intervals to once a year and continuing monthly serological testing for dealer premises. However, beginning in 2021, Italy discontinued its active SVD serological surveillance, offering serological testing if required by third countries [36].

Discussion

APHIS concludes from the surveillance data that SVD virus is not known to exist in Tuscany and Umbria. Furthermore, SVD has not been reported anywhere in Italy since 2015. APHIS noted in prior evaluations the importance of Italy's active SVD surveillance program [3]; however, given the absence of SVD detection for over five years, APHIS considers active surveillance for SVD to no longer be necessary. APHIS acknowledges that reliance on passive surveillance for detection of reintroduction of SVD may be delayed due to the subclinical presentation of SVD outbreaks as observed in recent years.

4.7. Diagnostic laboratory capabilities

The IZSs are veterinary public health institutes which provide a network of public laboratories at the national and regional level in Italy (see subsection 4.2.). At present there are 10 central IZSs covering the territory of one or more regions with 90 local diagnostic laboratories, each capable of carrying out serological screening tests (ELISA) [36]. The IZSs are subject to control and supervision by the regions and are coordinated by the MOH. The official laboratories perform official tests only with accredited methods, in accordance with the provisions of Regulation EU 625/2017 [40] and the WOAHP Diagnostic Manual. The national reference laboratory for swine vesicular disease (CERVES) is in Brescia and performs the SVD serological and virological confirmatory test (e.g., VNT, PCR, and virus isolation) [36], described in 4.6 above.

During the 2016 and 2017 site visits to Tuscany and Umbria, the APHIS teams were accompanied by technical experts from the IZS at Brescia and the IZS regional laboratories (the Zooprofilaxis Experimental Institute of Lazio and Tuscany and the Institute Zooprofilactic Experimental of Umbria and Marche) and received updated briefings on SVD surveillance in Italy.

APHIS has previously assessed Italy's laboratory capacity in previous reviews on swine diseases in the EU, including a visit to IZS Brescia (Italy's SVD national reference laboratory), and concluded that it consistently conformed to EC and international standards on swine diseases and that the laboratory capacity was adequate and capable of meeting the diagnostic needs should an outbreak of SVD occur [2, 3, 11]. APHIS did not identify any significant concerns related to the laboratory network and, therefore, considers Italy's laboratory capacity to be adequate and capable of meeting the diagnostic needs should an outbreak of SVD occur. Based on the favorable observations of previous site visits, the APHIS teams concluded it was unnecessary to revisit the laboratory [5, 6].

4.8. Emergency preparedness and response

Before enactment of the new Animal Health Law in April 2021, Council Directive 92/119/EEC stipulated general emergency response measures that were to be applied whenever a disease outbreak occurred in a Member State (see description in Subsection 4.2) [42, 52]. While most of the measures were general and applicable for outbreaks of various animal diseases, some measures were targeted for specific animal diseases, such as SVD. The new Animal Health Law carries over most of the general measures from Council Directive 92/119/EEC, but none of the specific measures for SVD, as the EU considers that SVD no longer exists in Italy [43].

Council Directive 92/119/EEC also stipulated a requirement that Member States have emergency contingency plans for specific animal diseases, including SVD [52]. While an emergency plan is no longer required for SVD under the new Animal Health Law, Italy maintains its SVD emergency plan on the CERVES website [62]. An official of Italy's National Emergency Center against Animal Disease accompanied the APHIS team during the site visit to Tuscany. During both site visits, the APHIS teams noted familiarity with the SVD emergency plan among veterinary officials at all levels of government, plant operators, and farm personnel [5, 6].

In this evaluation, APHIS assessed the emergency preparedness and response measures that were in effect while Italy was conducting its SVD eradication and monitoring program. The following is a description of the measures Italy applied upon suspicion and confirmation of SVD [52].

Measures to affected holdings:

- mandatory notification of suspicion of SVD to regional authorities and MOH
- immediate investigation by regional or local veterinary officials of all reports of SVD suspicion
- precautionary quarantine of a suspect holding with measures taken to prevent potential spread of virus
- depopulation of all susceptible swine upon SVD confirmation
- destruction or treatment of likely contaminated animal feed, litter, manure, slurry, or other substance or waste
- cleaning and disinfection of contaminated swine pens, animal transport vehicles, and equipment
- epidemiological investigation to determine the earliest date of probable infection; possible source of disease introduction; identification of potentially exposed swine holdings; and potential pathways of disease spread
- extend disease control measures to holdings with epidemiological links to confirmed positive holdings
- restocking of affected holding shall be authorized by the competent authority
- establishment of protection and surveillance zones around the affected holding, with minimum radius of 3 km for the protection zone and 10 km for the surveillance zone in consideration of geographical, administrative, ecological, and epidemiological factors

Measures applied to holdings within the 3 km protection zone:

- identification of all swine holdings within the protection zone
- periodic visits by veterinary officials to all swine holdings to conduct clinical examinations with records of visits maintained
- serological sampling of all holdings in the protection zone are made twice, 28-40 days apart to detect prevalence of SVD of 5% with a confidence interval of 95%; sampling begins 28 days after completion of cleaning and disinfection of the affected holding
- prohibition of movement and transport of swine, except under specified conditions as authorized and supervised by local veterinary authorities to move swine directly to a local facility for emergency slaughter or under exceptional circumstances to another holding located in the protection zone
- pork and pork products derived from the swine slaughtered in the protection zones are prohibited from entering intra-community or international trade
- vehicles used to transport swine, other livestock, or material (e.g., feed, manure, slurry, etc.) must be cleaned and disinfected in accordance with the procedures laid down by the national authority before being allowed to leave a holding located within the protection zone; all swine transport vehicles must be inspected by local veterinary authorities before leaving the zone
- measures applied in the protection zone shall remain in force a minimum of 28 days following completion of the following conditions:
 - depopulation, carcass disposal, and cleaning and disinfection of the SVD-affected holding, and
 - official visits to all holdings in the zone, with clinical examinations being made on all swine without suspicion or detection of SVD, and serological testing of a statistical sample of the swine with negative results

Measures applied to holdings within the 10 km surveillance zone:

- identification of all swine holdings within the surveillance zone
- serological sampling of all holdings in the surveillance zone are made once to detect prevalence of SVD of 5% with a confidence interval of 95%; sampling begins 28 days after completion of cleaning and disinfection of the affected holding
- prohibition of movement and transport of swine, except under specified conditions as authorized and supervised by local veterinary authorities
- measures applied in the surveillance zone shall remain in force until all measures required for the protection and surveillance zones have been completed

Pork and pork products, derived from swine slaughtered during the period between probable introduction of disease to the holding and implementation of official measures, were traced and destroyed under official supervision in such a way as to avoid the risk of spreading SVD.

In accordance with Council Directive 92/119/EEC, Member States were obligated to establish crisis units to provide full coordination of all measures necessary to ensure eradication of the disease as quickly as possible and to carry out epidemiological investigations. In Italy, a central

crisis unit was established within the MOH to facilitate outbreak response coordination at a national level. Crisis units acted at central, regional, and local levels in a coordinated response. The central crisis unit was the decision-making body. Their decisions were coordinated at the regional level and are implemented by local authorities. The IZS provided epidemiological and diagnostic support, as needed.

Discussion

During the period 1995-2015, Italy responded to over 700 outbreaks of SVD. Over seventy percent of these outbreaks can be accounted for in 3 epidemics of short duration. The high number of outbreaks was attributed to the unchecked spread of virus occurring before detection, a problem which was potentiated in areas with high-density swine populations.

Accordingly, Italian veterinary authorities adjusted their disease control and surveillance strategies as lessons were learned from their experiences and implemented extraordinary measures as circumstances necessitated. As a result of these enhancements, Italy was able to control SVD and has not experienced an outbreak in over six years. Tuscany has not had an outbreak of SVD since 2008, and the last SVD outbreak in Umbria was in 2009. In reviewing records describing the emergency response, APHIS could not identify any risk factors associated with Italy's emergency response capacity.

4.9. Entry assessment conclusions

APHIS found no evidence that SVD exists in Tuscany or Umbria. Italy last reported an outbreak of SVD in Tuscany in 2008 and in Umbria in 2009, and the last SVD outbreak anywhere in Italy was reported in Calabria in 2015. APHIS considers these findings to be evidence of the effectiveness of Italy's SVD eradication and monitoring program.

Based on evaluation of information obtained about the 8-factors defined in 9 CFR 92.2, APHIS considers that Italy possesses the detection capabilities, reporting and traceability systems, and emergency response systems necessary to respond to any reintroduction of SVD; to identify and remove exposed or potentially infected live swine, contaminated fresh pork, and contaminated pork products from the export market channel; and to comply with the certification requirements that APHIS intends to impose for exports to the United States from Tuscany and Umbria.

Previously, APHIS identified several risk factors in its SVD evaluation of regions in northern Italy [3]. Those factors were the persistence of SVD in parts of Italy; swine and pork movement from areas of Italy that APHIS considered to be SVD-affected; illegal movement of swine; and risky practices associated with dealer premises.

During the site visits to Tuscany and Umbria, the APHIS teams observed that farm, veterinary, and slaughterhouse/processing plant personnel were knowledgeable about SVD, biosecurity measures, movement requirements, vehicle cleaning and disinfection, disease surveillance, farm procedures and protocols, and emergency procedures for suspected foreign animal diseases. There appears to be satisfactory collaboration and cooperation between official veterinarians of various government units, private farm veterinarians, producers, and slaughterhouse/processing plant personnel. Biosecurity measures and record-keeping appear to be adequately implemented

and followed. Overall, the team found that oversight measures for dealer premises appeared to adequately address their level of risk of potential to spread SVD.

Although APHIS has not evaluated nine regions of Italy for SVD and therefore considers them to be regions where SVD exists, APHIS acknowledges that the last SVD outbreak in Italy was reported in 2015 and that Italy continued a robust SVD active surveillance program through 2020. APHIS considers this to be evidence that the likelihood of SVD being reintroduced into Tuscany and Umbria from other areas of Italy is negligible.

However, because swine, fresh pork, and pork products may freely move throughout Italy, APHIS intends to apply existing import prohibitions and restrictions that it also applies to areas of Italy that it considers to be SVD-free. In accordance with 9 CFR 94.14, APHIS prohibits importation of live swine that are moved from or transit regions that APHIS considers to be SVD-affected. APHIS considers this prohibition sufficiently mitigates the risk of importing undetected SVD-infected swine that may have legally moved into Tuscany and Umbria from areas of Italy considered by APHIS to be SVD-affected. APHIS also restricts the importation of fresh pork or pork products derived from swine originating in regions considered to be SVD-affected (9 CFR 94.13). Furthermore, the regulation prohibits the importation of pork or pork products that might have commingled with or were contaminated from pork or pork products derived from swine originating in SVD-affected regions. APHIS considers these prohibitions sufficiently mitigate the risk of importing undetected SVD-contaminated fresh pork or pork products from Tuscany and Umbria. APHIS has confidence that Italy's system of animal identification, holding registry and movement records provide sufficient basis for Italian authorities to ensure compliance with these APHIS prohibitions and restrictions.

In the past, illegal movements have played a role in SVD spread because they circumvent the mitigating effect of movement controls and biosecurity measures regarding the cleaning and disinfection of transport vehicles. According to MOH officials, illegal swine movement contributed to the spread of SVD in the 2007 epidemic in central and southern Italy and was associated with a single outbreak detected in Emilia-Romagna in 2008 [3]. However, the role of illegal movement is considered by APHIS to be negligible, especially for the commercial pork production market, given the high level of compliance from swine producers and the level of priority of control and enforcement activities by the regional and local authorities in Italy's major commercial production areas, including Tuscany and Umbria. APHIS concludes that existing Italian regulations satisfactorily mitigate this risk.

APHIS considers that mitigations implemented throughout Italy greatly reduced the likelihood of spreading SVD through dealer premises. APHIS previously made this observation in northern Italy and makes the same observation in this evaluation of Tuscany and Umbria.

For these reasons, APHIS concludes that the likelihood of importing SVD-infected live swine, contaminated fresh pork, and contaminated pork products from Tuscany and Umbria would be negligible.

Section 5: Risk Estimation

APHIS concludes from the entry assessment that SVD does not exist in Tuscany and Umbria. Furthermore, APHIS considers that Italy possesses the detection capabilities, reporting and traceability systems, and emergency response systems necessary to respond to any reintroduction of SVD; to identify and remove exposed or potentially infected live swine, contaminated fresh pork, and contaminated pork products from the export market channel; and to comply with the certification requirements that APHIS intends to impose for exports to the United States from Tuscany and Umbria. For these reasons, APHIS concludes that the likelihood of importing SVD-infected live swine, contaminated fresh pork, and contaminated pork products from Tuscany and Umbria is negligible. Thus, the risk of introducing SVD via swine commodities from Italy is negligible.

References

1. U.S. National Archives and Records Administration, *Code of Federal Regulations. Title 9, Animals and Animal Products. Part 94, Rinderpest, Foot-and-Mouth Disease, Newcastle Disease, Highly Pathogenic Avian Influenza, African Swine Fever, Classical Swine Fever, Swine Vesicular Disease, and Bovine Spongiform Encephalopathy: Prohibited And Restricted Importations in Title 9, Part 94*. 2021: Washington, DC, Office of the Federal Register.
2. USDA Animal and Plant Health Inspection Service, *Evaluation of Risk Factors for Swine Vesicular Disease in Certain Regions of Italy*. 1999: Riverdale, MD.
3. USDA Animal and Plant Health Inspection Service. *APHIS Evaluation of the Swine Vesicular Disease (SVD) Status of Northern Italy, July 2012 [APHIS-2012-0094-0002]*. 2012; Available from: Regulations.gov.
4. Italian Republic Ministry of Health, *Recognition of Italy as free for Swine vesicular disease*. 2020.
5. USDA Animal and Plant Health Inspection Service, *APHIS Evaluation of the Swine Vesicular Disease Status of the Region of Tuscany, Italy: Technical Site Visit Report*. 2016: Riverdale, MD.
6. USDA Animal and Plant Health Inspection Service, *APHIS site visit to evaluate the swine vesicular disease status of the Region of Umbria, Italy*. 2017: Riverdale, MD.
7. World Organisation for Animal Health (WOAH), *Chapter 2.1. Import Risk Analysis, in Terrestrial Animal Health Code*. 2021: Available online at https://www.woah.org/fileadmin/Home/eng/Health_standards/tahc/current/chapitre_import_risk_analysis.pdf.
8. U.S. National Archives and Records Administration, *Code of Federal Regulations. Title 9, Animals and Animal Products. Part 92 - Importation of animals and animal products: Procedures for requesting recognition of regions, in Title 9, Part 92*. 2021: Washington, DC, Office of the Federal Register.
9. Italian Republic Ministry of Health, *Tuscany Submission Nov. 2015 - Technical dossier supporting application of Region of Tuscany for SVD evaluation by APHIS*. 2015.
10. Italian Republic Ministry of Health, *Umbria Submission Apr 2017 - Technical dossier supporting application of Region of Umbria for SVD evaluation by APHIS*. 2017.
11. USDA Animal and Plant Health Inspection Service, *Recognition of Animal Disease Status of Regions in the European Union*. Federal Register, 2003. **68**(66): p. 16922-41.
12. USDA Animal and Plant Health Inspection Service, *Notice of a Determination Regarding the Swine Vesicular Disease Status of Certain Regions in Italy*. Federal Register, 2013. **78**(81): p. 24670-71.
13. World Organisation for Animal Health (WOAH), *Terrestrial Animal Health Code*. 2021: Available online at <https://www.woah.org/en/what-we-do/standards/codes-and-manuals/terrestrial-code-online-access/>.
14. World Organisation for Animal Health (WOAH). *World Animal Health Information Database (WAHIS) Interface*. 2022 [cited 2022; Available from: <https://wahis.woah.org/#/home>.
15. Center for Food Security and Public Health, T.I.S.U., „ *Swine vesicular disease*. 2017 December 2017; Available from: http://www.cfsph.iastate.edu/Factsheets/pdfs/swine_vesicular_disease.pdf.
16. World Organisation for Animal Health (WOAH). *Swine vesicular disease technical disease card*. 2020 [cited 2022; Available from: https://www.woah.org/fileadmin/Home/eng/Animal_Health_in_the_World/docs/pdf/Disease_cards/SWINE_VESICULAR_DISEASE.pdf.

17. Escribano-Romero, E., M.A. Jimenez-Clavero, and V. Ley, *Swine vesicular disease virus. Pathology of the disease and the molecular characteristics of the virion*. Anim Health Res Rev, 2000. **1**(2): p. 119-126.
18. Brocchi, E., et al., *Molecular epidemiology of recent outbreaks of swine vesicular disease: two genteically and anitgenically distinct variants in Europe, 1987--4*. Epidemiol. Infect., 1997. **118**: p. 51-61.
19. Zhang, G., et al., *Molecular evolution of swine vesicular disease virus*. J Gen Virol, 1999. **80**: p. 639-651.
20. World Organisation for Animal Health (WOAH). *Chapter 3.8.8. Swine Vesicular Disease*. Manual of Diagnostic Tests and Vaccines for Terrestrial Animals 2018; Available from: https://www.woah.org/fileadmin/Home/eng/Health_standards/tahm/3.08.08_SVD.pdf.
21. Lin, F. and R.P. Kitching, *Swine Vesicular Disease: An Overview*. Vet J, 2000. **160**: p. 192-201.
22. Government, S., *Swine Vesicular Disease Control Strategy, Annex to Scottish Government's Exotic Diseases of Animals Contingency Framework Plan, Version 2, October 2017*. 2017.
23. Brown, F., D. Goodridge, and R. Burrows, *Infection of man by swine vesicular disease virus*. J Comp Pathol, 1976. **86**(3): p. 409-414.
24. Bellini, S., et al., *Swine vesicular disease in northern Italy; diffusion through densely populated pig areas*. Rev. sci. tech, 2010. **29**(3): p. 639-648.
25. Lin, F., et al., *Persistent infection is a rare sequel following infection of pigs with swine vesicular disease virus*. Epidemiol Infect, 2001. **127**: p. 135-145.
26. Farez, S. and R.S. Morley, *Potential animal health hazards of pork and pork products*. Rev Sci Tech, 1997. **16**(1): p. 65-78.
27. Guerin, B. and N. Pozzi, *Viruses in boar semen: detection and clinical as well as epidemiological consequences regarding disease transmission by artificial insemination*. Theriogenology, 2005. **63**: p. 556-572.
28. Singh, E.L. and F.C. Thomas, *Embryo transfer as a means of controlling the transmission of viral infections. IX. The in vitro exposure of zona pellucida-intact porcine embryos to swine vesicular disease virus*. Theriogenology, 1987. **27**(3): p. 443-9.
29. Maes, D., et al., *Diseases in swine transmitted by artificial insemination*. Theriogenology, 2008. **70**(8): p. 1337-1345.
30. Mackay, D.K.J., *Swine Vesicular Disease*, in *Infectious Diseases of Livestock*, J. Coetzer and T. Tunstun, Editors. 2004, Oxford University Press: Cape Town, South Africa. p. 1313-1318.
31. Torres, A., *Swine Vesicular Disease*. Foreign Animal Diseases, ed. Committee on Foreign and Emerging Diseases of the United States Animal Health Association. 2008, Boca Raton, Florida: Boca Publications Group.
32. Callis, J.J., *Evaluation of the presence and risk of foot and mouth disease virus by commodity in international trade*. Rev Sci Tech, 1996. **15**(3): p. 1075-85.
33. McKercher, P.D., et al., *Swine vesicular disease: virus survival in pork products*. . Proceedings of the Annual Meeting of the U.S. Animal Health Association (78): 213a-213g, 1974.
34. McKercher, P.D., et al., *Thermal processing to inactivate viruses in meat products*. Proceedings of the Annual Meeting of the U.S. Animal Health Association (84): 320-328, 1980.
35. European Commission. *Italy Country Profile: Final Report of an Audit Carried Out in Italy from 26 November to 6 December 2019 In Order to Evaluate the System of Official Controls on Imports of Animals and Goods*. 2019 [cited 2021 Feb. 23]; Available from: https://ec.europa.eu/food/audits-analysis/country_profiles/details.cfm?co_id=IT.
36. Italian Republic Ministry of Health, *Southern Italy Submission Mar 2021 - technical dossier supporting application of remainder of Italy for SVD evaluation by APHIS*. 2021.

37. Toscana Regional Government, *Exchange of information during a technical site visit to Toscana by APHIS, May 2-6, 2016*. 2016.
38. Umbria Regional Government, *Exchange of information during a technical site visit to Umbria by APHIS, Oct. 16-19, 2017*. 2017.
39. European Commission. *Health and Food Audits and Analysis*. 2021 [cited 2021; Available from: https://ec.europa.eu/food/horizontal-topics/official-controls-and-enforcement/health-and-food-audits-and-analysis_en].
40. European Commission, *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)*, E. Commission, Editor. 2017.
41. European Commission. *Standing Committee on Plants, Animals, Food and Feed, Section Animal Health and Welfare, Agendas and Summary Reports*. 2021 [cited 2021; Available from: https://ec.europa.eu/food/horizontal-topics/committees/paff-committees/animal-health-and-welfare_en].
42. European Commission, *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')* E. Commission, Editor. 2016.
43. European Commission, *COMMISSION IMPLEMENTING DECISION (EU) 2019/470 of 20 March 2019 repealing Decision 2005/779/EC concerning animal health protection measures against swine vesicular disease in Italy*, E. Commission, Editor. 2019.
44. European Commission, *Commission Decision 2005/779/EC of 8 November 2005 concerning animal health protection measures against swine vesicular disease in Italy (as amended)*, E. Commission, Editor. 2005.
45. European Commission, *COMMISSION IMPLEMENTING DECISION (EU) 2017/1910 of 17 October 2017 amending Decision 93/52/EEC as regards the brucellosis (B. melitensis)-free status of certain regions of Spain, Decision 2003/467/EC as regards the official bovine brucellosis-free status of Cyprus and of certain regions of Spain, and as regards the official enzootic-bovine-leucosis-free status of Italy, and Decision 2005/779/EC as regards the swine vesicular disease-free status of the region of Campania of Italy* E. Commission, Editor. 2017.
46. European Commission, *COMMISSION DECISION of 20 August 2009 amending Decision 2005/779/EC as regards the inclusion of the region of Abruzzo in the list of Italian regions free of swine vesicular disease (2009/620/EC)*, E. Commission, Editor. 2009.
47. European Commission, *COMMISSION DECISION of 18 December 2008 amending Decision 2005/779/EC as regards the inclusion of Sicily in the list of Italian regions free of swine vesicular disease (2009/2/EC)*, E. Commission, Editor. 2008.
48. European Commission, *COMMISSION DECISION of 27 March 2008 amending Decision 2005/779/EC concerning animal health protection measures against swine vesicular disease in Italy (2008/297/EC)*, E. Commission, Editor. 2008.

49. European Commission, *COMMISSION DECISION of 18 December 2006 amending Decision 2005/779/EC concerning animal health protection measures against swine vesicular disease in Italy (2007/9/EC)*, E. Commission, Editor. 2006.
50. European Commission, *COUNCIL DIRECTIVE of 21 December 1982 on the notification of animal diseases within the Community (82/894/EEC)*, E. Commission, Editor. 1982.
51. European Commission, *COMMISSION DELEGATED REGULATION (EU) 2018/1629 of 25 July 2018 amending the list of diseases set out in Annex II to Regulation (EU) 2016/429 of the European Parliament and of the Council on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law')*, E. Commission, Editor. 2018.
52. European Commission, *COUNCIL DIRECTIVE 92 / 119/EEC of 17 December 1992 introducing general Community measures for the control of certain animal diseases and specific measures relating to swine vesicular disease*, E. Commission, Editor. 1992.
53. European Commission, *COMMISSION DECISION of 4 July 2000 establishing diagnostic procedures, sampling methods and criteria for the evaluation of the results of laboratory tests for the confirmation and differential diagnosis of swine vesicular disease (2000/428/EC)*, E. Commission, Editor. 2000.
54. European Commission, *COMMISSION DELEGATED REGULATION (EU) 2020/689 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for surveillance, eradication programmes, and disease-free status for certain listed and emerging diseases*, E. Commission, Editor. 2020.
55. World Organisation for Animal Health (WOAH). *HANDISTATUS II, Prototype, Last update: 14 December 2016 Interface. United States of America 2004 Annual Animal Disease Status*. 2016 [cited 2021; Available from: <https://web.oie.int/hs2/report.asp>].
56. Tamba M, P.F., Brocchi E, Ruocco L, *Eradication of Swine Vesicular Disease in Italy*. *Viruses*, 2020(12 (11): 1269).
57. Italian Republic Ministry of Health, *Ministerial Order dated April 12, 2008, Sanitary Measures for the Eradication of Swine Vesicular Disease and Surveillance of Classical Swine Fever*. 2008.
58. European Commission, *COUNCIL DIRECTIVE 92/102/EEC of 27 November 1992 on the identification and registration of animals*, E. Commission, Editor. 1992.
59. European Commission, *COUNCIL DIRECTIVE 2008/71/EC of 15 July 2008 on the identification and registration of pigs (Codified version)*, E. Commission, Editor. 2008.
60. International Trade Centre. *ITC Trade Map, Trade statistics for international business development, monthly, quarterly and yearly trade data. Import & export values, volumes, growth rates, market shares, etc.* 2021 [cited 2021; Available from: https://www.trademap.org/Country_SelProductCountry_TS.aspx?nvpm=1%7c381%7c%7c%7c%7c02%7c%7c%7c2%7c1%7c1%7c1%7c2%7c1%7c2%7c1%7c1%7c1].
61. USDA Animal and Plant Health Inspection Service. *Animal Health Status of Regions*. 2021 [cited 2021; Available from: <https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/animal-health-status-of-regions/animal-health-status-of-regions>].
62. Italian Republic Ministry of Health. *IZS Swine Vesicular Disease (SVD) Modules and Manuals*. 2021 [cited 2021; Available from: https://archive.izsler.it/pls/izs_bs/V3_S2EW_CONSULTAZIONE.mostra_pagina?id_pagina=1241].