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

# Report on the Review of Spain's Animal Health Statuses

## Classical swine fever, foot and mouth disease, and swine vesicular disease

Veterinary Services
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# 1 Executive Summary

The United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) recognizes the animal health status of foreign regions under the authority of 9 Code of Federal Regulations Part 92. APHIS periodically conducts reviews of animal health statuses held by foreign regions to determine whether conditions in the region support maintenance, suspension, or revocation of these statuses.

In 2019, APHIS reviewed the classical swine fever (CSF) status of the APHIS-defined European CSF region, EU zoning decisions for African swine fever (ASF), and the foot and mouth disease (FMD) and swine vesicular disease (SVD) statuses of 13 European Union (EU) Member States, including Spain. USDA APHIS considers Spain to be free of FMD and SVD. APHIS considers Spain to be low risk for CSF as part of the APHIS-defined European CSF region. ASF has not been detected in domestic swine or wild boar in Spain.

To evaluate Spain's ability to maintain its animal health statuses, APHIS collected and analyzed information relevant to the factors used to conduct evaluations to establish initial animal health statuses. The document review was conducted in partnership with the Canadian Food Inspection Agency (CFIA). Additionally, an APHIS/CFIA team conducted an in-country site visit September 9-13, 2019. APHIS' review concluded that the disease agents under review are not present in Spain, the country has adequate infrastructure and controls to exclude importation of these agents into the United States, and maintains adequate programs for detection and control of the disease agents under review in the event that they enter Spain. In addition, Spain has demonstrated a history of prompt reporting of disease events, taking appropriate measures to prevent their export to the United States.

While APHIS considers ASF to exist in parts of the EU, at the time of this report, it does not consider ASF to be present in Spain. APHIS recognizes EU zoning decisions for ASF rather than the ASF status of individual Member States, including Spain. APHIS concurrently reviewed the status of the EU ASF zoning and reported its findings in a separate overarching review of the European Commission (EC) emergency response framework for zoning decisions for ASF. ASF is discussed in this report in reference to swine health disease programs, the control and prevention of foreign animal diseases in Spain, and the EU regionalization (zoning) decisions for the control of ASF. The last reported detection of ASF occurred in 1994 [1]. Since then, Spain has not detected ASF in domestic swine or wild boar [1, 2].

Therefore, APHIS has concluded that the information provided by Spain and other publicly available and technical sources supports the continuation of APHIS-granted animal health statuses for FMD, SVD, and CSF and associated import requirements.

# 2 Table of Contents

# 3 Lists of Tables



# 4 Lists of Figures

# 5 Acronyms

| | |
|---|---|
| **AC** | *Comunidad Autónoma* (Autonomous Community) |
| **ADS** | *Agrupaciones de Defensa Sanitaria* (Health Defense Groups) |
| **APHIS** | Animal and Plant Health Inspection Service |
| **ASF** | African swine fever |
| **BIP** | Border inspection post (*Puesto de Inspección Fronterizo, PIF*) |
| **C&D** | Cleaning and disinfection |
| **CFR** | U.S. Code of Federal Regulations |
| **CFIA** | Canadian Food Inspection Agency |
| **CNIGRE** | *Comité Nacional de Identificación del Ganado y Registro de Explotación de las Especies de Interés Ganadero* |
| **CNSASV** | National Committee of the Veterinary Sanitary Alert System |
| **CVED** | Common Veterinary Entry Document |
| **CSF** | Classical swine fever |
| **DG SANTE** | Directorate General for Health and Food Safety (EU) |
| **DGSPA** | *Dirección General de Sanidad de la Producción Agraria* (General Directorate of Agricultural Production Health) |
| **ENAC** | *Entidad Nacional de Acreditación en España* (National Accreditation Entity of Spain) |
| **EU** | European Union |
| **FMD** | Foot-and-mouth disease |
| **FSIS** | USDA Food Safety and Inspection Service |
| **MAPA** | *Ministerio de Agricultura, Pesca y Alimentación* (Ministry of Agriculture, Fisheries and Food) |
| **MSCBS** | *Ministerio de Sanidad, Consumo y Bienestar Social* (Ministry Of Health, Consumption and Social Welfare) |
| **NRL** | National Reference Laboratory |
| **OIE** | World Organisation for Animal Health |
| **RASVE** | *Red de Alerta Sanitaria Veterinaria* (Veterinary Health Alert System Database) |
| **REGA** | *Registro General de Explotaciones Ganaderas* (General Registry of Livestock Farms) |
| **REMO** | *Registro de Movimientos de las Especies de Interés Ganadero* (Registry of Movements of Species of Livestock Interest) |
| **RIIA** | *Registro de Identificación Individual de Animales* (Registry of Individual Animal Identification) |
| **SEPRONA** | *Servicio de Protección de la Naturaleza de la Guardia Civil* (Environmental Protection Service of the Civil Guard) |
| **SGSHT** | *Subdirección General de Sanidad e Higiene Animal y Trazabilidad* (General Sub-directorate of Animal Health, Hygiene, and Traceability) |
| **SITRAN** | *Sistema Integral de Trazabilidad Animal* (Comprehensive Animal Traceability System) |
| **SVD** | Swine vesicular disease |
| **TRACES** | Trade Control and Expert System |
| **USDA** | United State Department of Agriculture |

# 6 Background

A status review is an assessment of animal health conditions in a foreign region that currently has one or more animal health statuses recognized by USDA APHIS. These reviews are conducted on a periodic basis to determine whether APHIS should maintain recognition of the region's animal health status(es).

United States regulations stipulate in Title 9 of the *Code of Federal Regulations* (9 CFR) Section 92.2(g) that regions granted animal health status under the provisions of those regulations may be required to submit additional information pertaining to their animal health status or allow APHIS to conduct additional information collection activities in order for the regions to maintain their APHIS-recognized animal health status. This review process is applicable only for regions that have not reported outbreaks of the disease or pest occurrence in commercial livestock or poultry since APHIS' most recent evaluation or review. This includes regions recognized as free, regions recognized as being low risk, and regions not recognized as disease- or pest-free but from which importation of certain products is allowed under specific conditions to mitigate certain risks. More information on APHIS' animal disease status review program can be found on the APHIS Regionalization web page.

In order to evaluate Spain's ability to maintain its APHIS-granted animal health statuses for foot-and-mouth disease (FMD), swine vesicular disease (SVD), and classical swine fever (CSF), APHIS collected and analyzed information relevant to the factors used to conduct evaluations to establish initial animal health statuses as described in 9 CFR Section 92.2. These factors allow APHIS to establish a comprehensive representation of the region's veterinary infrastructure and services, livestock demographics, livestock movement and marketing patterns, surveillance programs, disease control capabilities, veterinary laboratory diagnostic capabilities, and emergency response systems for the specified hazards[1]. The document review was conducted in partnership with the Canadian Food Inspection Agency (CFIA). Additionally, an APHIS/CFIA team conducted an in-country site visit September 9-13, 2019 to verify the information received. APHIS evaluated the information in order to determine that Spain meets the following overarching standards:

- The hazard is not present in the region and/or the commodity under review;
- The hazard is unlikely to infect or contaminate the commodity being exported to the United States because of measures that prevent the introduction of the hazard and/or epidemiological barriers (both natural and manmade) that separate the region from the hazard of concern; and
- If the region has a hazard incursion, the region can rapidly detect the hazard; promptly notify the United States and/or the World Organization for Animal Health (OIE)[2]; and respond to the outbreak sufficiently to prevent introduction of the hazard into the United States through the importation of commodities from the region. Additionally,

[1] A hazard is a biological, chemical, or physical agent in, or a condition of, an animal or animal product with the potential to cause an adverse health event. For the purposes of this report, hazard refers to the causative agent of any of the four diseases under review.

[2] The OIE is a reference organization recognized by the World Trade Organization as the standard-setting body for safe trade in animals and animal products. The OIE collects and disseminates information about the animal health status of its 181 member countries.

APHIS reviewed the region's export protocols to ensure its ability to properly certify exports in accordance with APHIS requirements.

These elements are addressed in the following sections.[3] The report concludes with a determination regarding maintenance of Spain's animal health statuses. Based on the results of the review, APHIS will determine which of the following actions is appropriate for each status: (1) maintain the current status and import requirements; (2) continue the current recognition but with recommendation to strengthen the import requirements or mitigations; or (3) downgrade the current animal disease status recognition.

At the beginning of this review process, APHIS considered Spain to be free or low risk of all of the hazards under review with no additional import measures required.

[3] Unless otherwise noted, APHIS considers the information in this report to be current as of January 2020 when the final report was completed.

# 7 Review

The following sections summarize the information regarding Spain's APHIS-granted animal health statuses and determines whether to maintain the current status(es) or change them as described above. The review is based on documentation provided by Spain and other published and technical sources as well as observations made during the APHIS/CFIA in-country site visit in September 2019 [3, 4].

## 7.1 Status of hazards under review in Spain

### 7.1.1 History of disease occurrence in domestic livestock

APHIS maintains a list of animal health status of regions on the APHIS website. APHIS considers Spain to be free of FMD and SVD. APHIS considers Spain to be low risk for CSF as part of the APHIS-defined European CSF region[4]. The last outbreak of FMD occurred in 1986. The last outbreak of CSF occurred in 2002. Spain has only had 3 outbreaks of SVD; the last outbreak of SVD occurred in 1993 [1, 3]. Since eradication of these diseases, no outbreaks have been reported in domestic livestock. The World Organisation for Animal Health (OIE) recognizes Spain (including Balearic Islands and Canary Islands) as FMD free where vaccination is not practiced and free from CSF [5].

While APHIS considers African swine fever (ASF) to exist in parts of the European Union (EU), at the time of this report, it does not consider ASF to be present in Spain. APHIS recognizes EU zoning decisions for ASF rather than the ASF status of individual Member States, including Spain. APHIS concurrently reviewed the status of the EU ASF zoning and reported its findings in a separate overarching review of the European Commission (EC) emergency response framework for zoning decisions for ASF. ASF is discussed in this report in reference to swine health disease programs, the control and prevention of foreign animal diseases in Spain, and the EU regionalization (zoning) decisions for the control of ASF. The last reported detection of ASF occurred in 1994 [1]. Since then, Spain has not detected ASF in domestic swine or wild boar [1, 2].

### 7.1.2 History of disease occurrence in susceptible wildlife

FMD or SVD has never been reported in susceptible wildlife species. CSF was endemic in Spain, including in wild boar, from 1952 until its eradication in 1986. Since eradication of these diseases, no outbreaks have been reported in susceptible wildlife species [3].

### 7.1.3 Vaccination

Spain prohibits vaccination for FMD, SVD, and CSF. The use of vaccines against FMD is prohibited in accordance to Article 49 of Royal Decree No. 2179/2004 (adapted from Council Directive 2003/85/EC). The use of vaccines against SVD is prohibited in accordance to Article 19 of Royal Decree No. 650/94 (adapted from Council Directive 92/19/EEC). Similarly, the use of vaccines against CSF is prohibited in accordance to Article 18 of Royal Decree No. 1071/2002 (adapted from Council Directive 2001/89/EC). For all three diseases, implementation of emergency vaccination strategies may be used if warranted by

[4] APHIS-defined European CSF region includes: Austria, Belgium, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Ireland, Slovakia, Slovenia, Spain, Sweden, Switzerland, and United Kingdom. The importation of pork, pork products, and swine from the APHIS-defined European CSF region is subject to restrictions specified in 9 CFR 94.31. In addition, swine semen imported from the APHIS-defined European CSF region is subject to restrictions specified in 9 CFR 98.38.

the epidemiological situation and approved by the national veterinary authorities and the European Commission [3].

### 7.1.4 Status of hazards conclusion

APHIS did not find evidence to suggest the presence of any of the hazards under review in Spain. For the diseases under review, the last reported disease event in domestic species occurred in 2002. APHIS does not have any available evidence to suggest that these diseases exist in wildlife populations in Spain. In addition, vaccination against these diseases is prohibited unless approved by the national veterinary authorities and the European Commission as an emergency measure for control of a disease outbreak.

## 7.2 Likelihood of hazard entry into Spain

Spain is located in the western portion of Europe, on the Iberian Peninsula, with France and Andorra to the north and Portugal to the west. Along the southern and eastern borders lies the Mediterranean Sea. The Strait of Gibraltar separates Spain from the continent of Africa by approximately 14 kilometers. On the southern tip of the Peninsula lies Gibraltar, a territory of the United Kingdom. Spain has additional territories outside continental Europe, including: the Canary Islands, Baleares Islands, Chafarinas Islands, the Rock of Vélez de la Gomera, the Alhucemas Islands, and Alborán Island. Two autonomous cities, Ceuta and Melilla, are located on the continent of Africa (Morocco); fencing separates the cities of Ceuta and Melilla from the territory of Morocco. Spain is a Member State of the EU.

Spain's proximity to North Africa along with the international trade of animal and animal products, both legal and illegal pathways, and the movements of humans and wildlife make entry of foreign animal diseases an on-going risk for Spain and the EU. Thus, APHIS collected information on Spain's veterinary infrastructure, including legal authority for the animal health activities, organizational structure of the veterinary services, import requirements for animal commodities, and international certification protocols to determine the effectiveness of measures to prevent incursions of the hazards under evaluation.

### 7.2.1 Veterinary infrastructure and organization

The Government of Spain operates under a parliamentary monarchy with political and administrative organization divided into central, regional, and local levels. The central level is responsible for developing national policies and adapting EU legislation and international guidelines into national legislation. It also coordinates and oversees the activities in the 17 Autonomous Communities (AC) and 2 autonomous cities, Ceuta and Melilla [3]. See Figure 1 below.


Figure 1: Political map of Spain with Autonomous Communities and Autonomous Cities

**Central level**

Within the central government, the veterinary infrastructure for animal health programs and official veterinary services is headed by the *Ministerio de Agricultura, Pesca y Alimentación* (Ministry of Agriculture, Fisheries and Food, MAPA). Within MAPA, the *Subdirección General de Sanidad e Higiene Animal y Trazabilidad* (General Sub-directorate of Animal Health, Hygiene, and Traceability, SGSHT) under the *Dirección General de Sanidad de la Producción Agraria* (General Directorate of Agricultural Production Health, DGSPA) is responsible for the oversight of animal health and animal traceability and identification issues at the central level. SGSHT is responsible for the regulatory structure for animal health programs and activities, including control of animal disease outbreaks, national surveillance programs, national laboratories, emergency contingency plans, control and eradication programs, and organization of veterinary laboratories. SGSHT also is responsible for the adaptation of EU legislation into the national legislative framework [3].

In conjunction with MAPA, the *Ministerio de Sanidad, Consumo y Bienestar Social* (Ministry of Health, Consumption and Social Welfare, MSCBS) is responsible for the oversight of government policy on public health and food safety, healthcare, and consumer protection. In particular, the *Dirección General de Salud Pública, Calidad e Innovación* (Directorate General for Public Health, Quality and Innovation) and *Agencia Española de Seguridad Alimentaria y Nutrición* or AESAN (Spanish Agency for Food Safety and Nutrition) provide the regulatory structure, policies and authority for food safety programs and activities, from the slaughterhouse to the distribution of food commodities to national, EU, and international markets [3, 4].

Policies and programs for official veterinary services among MAPA, MSCBS, and the regional ACs are coordinated through a system of inter-disciplinary sectoral councils and institutional committees that organize and manage the administrative and operational activities for shared activities and competencies pertaining to animal health and food safety. For example, the General Directorates from

MAPA and MSCBS and regional authorities from the ACs (along with one member from the Ministry of Economy and Business) work through the Committee for Veterinary Export Certification to coordinate the animal health, food safety, and financial aspects of the export certification process [4]. A complete organizational chart of MAPA and MSCBS can be found on the MAPA website and the MSCBS website, respectively.

Within MAPA, SGSHT manages coordination of animal health activities through the National Committee of the Veterinary Sanitary Alert System, CNSASV. CNSASV acts as the coordinating unit between MAPA and the ACs. It has oversight from the Director General of DGSPA with representatives from each AC and from the National Reference Laboratories. CNSASV was created under Royal Decree No. 1440/2001 (System for Veterinary Sanitary Alerts) with regulatory authority based in Article 28 of Animal Health Law 8/2003 and the Administrative Procedure Law 39/2015. CNSASV coordinates national eradication programs and contingency plans among the ACs for livestock diseases.

SGSHT coordinates the identification and registration of livestock through the National Committee for Livestock Identification and Registration of Livestock Interest Species (*Comité Nacional de Identificación del Ganado y Registro de Explotación de las Especies de Interés Ganadero,* CNIGRE), created under Royal Decree No. 479/2004. The Committee is headed by Sub-directorate General of SGSHT with representative from each AC and other sub-directorates within DGSPA. In conjunction, the National Committee for the Electronic Identification of Animals (*Comité Español de Identificación Electrónica Animal*, CEIEA) established in Ministerial Order APA/2405/2002 coordinates technical guidance, along with input from academic and private sector subject matter experts, to CNIGRE committee on electronic identification of livestock species.

SGSHT is responsible for the Comprehensive Animal Traceability System (*Sistema Integral de Trazabilidad Animal*, SITRAN) which includes 3 databases, accessible to all ACs: REGA (General Registry of Livestock Farms, created by Royal Decree No. 479/2004); RIIA (Registry of Individual Animal Identification for cattle, sheep, goats and horses); and REMO (Registry of Movements of Species of Livestock Interest, individual and in groups). These last two databases (RIIA and REMO) were created by Royal Decree No. 728/2007 [3].

**Regional and local level**

At the regional level, each AC has its own autonomic statutes that organize its territorial limits, authority, and roles and responsibilities transferred from the central level. Each AC has its own autonomic parliament, government, president, and judicial tribunal. Animal health services are funneled down from the central level to each AC, headed by its own General Directorate of Livestock of the CAG-AC (*Consejería de Agricultura y Ganadería de la Comunidad Autónoma*), with central veterinary offices located within the province or territorial service unit. At the local level, each AC is divided into provinces which are further divided into counties, where animal health services and activities are located out of the county office or the local veterinary unit (UVL). Spain has approximately 500 UVLs throughout its territory.

At the local level, field veterinary services for animal health in each AC, such as sampling for surveillance, vaccinations, and inspection activities related to control and eradication programs are conducted by official veterinarians of the AC or by veterinarians from companies or associations authorized by the AC to conduct field activities and programs on their behalf (e.g., *Agrupaciones de Defensa Sanitaria* or

Health Defense Groups, ADS). Official duties such as livestock movement certification, export certification, and inspection and audit activities are performed and issued by an official veterinarian of the AC. Other duties, such as routine preventive care, surveillance sampling for program diseases, or vaccination campaigns may be performed by ADS veterinarians or the company veterinarian [3].

ADS veterinarians are employed by groups of producers in the same geographic region. Their duties are described in an annual sanitary plan approved by both the producers and the competent veterinary authorities of the AC. They are partially funded by the budget of the AC via the General State Administration (*Administración General del Estado,* AGE) from the central level. Additionally, the competent veterinary authorities of the AC provide oversight for official activities that are performed in lieu of the official regional veterinarian. When the official veterinary services of the region selects an agency such as ADS that sub-employs veterinarians to run such activities, official control and oversight is provided by the competent authority of the AC. Violations detected in relation to animal movement (or other field activities) are notified to the competent authority of the animal health services in the AC. In times of emergency disease outbreaks, the competent veterinary authorities of the AC can call upon the ADS veterinarians to provide support for control and eradication activities. Additionally, the SEPRONA body from the Civil Guard (*Servicio de Protección de la Naturaleza de la Guardia Civil*) can provide police enforcement related to animal movement controls or other emergency measures [3, 4].

**Animal health laboratories**

In Spain, there are 6 EU reference laboratories and 14 national reference laboratories for public health animal health. For animal health diagnostics, there are three national reference laboratories: Central Veterinary Laboratory in Algete (Madrid); Central Veterinary Laboratory in Sante Fe (Granada); and the Marine Research Activities Laboratory in Vigo (Galicia). The Central Veterinary Laboratory in Algete is the national reference laboratory (NRL) for FMD, CSF, and SVD and responsible for coordination of laboratory activities for all 17 ACs, each with their own regional reference laboratories located within the AC. It is also an EU reference laboratory for animal health diagnostics. At the regional level, there are 74 public health laboratories and 93 animal health laboratories. The NRLs and the AC regional laboratories are audited and accredited by *Entidad Nacional de Acreditación en España* (National Accreditation Entity in Spain, ENAC) in accordance with the international laboratory standards established in ISO/IEC 17025:2005 [3, 4].

An overview of the units and agencies involved with the veterinary control system for animal health in Spain is provided in Appendix I.

### 7.2.2 Legal authority for animal health activities

Primary legal authority for animal health activities comes from the Animal Health Law 8/2003 (*Ley 8/2003, de 24 de Abril, de Sanidad Animal*). Additional legal statutes and regulations provide regulatory authority for animal health activities within Spain, including disease notification, on-farm inspections, livestock movement controls, quarantine of animals or farms, vaccination, disease surveillance, control and eradication of diseases, animal identification and farm registration, and emergency response activities (Veterinary Health Alert System). As a Member State of the EU, Spain adheres to all applicable EU Regulations, Directives and applicable Decisions related to animal health and control of infectious animal diseases. All EU Directives pertaining to animal health have been adapted into the Spanish legal framework. There are no derogations to the EU legislation pertaining to the diseases under review. A

complete list of legal acts, regulations, and orders that provide regulatory authority to conduct animal health activities in Spain can be found in Appendix II [3].

### 7.2.3 Human and financial resources for veterinary services

Spain has approximately 3,200 veterinarians and 5,300 para-veterinary and administrative personnel employed by the national and AC official veterinary services. Additionally, Spain has approximately 6,800 personnel working in public health and food safety [3, 4].

**Table 1: Official veterinary services personnel in Spain**

| | Veterinarians | | Veterinary technicians | | Other animal health professionals | | Administrative staff | |
|---|---|---|---|---|---|---|---|---|
| | Filled posts | Vacant posts | Filled posts | Vacant posts | Filled posts | Vacant posts | Filled posts | Vacant posts |
| Central service | 347 | --- | 185 | --- | 115 | --- | 71 | --- |
| Regional service | 688 | --- | 2,081 | --- | 951 | --- | 96 | --- |
| Local service | 1,640 | --- | 444 | --- | 183 | --- | 508 | --- |
| Border controls | 196 | --- | 44 | --- | 2 | --- | 42 | --- |
| Laboratory service | 337 | --- | 444 | --- | 83 | --- | 88 | --- |

Source: [3]

Spain has approximately 29,541 private veterinarians that are registered within the seventeen ACs and 2 autonomous cities of Ceuta and Melilla. Of that total, approximately 9,867 private veterinarians conduct official veterinary services related to animal health at the central, AC, and local levels. Approximately 1,506 private veterinarians work in activities related to animal health. Private veterinarians who conduct official animal health services on behalf of the AC and/or MAPA are employed by ADS. The ADS are Health Defense Groups which are authorized and approved to perform official veterinary services. Each ADS must have an approved sanitary plan or contract with supervision and oversight from the competent veterinary authority in the AC. Under this system, private veterinarians perform their duties in compliance with the general requirements of animal health policies within the AC and national policies within MAPA [3, 4].

Financial support for Spain's veterinary services is sourced from MAPA from an annual national budget approved by Parliament. Each AC receives a portion from the national budget. In case of an animal disease outbreak, a national emergency can be declared, and additional funds are allocated to the control and eradication efforts. Expenditures related to animal disease outbreaks, including indemnity for livestock, is funded from the budgets of MAPA, the AC, and the EU as laid down in Council Decision 2009/470/EC (consolidated version of Decision 90/424/EEC and its subsequent amendments). Certain control measures for animal health are co-financed by the EU and can be used in accordance to Commission Regulation (EC) No. 2014/652 [3].

### 7.2.4 Livestock demographics for species susceptible to the diseases under review

On a global level, Spain is the fourth largest pork producing nation (after China, US, and Germany); while, at the EU level, Spain ranks second in pork production behind Germany. Spain has approximately 30.8 million pigs, 29,000 boars, and 2.5 million sows. This includes approximately 3.6 million Iberian

pigs[5]. Spain is the third largest exporter of pork and pork products in the EU and the fourth largest exporter worldwide with a significant volume of exports to third countries, in particular China, which has become the top importer of Spanish pork meat. In Spain, holdings eligible for export to third countries and intra-EU trade are predominately vertically integrated, conglomerate farms, encompassing all elements of the production cycle from the breeding swine to feed to the slaughterhouse. These farms maintain the highest biosecurity standards and production standards to meet food safety, animal health and animal welfare regulations [3, 4, 6].

For the other livestock species susceptible to FMD, Spain has approximately 6.6 million head of cattle; the fifth largest number (of head) in the EU. For sheep and goats, Spain has the 16 million sheep, the second largest in the EU after the United Kingdom. Likewise, after Greece, Spain has the second largest number of goats in the EU with 3.1 million goats [7].

Generally, the domestic movement patterns for swine flows from the breeding production farms in the central and western regions of Spain towards the fattening premises in the eastern part of the country. Movement of calves takes place mainly from the breeding farms in the west and southwestern regions of the country to fattening premises in the east. Cows are moved from the north to the west and southwest to take advantage of the pastures of the *Dehesa* agro-systems primarily during the spring months. In the case of small ruminants, the movements are less patterned, but somewhat similar to that described for cows and calves [3].

### 7.2.5 Registration of holdings and livestock

MAPA's SGSHT is responsible for the Comprehensive Animal Traceability System (*Sistema Integral de Trazabilidad Animal*, SITRAN) which includes 3 databases: REGA (General Registry of Livestock Farms, created by Royal Decree No. 479/2004); RIIA (Registry of Individual Animal Identification for cattle, sheep, goats and horses); and REMO (Registry of Movements of Species of Livestock Interest, individual and in groups). These last two databases (RIIA and REMO) were created by Royal Decree No. 728/2007. The SITRAN system complies with national and EU regulations pertaining to animal identification and traceability. Currently, the database holds information on more than 813,000 registered holdings, nearly 50 million registered animals, and over 20 million animal movements annually [3, 4].

Animal Health Law 8/2003 stipulates that all livestock holdings must be registered in the AC where they are located and basic demographic information must be included on the national registration system, SITRAN. The Law establishes the obligation of owners, producers, and caretakers of livestock to communicate to official veterinary authorities of the AC information related to internal movements of livestock into and out of registered holdings. Similarly, notification of domestic movements of livestock between ACs must be inputted into SITRAN.

STIRAN consists of three main databases:

- **REGA**: This database houses basic demographic information of more than 813,000 livestock holdings in Spain, including farms, slaughterhouses, border inspection posts (BIPs), assembly

[5] Iberian pigs are a traditional breed of domestic pig native to the Iberian Peninsula (Spain and Portugal). Pigs are dark in color, ranging from deep reds to black, giving rise to the nickname of *pata negra* or black hoof. Iberian pigs spend a portion of their production cycle outdoors (free-range); feeding on acorns in the oak forests (known as *dehesas*). Iberian pigs are reared for specialty dry-cured ham products or *jamón ibérico*. Iberian pigs are found primarily in the Autonomous Communities of Extremadura, Andalucia, Castilla y León, and Castilla-La Mancha.

centers, dealers, equestrian centers, zoological centers and experimental facilities. Each holding is assigned a unique holding code linked to the primary owner and the municipality. Additionally, each holding is assigned to an official veterinary service and veterinarian. Along with information on the holding, REGA contains information on animal husbandry, animal health, geographical data for mapping and epidemiological tools, sanitary status, movement restrictions (including authorizations for intra-EU movements), inspection reports, and real-time census and capacity data for each holding.

- **REMO**: This database compiles information related to animal movements for cattle, sheep, goats, swine, horses, poultry, and others. For each movement, two notifications are recorded in REMO: one from the holding of origin and the other at the destination holding upon arrival. REMO also contains information on transportation mode, entry BIP for imports, the classification of the movement type (e.g., within the AC, between ACs, importation, intra-EU, etc.), and, for individually identified species, the complete list of animals in the shipment.
- **RIIA**: This database collects information related to the individual identification of cattle, sheep, goats and horses. Swine and poultry are identified by groups or batches of animals. Individual animal information includes, among other data, breed, sex, date of birth, place of birth, holding of birth, place of fattening, dates and holdings through lifespan, death data from slaughterhouse, import/export data, identification of the dam (bovines), individual animal health data, and re-tagging information as needed.

For each of these databases, information is provided by the owner, producer or caregiver of livestock to the AC competent authorities, which registers the information into the appropriate database through an electronic messaging system. The data undergoes quality assessment before it is uploaded into the central SITRAN database. Records of this data are maintained by the regional competent authority. Any non-compliance with animal identification, farm registration, or animal movement is punishable in accordance to Animal Health Law 8/2003. Official veterinary services from each AC are responsible for detecting non-compliances and have the authority to impose sanctions based on the severity of infraction.

For animal identification, cattle, sheep, goats and horses are individually identified. The types of individual identification varies by species and includes conventional ear tags, a ruminal bolus, pastern bands, and injectable transponders. Some species use more than one type of identification. For example, cattle are identified with two conventional ear tags. Other species such as swine, poultry and bees are identified in groups using a unique holding code assigned to each registered holding. Swine, for example, are identified in groups (or lots) with an ear tag and/or tattoo containing the unique holding code [3, 4].

### 7.2.6 Domestic and intra-EU movement controls for animals and animal products

Spain has an organized, effective system for documentation, traceability, and movement control for animals and animal products. Three network IT systems are involved with documentation and traceability of movements: SITRAN/REMO for live animal movements within Spain; CEXGAN for foreign (third-country) trade; and TRACES for intra-EU trade and importation of animals, semen and embryo, food, feed and plants.

Under Article 50 of the Animal Health Law 8/2003, all livestock movements must be approved and accompanied by an *Origin Sanitary Certification* document (*Guía Sanitaria*), issued by an official

veterinarian or authorized veterinarian, certifying the movement is in compliance with animal health and welfare requirements under Animal Health Law 8/2003 and the Animal Welfare Law 32/2007. Movements of livestock species within Spain must be registered into REMO. The premises of origin must communicate the movement to the AC competent authority and the premises of destination must confirm the movement upon arrival to the AC competent authority. Both regional competent authorities (origin and destination) must input the movement data into their databases to be reflected within the central database of SITRAN/REMO.

Any detections of non-compliance in relation to animal identification, registration of farms, or movement of livestock is punishable in accordance to Animal Health Law 8/2003. Infractions would be classified into different groups (mild, severe, very severe) in proportion to its severity. Official veterinary services from the AC are responsible for detecting non-compliances as well as imposing sanctions, including measures such as banning livestock movements, suspending (temporary or permanent) farm registration, and/or monetary fines [3, 4].

**Swine production movements**

For swine moving through the export production cycle, piglets move from the sow farms to the fattening farms with the *Guía Sanitaria* document generated via SITRAN/REMO. Additionally, the truck must arrive with a cleaning and disinfection certificate at loading and delivery of the piglets. After fattening, the pigs are transported to the slaughterhouse with the DVR, *Declaración de Veterinario Responsable*; ICA, *Información Cadera Alimentaria*; and *Guía Sanitaria*. Again, this movement is recorded within SITRAN/REMO. The documents are signed and issued by an official veterinarian or authorized veterinarian when the animals leave the holding of origin.

- DVR: Certifies that, in the past 6 or 12 months, the holding has not had animal health issues with various diseases such as porcine reproductive and respiratory syndrome, atrophic rhinitis, brucellosis, leptospirosis, porcine pleuropneumonia, porcine paratuberculosis and anthrax.
- ICA: Verifies information related to food safety, such as names and dates of treatment drugs (including vaccines) administered in the previous 30 days and the withdrawal times; place of birth and fattening; sanitary status of the holding (e.g. Aujeszky status); disease status of the animals; and diagnostic analyses for zoonotic disease or chemical residues.
- *Guía Sanitaria*: Contains data on the shipment (holding of origin REGA code, batch number, etc.) transport identification and cleaning and disinfection certificate for the transport vehicle, verifies the health of the animals (e.g., no clinical signs of disease in the past 48 hours), and verifies the sanitary rating of the holding (e.g. Aujeszky status).

After slaughter and processing, the shipment of pork products is accompanied by the pre-export certification – *Sanitary Certificate for Export of Food Products* – issued, signed, and stamped by the official veterinarian of the slaughter plant, verifying the products have been properly inspected and found to be fit for human consumption. The final export certificate is signed by the official veterinary services at the BIP or export certification units. The export certificate is printed on security paper (similar to printed money paper) which is distributed by the central authority. The original documents accompany the shipment, copies are uploaded into CEXGAN and records are maintained at BIP. Thus, for live swine and pork products moving through the export chain, documentation, traceability, and movement control is captured in multiple, integrated networks, including SITRAN and CEXGAN, with

oversight from official regional veterinarians of the AC (under MAPA), official veterinarians at the slaughterhouse (under MSCBS), and the veterinary services at the BIP (under MAPA) [3, 4].

**Intra-EU movements**

As a member of the EU, Spain is part of the European single market allowing, among other things, the free movement of commodities, including animals and animal products between Member States. Intra-EU movements are equivalent to domestic movements within Spain and are not subject to additional movement controls or inspection requirements by the veterinary authority of other Member States at border inspection posts[6] or elsewhere.

Intra-EU movements of animals and animal products must be accompanied and certified by the Trade Control and Expert System or TRACES document issued by an official veterinarian within the AC of the holding of origin. TRACES is the European Commission's online management tool to record the movements of animals, products of animal and non-animal origin, feed and plants transiting EU countries or imported from outside the EU, in order to ensure the safety of food and public health. Commodities, in most cases, are accompanied by health certificates or commercial documents and the competent authorities may issue these documents online through TRACES. TRACES aims to facilitate trade, speed up administrative procedures and improve the management of health threat risks, as well as combat fraud and improve the safety of the food chain and animal health [8, 9].

EU legislation for TRACES includes:

- Commission Decision 2003/623/EC of 19 August 2003 on the development of an integrated veterinary computer system called TRACES;
- Commission Decision 2004/292/EC on the implementation of the TRACES system and amending Decision 92/486/EEC, the system became mandatory for all Member States from 1 January 2005;
- Council Directive 90/425/EEC on veterinary and zootechnical controls applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market; and
- Commission Regulation (EC) No 599/2004 of 30 March 2004 on the adoption of a harmonized model of certificate and inspection minutes for intra-Community trade in animals and products of animal origin.

As part of the European single market, intra-EU movement of animals and products are not subject to document or physical inspection at land border checkpoints, ports of entry, seaports or airports when shipments move between two Member States. To decrease the likelihood of spread of highly contagious animal diseases among EU Member States, intra-EU movement of animals and animal products is only authorized when animals or their products come from holdings that are in compliance with pertinent legislative requirements (both EU and Member State) and are authorized and registered by the competent authorities from the Member State of origin. In accordance to Council Directive 2008/73/EC,

[6] There are no official checkpoints or inspections posts between EU Member States for intra-EU trade. Border inspection posts (BIPs) exist for the exchange of goods and people between Member States and non-EU (third country) regions. Approved BIPs are listed in Commission Decision 2009/821/EC. Procedures for veterinary checks for animals and animal products entering the EU from third countries are stipulated in Commission Directive 91/496/EEC and Commission Directive 97/78/EC.

Member States must develop, update and make available the list of authorized holdings, as well as national reference laboratories and other designated laboratories in compliance with EU legislative requirements [3, 8]. Livestock movements must also adhere to other EU legislation, namely, the Directives with specific animal health requirements for intra-EU trade of cattle, sheep, goats, and swine. These include Council Directives 97/12/EC, 98/46/EC, 98/99/EC, 2000/15/EC, and 2000/20/EC which are adapted into Spanish legislation by Royal Decree No. 1716/2000 [3].

### 7.2.7 Importation of animals and animal products from third countries

From 2016-2018, an estimated 6,575,028 livestock species susceptible to the diseases under review were imported into Spain; 99.99% of these animals (mostly swine) came from other EU Member States, primarily Germany, Netherlands, Portugal and Denmark. Only 618 swine (32 consignments) were imported from third countries. Typically, for swine, third country imports are boars imported for their high genetic value and are destined for swine reproductive centers in Spain. Similarly, only 545 consignments of animal products were imported from third countries. Third country trade partners include Brazil, Chile, China, United States, and Serbia [3].

As part of the European single market, the importation of animals or products from third countries can occur through any approved BIP of an EU Member State and then circulate throughout the EU with no additional controls or inspections by the official veterinary services of other Member States. Thus, importation procedures at all EU BIPs and the authorization procedures for approving third country imports are harmonized across all EU Member States.

According to EU legislation, Council Directive 91/496/EEC and Council Directive 97/78/EC, airports, ports, and other entry routes for animals and animal products are categorized by the following:

- BIP - border inspection post according to Commission Decision 2009/821/EC
- PE – points of entry for non-animal origin feed according to Article 17 of Commission Regulation (EC) No. 2004/882
- DPE – designated points of entry for imported products according to Article 3 of Commission Regulation (EC) No. 669/2009
- DPI – points of entry for animal feed according to Article 1 of Commission Regulation (EC) No. 884/2014

Currently, there are 24 BIP, 37 PE, DPE and 14 DPI authorized for the importation and inspection of live animals, products of animal origin not intended for human consumption, animal feed, and livestock vehicles[7]. These commodities are inspected by official veterinarians of MAPA. Animal products intended for human consumption are inspected by official veterinarians MSCBS to ensure compliance with national and EU food safety and public health requirements. A full list of authorized entry points in Spain can be found HERE. See Appendices III and IV for map and information on BIPs in Spain [3, 4].

For importation of animals and animal products from third countries, Spain follows Council Directive 2004/68/EC (adapted into Spanish legislation Royal Decree No. 1085/2005) as well as Commission Regulation (EU) No. 206/2010, which establishes a list of third countries or parts of third countries

[7] The autonomous cities of Ceuta and Melilla are not considered part of the European single market and commodities are regulated as coming from outside the EU territory. Thus, all goods and animal movements (pets and horses) must undergo inspection procedures at the BIP. There are no approved establishments in these cities; all meat and milk products are prohibited entry into Spain.

where sanitary and phytosanitary certification conditions are approved for imports into the EU of live animals and their products. To be authorized as an approved third country for imports, the interested third country must send an official request form and the required information to the EU Commission's Directorate General for Health and Food Safety (DG SANTE) – Directorate for Audits and Analysis (what was previously known as the Food and Veterinary Office, FVO). DG SANTE reviews the information and performs an audit inspection visit to the country. If the evaluation is satisfactory, the country will be listed as an approved third country partner for importation of the specified commodity [3].

For importation of animals and animal products, there may be additional animal health requirements set out in specific Commission Decisions. For live pigs, additional requirements can be found HERE. Import requirements for bovines and sheep/goats from third-countries are also laid out. For meat products, additional requirements can be found HERE.

When disease outbreaks occur in adjacent, third country regions such as North Africa, additional import restrictions are put into place. For example, an outbreak of FMD in Morocco in November 2015 triggered Spanish Ministerial Order AAA/2444/2015 (updated Order APM/607/2018) which contained the emergency mitigations against FMD in the Maghreb[8]. These measures were preceded by Commission Implementing Decision (EU) 2017/675 to prevent the introduction of FMD into the EU from Algeria, Tunisia, Libya and Morocco. Such actions aim to prevent disease introductions from third countries into Spain which could subsequently spread into the EU [3].

In general, imports of animals and animal products must be accompanied by the following documentation:

- Common Veterinary Entry Document (CVED)
- Veterinary health certificate
- Other documents such as the commercial invoice, bill of lading or air waybill, and diagnostic laboratory reports

In Articles 3 and 5 of Council Directive 97/78/EC, it states the requirement for the official veterinary service to provide a certificate confirming that veterinary checks have been carried out. This certificate is known as a Common Veterinary Entry Document (CVED). The certificate is produced via the TRACES system. The certificates must only be signed by the official veterinary service - it is not acceptable for the certificate to be signed by other officers. Each certificate is assigned a serial number by TRACES. The official veterinary service must retain copies of the CVEDs and original third country health certificates or health documents accompanying consignments for 3 years.

The veterinary health certificate must be signed by an official veterinarian of the competent authority of the exporting third country guaranteeing that the conditions for import into the EU have been met. Upon arrival and entry to the EU, the animals and animal products with their accompanying certificates must be verified and checked by official veterinarians at a designated BIP. Further checks on the animals may also be carried out at the final destination. At designated BIPs, an official veterinarian performs an inspection consisting of [3, 4]:

[8] The Maghreb refers to the region in North Africa, consisting primarily of the countries and territories of Algeria, Morocco, Tunisia, Libya, Mauritania, Western Sahara and the autonomous cities of Melilla and Ceuta.

- Document checks – Performed on 100% of consignments - verifies information on the veterinary health certificate, including verifying the goods come from an authorized country and establishment, and other documentation per Commission Regulation (EU) No. 206/2010;
- Identity checks– Performed on 100% of consignments - verifies proper identification (e.g., seal on shipping container or individual identification) for traceability to exporting country and the holding of origin; and
- Physical checks for animal products– Performed on percentage of consignments per National Sampling Plan and EU directive, suspicion, or notifications via TRACES – verifies integrity of goods via sensory examination, labeling, testing of temperature or pH, and other diagnostic tests for residues, pathogenic agents, and contaminants. For live animals, physical checks are performed on all shipments to verify animal welfare compliance, check for clinical signs of disease and, for a certain percentage, conduct blood sampling for diagnostic serological testing.

Animals and animal products are refused if the shipment does not pass the above inspection or is not in compliance with Commission Regulation (EU) No. 206/2010. Refused products are destroyed, treated/transformed or re-exported to the country of origin. Live animals may be quarantined, destroyed or re-exported to the country of origin. If refused, the CVED and other import documents are invalidated in TRACES. Notifications of refused shipments are recorded in TRACES to prevent attempts to re-enter at other BIPs in the EU. If considered necessary, an import ban against the country or importer could be issued [3, 4]. See Appendix IV for list of BIPs in Spain approved for entry of animal commodities.

### 7.2.8 Live-haul trucks, personal vehicles and baggage, swill feeding and international catering waste

In addition to the movement of animals and animal products, other vulnerable entry pathways for the diseases under review include contaminated livestock vehicles, animal-origin commodities carried into the country via personal vehicles and passenger baggage, feeding improperly cooked food waste to swine, and improper disposal of international catering waste. The EU and Spain have prevention mechanisms in place for these entry pathways.

For live-haul trucks, Royal Decree No. 1559/2005 stipulates basic requirements and conditions for centers dedicated to cleaning and disinfection (C&D) of road vehicles that transport live animals, animal products, animal feed, and animal by-products not intended for human consumption. The C&D centers are authorized by the competent authority of the AC or the autonomous cities of Ceuta and Melilla. Each C&D center is registered with the competent authority and assigned an authorization number consisting of a unique code that corresponds to the Province and the center. Among other requirements, truck drivers are obligated to clean and disinfect vehicles after each use and before loading new animals. A valid certificate of cleaning and disinfection must accompany the truck when loading or unloading animals and animal products.

At BIPs, vehicle license number and registry number are recorded for live-haul vehicles (horses, cattle, small ruminants) or agricultural-related vehicles (farm equipment) when exiting Spain for third countries. The empty live-haul trucks returning to Spain from the autonomous cities of Ceuta and Melilla or North Africa must arrive with a C&D certificate and pass through the C&D station prior to customs clearance and release back into Spain. When trucks arrive to the C&D station, the official veterinary services of the BIP verify the C&D certificate, visually inspect the truck to verify proper

cleaning of the interior and exterior. If the truck arrives without a C&D certificate, the truck will be re-exported back to the third country. If visibly clean, the truck is disinfected. If not clean (e.g. horse manure), the interior and exterior is thoroughly cleaned and disinfected[9]. Organic material is removed into designated receptacles and disposed of as Category II materials[10]. This service is provided by an authorized C&D company; the company issues the C&D certificate upon completion. Once completed, the trucks are permitted to proceed through customs clearance [3, 4].

Under the Animal Health Law 8/2003, non-compliance of the C&D center or the driver is considered a serious infraction, resulting in suspension (temporary or permanent) of center registration and/or monetary fines. Full details regarding cleaning and disinfection centers can be found in Royal Decree No. 1559/2005 and the *Guide of Good Practices for Vehicle Cleaning and Disinfection Centers* [3].

For non-commercial goods from third countries carried in personal vehicles and passenger baggage, the official veterinary services follow procedures in Commission Regulation (EC) 206/2009. This Regulation lays down rules concerning the introduction of personal consignments of animal-origin products in personal luggage, personal vehicles, or items sent to private persons ordered via mail, telephone or internet. Personal consignments of meat, meat products, milk and milk products are not permitted from outside the EU other than Andorra, the Faeroe Islands, Greenland, Iceland, Liechtenstein, Norway, San Marino and Switzerland. Thus, personal consignments of animal-origin products are subject to inspection and seizure by the official veterinary services or other enforcement officials of the BIP.

For example, at BIP Algeciras, all personal vehicles, passenger vans, and small trucks/buses are sent through customs control. The enforcement officials (Guardia Civil) perform an identity control on each vehicle (passport verification) and ask the driver/passengers to declare agricultural goods or pets in possession. All vehicles are visually or physically inspected for animal-origin products and pets. Inspection canines (trained for meat/milk products) are employed at the customs checkpoint. If pets are present, proper documentation is required to accompany the pet. If documents are not in compliance, the pet(s) will be seized and official veterinary services of the BIP will be notified. Non-compliant pets are either held until resolution of documentation or re-exported back to point of origin. For animal-origin products, the goods are seized, stored in locked freezers, and periodically destroyed as Category I materials. Informational posters advising tourists and travelers not to bring animal-origin products into Spain are posted in airports, rest stops, and BIPs. Additionally, truck drivers are provided with brochures and leaflets regarding the prohibition against personal consignments of animal-origin products from third countries [3, 4].

To further prevent introduction and spread of animal diseases, the ban on feeding food waste to swine in the EU and disposal of international catering waste from cruise ships, airports, etc. is regulated by the Commission Regulation (EC) No. 1069/2009 and Commission Regulation (EU) 142/2011 implemented by

[9] From North Africa, only horses are permitted to enter the EU. Upon arrival, the horses are unloaded into the live animal holding area of the BIP for diagnostic sampling, food and water. At intake, each horse undergoes the document and identity check and its hooves are disinfected. The horses remain in the stalls while the truck undergoes C&D. Once the C&D is complete, the horses are re-loaded and processed through custom clearance.
[10] In Commission Regulation (EC) 1069/2009, animal by-products are categorized into Category I, II, or III to reflect the level of risk to public and animal health arising from those animal by-products. The assigned category determines the disposal and use of the animal by-product material. Category I material is considered to pose the highest risk to public and animal health and has the most stringent disposal and use requirements.

Royal Decree No. 50/2018. Swill feeding or garbage feeding to swine is prohibited in the EU. Catering waste from cruise ships and airports is destroyed as Category I materials. Collectively, these measures are in place to control and prevent incursions and spread of animal diseases that can be transmitted through animal-origin products.

#### 7.2.9 Hazard entry conclusions

APHIS concludes that Spain's MAPA has an appropriate veterinary infrastructure and legal authority to carry out the animal health activities necessary to maintain the health and safety of Spain's livestock populations and animal products. Spain has an effective system for livestock movement control within the country and as well as traceability of animals and animal products transiting through the territory. As an EU Member State, Spain effectively implements the movement requirements for intra-EU trade through TRACES and related EU legislation. Furthermore, APHIS concludes that Spain (through EU and national legislation) imposes an effective system of import controls for animals and animal products from third country (non-EU) trade partners. This system includes harmonized EU legislation for importation from approved export establishments for animals and animal products, and a harmonized system of import requirements for verification and inspection at BIPs. Spain also imposes stringent cleaning and disinfection requirements for agricultural vehicles, conducts inspections for imported agricultural goods in personal vehicles and baggage, prohibits swill feeding, and properly disposes of international catering waste; all measures are in place to prevent the inadvertent introduction of hazards. If an incursion of disease occurs, the system of movement documentation (SITRAN and TRACES), livestock and holding registration, and individual or group identification would be able to identify vulnerable animals and animal products and remove them from the market chains, including the U.S. export channels. Collectively, these controls form an effective barrier to introduction of the hazards into Spain (and the EU) and, subsequently, into the United States.

### 7.3 Likelihood of hazard detection, response, and notification

#### 7.3.1 Surveillance

For domestic swine, Royal Decree No. 599/2011 establishes the National Sanitary Surveillance Program for Domestic Swine for CSF, SVD and ASF. The surveillance program's main objective is to demonstrate the absence of the diseases. The program includes a passive surveillance component, based on early detection and notification by producers and private veterinarians of any suspect case to the official veterinary services of the AC, and a targeted active surveillance component of serological sampling based on the swine census of each AC. Due to the de-listing of SVD by the OIE and the historical absence of disease in Spain, SVD was removed from the active surveillance program per Ministerial Order APA/841/2019. SVD remains a reportable disease; thus, part of the passive surveillance system [3, 4].

**Active surveillance**

Active surveillance has the following components: 1) periodic serological sampling of a sample of the population so that it is representative of the national swine census; 2) serological, virological and clinical surveillance in intra-EU and third-country animal movements; 3) surveillance in slaughterhouses; and 4) wildlife surveillance (wild boar). The surveillance consists of periodic serological sampling performed according to the swine census in each AC. Swine holdings registered in REGA with 10 or greater breeding sows and fattening holdings with 20 or greater pigs are the main target of surveillance sampling.

The sampling scheme is stratified in two stages. First, holdings are selected in proportion to the number of holdings of each AC. Secondly, in each AC, the holdings are selected on the basis of the risk of infection. Risk-based factors include introduction of live animals on the holding, especially those receiving live animals from intra-EU trade; the use of genetic material from EU or third countries; and the productive system and type. The sample size allows the detection of ASF if the prevalence is greater than 5% with 95% confidence interval and the detection of CSF if the prevalence is 15% with 95% confidence interval. Each year, a total of 1,200 holdings are sampled among all the ACs resulting in 70,800 and 11,400 serological samples for ASF and CSF, respectively. For ASF and CSF, the regional (AC) laboratory performs screening testing with enzyme-linked immunosorbent assays (ELISA). For confirmatory testing of ASF, NRL performs reverse transcriptase polymerase chain reaction (PCR) on virological samples and indirect immunoperoxidase (IPT) on serological samples. For confirmatory testing of CSF, NRL performs real-time reverse transcriptase PCR on virological samples and neutralizing peroxidase-linked assay (NPLA) on serological samples. Results are provided to the veterinary services of the AC via email or online systems. NRL reports all positive findings of reportable diseases directly to MAPA.

Similarly, surveillance at nine slaughterhouses is conducted by post-mortem inspection targeted specifically at hemorrhagic lesions. If compatible lesions are identified on a carcass, an investigation is conducted to rule out suspicion of ASF or CSF. If the investigation cannot rule out these diseases, virological samples are sent to NRL for diagnostic laboratory testing. Slaughter facilities are selected according to the number of pigs slaughtered per year and the production type (intensive versus outdoor/Iberian). For slaughterhouses, a total of 26,100 carcasses are inspected annually.

For wild boar, the National Surveillance Program for Wild Boar is based on sampling from wild boar killed in hunting grounds. The objective of the surveillance program is to demonstrate absence of disease of ASF, CSF, and SVD in wildlife and to monitor the epidemiological situation of other diseases affecting wildlife (e.g., Aujeszky disease, tuberculosis, etc.). Each AC is assigned a minimum number of wild boar to be sampled each year based on the estimated wild boar density in the region. The sample size aims for disease detection if the prevalence is greater than 5% with 95% confidence interval with a minimum of 2,070 samples per year. The program also includes a passive surveillance component with mandatory reporting of dead wild boar carcasses and suspect or sick wild boar to the official veterinary services of the AC [3, 4].

Active surveillance data is provided in the Appendix V.

**Passive surveillance**

For all diseases under review, passive surveillance is an important component of the overall national surveillance system for early disease detection. The passive surveillance system is based on two key pillars: 1) study and recognition of clinical symptoms in different susceptible species, and 2) immediate notification to official veterinary services of any suspect case. Passive surveillance performed for the diseases under review is in compliance with international rules established by the OIE and the EU legislation, and is equivalent to strategies used in other Member States [3, 4].

Compulsory reporting to competent veterinary authorities for the diseases under review is mandatory under the Animal Health Law 8/2003 and Royal Decree No. 526/2014. Disease reporting is the responsibility of veterinarians, paraprofessionals, producers, livestock and poultry owners, and the

general public in Spain. Reporting is made to the official veterinary services of the AC where the holding is located. Upon receiving a report of suspect disease, the official veterinary services of the AC investigates the report and pursues the appropriate actions, including visiting the holding, conducting examinations for signs of clinical illness, taking diagnostic samples, and/or implementing temporary movement restrictions or quarantine [3].

For FMD, seven suspect cases were reported in 2016; six were reported in 2017; and none were reported in 2018. Overall, the official veterinary services took 119 samples that were confirmed to be negative by the NRL. For CSF, 3 suspect cases were reported under the passive surveillance system; two in 2017, one in 2018, and none in 2016. Samples were confirmed to be negative to CSF (and ASF) by the NRL. For SVD, no suspect cases have been reported in the last 3 years. Samples taken from suspect cases under passive surveillance are tested by ELISA at official regional laboratories. In the case of non-negative results, confirmatory testing is conducted at NRL using IPT or NPLA for serological samples and using PCR and partial sequencing for virological samples. Results are provided to the veterinary services of the AC via email or online systems. NRL reports all results of reportable diseases directly to MAPA [3].

**Ancillary activities for disease detection, prevention and awareness**

In addition to the active and passive surveillance systems for the diseases under review, Spain bolsters their disease detection strategy through various means with awareness campaigns to the public and agricultural stakeholders; coordinated disease control activities with hunting associations and forestry agencies; development of national strategic plans for biosecurity in swine holdings; development of strategies for wild boar management; enforcement of regulations regarding the illegal movement of wild boar; and conducting emergency response trainings and simulation exercises on the diseases of concern [3, 4]. Collectively, Spain maintains a comprehensive approach towards detection, prevention and awareness, both in commercial swine holdings and wild boar, for the diseases under review.

### 7.3.2 Animal disease investigation and response

As discussed above, compulsory reporting to competent veterinary authorities for the diseases under review is mandatory under the Animal Health Law 8/2003 and Royal Decree No. 526/2014. Upon receiving a report of a suspect disease, the official veterinary services of the AC visits the holding, conducts examinations for signs of clinical illness, takes diagnostic samples, and/or implements temporary movement restrictions or quarantine. Diagnostic samples are sent to the authorized animal health laboratory in the AC for testing. Confirmatory testing is conducted at the NRL. On average, sampling and reporting times can be done in 2 days for PCR and ELISA; 5 days for seroneutralization; and 1-2 days for confirmatory testing at the NRL. If deemed necessary, diagnostic samples can be sent directly from the farm to NRL to shorten the diagnostic testing and confirmation time. If a positive detection of CSF, FMD or SVD is confirmed, NRL reports the findings directly to MAPA; MAPA, in turn, reports the results to the official veterinary services of the AC, triggering the emergency response protocol outlined in the National Coordinated Alert Plan [3].

The legal basis for the emergency response framework to a disease outbreak is established in the Animal Health Law 8/2003. Several Royal Decrees form the regulatory infrastructure for Spain's disease emergency response system, including [3]:

- Royal Decree No. 526/2014 containing the list of notifiable animal diseases and mandatory reporting;

- Royal Decree No. 1440/2001 establishing the system for animal health alerts;
- Royal Decree No. 1071/2002 for control measures for CSF;
- Royal Decree No. 2179/2004 for control measure for FMD; and
- Royal Decree No. 650/94 for control measures for SVD.

Upon confirmation of a disease outbreak, the chain of command for the disease incident, consisting of decision-making bodies, advising bodies, and executive bodies, is immediately stood up. In command, the RAVSE Committee (*Red de Alerta Sanitaria Veterinaria*, RASVE) consists of members from SGSHT/DGSPA/MAPA, the ACs, and NRL. The RASVE Committee coordinates emergency response measures through the National Emergency Center which in turn coordinates with the Local Crisis Center of the affected AC(s); expert groups, monitoring units and NRL; and the Rapid Intervention/Assistance System. The roles and responsibilities of the official veterinary services at national, regional and local levels are described in the National Coordinated Alert Plan. A flow chart summarizing the communication and coordination of multi-sectoral agencies and units is provided below [3].

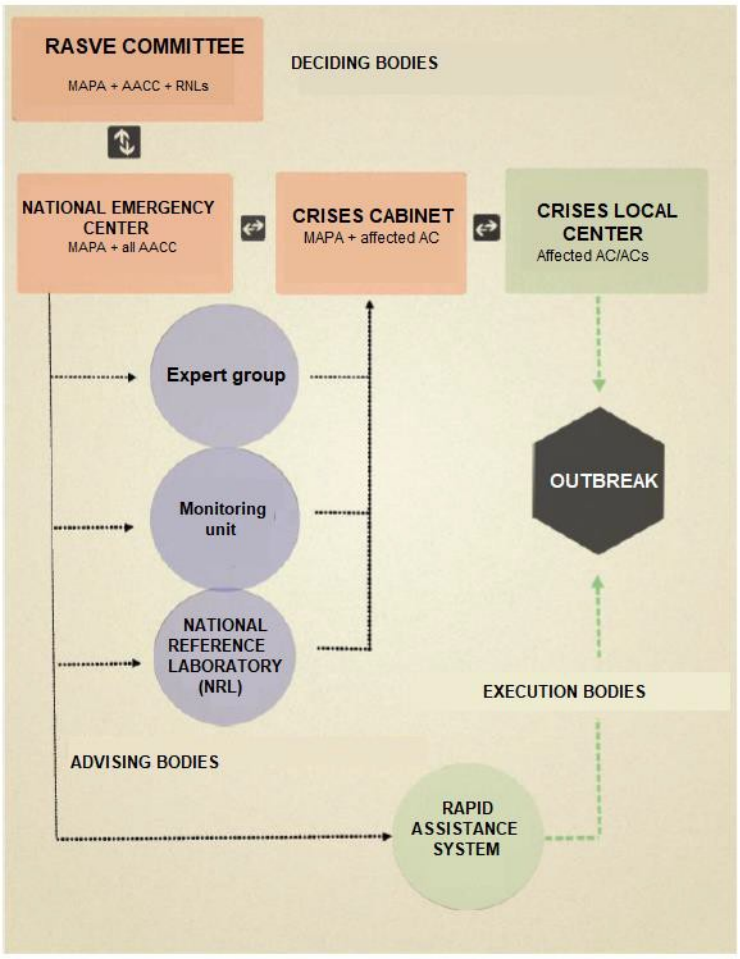


**Figure 2: Organization of incident command units for disease outbreak events**

Further details of emergency response actions are laid out in each disease specific operational disease manual. Spain has emergency contingency plans for each of the diseases under review, each providing standard operating procedures to investigate disease cases and activate emergency response measures

to control and eradicate the disease. Financial support, including indemnity, comes from the EU and MAPA's national budget as well as the AC in which the outbreak occurs. For an outbreak of a foreign animal disease, a national emergency can be declared, and additional special funding can be allocated towards the control and eradication of the disease. In some cases, the emergency efforts are co-financed by the EU under Commission Regulation (EU) No. 652/2014 [3].

### 7.3.3 Reporting history

Compulsory reporting to competent veterinary authorities for the diseases under review is mandatory under the Animal Health Law 8/2003 and Royal Decree No. 526/2014. Disease reporting is the responsibility of veterinarians, paraprofessionals, producers, livestock and poultry owners, and the general public in Spain. Notification must be made to the veterinary services of the AC which then communicates directly to SGSHT/DGSPA/MAPA at the central level. Failure to report a disease of mandatory declaration would be classified as a severe or very severe infraction and can result in administrative (monetary) sanctions [3].

MAPA reports to the European Commission and its Member States through the *Red de Alerta Sanitaria Veterinaria* (RASVE) system (Veterinary Health Alert System Database) and the EU's Animal Disease Notification System, ADNS (legal basis created under Council Directive 82/894/EEC). RASVE[11] was created by Royal Decree No. 1440/2001, with the aim of preventing the entry of infectious diseases, preventing their spread and eradicating those already present. Concurrently, MAPA reports to the OIE. For the diseases under review, notification must be made within 24 hours of confirmation [3].

Spain has been an active member of OIE since 1924. As a member of the OIE, Spain has a history of consistent biannual reporting of hazards. In the case of reportable animal disease events, MAPA provides an immediate notification to the OIE within 24 hours of a laboratory confirmation. Information on the OIE website indicates Spain has promptly reported the animal health status of the country to OIE since at least 1996, the earliest available online reporting information [1, 3].

### 7.3.4 Export controls

**Overview of Spain's export process**

Spain's legal authority for the exportation of animals and animal products comes from the Animal Health Law 8/2003. The regulatory procedures and the official veterinary certification requirements for exportation of animal and animal products are laid out in Royal Decree No. 993/2014. This regulation also standardizes the conditions that must be met by establishments involved with exports as well as databases and recordkeeping managed by MAPA and MSCBS. Similarly, it coordinates the various competent authorities at the national, AC, and local levels involved in the export certification process. All exports of animals and animal products to third countries (including the United States) are subject to veterinary inspection and must comply with the animal health requirements of the third country of destination. Establishments in Spain involved with exporting animals and animal products to third

[11] RASVE is an online network that integrates animal health information from national, EU and international sources and disseminate this information in the form of alerts to decision-makers and the general public. It collates information from the epidemiological surveillance networks of the ACs and ADNS and integrates with EU's TRACES and Spain's SITRAN. This allows for quick, efficient and coordinated action as it facilitates decision-making of emergency actions for the prevention, control and eradication of animal diseases.

countries must comply with EU regulations as well as the requirements and conditions agreed upon with the third country of destination [3, 4].

The export of animals and animal products requires the presentation of a veterinary health certificate to the competent authorities of the destination country. The veterinary health certificate may be generic (where the importing country does not require specific requirements) or country-specific (where the importing country negotiates the requirements and it is necessary to agree upon a certificate model). To start the export process, exporters must consult the requirements of the importing country to determine if there is an agreement to export the commodity; if the importing country requires the commodity come from an authorized establishment; and what type of export certificate(s) and other documentation is required by the importing country. Next, a request for an inspection from official veterinary services at the regional/local level at the establishment or holding for the issuance of the veterinary health certificate (e.g., *Sanitary Certificate for Export of Food Products*) is made. This veterinary health certificate must meet EU and third country requirements for exportation of animals and animal products. The sanitary certificate accompanies the shipment to the designated BIP.

Concurrently, the exporter applies for export approval and certification through MAPA's online CEXGAN[12] application. On the public interface, CEXGAN provides access to veterinary (export) health certificates, the list of approved establishments, and information on the export procedure, including EU and national legislation regarding the export process. On the secure interface, exporters, establishment operators, and official veterinary services have access to the management and issuance of documentation as well as traceability of trade activities into and out of Spain.

Through CEXGAN, the exporter will obtain information on the additional documentation to be provided to the official veterinary services at the BIP. CEXGAN allows for electronic approval and signature of export documentation. If the documentation is not electronically signed in CEXGAN by the official veterinarian responsible for issuing it, the exporter must submit the original documents to the official veterinary inspector at the BIP in order to complete the export process. BIP inspectors perform document and identity checks on all (100%) export applications and physical checks on a sampling of applications (dependent on risk-based determinants of the commodity). Once completed, the BIP inspector issues (or rejects) the export certification documents and notifies the exporter through the CEXGAN system.

Several mechanisms are in place to prevent tampering or circumventing the export certification process. These mechanisms include negotiating country-specific export certificate models; integration of the CEXGAN system which assigns a unique serial number to each transaction and coordinates export controls among the exporter, the approved establishment, and the official veterinary services of the BIP; the use of security paper for official health certificates; recognized signatures of official veterinary inspectors; and harmonized stamps and serialized container seals, both under the control of the official veterinary inspectors [3, 4].

[12] CEXGAN is Spain's foreign trade database network for coordinating and traceability of trade activities into and out of the territory.

**Exports to the United States**

Spain is currently eligible to export meat products to the United States. Spain currently exports the following categories of raw and further processed pork products to the United States: intact and not intact raw products; fully cooked, not shelf stable products; not heat-treated, shelf stable products; and heat-treated, not fully cooked, not shelf stable. A complete list of eligible products can be found HERE. The import data on pork products from Spain to the United States are provided in the Appendix VI. Spain has not exported fresh, chilled or frozen bovine or small ruminant products in the previous 3 years (2016-2018). Spain has not exported live animals (swine, cattle, sheep or goats) to the United States in the previous 3 years (2016-2018) [10].

For exportation of meat products, Spain's competent authority for the food safety inspection system is the MSCBS. The Sub-directorate General of Foreign Health (*Subdirección General de Sanidad Exterior*) under the Directorate General for Public Health, Quality and Innovation (*Dirección General de Salud Pública, Calidad e Innovación*) is responsible for regulating inspection activities related to the export of meat products to the United States. At the AC level, veterinary supervisors provide direct supervisory authority over the establishments certified to export to the United States and are also responsible for conducting periodic supervisory reviews at the establishments certified to export to the United States. At the local level, the in-plant inspection personnel, official veterinarians of MSCBS, perform official controls and inspection activities continuously during slaughter operations and with regular frequency during processing operations [11].

In Spain, only official veterinarians are authorized to sign export certification documents. For live animals, the official veterinarians of the AC (under the supervision and oversight of MAPA) are in charge of conducting inspections or diagnostic testing for export of live animals and issuing the animal health certificates for export. For the export of meat products, the official veterinarians in the establishments (under the supervision and oversight of MSCBS) are authorized to sign and issue the sanitary certificate (e.g., *Sanitary Certificate for Export of Food Products*), verifying adherence of food safety requirements. For the veterinary services at the BIP, the official veterinarians (under the supervision and oversight of MAPA) are authorized to issue USDA's *Official Health Inspection Certificate* after completion of the document, identity, and physical checks. In order to qualify for employment and issue/sign health certificates, official veterinarians under MAPA and MSCBS must pass formal examinations and undergo 200 hours of training (divided over weeks to months) on animal health activities [3, 4].

In June 2019, USDA Food Safety and Inspection Service (FSIS) performed an on-site equivalence verification audit on a sample of eleven approved export establishments (out of 26 approved establishments) in Spain for pork products as well as one government microbiological laboratory and one government national reference chemical residue laboratory. The purpose of the audit was to determine whether Spain's food safety system governing raw and further processed pork products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. The audit did not find any significant findings that represented an immediate threat to public health and the approved facilities and food safety enforcement systems thereof remain in good standing [11].

### 7.3.5 Hazard detection, response, and reporting conclusions

Spain has provided supporting documentation to demonstrate that surveillance systems are in place to rapidly detect the hazards under review, promptly notify the United States and/or the OIE of hazard events, and respond to the outbreak event sufficiently to prevent introduction of the hazards into the United States. Information supplied by Spain, observations made on the site visit by the APHIS/CFIA delegation, and resources made publicly available by MAPA demonstrate that Spain has implemented and maintained comprehensive surveillance and awareness programs capable of detecting the hazards under review. The national surveillance plans for the diseases of concern appear appropriate given the disease history, disease prevalence, and risk of disease introduction through trade, animal movement, and other means.

Furthermore, Spain appears to have adequate animal disease detection mechanisms, investigation procedures, emergency response measures, and control programs for the diseases under review. Animal disease events are investigated by official veterinarians of the AC with diagnostic support from the NRL and oversight by MAPA, the competent veterinary authority. Protocols for response to suspected animal disease events are comprehensive and demonstrate MAPA's authority to contain disease spread. Historically, Spain has promptly reported disease occurrence to the EU, trading partners, and the OIE.

Finally, the documentation provided by Spain and publicly available resources, the observations made during the APHIS/CFIA site visit, and the recent USDA FSIS equivalence verification audit demonstrates Spain's capability to properly certify animal and animal products for export to the United States and to prevent the export of infected animals or contaminated animal products to the United States should a disease incursion occur.

# 8 Review conclusions and recommendations

Based on documentation provided by Spain in its submissions to USDA APHIS, observations made by the APHIS/CFIA delegation on the site visit, and information available on MAPA's website and from the OIE and other publicly available sources, APHIS concludes that Spain is free of the hazards under review, conducts sufficient control measures to prevent their entry, and, in the event of a hazard incursion, Spain is capable of detecting the hazard and containing its spread, and will promptly report them to trading partners and the OIE, taking necessary measures to prevent their export to the United States.

Based on the favorable conclusions of APHIS' review of Spain's animal health statuses, APHIS recommends that the current conferred statuses and import mitigations for CSF, FMD, and SVD are appropriate. Recognition of these statuses will be maintained until the next APHIS review or until a change in Spain's animal health status is reported.

# Appendix I

## Control Systems for Animal Health in Spain

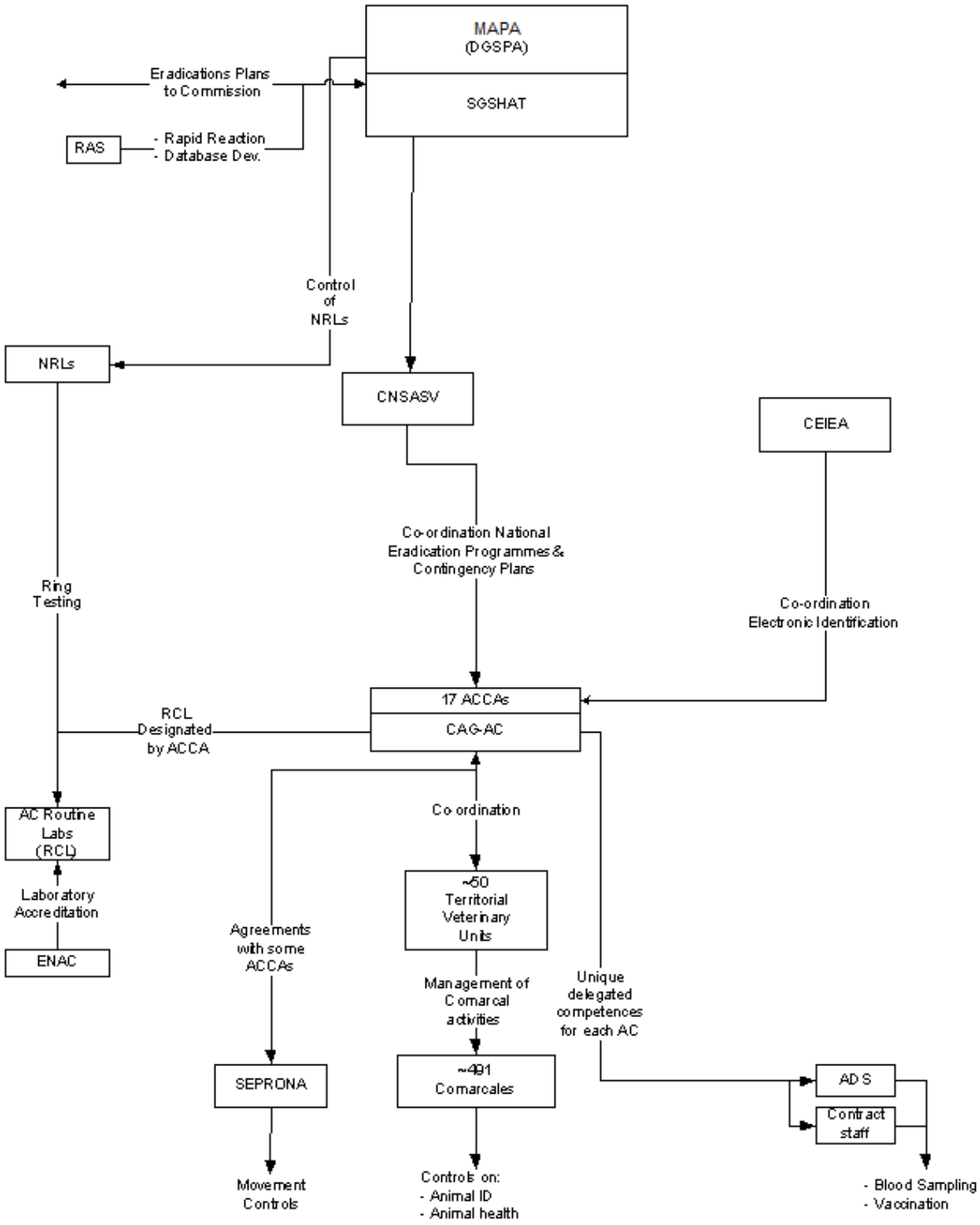


**Figure 3: Flow chart on coordination of animal health systems in Spain**

# Appendix II

## Legal acts, regulations and orders

**Table 2: Legal acts and regulations pertaining to FMD, CSF and SVD**

| Animal Health Activity | Brief Description | Authorizing Legal Act(s) or Regulation(s) | Date Last Amended |
|---|---|---|---|
| **Disease notification** | Notification of confirmed outbreaks of FMD, CSF, SVD, ASF within the territory of Spain | Animal Health Law 8/2003<br><br>Regulation (EU) 2016/429, "Animal Health Regulation"<br><br>Royal Decree No. 526/2014, List of Notifiable Animal Diseases<br><br>Council Directive 2003/85/EC, adapted to Spanish legal frame through Royal Decree No. 2179/2004 (Control measures for FMD)<br><br>Council Directive 2001/89/EC, adapted to Spanish legal frame through Royal Decree No. 1071/2002 (Control measures for CSF)<br><br>Council Directive 1992/119/EEC, adapted to Spanish legal frame through Royal Decree No. 650/94 (Control measures for SVD)<br><br>Spanish Contingency Plans (Operational Manuals) for FMD, CSF, SVD<br><br>National Sanitary Surveillance Program in Swine Livestock (RD 599/2011)<br><br>Royal Decree No. | Royal Decree No. 2179/2004 last updated June 17, 2013, through Royal Decree No. 402/2013.<br><br>Ministerial Order AAA/2444/2015, with preventive emergency measures due to FMD in Magreb, last modified by Order APM/607/2018. |
| **On-farm inspections** | Control and inspection activities performed by private veterinarians or official veterinarians in farms and holdings | | |

| | | | |
|---|---|---|---|
| | | 1440/2001 (system for veterinarian sanitary alerts) | |
| **Import, export, and internal movement controls** | Control and inspection activities to be performed on the movement of live animals and products within Spain, between EU Member States, and to/from third countries | Animal Health Law 8/2003<br><br>Regulation (EU) 2016/429, "Animal Health Regulation"<br><br>Internal live-animal movements within Spain: Royal Decree No. 728/2007 (REMO)<br><br>Council Directive 90/425/EEC, related to control of animal movement and products within European Union, adapted to Spanish frame by Royal Decree No. 1316/1992<br><br>Council Directive 89/662/EEC, related to control of animal products within European Union, adapted to Spanish frame by Royal Decree No. 49/1993<br><br>Council Directive 91/496/EC, related to control of live animals to be imported from third countries, adapted to Spanish frame by Royal Decree 1430/1992<br><br>Council Directive 97/78/EC, related to control of animal products to be imported from third countries, adapted to Spanish frame by Royal Decree 1977/1999 | Ministerial Order AAA/2444/2015, with preventive emergency measures due to FMD in Magreb, last modified by Order APM/607/2018. |

| | | | |
|---|---|---|---|
| | | Royal Decree No. 993/2014, related to control of live animals and animal products to be exported to third countries<br><br>Regulation (EU) 2017/625,related to official control | |
| **Quarantine of animals or farms** | Maintaining animals under official quarantine in order to prevent the transmission of animal disease(s) | Animal Health Law 8/2003<br><br>Regulation (EU) 2016/429, "Animal Health Regulation"<br><br>Royal Decree No. 526/2014, related to the list of Notifiable Animal Diseases<br><br>Council Directive 2003/85/EC, adapted to Spanish legal frame through Royal Decree No. 2179/2004 (Control Measures for FMD)<br><br>Council Directive 2001/89/EC, adapted to Spanish legal frame through Royal Decree No. 1071/2002 (Control Measures for CSF)<br><br>Council Directive 1992/119/EEC, adapted to Spanish legal frame through Royal Decree No. 650/94 (Control Measures for SVD)<br><br>Spanish Contingency Plans (Operational Manuals) for FMD, CSF, SVD | Royal Decree No. 2179/2004 last updated June 17th, 2013, through Royal Decree No. 402/2013<br><br>Ministerial Order AAA/2444/2015,with preventive emergency measures due to FMD in Magreb, last modified by Order APM/607/2018 |
| **Vaccination** | Vaccination program(s) to be permitted if deemed necessary (protective/suppressive strategies) | | |
| **Surveillance** | Active and passive surveillance activities to verify absence of disease and/or to increase the detection of disease incursion(s) | | |
| **Control and eradication of animal disease(s)** | Control measures applied to control and eradicate outbreaks of animal disease(s) | | |

| | | | |
|---|---|---|---|
| | | National Sanitary Surveillance Program in Swine Livestock (RD 599/2011)<br><br>Royal Decree No. 1440/2001 (system for veterinarian sanitary alerts) | |
| **Animal identification and farm registration** | Regulations pertaining to the registration of farms and the identification, both individuals and groups, of species susceptible to FMD, CSF, SVD, ASF | Identification of bovines: Royal Decree No. 1980/1998 & Regulation (EU) 1760/2000<br><br>Identification of ovines/caprines: Royal Decree 685/2013<br><br>Identification of swine: Royal Decree No. 205/1996.<br><br>Farm registration: Royal Decree 479/2004 | Royal Decree No. 1980/1998 last updated on December 6, 2008<br><br>Royal Decree No. 685/2013 last updated December 17, 2016<br><br>Royal Decree No. 205/1996 last updated September 30, 2013<br><br>Royal Decree No. 470/2004 last updated July 29, 2014 |
| **Emergency response activities** | Activities to be carried out in case of emergency outbreak(s) of animal diseases, including seizure, depopulation, and indemnity | Animal Health Law 8/2003<br><br>Regulation (EU) 2016/429, "Animal Health Regulation"<br><br>Royal Decree No. 526/2014, related to the list of Notifiable Animal Diseases<br><br>Council Directive 2003/85/EC, adapted to Spanish legal frame through Royal Decree No. 2179/2004 (Control Measures for FMD)<br><br>Council Directive 2001/89/EC, adapted to Spanish legal | Ministerial Order AAA/2444/2015, with preventive emergency measures due to FMD in Magreb, last modified by Order APM/607/2018 |

| | | | |
|---|---|---|---|
| | | frame through Royal Decree No. 1071/2002 (Control Measures for CSF)<br><br>Council Directive 1992/119/EEC, adapted to Spanish legal frame through Royal Decree No. 650/94 (Control Measures for SVD)<br><br>Spanish Contingency Plans (Operational Manuals) for FMD, CSF, SVD<br><br>Royal Decree No. 1440/2001 (system for veterinarian sanitary alerts) | |

In Spain, there are no derogations allowed by the European Commission to the above statutes, regulations, or ministerial orders.

# Appendix III


Figure 4: Map of official entry ports in Spain
*Figure key: PIF Puerto = BIP at port; PIF Aeropuerto = BIP at airport; PE Vegetales = point of entry for plants*

# Appendix IV

## List of BIPs in Spain approved for entry of animal commodities [3]

**Table 3: Information and data for BIPs in Spain**

| **Autonomous Community in Spain** | | GALICIA | | | | | | | ANDALUCÍA |
|---|---|---|---|---|---|---|---|---|---|
| **Province in Spain** | | A CORUÑA | | | PONTEVEDRA | | | | ALMERÍA |
| **Name of entry point** (*use one column for each entry point; add columns if necessary*) | | A Coruña – Laxe (Port) | Santiago de Compostela (Airport) | Ferrol (A Coruña) (Port) | Vigo (Airport) | Vigo (Port) | Marín (Port) | Vilagarcia de Arousa (Port) | Almería (Port) |
| Number of days open each week | | 5 | 5 | 5 | 7 | 7 | 5 | 5 | 6 |
| Hours of operation | | 8 | 8 | 8 | 24 | 24 | 8 | 8 | 12 |
| Staff Nos. | Total | 7 | | | 27 | | | | 3 |
| | Veterinarians | 7 | | | 20 | | | | 2 |
| | Veterinary technicians | 0 | | | 3 | | | | 1 |
| | Administrative | 0 | | | 4 | | | | 0 |
| Eligible commodities (such as live animals, meat/products, semen/ova, etc.) | | BIP, PE, DPE | PE, DPE | PE, DPE | PE, DPE | BIP, PE, DPE, DPI | BIP, PE, DPE | BIP, PE, DPE, DPI | BIP, PE, DPE, DPI, PEV |
| No. consignments received* | | 1.332 | --- | 9 | 13.253 | | 3.649 | 248 | 6.929 |
| No. refused entry† | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

* Total number of consignments requiring veterinary inspection received at the entry point in the past 12 months.

† Number of live swine or pork products received that were seized, returned, or otherwise denied entry into the region.

| **Autonomous Community in Spain** | | ANDALUCÍA | | | | | | | MADRID |
|---|---|---|---|---|---|---|---|---|---|
| **Province in Spain** | | CÁDIZ | | MÁLAGA | | HUELVA | SEVILLA | | MADRID |
| **Name of entry point** (*use one column for each entry point; add columns if necessary*) | | Algeciras (Port) | Cádiz (Port) | Málaga (Airport) | Málaga (Port) | Huelva (Port) | Sevilla (Airport) | Sevilla (Port) | Madrid (Airport) |
| Number of days open each week | | 7 | 5 | 5 | 5 | 5 | 5 | 5 | 7 |
| Hours of operation | | 24 | 8 | 8 | 8 | 8 | 8 | 8 | 24 |
| Staff Nos. | Total | 47 | 3 | 6 | | 2 | 3 | | 33 |
| | Veterinarians | 29 | 3 | 5 | | 2 | 3 | | 26 |
| | Veterinary technicians | 7 | 0 | 1 | | 0 | 0 | | 3 |
| | Administrative | 8 | 0 | 0 | | 0 | 0 | | 4 |
| Eligible commodities (such as live animals, meat/products, semen/ova, etc.) | | BIP, PE, DPE, PEV | BIP, PE, DPE | BIP, PE, DPE | BIP, PE, DPE, DPI | PE, DPE | PE, DPE | BIP, PE, DPE, DPI | BIP, PE, DPE |
| No. consignments received* | | 62.498 | 205 | 110 | 481 | 220 | 45 | 485 | 25.856 |
| No. refused entry† | | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 6 |

* Total number of consignments requiring veterinary inspection received at the entry point in the past 12 months.

† Number of live swine or pork products received that were seized, returned, or otherwise denied entry into the region.

| **Autonomous Community in Spain** | | CATALUÑA | | | COMUNIDAD VALENCIANA | | | | MURCIA |
|---|---|---|---|---|---|---|---|---|---|
| **Province in Spain** | | BARCELONA | | TARRAGONA | ALICANTE | CASTELLÓN | VALENCIA | | MURCIA |
| **Name of entry point** (*use one column for each entry point; add columns if necessary*) | | Barcelona (Airport) | Barcelona (Port) | Tarragona (Port) | Alicante (Port) | Castellón (Port) | Valencia (Airport) | Valencia (Port) | Cartagena (Port) |
| Number of days open each week | | 7 | 7 | 5 | 5 | 5 | 7 | 7 | 7 |
| Hours of operation | | 24 | 24 | 8 | 24 | 8 | 24 | 24 | 24 |
| Staff Nos. | Total | 32 | | 7 | 7 | 1 | 30 | | 5 |
| | Veterinarians | 21 | | 5 | 5 | 1 | 21 | | 3 |
| | Veterinary technicians | 5 | | 2 | 1 | 0 | 5 | | 0 |
| | Administrative | 6 | | 0 | 1 | 0 | 4 | | 2 |
| Eligible commodities (such as live animals, meat/products, semen/ova, etc.) | | BIP, PE, DPE | BIP, PE, DPE, DPI | BIP, PE, DPE, DPI | BIP, PE, DPE, DPI | BIP, PE, DPE, PEV | BIP, PE, DPE | BIP, PE, DPE, DPI | BIP, PE, DPE, DPI |
| No. consignments received* | | 1.791 | 17.722 | 2.997 | 1.398 | 514 | 161 | 36.621 | 1.940 |
| No. refused entry† | | 1 | 2 | 0 | 0 | 0 | 0 | 2 | 0 |

* Total number of consignments requiring veterinary inspection received at the entry point in the past 12 months.

† Number of live swine or pork products received that were seized, returned, or otherwise denied entry into the region.

| **Autonomous Community in Spain** | | ASTURIAS | | PAÍS VASCO | | | ISLAS CANARIAS | | |
|---|---|---|---|---|---|---|---|---|---|
| **Province in Spain** | | ASTURIAS | | VIZCAYA | | GÜIPUZCOA | GRAN CANARIA | SANTA CRUZ DE TENERIFE | |
| **Name of entry point** (*use one column for each entry point;add columns if necessary*) | | Avilés (Port) | Gijón (Port) | Bilbao (Airport) | Bilbao (Port) | San Sebastián (Airport) | Las Palmas de Gran Canaria (Port) | Santa Cruz de Tenerife (Port) | Tenerife Sur (Airport) |
| Number of days open each week | | 5 | 5 | 7 | 7 | 5 | 7 | 5 | 5 |
| Hours of operation | | 8 | 8 | 24 | 24 | 8 | 12 | 12 | 8 |
| Staff Nos. | Total | 5 | | 12 | | 1 | 25 | 8 | |
| | Veterinarians | 2 | | 9 | | 1 | 15 | 3 | |
| | Veterinary technicians | 3 | | 1 | | 0 | 4 | 1 | |
| | Administrative | 0 | | 2 | | 0 | 6 | 4 | |
| Eligible commodities (such as live animals, meat/products, semen/ova, etc.) | | PE | BIP, PE, DPE | PE, DPE | BIP, PE, DPE, DPI | PE, DPE | BIP, PE, DPE, DPI | BIP, PE, DPE, DPI | BIP, PE, DPE |
| No. consignments received* | | 1.338 | --- | 12 | 4.657 | --- | 1.931 | 1.786 | 14 |
| No. refused entry† | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

* Total number of consignments requiring veterinary inspection received at the entry point in the past 12 months.

† Number of live swine or pork products received that were seized, returned, or otherwise denied entry into the region.

| **Autonomous Community in Spain** | | ISLAS BALEARES | | CANTABRIA | |
|---|---|---|---|---|---|
| **Province in Spain** | | ISLAS BALEARES | | CANTABRIA | |
| **Name of entry point** (*use one column for each entry point; add columns if necessary*) | | Palma de Mallorca (Airport) | Palma de Mallorca (Port) | Santander (Airport) | Santander (Port) |
| Number of days open each week | | 5 | 5 | 5 | 5 |
| Hours of operation | | 8 | 8 | 8 | 8 |
| Staff Nos. | Total | 1 | | 2 | |
| | Veterinarians | 1 | | 2 | |
| | Veterinary technicians | 0 | | 0 | |
| | Administrative | 0 | | 0 | |
| Eligible commodities (such as live animals, meat/products, semen/ova, etc.) | | PE, DPE | PE, DPE | PE, DPE | PE, DPE |
| No. consignments received* | | --- | --- | 37 | --- |
| No. refused entry† | | 0 | 0 | 0 | 0 |

* Total number of consignments requiring veterinary inspection received at the entry point in the past 12 months.

† Number of live swine or pork products received that were seized, returned, or otherwise denied entry into the region.

# Appendix V

## Swine surveillance data [3, 4]

**Table 4: Active surveillance in swine holdings, 2016 - 2018**

| Year | ASF | | CSF | | SVD | |
|---|---|---|---|---|---|---|
| | No. of inspected holdings | No. of samples | No. of inspected holdings | No. of samples | No. of inspected holdings | No. of samples |
| **2016** | 2,133 | 100,466 | 1,409 | 47,849 | 1,712 | 45,552 |
| **2017** | 2,470 | 92,845 | 1,523 | 34,149 | 1,755 | 45,580 |
| **2018** | 2,790 | 92,137 | 1,630 | 56,421 | --- | --- |

**Table 5: Active surveillance in swine slaughterhouses, 2018**

| Slaughterhouse region (AC) | No. of holdings | No. of animals |
|---|---|---|
| Aragón | 98 | 2,842 |
| Castilla La Mancha | 99 | 3,021 |
| Castilla y León | 208 | 5,010 |
| Cataluña | 106 | 18,258 |
| Extremadura | 120 | 3,480 |
| Galicia | 105 | 3,045 |
| Murcia | 100 | 2,900 |
| **TOTAL** | **836** | **38,556** |

**Table 6: Active surveillance data for ASF in wild boar, 2015 - 2018**

| Autonomous Community | No. of ELISA samples 2015 | No. of ELISA samples 2016 | No. of ELISA samples 2017 | No. of ELISA samples 2018 |
|---|---|---|---|---|
| Andalucía | 385 | 236 | 2,377 | 1,043 |
| Castilla-la mancha | 241 | 183 | 582 | 1,013 |
| Castilla y león | 1,837 | 1,900 | 2,030 | 1,517 |
| Aragón | --- | --- | 172 | 167 |
| Cataluña | 679 | 832 | 815 | --- |
| Extremadura | 293 | 348 | 600 | 559 |
| Galicia | 59 | 71 | 50 | --- |
| Madrid | 142 | 247 | 102 | 131 |
| Murcia | 398 | 435 | 311 | 629 |
| Navarra | 62 | 56 | 60 | 148 |
| País vasco | 50 | 16 | 10 | 8 |
| La rioja | 85 | 72 | 112 | 121 |
| Valencia | 184 | --- | 145 | --- |
| Asturias | 478 | 274 | 37 | 391 |
| Cantabria | 23 | 2 | 18 | 9 |
| **TOTAL** | **4,917** | **4,672** | **7,421** | **5,736** |

**Table 7: Active surveillance data for CSF in wild boar, 2015 - 2018**

| Autonomous Community | No. of ELISA samples 2015 | No. of ELISA samples 2016 | No. of ELISA samples 2017 | No. of ELISA samples 2018 |
|---|---|---|---|---|
| Andalucía | 385 | 235 | 131 | 60 |
| Castilla-la mancha | 180 | 193 | 0 | 109 |
| Castilla y león | 1,837 | 1,877 | 2,043 | 1,502 |
| Aragón | --- | 315 | 217 | 167 |
| Cataluña | 677 | 847 | 828 | --- |
| Extremadura | 246 | 348 | 600 | 559 |
| Galicia | 54 | 71 | 50 | --- |
| Madrid | 142 | 247 | 102 | 131 |
| Murcia | 391 | 435 | 295 | 589 |
| Navarra | 62 | 56 | 60 | 146 |
| País vasco | 43 | 103 | 20 | 22 |
| La rioja | 85 | 72 | 112 | 122 |
| Valencia | 191 | --- | 145 | --- |
| Asturias | 478 | 275 | 39 | 67 |
| Cantabria | 24 | 2 | 18 | 13 |
| **TOTAL** | **4,795** | **5,076** | **4,660** | **3,487** |

**Table 8: Active surveillance data for SVD for wild boar, 2015 - 2018**

| Autonomous Community | No. of ELISA samples 2015 | No. of ELISA samples 2016 | No. of ELISA samples 2017 | No. of ELISA samples 2018 |
|---|---|---|---|---|
| Andalucía | 394 | 228 | 84 | 0 |
| Castilla-la mancha | 251 | 183 | 6 | 0 |
| Castilla y león | 1,837 | 1,781 | 0 | 0 |
| Aragón | --- | 314 | 256 | 167 |
| Cataluña | 692 | 839 | 319 | --- |
| Extremadura | 295 | 348 | 600 | 559 |
| Galicia | 59 | 71 | 50 | --- |
| Madrid | 142 | 216 | 102 | 12 |
| Murcia | 64 | 31 | 11 | 0 |
| Navarra | 62 | 56 | 60 | 10 |
| País vasco | 31 | 47 | 11 | 11 |
| La rioja | 85 | 72 | 112 | 0 |
| Valencia | 184 | --- | 144 | --- |
| Asturias | 0 | 296 | 38 | 0 |
| Cantabria | 24 | 2 | 18 | 8 |
| **TOTAL** | **4,120** | **4,170** | **1,811** | **,767** |

# Appendix VI

## Import data of pork products from Spain to the United States

**Table 9: Import data of pork products (fresh, chilled, frozen) from Spain to the United States, kilograms, 2016-2018**

| HTS Description | HTS Number | Year 2016 | Year 2017 | Year 2018 |
|---|---|---|---|---|
| Fresh or chilled retail cuts of ham, shoulders and cuts thereof, with bone in | 0203.12.10 | 308 | 0 | 65,143 |
| Meat of swine NESI, retail cuts, fresh or chilled | 0203.19.20 | 21,294 | 2,700 | 823,583 |
| Meat of swine, NESI, non-retail cuts, fresh or chilled | 0203.19.40 | 0 | 0 | 1,694 |
| Frozen retail cuts of hams, shoulders and cuts thereof, with bone in | 0203.22.10 | 1,148 | 7,161 | 0 |
| Frozen hams, shoulders and cuts thereof, with bone in, other than retail cuts | 0203.22.90 | 27,749 | 28,174 | 63,340 |
| Frozen retail cuts of meat of swine, NESI | 0203.29.20 | 2,216 | 0 | 50,193 |
| Frozen meat of swine, other than retail cuts, NESI | 0203.29.40 | 4,725,191 | 8,493,467 | 7,006,217 |

Source: [10]
NESI = Not elsewhere specified or indicated

**Table 10: Import data of processed pork products (e.g., Serrano hams) from Spain to the United States, kilograms, 2016-2018**

| HTS Description | HTS Number | Year 2016 | Year 2017 | Year 2018 |
|---|---|---|---|---|
| Hams, shoulders and cuts thereof with bone in, salted, in brine, dried or smoked | 0210.11.00 | 563,975 | 898,969 | 1,038,417 |
| Bellies (streaky) and cuts thereof of swine, salted, in brine, dried or smoked | 0210.12.00 | 0 | 0 | 102 |
| Meat of swine other than hams, shoulders, bellies (streaky) and cuts thereof, salted, in brine, dried or smoked | 0210.19.00 | 624,720 | 573,274 | 661,438 |

Source: [10]

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