Risk Analysis:

Risk of Importing Foot-and-Mouth Disease in Susceptible Species and Products from a region of Patagonia, Argentina

Veterinary Services

National Import Export Services

Regionalization Evaluation Services

Updated January 2014

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LIST OF ABBREVIATIONS

APHIS:	Animal and Plant Health Inspection Service
BSL2:	Biosafety Level 2
BSL3:	Biosafety Level 3
CCFyC:	Quarantine, Borders and Certifications Unit
CFR:	United States Code of Federal Regulations
CONALFA:	National FMD Eradication Committee
COPROSA:	Provincial Animal Health Committee
CUIG:	Unique Holding Identification Code
DILACOT:	Laboratories and Technical Control Office
DNFA:	National Agrifood Inspection Office
DNSA:	National Animal Health Office
DTA:	Animal Transport Document
EITB:	Enzyme-linked Immunoelectrotransfer Blot
ELISA:	Enzyme-linked Immunosorbent Assay
EU:	European Union
FUNBAPA:	Patagonian Barrier Foundation
FMD:	Foot-and-Mouth Disease
INTA:	National Farming Technology Institute
NESS:	National Epidemiological Surveillance System
OIE:	World Organization for Animal Health (Office International des Epizooties)
PCR:	Polymerase Chain Reaction
RENSPA:	National Sanitary Registry of Ag-producers
SAGPyA:	Argentine Office of Agriculture, livestock, fisheries, and food
SENASA:	National Health and Agrifood Quality Service
USDA:	United States Department of Agriculture
VIAA:	Virus Infection Associated Antigen

Figure 1. Map of Argentina and List of Associated Provincial Acronyms

PROVINCES

BUE	BUENOS AIRES
CAT	CATAMARCA
CBA	CORDOBA
CHA	CHACO
CHU	CHUBUT
CRR	CORRIENTES
DOZ	MENDOZA
ERI	ENTRE RIOS
FSA	FORMOSA
JUA	SAN JUAN
JUJ	JUJUY
LAP	LA PAMPA
LAR	LA RIOJA
MNE	MISIONES
NEU	NEUQUEN
RIN	RIO NEGRO
SAL	SALTA
SCZ	SANTA CRUZ
SDE	SANTIAGO DEL ESTERO
SFE	SANTA FE
TDF	TIERRA DEL FUEGO
TUC	TUCUMAN
UIS	SAN LUIS

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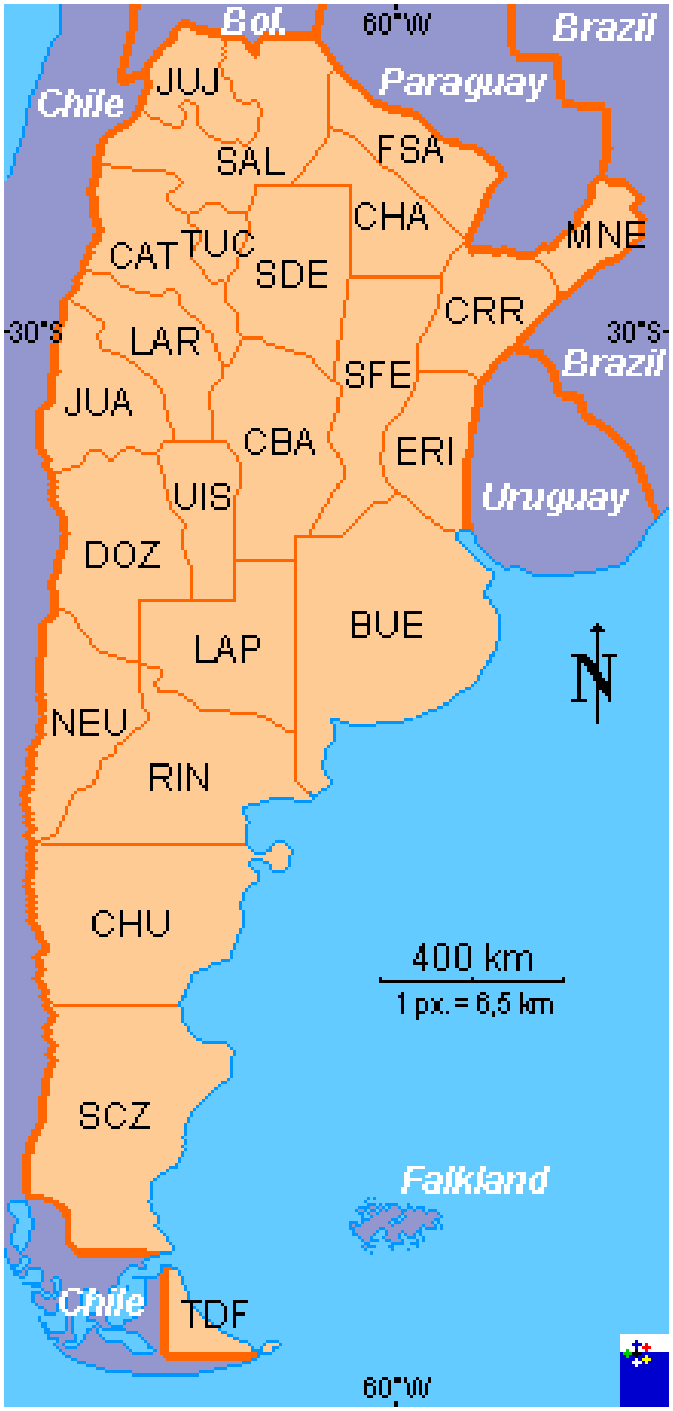


Executive Summary

Argentina requested that the U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) recognize the Patagonia Region of Argentina as free of foot-and-mouth disease (FMD). The Patagonia Region includes the region located south of the 42nd parallel known as Patagonia South, and the region immediately north of the 42nd parallel known as Patagonia North B. The last outbreak of FMD in the region occurred in 1994. Due to the historic lack of FMD occurrence in this part of Argentina, APHIS conducted a qualitative risk assessment to evaluate the FMD status of the Patagonia Region.

Argentina's Servicio Nacional de Sanidad y Calidad Agroalimentaria (SENASA) initially submitted information to support the request for recognition of FMD freedom of Patagonia South. APHIS evaluated the submission and conducted a site visit to Argentina in December 2003 to substantiate the information reported in the documentation and collect any new data. The site visit focused on the veterinary and legal infrastructure of SENASA, border control procedures, laboratory and diagnostic capabilities, biosecurity procedures on sheep farms and in slaughter facilities, animal health recordkeeping systems, movement controls, and disease surveillance systems. APHIS completed the Patagonia South risk analysis in 2005 and published it in the Federal Register in January 2007.

As a result of public comments stating that the information described in the risk analysis was not current, APHIS revisited this region in February 2009 in order to update the 2005 risk analysis. Additionally, APHIS conducted another site visit in November 2013 to further update its risk analysis, to fully incorporate Patagonia North B into its evaluation of the FMD status of the Patagonia Region, and to expand its assessment of the ability of SENASA to comply with APHIS' requirements for exporting FMD-ruminant susceptible commodities. APHIS has visited the region north of the 42nd parallel of Argentina on three occasions: (1) a site visit to evaluate the risk of importation of beef (under certain mitigations) in 2005; (2) a visit to the Corrientes province (near Paraguay) where an FMD outbreak occurred in 2006; and (3) a visit to the province of Buenos Aires to further evaluate the risk of importation of fresh beef in 2013. The current version of the risk analysis is updated to include new evidence gathered since the 2005 Patagonia South risk analysis was finalized.

This document describes the animal health system in the Patagonia Region and the adjacent buffer zone of Patagonia North A. It identifies potential areas of risk, and discusses how this risk is mitigated. The following factors were considered to be of particular importance in determining the FMD status of the Patagonia Region:

- No FMD outbreaks have occurred in the Patagonia Region since1994;
- Comprehensive surveillance programs are in place and have not detected the presence of the FMD virus in this region since that time;
- No FMD vaccination is carried out in the Patagonia Region, so any susceptible species in that region would act as good sentinel animals if exposed to the FMD virus; and

- Argentina has in place a comprehensive system of movement controls for animals and animal products going into or moving within the region.

Based on these and other observations, APHIS concludes that the legal framework, animal health infrastructure, movement and border controls, diagnostic capabilities, surveillance programs, and emergency response capacity provide a comprehensive system with redundant safeguards, and thus are sufficient to detect, prevent, and control and eradicate FMD outbreaks within the boundaries of the Patagonia Region of Argentina. Moreover, the Argentine veterinary authority is capable of complying with the requirements specified in the U.S. *Code of Federal Regulations* (CFR) to prevent the commingling of FMD-susceptible animals or products from the region with animals or products originating in regions with a different FMD status.

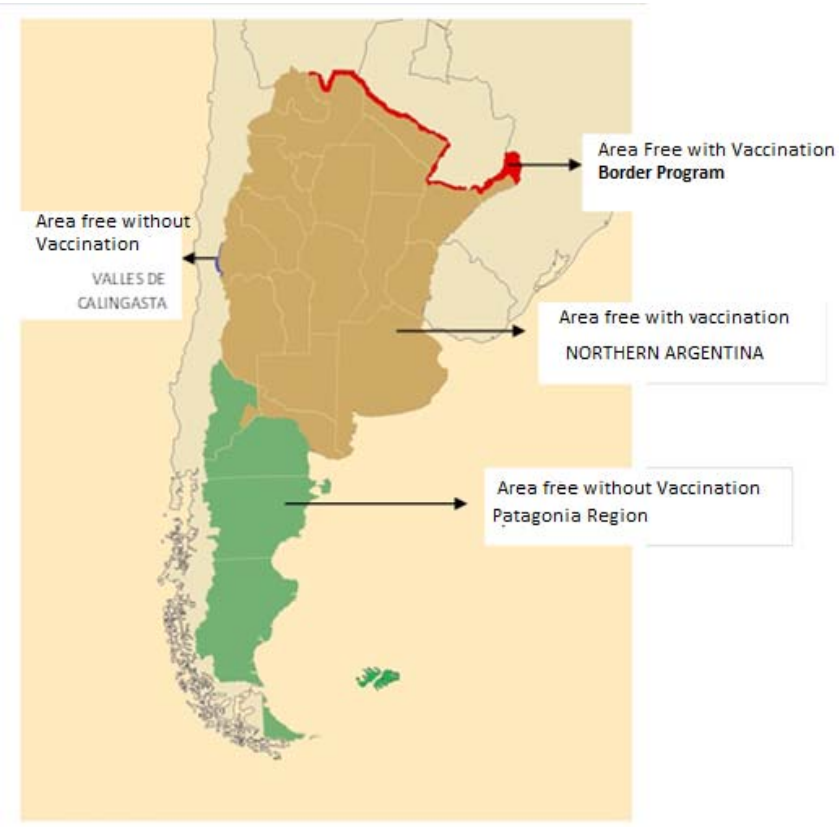
Although the expected consequences of an FMD outbreak in the United States would be severe, the likelihood of such an outbreak occurring due to exposure of the domestic livestock population to FMD-susceptible animals and products imported from the Patagonia Region of Argentina is very low. Therefore, the overall risk of FMD to U.S. animal health from imports of these commodities is also very low.

Background

Argentina requested that APHIS recognize a region of Patagonia which consists of Patagonia South (the region of Argentina south of the 42nd parallel), plus the adjacent region known as Patagonia North B, as free from FMD. Susceptible species in these regions are not vaccinated against FMD. Both of these areas are recognized as free of FMD by the World Organization for Animal Health (OIE). For the purposes of this risk analysis, these two areas will be referred to collectively as the Patagonia Region[1] (Figure 2). The last outbreak of FMD in the Patagonia Region occurred in 1994.

Animal health officials from SENASA first submitted documentation in support of their request for recognition of FMD freedom of Patagonia South in 2002. APHIS conducted a site visit in December 2003 to verify and complement the information submitted by Argentina. It focused on the legal framework and veterinary infrastructure, border and movement controls, agricultural practices, laboratory diagnostics, and surveillance programs. APHIS completed the Patagonia South risk assessment in 2005 and published it in the Federal Register in January 2007.

Figure 2: Map of Argentina FMD Regionalization Status Recognized by the OIE



As a result of public comments stating that the information described in the risk analysis was not current, APHIS revisited this region in February 2009 in order to update the 2005 risk analysis. APHIS conducted another site visit in November 2013 to further update its risk analysis, to fully incorporate Patagonia North B into its evaluation of the FMD status of the Patagonia Region, and to expand its assessment of the ability of SENASA to comply with APHIS' requirements for exporting FMD-susceptible commodities. Additionally, APHIS has visited the region north of the 42nd parallel of Argentina on three occasions: (1) a site visit to evaluate the risk of importation of beef (under certain mitigations) in 2005; (2) a visit to the Corrientes province (near Paraguay) where an isolated FMD outbreak occurred in 2006; and (3) a visit to the province of Buenos Aires to further evaluate the risk of importation of fresh beef in 2013. This version of the risk analysis is updated to include new evidence gathered since the 2005 Patagonia South risk analysis was finalized.

The final analysis was based upon information obtained from the site visits, in writing from Argentina, and from published reports.

Objectives

This document is an analysis of the risk of introducing FMD virus into the United States in FMD-ruminant susceptible species and associated unprocessed products from the Patagonia Region of Argentina (because rinderpest has never been established within the continent it will not be addressed further within this document). The risk analysis is intended as a decision-making tool that will enable APHIS to determine whether and under what conditions to allow imports from the Patagonia Region and allow development of appropriate regulatory conditions and mitigations to address any potential risks of disease introduction if trade is initiated. It also constitutes an information source for APHIS stakeholders, providing justification for the conditions proposed in any resulting rulemaking.

Supporting data

The analysis is based on documentation provided by SENASA [1-8], and observations made by a joint APHIS and Canadian Food Inspection Agency (CFIA) site visits in 2003 and 2009. The analysis also includes observations made by the APHIS teams visiting Argentina in 2005, 2006, and 2013[9-14], as well as published information. SENASA, which translates into English as the National Health and Agrifood Quality Service, is the government agency in Argentina responsible for animal health activities.

Hazard identification

APHIS has identified several OIE listed diseases [15] as the primary hazards associated with initiating trade in animals and animal products from foreign regions. Listed foreign animal diseases of primary concern are addressed specifically in APHIS regulations (9 CFR Part 94). FMD is recognized in APHIS regulations as such a hazard [16]. In this regard, before opening or resuming trade in FMD-susceptible species and related products with any region or country that is not recognized by APHIS as free of FMD, APHIS routinely conducts an evaluation to support its decision-making (9 CFR 92.2) [17].

The hazard identified is the FMD virus. Epidemiological characteristics of the disease agent relevant to the import risk it may pose are described in Appendix 1.

Risk analysis

This analysis is composed of four components: the release assessment, the exposure assessment, the consequence assessment, and the risk estimation. These components are defined in OIE guidelines and represent the internationally accepted components for conducting animal health import risk analysis.

Release assessment

For the purpose of this report, the term *release assessment* refers to the evaluation of (1) the likelihood that FMD exists in the Patagonia Region of Argentina, and (2) the likelihood that FMD (if present) would be introduced into the United States through imports of FMD-susceptible animals or their products. The report includes an in-depth assessment of the 11 factors [17] used by APHIS to evaluate the animal health status of a region prior to 2012. In 2012, APHIS consolidated the eleven factors listed in 9 C.F.R. § 92.2(b) into eight factors. APHIS introduced this simplification in order to facilitate the application process; however, since the evaluation of the Patagonia Region started before 2012, and the topics addressed by the 11 factors are encapsulated in the eight, this report follows the 11 factor format. Appendix II describes the consolidation of the 11 factors into eight. The 11 factors described in this evaluation are:

1. The authority, organization, and infrastructure of the veterinary services organization in the region;
2. Disease status (i.e., is the restricted disease agent known to exist in the region?);
3. The status of adjacent regions with respect to the agent;
4. The extent of an active disease control program, if any, if the agent is known to exist in the region;
5. The vaccination status of the region;
6. The degree to which the region is separated from adjacent regions of higher risk through physical or other barriers;
7. The extent to which movement of animals and animal products is controlled from regions of higher risk, and the level of biosecurity regarding such movements;
8. Livestock demographics and marketing practices in the region;
9. The type and extent of disease surveillance in the region;
10. Diagnostic laboratory capacity; and
11. Policies and infrastructure for animal disease control in the region.

Risk factors are identified from the information gathered on these topics and applicable mitigations are discussed.

Eleven-factor analysis

This evaluation focuses on the Patagonia Region of Argentina, which includes the region that lies south of the 42nd parallel (Patagonia South) and the adjacent North B region. Livestock systems in the Patagonia Region are mainly extensive (animals are grass-fed and range over vast areas of land with minimum labor or expense). The climate and the environment of the Patagonia Region are major factors that make the sheep industry the prevailing livestock activity.

1. The authority, organization, and infrastructure of the veterinary services organization in the region

Central authority

All regulations related to the control of FMD are based on the General Animal Health Enforcement Law (Law No. 3959/1903). This law, along with its accompanying regulations of 1906, grants authority to the Government to restrict and regulate individual rights to pursue the general welfare and establishes the measures necessary to protect safety and health. Legal authority for control relative to Argentina's FMD status is provided by several SENASA resolutions and other decrees, laws, and resolutions. National Law No. 24.305/93, along with Decree No. 643/96, establishes the FMD National Eradication Plan and requires immediate and mandatory reporting of FMD cases in Argentina. SENASA Resolutions 5/2001, 18/2001, and 58/2001 are additional regulations that complement and provide authorization for the FMD National Eradication Plan. SENASA Resolution No. 234/96 implements the National Epidemiological Surveillance System (NESS), authorizing the involvement of certain government and private sector offices and units to work at local, provincial, and national levels to control reportable animal diseases. SENASA Resolutions Nos. 478/99, 779/99, 192/2001, 370/2001, 383/2001, 510/2001, and 37/2002 and SAGPyA (Secretariat of Agriculture, Livestock, Fisheries, and Food of Argentina) Resolution No. 378/99 establish measures in controlling FMD outbreaks including sanitary steps with susceptible, ill, and in-contact animals in the region of the outbreaks, notification, and operative procedures if FMD is detected on a farm, prevention of spread of the disease, and implementation of the National Sanitary Emergency System. There are also a large number of resolutions that establish procedures and conditions for the import of various animals and animal products, disposal of organic waste from ships and airplanes, passenger and luggage control procedures, and movement of animals within the country. SENASA Resolutions Nos. 495/2001 and 115/2002 establish requirements for shipping FMD-susceptible livestock to slaughter for export of meat and meat products to the European Union (EU) or from farms approved to export to the EU or markets with equivalent requirements [1-3].

SENASA is divided into several sections, three of which focus on animal health issues: (1) the National Animal Health Office (DNSA); (2) the National Agrifood Inspection Office (DNFA); and (3) the Laboratories and Technical Control Office (DILACOT). These offices report directly to the President of SENASA. This structure reflects organizational changes made in 2001 and 2002 [1, 2, 11] to address issues and problems identified during the FMD outbreaks that occurred north of the Patagonia Region in 2000/2001.

The DNSA organization and structure is defined in SENASA Resolution No. 274/2002 [2]. The DNSA is specifically responsible for border controls, animal health control and eradication programs, including the necessary preventive, control and eradication actions to ensure compliance with current statutes. The actions of this office are carried out in the region of Patagonia South and Patagonia North by the 29 and 16 local offices, respectively [14]. The Epidemiology Office of DNSA carries out, coordinates, assesses, and oversees the FMD program in Argentina. The DNSA is also responsible for strategic prevention activities, risk analysis, and surveillance and assessment of the vaccination programs [1]. Within the DNSA, there is also a department responsible for overall coordination in the area of identification and registration of animals, animal movement controls, and traceability.

The General Field Coordination Unit, which reports to the DNSA, implements its responsibilities through the local offices and regional supervisors. Its duties include [2]:

- Coordination and management of the prevention, control and eradication actions of animal disease control programs;
- Control of compliance of sanitary actions and enforcing the Law of Sanitary Police and pertinent regulations; and
- Supervision of livestock movement, premises approval and certification.

The responsibilities of the local SENASA veterinarians include:

- Implementation of prevention, control, and eradication actions of the animal control programs in their jurisdiction;
- Investigation of notifications, suspicions, and outbreaks;
- Permanent monitoring of diseases of interest and epidemiological tasks;
- Implementation of sanitary police actions and compliance of the regulations in force;
- Control and supervision of livestock movement and transport and issuance of the pertinent certificates; and
- Updating producers' document registries, establishments, livestock existences, movements, and sanitary and administrative controls in their jurisdiction.

The responsibilities of the regional supervisors include:

- Supervision of disease prevention, control, and eradication actions in their jurisdictions and epidemiological surveillance actions;
- Supervision of compliance of legal regulations in force;
- Organization and operation of local offices;
- Assessment of the field staff performance; and
- Official representation of SENASA in their zone.

The DNICA (Directorate of National Quality and Food Safety) is responsible for enforcing hygiene and health requirement compliance in slaughtering plants, processing plants, and storage facilities for animal and plant products and byproducts (edible or inedible). The Veterinary Inspection Service performs these controls at slaughtering plants approved for export [1].

The DILACOT has two units – the Laboratory for Animal Products and Byproducts and the Laboratory for Plant Products and Byproducts. This office operates the National Reference

Laboratory for food safety and animal and plant health. In addition, the DILACOT has regional laboratories and manages a network of laboratories accredited by SENASA (for more information on DILACOT please refer to factor ten). The functions of the DILACOT are as follows [1]:

- Establish the methods and test protocols that are used at the Central Laboratory and the laboratories that participate in the national network;
- Intervene in dispute resolution;
- Confirm positive test results issued by the laboratories in the network;
- Carry out and participate in interlaboratory tests;
- Audit the network of laboratories;
- Provide assistance to other SENASA offices to assess analytical results; and
- Participate in reviewing regulations pertinent to its field of action and participate in international meetings (e.g. Codex Alimentarius, MERCOSUR, OIE).

Under the 2013 structure, the Quarantine, Borders, and Certifications Unit (CCFyC) falls under DNSA. The CCFyC oversees the Animal and Plant Quarantine Unit, the International Movements Unit, and the Borders and Sanitary Barriers Unit. The Borders and Sanitary Barriers Unit operates the control posts at the inland sanitary barriers and border crossings (fluvial and marine ports, airports, and border crossings) [1, 14].

The 14 Regional Operative Offices (ROs – Centros Regionales) report directly to the SENASA's General Manager. Support for the animal health system comes from a participatory structure based on 360 local animal health offices, 30 of which are located in the Patagonia Region. These local offices represent various local organizations and have technical subcommittees chaired by official or private veterinary physicians that practice in the area that work closely with SENASA officials [1]. These offices, as authorized by Law No. 24.305, are part of the Epidemiological Surveillance System (NESS) in accordance with the responsibilities and functions spelled out in the legal regulations in force. Officials work at the local, provincial, and national levels and comply with established methodologies, procedures, and operations [2].

At the regional level, 24 Provincial Animal Health Committees (COPROSAS) participate in the National FMD Eradication Committee (CONALFA). CONALFA provides a forum for consensus where the provincial governments, SENASA, and representatives of the farmers associations define the operational strategies to carry out the zoosanitary policies defined by SENASA [1].

SENASA's Reorganization

SENASA's reorganization focused in three major areas [11]:

(1) Structure
(2) Financial resources
(3) Human resources

Structure:

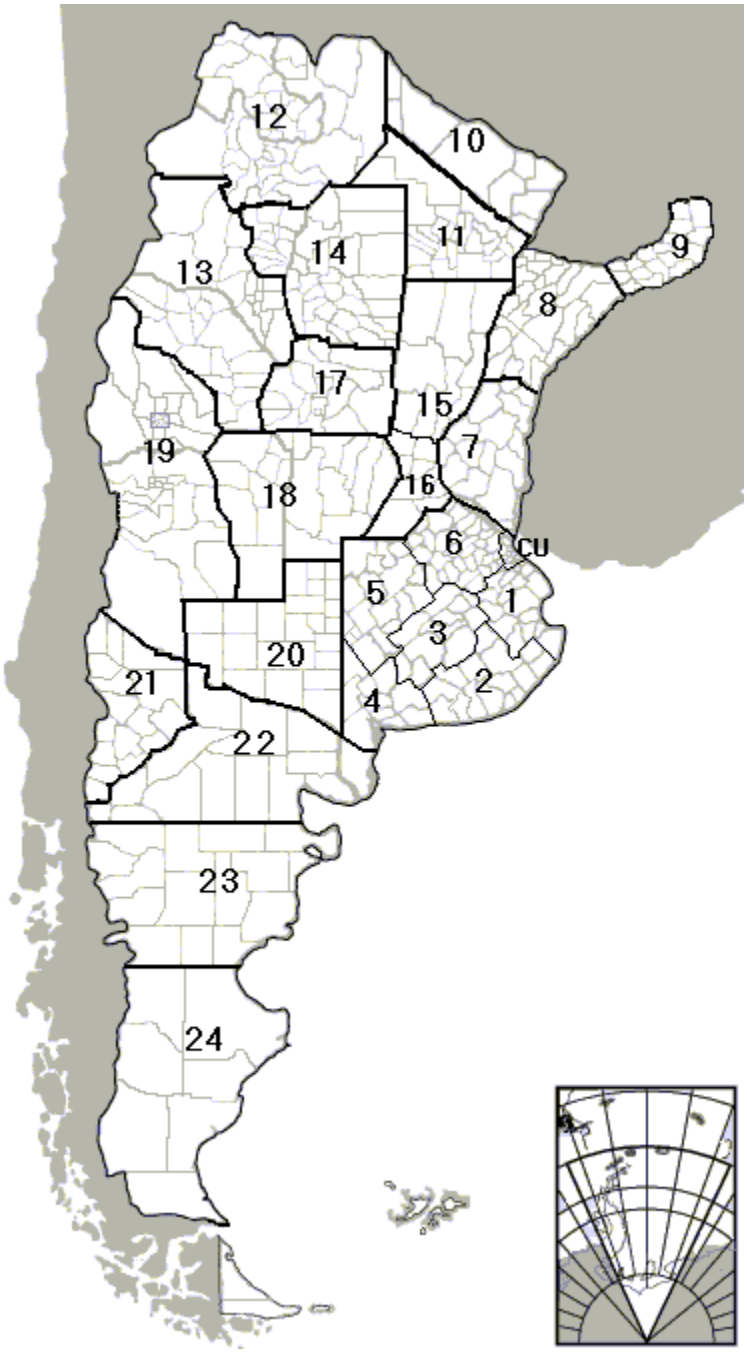
The first important SENASA reorganization was defined by Decree 394/2001 [2]. It was intended to increase the efficiency of the existing geopolitical system and address international perception that SENASA had not been transparent with its trading partners about its FMD situation. In fact, in 2000, SENASA failed to report the first FMD outbreaks for several months after they had been detected [18].

In the 2001 structure of SENASA, the veterinary units were no longer based on political borders and the chain of command was changed to address issues that arose during the 2000/2001 FMD outbreaks, including centralization of command and control of the animal health programs. Prior to the 2006 reorganization, SENASA personnel in each province reported to one of three regional directors, each of which administered huge regions. Resources were not allocated to address the regional workload. Specifically, regions with high levels of activity (large livestock population and movements) were assigned the same number of personnel as regions with lower levels of activity, so the system was inefficient. Also, SENASA concluded that there was too much autonomy given to the regional directors.

The regional directors had too much discretion in carrying out the orders from the central office, and the field people had such a wide range of duties that they had trouble focusing on animal health. In regard to transparency, many of the reorganization elements addressed issues of internal monitoring, accountability, and compliance with national policies.

In the 2006 reorganization, boundaries of regional units were redefined so that personnel were assigned at a level appropriate to the activity occurring in the region. For example, the province of Buenos Aires, which constituted a very busy single region before the reorganization, was broken into six separate units. This increased the efficiency of the system by distributing the workload more evenly [11]. Region 21 and most of region 22 on the map in figure 3 make up the Patagonia North B region. Regions 23 and 24 make up Patagonia South. The 2006 reorganization also addressed international standards, certification requirements, and an increased emphasis on border controls [11].

Figure 3. Map of SENASA Regional and Local Units as of 2006

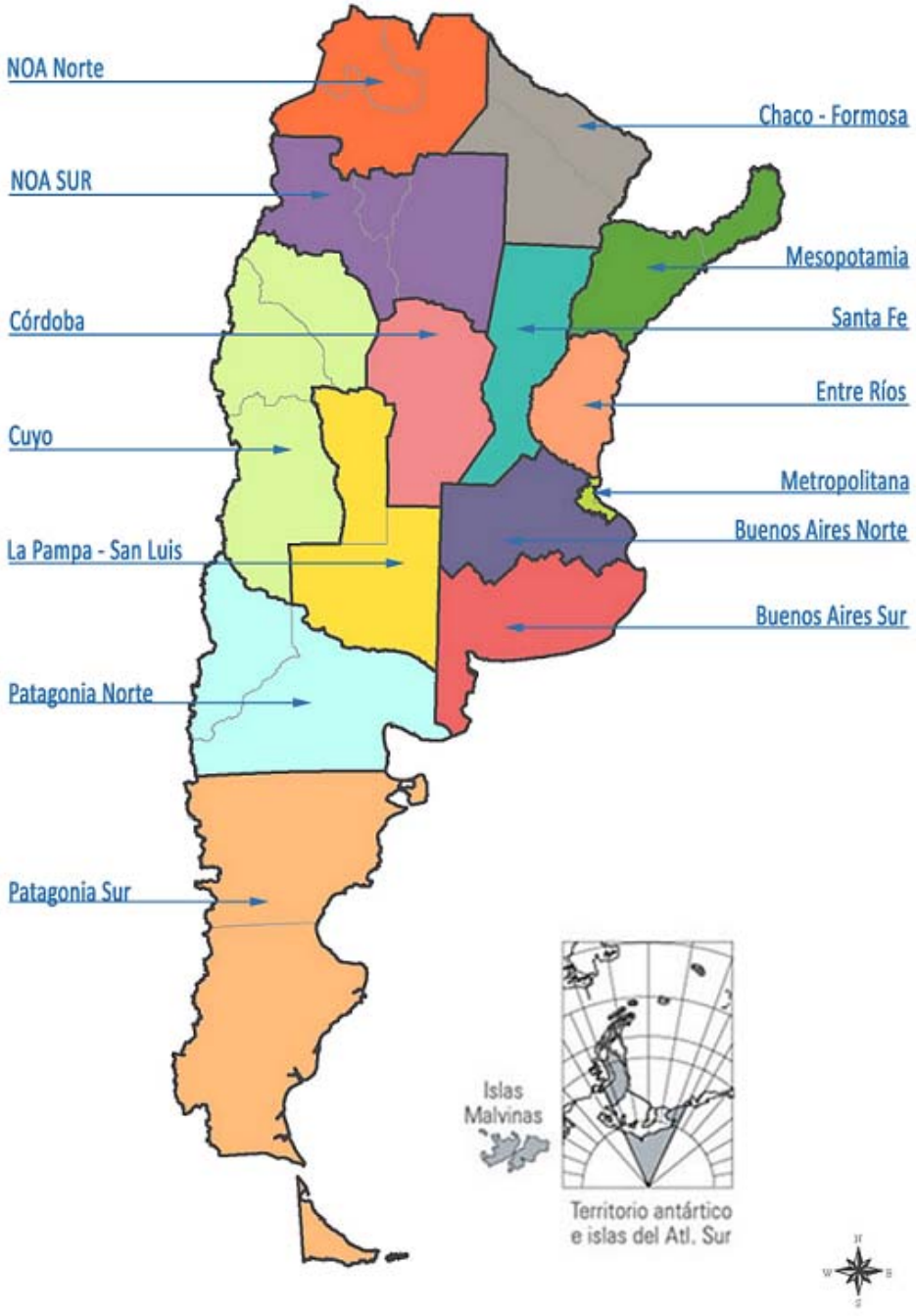


In 2007, SENASA redefined its regional units by issuing Resolutions 225/2006, 335/2007, and 362/2007, and created a Regional Operative Unit (Unidad Regional Operative) (ROU) within the Central Unit (Vice-presidential Unit) to coordinate activities of the 14 Regional Operative Offices.

The objective of this structure was to facilitate communications between the central and regional levels and to improve interactions with the local government (e.g., provincial, municipal) and non-governmental authorities.

The ROU represents a liaison between SENASA central and regional levels. The regional offices provide the oversight to the local field offices and coordinate regional animal health programs. SENASA assigns a budget to each of the regional offices, based on its needs. For instance, the Buenos Aires Regional Unit is the largest (comprises 13 percent of the total budget), and oversees 43 local SENASA offices. Regional Operative Offices are shown in figure 4.

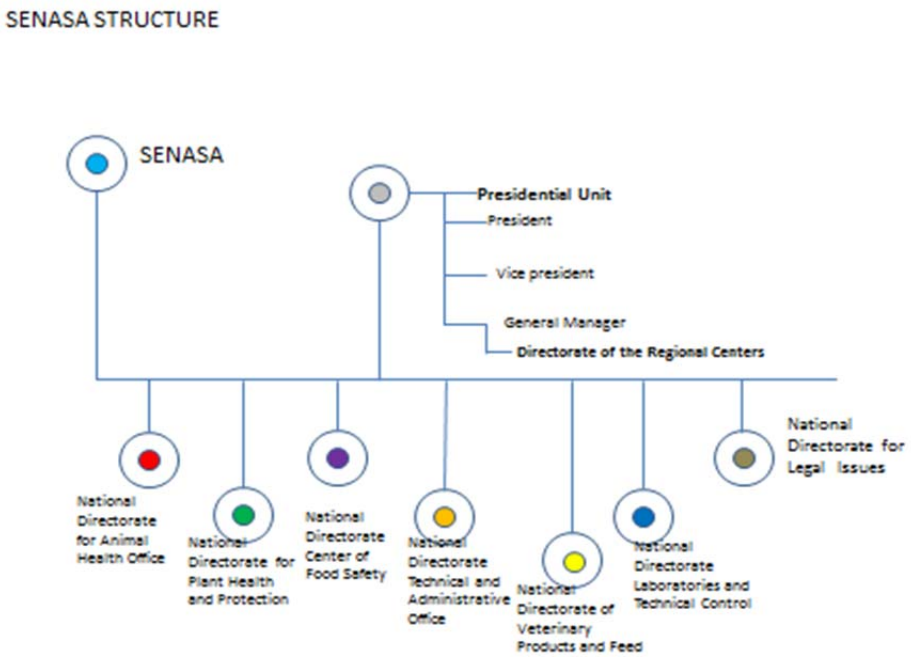
Figure 4. Regional Operative Offices of SENASA



In 2013, SENASA established the direct reporting between Regional Units and the Central Manager by issuing Resolution 354/2013. The 2013 Resolution also assigns to the General Manager other responsibilities, such as the coordination and monitoring of the Regional

Operative Offices. Further, it adds a research component to the SEANSA's functions and responsibilities. The diagram of the new structure is represented in Figure 5

Figure 5. SENASA's Structure



Financial resources:

SENASA reported that its 2013 budget was 1.3 billion pesos (approximately $200.7 million U.S. dollars). SENASA officials described the system as self-sufficient because user fees are required for almost every service SENASA provides, including slaughter surveillance, issuances of certificates, and laboratory tests [19]. The budget for the laboratory is 60 million pesos (approximately $12 million U.S. dollars)

Human resources:

In November 2013, SENASA reported a total of over 5,500 employees, which includes plant as well as animal personnel. Of these, over 80 percent have a professional degree, of which 1,054 are veterinarians. Rules are in place for employees to address conflict-of-interest issues. For example, slaughter plant and field inspectors are not allowed to own livestock or sell beef.

SENASA can expand its staff, when necessary, by hiring contract personnel, including veterinarians and animal health technicians. Contract personnel are hired on the basis of a standardized profile defined by SENASA for four month increments, and their contracts are renewable. Permanent and contract veterinarians have the same authority.

SENASA can also broaden the scope of its activities through agreements with outside parties. For example, it has entered into agreements with some academic institutions to cooperate in activities such as conducting risk analyses. Other agreements have been implemented with enforcement agencies like the border police, who assist with security at border control points along land or water borders. Border police also assist SENASA with enforcement of quarantines. They played a significant role in security during previous FMD outbreaks. Security forces that work at slaughter facilities also assist in the disease control program [11]. SENASA can call upon border police and other security forces to help prevent entry of disease into Argentina. The number of animal health officials and affiliates in the Patagonia Region is listed in Table 1.

Table 1. Animal Health Personnel in the Patagonia Region, 2013 [14]

	Neuquén	Río Negro	Chubut	Santa Cruz	Tierra del Fuego
SENASA local offices	**4**	**11**	**6**	**6**	**2**
SENASA's Commisions	**12**	**19**	**0**	**0**	**0**
SENASA's Veterinarians	**4**	**19**	**12**	**12**	**1**
SENASA Technical personnel	**4**	**7**	**9**	**4**	**0**
SENASA's Administrators	**5**	**11**	**3**	**5**	**3**
Private/acredited veterinarians	**66**	**94**	**237**	**33**	**49**

Veterinarian licensure, training and roles in the animal health programs

Veterinarians in Argentina are licensed after obtaining a veterinary degree authenticated at the Ministry of Culture and Education. They are registered at the National or Provincial Professional Association of Veterinary Physicians in the jurisdiction of employment. The respective association issues their license. National and provincial licensure is mandatory [2].

The National Private Veterinary Physician Registry, created by SENASA Resolution No. 470/95, registers private veterinarians that take part in the NESS. Registered veterinarians must notify the local DNSA commission of suspect cases of notifiable diseases, including suspect cases of FMD. In addition, SENASA Resolutions Nos. 234/96 and 422/03 incorporate Veterinary Physician Professional Associations and Councils into the NESS. Registration must be renewed annually and veterinary licensure must be kept up-to-date. SENASA issues the Registry Veterinarian certificate and guarantees the necessary training for proper performance of duties. This registry has different sections, according to the areas of responsibility of the corresponding office or unit. These veterinarians must comply with a continuous training program which includes procedures and standards that are currently in force to control reportable diseases [2].

In 2003, SENASA Resolution No. 181 was enacted. It establishes the requirements to accredit private veterinarians in the FMD National Eradication Program, including verification that the veterinary license is up-to-date and compliance with scheduled training goals. The 2009 and 2013 site visit team verified that the resolution was fully implemented.

Private veterinarians accredited by SENASA also perform FMD vaccinations in some regions of the country and preloading inspection on bovine and ovine animals intended for slaughter to export meat and meat products to the EU. They verify the health status of the animals and the accuracy of the premises documents. If satisfactory, then a health pre-certificate is issued which is later endorsed by the local SENASA veterinarian.

Official and accredited SENASA veterinarians must comply with training requirements that are in line with the main strategies in the FMD National Eradication Plan. The goal of the Plan is to promote measures to strengthen the national and continental structure of FMD surveillance programs. These measures include training activities for the different participants of the program (technicians and administrative staff) and promotion of the different activities of the Plan. The purpose of the Plan is to provide technical resources to the SENASA staff in important subjects such as FMD control.

Training of official SENASA employees is part of a central theme in the development of national animal health programs. Training programs for all the staff levels are developed within the Bureau of Human Resources and Training of SENASA. Staff is responsible for supervising each activity of the FMD National Eradication Plan and their adequate performance is vital to meet the established goals. The content of training courses meets the technical guidelines established by the FMD National Eradication Plan and the specific bibliography of the OIE. Veterinarians must also comply with the guidelines of the Training Operative Plan established by SENASA and the Civil Service National Institute, which includes training on various animal diseases besides FMD. All programs are conducted by experts and teachers from SENASA and other institutions through agreements with national universities, research institutes such as INTA (National Institute for Agricultural Technology), and others (FAO, etc.). Training activities for SENASA staff and laboratory were provided during the site visits, including the latest training activities in 2013 [20].

Training for staff in the DNFA includes the following subjects: legislation in force (Decree 4238/68 and others), approval of establishments producing products intended for domestic consumption and export, hazard analysis and critical control point principles, good manufacturing practices, standard operating procedures (for establishments treating products and by-products of animal origin of all species, including birds and fish), diseases spread by food, animal welfare, traceability, residues, and hygiene control [1].

Provincial veterinarians also take an active role in the sanitary commissions that fight against endemic diseases. They work together with SENASA official veterinarians, private veterinarians, cattle farmers, and others, along with the respective COPROSAs of each province as part of the Epidemiological Surveillance Commissions (Resolution 445/95 – Regional Patagonia Plan) [2].

SENASA Field offices

Field offices implement local prevention and control measures, eradication, compliance, emergency actions, health actions (e.g., vaccination), premises identification, movement controls, and recordkeeping. Many of these responsibilities are controlled through registration of premises and assignment of a unique premises identification number, which, in addition to other information on premises, is maintained in a national database.

Through the years, the APHIS site visit team visited several local offices. At the different locations, the team observed that SENASA's personnel at the local offices were diligent and efficient in implementing control and management activities as issued at the national level and were well integrated with the regional offices in terms of communication, oversight, and supervision. In 2009, the site visit team visited regional and field offices in Viedma, Carmen de Patagones, and Choele Choel in Patagonia North A and in Río Grande in the Tierra del Fuego province and Río Gallegos in the Santa Cruz province in Patagonia South. In 2009, the team visited the regional office of Bahia Blanca (located north of the 42nd parallel), the local office of San Antonio Oeste (in Patagonia North A), the local office of Bariloche (in Patagonia North B), and the local office of Esquel and Trelew (in Patagonia South). The last three of these offices are audited by their regional SENASA office at least three times per year.

The Rio Grande office mainly deals with animal movement control and recordkeeping and inspections at the local airport. The emergency response system was tested when an outbreak of sheep scabies occurred in Tierra del Fuego in 1998. The disease was quickly contained and eradicated. When a suspect animal is reported to SENASA, an investigator must be sent out within 12 hours or less to investigate the case. A notification document is sent to Buenos Aires and the regional supervisor is informed only after the SENASA official confirms the suspect case after examination [10].

The Río Gallegos office is one of three local offices in Santa Cruz province. The office has the same duties as the Río Grande local office, but also has additional staff that inspects baggage on the Argentina-Chile border at the Monte Aymond border post.

FUNBAPA (Fundacion Barrera Patagonica [Patagonian Barrier Foundation]) is a contract foundation that coordinates with SENASA to guarantee the health and quality of agriculture products in Patagonia. The Foundation was set up by a SENASA resolution, but no money comes from the SENASA budget. The annual budget in 2009 was about $3 million U.S. dollars, which is acquired through the collection of fees (50 percent from spraying fees and 50 percent from producers moving products). Contributions mainly come from fruits and vegetables, about $1 per ton of fruit or product that is exported out of the region.

SENASA sets the regulations related to the control of FMD and FUNBAPA enforces them. The chair of FUNBAPA is the president of SENASA. FUNBAPA's responsibilities at land and airport border control facilities are discussed in Section 7 below.

Swill feeding

SENASA Resolution No. 225/95 regulates housing and maintenance of pigs. This resolution bans feeding pigs with raw viscera of any origin, including kitchen garbage; hospital, clinic, or nursing home garbage; and garbage from national or international ports and airports. It authorizes feeding pigs with leftovers of food substances of animal origin coming from stores approved by the competent authority to manufacture or sell food. Authorization is on condition of compliance of the following requirements:

- The swill is subjected to a cooking process guaranteeing destruction of pathogenic organisms, and
- The existence on the premises of equipment necessary to carry out the requirements of the above cooking process with an operation capacity allowing treatment of all the leftovers in a period of time not longer than eight hours after arrival on the premises.

There are no establishments exclusively approved to process swill. Swill treatments are carried out by the pig producer in the establishment, or the producer obtains the processed swill from slaughtering establishments [2]. Compliance is monitored using regulations that deal with other sanitary/hygiene issues. SENASA Resolution No. 350/98 sets up a mechanism by which SENASA veterinarians can more easily confiscate animals infected with Trichinella or that constitute a risk because of inadequate sanitary conditions, due to failure to comply with SENASA Resolution No. 225/95. Also, work is presently being done on a regulation combined with 350/98 to regulate pig activity and widen the scope of the current regulations with the

purpose of more effectively controlling trichinellosis. As a consequence, there will be safeguards that spill over to grant additional sanitary protections against FMD contamination of feed [2].

Conclusions

Argentina has the veterinary and regulatory organization and infrastructure to adequately monitor and control any incursion of FMD into the country. APHIS considers that SENASA has sufficient legal authority to carry out official disease control, eradication, and quarantine activities. There is sufficient monitoring of animal premises and movements to permit effective surveillance and detection programs that would result in sufficient administration of eradication efforts, if needed.

APHIS recognizes that there were substantial delays (approximately nine months) in reporting of the FMD outbreaks in Argentina in 2000-2001 that raised questions in the international arena regarding SENASA's transparency with regard to disease reporting. For this reason, APHIS has been particularly thorough in its subsequent reviews of Argentina's veterinary infrastructure. Despite earlier problems, APHIS observed during site visits to the Patagonia Region and Northern Argentina, which included the regions where isolated outbreaks were detected in 2003 and 2006, that Argentina had made changes to its veterinary infrastructure since the 2000-2001 outbreaks. APHIS confirmed that these improvements were effectively implemented and maintained in its subsequent visits to Argentina in 2006, 2009 and 2013. Based on these observed changes and the responses SENASA personnel provided to the site visit teams' questions, APHIS is confident that, in the event of another outbreak, reporting would be prompt and transparent.

2. Disease status

The Patagonia Region of Argentina has not recorded an outbreak of FMD since 1994, when six outbreaks were reported. A stamping-out policy was applied and a total of 565 cattle, 8,286 sheep, 296 pigs, one goat and one camelid were destroyed (ill and contact animals). SENASA imposed quarantine and movement restrictions on all adjacent departments, established control and disinfection posts on highways and other strategic locations, carried out stamping-out of contact susceptible species in the focal area, and conducted ring vaccination in perifocal and surveillance areas. Results of the epidemiological investigation concluded that the virus originated in Patagonia North A and entered into Patagonia North B, either through infected bovine slaughtered in Patagonia North B or through the movement of infected bone-in beef and offal. The investigation further concluded that the disease was spread through the feeding of contaminated slaughter waste to swine. Molecular characterization of the virus revealed that the strain was closely related to a vaccine virus strain commonly used in South America (O1/Campos/Brazil 58) [1, 2].

The area south of parallel 42 reported the last outbreak in 1976 in the Chubut Province. The virus, which was type A, was introduced into the province from animals that had come from northern Argentina. When the suspicion of FMD became known, SENASA implemented quarantine procedures, closed streets and neighboring roads, established control and disinfection posts, and conducted epidemiological tracing and staff reinforcement. Animal movement

restrictions and ring vaccination were carried out to stop the spread of the disease. The animals vaccinated included 4,789 bovine, 8,881 sheep, and 391 pigs. This was the only case when a stamping-out policy was not applied [1, 2].

No reports of suspect vesicular diseases were made in 2012 or 2013 in the Patagonia Region. Sheep are the predominant livestock species in Patagonia South. Almost 60 percent of the sheep in Argentina reside in Patagonia. The livestock density is less than one animal per hectare. Due to extensive husbandry practices and low animal density, contact between sheep and other species and with other sheep is minimized [1, 2]. No vaccination is carried out in the Patagonia Region, so any cattle or swine in that region exposed to the FMD virus would act as good sentinels of an outbreak.

Federal, provincial, and municipal authorities, veterinarians in private practice, and citizens must report any signs of FMD, the existence of suspect cases of this disease, or positive test results for this disease to the local animal health authorities or to the National Animal Health Office of SENASA (Law No. 3959/1903, Law No. 24.305/93, Decree No. 643/96) [1, 5, 6]. There is no indemnification for destroyed animals if the disease is not reported and anyone that fails to report the disease is fined.

Conclusions

The last FMD outbreak in the Patagonia Region of Argentina occurred in 1994. There is no evidence that any species has been infected with the FMD virus in this region since 1994.

3. The status of adjacent regions with respect to the agent

Argentina is bordered by Paraguay to the north, Bolivia to the northwest, Uruguay and Brazil to the northeast, and Chile to the west. APHIS only considers Chile to be FMD-free [30]. The Patagonia Region itself is bordered by either the ocean or areas that are FMD-free without vaccination (Chile) or FMD-free with vaccination (Patagonia North A) according to OIE standards.

Argentina recognizes the FMD status for surrounding countries as classified by OIE. Chile is recognized as FMD-free without vaccination (last FMD outbreak reported in 1987). Uruguay is considered FMD-free with vaccination (last FMD outbreak reported in 2001). The Brazilian States of Río Grande do Sul and Santa Catarina, which border Argentina, are recognized as FMD-free regions with and without vaccination, respectively. The OIE recognizes a region in Bolivia that is located in the Macro-region of the Altiplano as FMD-free and the following three zones as FMD-free with vaccination: (1) zone of Chiquitania; (2) zone adjacent to the east of Chiquitania; and (3) zone consisting of the regions of Chaco and part of Valles) [2, 4]. In November 2013, Paraguay was recognized by the OIE as FMD-free with vaccination (last FMD outbreak reported in 2012).

Information on the epidemiological situation of the countries in the region around Argentina is acquired through data systematically and periodically submitted by the Pan American Foot-and-Mouth Disease Center (PANAFTOSA), bilateral agreements, and joint border programs. Since

the regional FMD outbreak in 2000-2001, a program of joint actions and adoption of strategies among the countries of the region was established within the action plan of the Hemispheric Program for FMD Control and Eradication (PHEFA). This program comprises border work subprojects, reimplementation of vaccination against FMD, epidemiological surveillance actions, and improvement of the Continental System of Information. In response to this effort, Argentina incorporated border programs, guaranteeing full notification of the epidemiological situation in the country, development of the vaccination campaigns, joint training, and reciprocal guarantees strengthening the Regional and National Epidemiological Surveillance Systems [2].

The PHEFA is coordinated by PANAFTOSA. As a subprogram of the Hemispheric Plan, the Cuenca del Plata Agreement for the Eradication of FMD coordinates common strategy between Argentina, Brazil, and Uruguay in the fight against FMD. The initial agreement was signed in 1987 in Porto Alegre, Brazil. The strategic program was developed in 1988 by technicians of the three countries and was implemented in 1989. Paraguay signed on in 1992 and then Bolivia joined the agreement. Chile participates as an observer country. The agreement works through an executive committee made up of the animal health authorities of each one of the member countries, with a technical group advising the Committee. The technical group includes five veterinarians from each country and two permanent consultants, the Coordinator and the epidemiologist, all of which advise the member countries. The group meets four times a year. All of the activities of the agreement are channeled through this group.

Argentina provides technical assistance to Bolivia by transferring technology and aiding in technical matters in the fight against FMD. The Bureau of Laboratories of SENASA has trained scientists from Bolivia on performance and standardization of FMD diagnostic serological tests (VIAA and EITB).

Argentina has a bilateral agreement with Paraguay to make a joint effort to establish an FMD vaccination, prevention, and epidemiological surveillance program in the border area between the two countries. The aim of the program is to mitigate the risk of an FMD occurrence in the area. In 2003, SENASA signed a letter of intent with SENACSA (Paraguay's sanitary service) and the White Helmet Commission to "agree on a participation and cooperation mechanism" of the latter on both sides of the border, within the framework of the Regional Program for the Eradication of FMD and supported by the South Farming Council. The White Helmets, a United Nations-sponsored group that deals with emergency situations related to public health throughout the world, has played a role in enhancing communications in the region.

FMD outbreaks in the rest of Argentina since 2001.

Patagonia North A, 2001

Patagonia North A serves as a buffer zone between the Patagonia Region and most of northern Argentina. Vaccination in Patagonia North A was stopped in March 2013 by SENASA Resolutions 82/2013 and 141/2013. At the time of the 2013 site visit, SENASA was in the process of submitting the FMD dossier to the OIE for FMD freedom recognition of Patagonia North A.

The last FMD outbreaks in Patagonia North A occurred in 2001 with seven outbreaks reported in the region. All the outbreaks were confirmed to be caused by a type A virus. The source was most likely from the central zone where the epidemic developed. Five outbreaks were registered in the Department of Patagones, Province of Buenos Aires. They took place between May 11 and July 23, 2001. The exposed population included 3,268 cattle, 2,690 sheep and 35 pigs. One hundred ninety-nine young cattle under two years of age were the only clinically ill animals. Initial attack rates varied from 0.3 to 12 percent.

Two more isolated outbreaks occurred in the Province of Río Negro in Patagonia North A as a consequence of entry of the virus from the central zone where the epidemic developed. Between August 2 and August 8, 2001, two suspicious cases were detected in the Department of Pichi Mahuida, Province of Río Negro. Both were located on premises on the south bank of the Colorado River. The second outbreak occurred near the Department of Patagones like the earlier ones. A link between the last case, which was the only confirmed (by laboratory diagnosis) FMD-positive case among the later outbreaks, and the primary affected area in Patagones was established. There was a familial relationship between owners of the affected premises in the initial affected area and the later outbreak in Patagones which probably resulted in transport of the virus to the other premises. Control of the outbreaks included animal quarantine and movement controls along with ring vaccination of animals in the surrounding areas.

Salta, 2003
In 2003, Argentina reported an outbreak in the city of Tartagal, province of Salta.

Corrientes, 2006
In 2006, SENASA reported an outbreak of virus type O in San Luis del Palmar (Corrientes) near the border with Paraguay. This outbreak was contained and eliminated. Molecular characterization of the virus revealed that the strain was indigenous to the region and shared common similarities with the isolates responsible for the type O outbreaks in South America between 2000 and 2005. Specifically, studies showed that the virus presented a high degree of homology (96 percent) with virus types isolated in Pozo Hondo (Paraguay) in 2003 and in Tarija (Bolivia) in 2000, and with 92 percent homology with virus isolated in Mato Grosso do Sul (Brazil) in 2005 [31].

Both of the outbreaks had limited spread and were quickly identified; the disease was contained and eradicated within a few months and international authorities were timely notified.

Conclusions

There is no evidence that FMD has been transported from surrounding countries or other regions of Argentina into the Patagonia Region in almost 20 years. All sides of this region are bordered by either the ocean or areas that are free of FMD with or without vaccination according to OIE standards. Administrative barriers to animal movement in Argentina prevented the introduction of FMD into the rest of the country during the 2003 and 2006 outbreaks in Northern Argentina. In addition, FMD was not introduced into the Patagonia Region as a consequence of the 1987 outbreak in Chile or the 2001 outbreak in Patagonia North A.

4. The extent of an active disease control program, if any, if the agent is known to exist in the region

No active disease control program is currently being carried out in the Patagonia Region since no FMD outbreaks have occurred since 1994 [1, 14, 19]. Surveillance programs do exist, but passive surveillance and strong border and animal movement controls are the major defenses against an incursion of disease into this area.

Any Argentine citizen is responsible for reporting FMD. Indemnification is provided only when disease is reported, a situation that should serve to encourage reporting. Indemnities are paid at market value.

Conclusions

There is no evidence that FMD is present in the Patagonia Region. No FMD outbreak has occurred in the region since 1994; therefore, there is not an active disease control program. There are measures in place, including strict animal movement controls, border inspections, and clinical surveillance for prevention and early detection if the disease were introduced. Argentina has a control program and a national plan sufficient to respond quickly to any FMD emergencies. Argentina has a system of FMD indemnity which provides compensation at market value.

5. The vaccination status of the region

Vaccination is not practiced in Patagonia South and has never been systematically applied. Vaccination is also not performed in North Patagonia B. Administration of serum against FMD infection is not permitted in these regions [1].

Conclusions

Vaccination is prohibited in the Patagonia Region. In the absence of vaccination, it is likely that clinical signs compatible with FMD resulting from an incursion of disease would be quickly identified.

6. The degree to which the region is separated from adjacent regions of higher risk through physical or other barriers

The Patagonia Region is located in the southern region of the country and is made up of the provinces of Chubut, Santa Cruz, and Tierra del Fuego, islands of the South Atlantic and part of Antarctica, and a large part of Río Negro and Neuquén Provinces. In May 2002, the OIE recognized the area south of the 42nd parallel (Patagonia South) as FMD free without vaccination. In May 2007, the OIE recognized Patagonia North B as FMD free without vaccination. The geographic description of the Patagonia Region borders is as follows:

- Chile (west and south);
- Atlantic Ocean (south and east); and
- Northern Argentina and Patagonia North A regions, Argentina (north).

The border with Chile consists of the Southern Andes Range, which forms a natural border between the Patagonia Region and Chile. This area has an average height of 2,500 meters above sea level, with dry and cold climatological conditions that do not favor livestock production. Chile does not conduct vaccination against FMD and is considered to be free of FMD by the OIE and the United States. The northern border of the Patagonia Region abuts an area of Argentina which is considered by the OIE to be free of FMD with vaccination (Northern Argentina) and an area known as Patagonia North A, a buffer zone where vaccination against FMD was halted in 2013. The Patagonia Region under evaluation in this document is separated from Northern Argentina by the Barrancas River, which separates Neuquén from the Province of Mendoza, to the north.

The Patagonia North A region comprises the area of Río Negro Province located between the Colorado and Negro Rivers, the district of Patagones, Buenos Aires Province, and the Confluence area of the Province of Neuquén. The Patagonia North A and B regions are bordered by constantly flowing rivers that make crossing difficult.

The climate in the Patagonia Region is mostly dry and windy in the summer and cold, windy, and snowy in the winter. The land is not used for growing crops, but mainly for sheep meat and wool production. The terrain and desolate nature of the area act as an effective barrier to disease incursion through illegal trafficking of prohibited products. Areas where there are no natural barriers have control mechanisms which include mobile patrols and a permanent coordination between national and provincial entities to maintain a constant presence at the region route controls (National Border Police and other police authorities).

Conclusions

Most of the Argentine border is protected by natural barriers that help reduce the unrestricted flow of animals and animal products from areas of higher risk. Government movement control measures compensate in those areas where natural barriers do not exist. In addition, Argentina has sanitary barriers in place between the Patagonia Region and other areas in Argentina with different FMD status that function to preserve the FMD-free status of the Pagatonia Region.

7. The extent to which movement of animals and animal products is controlled from regions of higher risk, and the level of biosecurity regarding such movements

Both international and domestic movement of animals and their products and byproducts are regulated by federal rules. International and national border controls are administered by SENASA's Quarantine, Borders, and Certifications Unit [4]. Importations of live animals, genetic material, animal products, and animal by-products are allowed only under permit issued by SENASA. Animals and animal products may only enter the country through one of 45 authorized border stations, which include terrestrial, maritime, and river ports and airports. International border crossings authorized by SENASA in the Patagonia Region are listed below:

Chile

- Cardenal Samoré crossing (Province of Neuquén in Patagonia North B)
- Huemules crossing (Province of Chubut in Patagonia South)
- Coandhaique crossing (Province of Chubut in Patagonia South)
- Integración Austral crossing (Province of Santa Cruz in Patagonia South)

SENASA officials are assisted at border control points by various security forces, including the National Border Patrol, the Argentine Coast Guard, and the National Aeronautical Police [23]. National Border Control agents assist along international borders and number around 14,000 in the entire country. Coast Guard personnel assist at seaports and Aeronautical Police at airports. Permanent SENASA personnel at border crossing points numbered 394 in 2003, including veterinarians, agricultural engineers, and administrative personnel [7]. Cooperation with these groups occurs under the terms of official agreements [7, 11]. Other groups assisting with border inspections include the National Customs Bureau and Provincial and Local institutions. SENASA considers agreements with the security forces to be critical to the control program. Argentina port authorities check and confiscate products prohibited for movement domestically (because of potential FMD risk to Patagonia, which Argentina considers to be FMD-free without vaccination) and internationally. Human resources associated with control posts in the Patagonia Region and Patagonia North A in 2012 are listed in table two.

Table 2. Human Resources at Strategic Control Posts in the Three Patagonia Sanitary Regions in 2012

Sanitary Regions	Human Resources					
	Professional Barrier Coordinator	Provincial Link SENASA	Local Link SENASA	Supporting professionals/ Technician Point Chief	Supervisor/ auxiliary	Administrative
Patagonia North A Colorado River barrier	2	2	5	8	15	4
Patagonia North B Terrestrial points – airports	2	2	3	3	2	--
Patagonia South Terrestrial points – airports	2	3	10	2	10	--
Totals	2*	5*	18	13	27	4

*Some of the personnel have responsibilities for the 3 regions

FUNBAPA plays an instrumental role in the operations of land and airport border control stations, providing staff for the conduct of inspections at 38 posts. In addition, FUNBAPA employs the use of approximately 25 dogs that are trained to detect agricultural products. These dogs are primarily used at the busiest land and air ports and can be rotated to meet the needs at various locations.

Commercial imports

Prior to 2005, SENASA Resolution 9/2001, as amended by SENASA Resolutions 25/01 and 58/01, implemented a sanitary barrier by law at the 42nd parallel in order to preserve the area south of the Parallel as a region free from FMD without vaccination [2]. Since 2002 (Resolution 1051/02), Argentine authorities do not allow live susceptible animals to enter the Patagonia Region except from regions or countries recognized as FMD free without vaccination by the OIE and SENASA. In 2005, SENASA published Resolution 109/2005 recognizing the regions located south of the 42nd parallel and Patagonia North B as having the same FMD sanitary status. The same year, Resolution 725/2005 specified traceability requirements (see following section on "Livestock demographics and marketing practices") as well as the additional conditions listed below for moving FMD-susceptible animals from Patagonia North B to Patagonia South (areas were FMD vaccination was not practiced):

- FMD-susceptible animals must have remained in the source facilities for at least 90 days prior to movement application;
- Two negative serological tests for FMD from FMD-susceptible species within an interval of 21 days between tests, during which period the animals must be isolated under quarantine from other animals or other species;
- Two negative Probang tests from cattle and sheep with an interval of 21 days between samples;
- Movement of animals to destination with official dispatch and previous notice;
- Animals must be transported in sealed trucks and shall not move through zones where FMD vaccination is practiced; and
- Animals must be kept isolated for 21 days at the destination, after which period premises shall be cleared of potential disease contamination after a clinical inspection of FMD-susceptible animals on the premises.

In 2008, after the EU recognized Patagonia North B as free of FMD without vaccination, SENASA published Resolution 148/2008 (which amended Resolution 725/2005) and Resolution 370/2008, allowing the movement of FMD-susceptible species from Patagonia North B into Patagonia South under some restrictions [32]. These restrictions include:

- Animals must be transported in SENASA authorized trucks with a valid truck disinfection certificate;
- The owner of the farm must submit to SENASA the itinerary that the truck must follow;
- Animals must be transported in sealed trucks and must not move through zones where FMD vaccination is practiced;
- If animals are destined to slaughter, the shipment will be authorized only to slaughterhouses inspected and authorized by SENASA;
- The owner of the farm receiving the animals must communicate to SENASA within 48 hours of arrival of the animals; and
- Upon arrival at the destination farm, the animals must remain separated from all other animals of FMD susceptible species for 21 days; during that time, animals may be sent to slaughter only if authorized by the local SENASA veterinarian.

Shipping of animal-origin products to the Patagonia Region can only be done from official establishments under SENASA control.

Matured, deboned fresh beef is imported into the Patagonia Region from areas in northern Argentina for local consumption only, since beef is not produced in sufficient quantities for local demand. This meat has a very low risk of introducing the FMD virus into the export region since it must go through a maturation and deboning process consistent with EU and current U.S. requirements. The drop in pH that occurs during maturation inactivates the FMD virus. Border control posts visited during the site visits appeared capable of monitoring this movement and preventing illegal entry of animals and animal products into the Patagonia Region. Additionally, swill which may contain meat scraps must be properly treated before being fed to pigs, and sheep do not come into contact with the meat since they go directly from the range to the slaughter facilities.

Imports to Northern Argentina

Argentina requires a risk analysis for all imports of live animals to determine the epidemiological status of the country or region of origin, the existence of national or regional programs to control exotic diseases, the specific capabilities of the laboratories or quarantine facilities and their staff, and other factors that reduce the risk of importing exotic or high risk diseases into the country. SENASA Resolution 1354/94 defines the pre-importation procedures and the health certificate requirements for live animals and their reproductive material.

Argentina follows OIE guidelines in its importation policy regarding products of animal origin considered as possible carriers of the FMD virus from countries or regions with a lower sanitary status. Argentina requires risk assessment and mitigation to minimize the potential risks associated with the importation of these products. SENASA resolutions that regulate and set sanitary standards for importation of such products specifically to Patagonia South include 58/01 and 1051/02. Resolution 816/02 defines the general pre-importation procedures and controls for animal products and byproducts [1, 2].

The procedures and criteria applied by Argentine officials for imported live animals, animal genetic material, and animal products and byproducts are based on the principles of Risk Analysis, Regionalization and Equivalence in the Agreement on Sanitary and Phytosanitary Measures of the World Trade Organization (WTO) and the standards set by the OIE. Permits to import such items are required before the goods arrive in the country. The importer is issued an import permit only after all the applicable zoosanitary requirements stated in SENASA regulations are met. The import permits must be approved by the SENASA Central Office.

The procedures to assess the risk and approve processing plants and processing procedures in the country of origin are stated in Resolution 816/02. Import permits may be issued after an analysis of the following [1]:

- The type of product that will be imported;
- The health status of the exporting country;
- Approval of the slaughtering or processing plant in the country of origin;

- Type of shipment;
- Transit of the product through other countries;
- Border post at the point of entry into Argentina; and
- Expected use of the product.

All products and live animals that require approval from SENASA must meet similar security requirements. Import requirements are summarized as follows [1]:

- Pre-importation authorization;
- Verification of the health certificate issued by the country of origin;
- Physical inspection, document control and verification of the identity of the imported products; and
- A Restricted Transit Permit for shipments of animal products to processing plants with official SENASA veterinary inspection. Live animals must be placed in quarantine at the Official Quarantine Facility.

After inspection, the imported products are sampled for the purpose of the CREHA (National Residue Control in Food Products and Hygiene) program, and the release document is issued. In the case of live animals, the release document is issued at the end of the quarantine period if no evidence of disease is found.

Imported animals are placed in SENASA's quarantine facility, "Lazareto Capital" in Buenos Aires. Animals that require special conditions or treatment are placed in special quarantine facilities (e.g., zoo animals, ornamental birds, fish). The duration of the quarantine period varies to allow sufficient time for completion of all required testing procedures, depending on the species and the place of origin. The quarantine period is between 15 and 60 days. At the end of the quarantine period, the imported animals are placed under observation at the farm of destination for a period of 60 days. After this period, the local SENASA veterinarian must issue a report certifying that the post-quarantine period has been completed.

Inspections of imports are conducted in all cases, without exemptions, if the products are under SENASA jurisdiction. Documents are checked, and products or animals are physically inspected and identified. Two inspection modes are used at borders [2]:

- Direct inspection: Questioning, observation, and manual inspection of luggage and vehicles (e.g., trunks, rooms, cabins, boxes), and
- Indirect inspection at the most relevant entry points: Auxiliary methods used to detect organic products that could be potential carriers of pests or diseases (e.g., organic material scanner, beagle dog squad)

In case of animal health emergencies in the region or in neighboring regions or countries, additional control mechanisms are activated such as reinforcement of regulations and personnel, increasing vehicular disinfection tasks and strengthening of patrol and control tasks. Security forces (National Border Police, Argentine Navy, National Air Force Police) that carry out sanitary supervision tasks at the border will be alerted to be more vigilant.

At the inspection posts, shipments into all Argentina are inspected and checked for proper documentation and identification. If the shipment has the proper documents and passes inspection, it is authorized to continue to its destination after resealing the vehicle and recording that the shipment had passed through the check point region [2, 10].

Noncommercial traffic

The proportion of travelers, means of transportation, and types of luggage inspected varies according to the recommendations of the procedures manual and regional characteristics of each control post. The particular types of inspection activities that occur depend on the control posts. Direct inspections (e.g., observation, questioning, manual inspection) are carried out mainly at terrestrial posts and sea ports while indirect inspections with detecting scanners are used at the main airports of the region (Aeroparque Jorge Newbery, Bariloche, Neuquén, Comodoro Rivadavia, Ushuaia and, soon, El Calafate) and some sea ports.

Sanitary barriers were established to prevent unauthorized crossings at points other than border posts. Control posts are located in strategic places along the borders. Trained staff are present at all times and interact with security forces to enforce sanitary regulations. It is difficult to accurately estimate the amount and frequency of unauthorized crossings because they are conducted illegally, but the measures explained above aim at minimizing the risk of introduction of animals or products of risk through illegal means [2].

Property confiscation and transport infringements

Controls applied at the Patagonia sanitary barriers follow federal transit standards by prohibiting entry of forbidden and restricted animals and products as well as low-risk products such as cold meats or eviscerated chicken.

Airports [10]

During the several visits to Argentina, the site teams visited several airports which act as control points mainly for tourist traffic. The Jorge Newberry Airport in Buenos Aires handles a significant level of traffic to Patagonia. 80 percent of the flights are domestic and 20 percent are international (from Uruguay). Two airlines handle the Uruguay traffic which numbers about 400-500 passengers/day. Four airlines fly to the south into Patagonia carrying about 2500 passengers/day to the Patagonia Region and Patagonia North A. A number of safety measures (described below) are implemented to prohibit the introduction of risky material to Patagonia. Other airports visited in the Patagonia Region included the Río Grande, Ushuaia, Río Gallegos, and Neuquén airports.

The security measures implemented at the Jorge Newberry Airport are thorough. Aeronautical police assist SENASA in its activities. All carry-on baggage is put through scanners that can differentiate organic materials from other substances. Checked baggage from domestic flights is usually not scanned unless it is going to Patagonia. International flights from Uruguay have a

separate line to scan baggage, and all checked baggage and hand carried luggage from international flights is examined by scanner. During the 2009 site visit, Jorge Newberry Airport officials indicated that approximately 35 kg of plant and animal products are confiscated daily during the high tourist season. The average volume of confiscations drops to 8 kg during the low travel season. This airport employs a staff of ten individuals who work in shifts between 4 a.m. and 11 p.m. daily.

Passengers are provided with information on prohibited substances and are required to fill out a customs declaration form if arriving on an international flight. Passengers carrying food products are given information on prohibited material regardless of destination. Any unauthorized cargo is confiscated. In 2003, a new statement was developed to accompany packages stating that certain products are not being shipped in the packages or with a passenger. The statement is used for all airplane and bus travelers. One side has the declaration statement and signature stating that no prohibited plant or animal products are being carried by the passenger and the other side lists the Resolutions involved and prohibited items. If undeclared prohibited items are found on inspection, SENASA conducts a review to determine if a fine should be levied.

Products shipped as cargo directly from plants must be accompanied by relevant documentation. Air freight of perishable goods is rare but would be checked at the airport of destination and not released until after SENASA approves.

Checked baggage heading for a different destination than Newbery is subject to inspection by the Beagle patrol. A beagle dog is used to sniff for prohibited substances in baggage on the carts outside. Luggage that is suspect is identified, sealed, and inspected at the point of destination. A fax is sent to the destination airport to notify them of the suspect package. The luggage can only be opened with the owner present. Any confiscated material is denatured and then treated as waste and sent to the landfill. The destination airport then sends a report back to the airport office from where the package had been shipped.

Members of the site visit team observed a beagle working that, in the process, detected a suspect package. The SENASA official labeled it so officials at the point of destination would investigate the package. They do not open these packages at the airport where the dog detects something suspicious. The package is flown to its destination and then the owner is notified and SENASA opens the package with the owner present.

The site visit team noticed that all carry-on luggage was examined by inspectors when passengers entered the airport and checked baggage was spot checked in the presence of the owner at the Río Grande airport. Passengers walked over a carpet with disinfectant (usually Virkon S) as they entered the terminal from the tarmac.

Checked baggage is usually scanned at the Ushuaia airport, but at the time of the visit, the scanner was not operational and all such baggage was examined manually along with the carry-on baggage. A footbath with Virkon S was located in the passenger exit ramp to disinfect shoes. Any baggage that was identified in Buenos Aires as suspect by the beagle and tagged is examined by the officials in this airport with the owner present. A report of the investigation is

sent back to Buenos Aires. Confiscated material from passengers is denatured and disposed of as waste.

All baggage originating north of Patagonia North B is examined by SENASA officials at the Río Gallegos airport. Baggage originating from within Patagonia is randomly checked. Any prohibited material seized is kept in the office, treated with methylene blue, picked up by a SENASA official at the end of the day and destroyed in the digester at a slaughter plant. Cargo is usually scanned. Suspicious packages go to the SENASA main office. Perishables are refrigerated. The owner must go to the office to retrieve the cargo and be present when SENASA opens it.

APHIS visited the Neuquén airport in 2003 and 2009. The airport has a zoophytosanitary post operated to enforce Resolution 58/01, which prohibits the entrance of products that could potentially carry the FMD virus. It is a control point that examines passenger carry-on and checked luggage and commercial cargo from northern Argentina. This airport deals mainly with small cargo, although it is a commercial airport that could potentially receive larger cargo shipments.

There are six domestic flights from the Jorge Newbury airport to the Neuquen airport daily, about three hours apart. Charter flights occasionally fly in from Chile. Three employees work at the airport for FUNBAPA, and SENASA staff is not present at this airport. There is at least one person on duty at all times in case an unscheduled flight arrives or any other sanitary questions arise.

All baggage is scanned (carry-on and checked) using a scanner capable of detecting organic material. Very few animal products are found; most material is fruit. Most of the travelers are people from the area going to Buenos Aires, so most are aware of the sanitary situation and the restrictions. There is very little tourism to this area. All confiscated items and airplane garbage are incinerated daily on the premises, and items confiscated are recorded. During 2008, the airports confiscated 82 kg of plants/vegetable products and 16.8 kg of animal products from local flights. In 2012, SENASA the same airport confiscated 73kg from local flights. There were no reports on confiscations of plants/vegetable and animal products from international flights between 2008 and 2012 [14, 19].

During the 2009 site visit, activities at the Trelew airport were also observed. Trelew airport was equipped with a state-of-the-art scanner and all incoming passenger luggage is scanned. Officials at the Trelew airport confiscated over 400 kg of fruit in 2008, and over 260 kg of animal products between 2007 and 2008. In 2012, the same airport confiscated 72 kg of animal products.

The airports in the Patagonia region with sanitary inspection are listed in Table 3.

Table 3. Airports with Sanitary Inspection in Patagonia South and North A and B

Sanitary Region	Airports
North A	3 (Viedma, G. Roca (closed), Neuquén)
North B	3 (R. Sauces, Bariloche, Capelco)
South	9 (Pto. Madryn, Rawson, C. Rivadavia, Trelew, Esquel, Río Gallegos, Calafate, Río Grande, and Ushuaia)
Total Airports	14

Land ports

General: International borders

Permanent SENASA personnel are stationed at each international border port; however, SENASA is not the only group responsible for biosecurity at borders. The number of personnel available for border control is supplemented through agreements with security forces like the gendarmeria (special type of military forces). As a result, 14,000 officials are stationed along 9,370 miles of border [11]. As previously mentioned, SENASA is assisted at import centers by several designated security forces. SENASA officials emphasized the importance of the national forces (i.e., the land, water and border police) in identification of illegal imports [11]. If needed, SENASA also has the authority to call upon local police to assist.

SENASA checkpoint officials are notified approximately 15 days before an agricultural animal or animal product shipment arrives. This minimizes potential problems with the customs authority and helps facilitate and expedite the process. All exporters and importers must be registered with SENASA. The shipment must be accompanied by a permit and must originate from an approved location. Both the origin and the destination of the product appear on the permit.

Shipments can be rejected if documentation is incomplete or if it appears to be falsified. There are no fines for commercial shipments that are rejected because the paperwork is incomplete; however, the shipments are denied entry and SENASA may confiscate and destroy the product. In comparison, if SENASA detects deliberate falsification of documents, a fine of 800 pesos is levied. This is equivalent to one month's salary [11].

Border patrol police on land, on water, and at the ports are the primary personnel responsible for identifying illegal shipments. The number of illegal shipments has been reduced significantly since the economic collapse in Argentina in 2001. SENASA has monthly meetings with these border patrols to discuss issues and procedures.

Patagonia Region: International border

The Patagonia Region borders one country, Chile. As previously mentioned, Argentina is separated from most of Chile by the Andes Mountains and works with Chile on joint surveillance for the monitoring of movement across the border (i.e., monitoring transport of prohibited

materials/animals by people crossing the border). Much of the movement control focus is directed towards FMD. In this regard, since the OIE recognizes Chile as FMD-free without vaccination, SENASA does not consider Chile as a high-risk region [33]. Chile is also recognized as FMD-free (without vaccination) by the United States.

Four terrestrial border stations are located along this border [1]:

1. Los Huemules in the Andes Mountains in Chubut Province;
2. Cohayque in the Andes Mountains in Chubut Province;
3. Intergración Austral (Monte Aymond) in the southern part of Santa Cruz Province; and
4. Cardenal Samoré crossing in Neuquén.

The site review team visited the border post at Monte Aymond. This post is under the joint control of the Argentine and Chilean governments. Argentina inspects Chilean shipments, and Chile checks Argentine shipments. Joint inspection teams are made up of Border Patrol staff which act as an international trade enforcement authority. The plan is to integrate the two border post facilities into one unit with integrated staff from both countries.

Bus traffic between Santa Cruz and Tierra del Fuego Provinces must go through several posts for inspection. When leaving Argentina to enter Chile, passengers must pass through Joint Argentine-Chilean Immigration and Customs and repeat this step again when entering Tierra del Fuego from Chile, where customs officials checks passports and luggage. Customs then passes passengers on to the Border Patrol. If someone is suspected of carrying hazardous agricultural or food items they are passed on to a SENASA inspector. If SENASA personnel are not present, the Border Patrol staff carries out SENASA duties. When the joint border post is in operation, SENASA staff will be present 24 hours a day.

Tri-language (English, Spanish, and Portuguese) notices are posted at border crossings and other ports of entry to inform visitors of biologically hazardous materials and products. A scanner that can detect organic materials is present at the Monte Aymond post but was not in operation at the time of the 2003 site visit. Officials stated that it would be in operation in a month from the time of the visit.

The FMD status of Chile and the Patagonia Region is recognized as equivalent by both countries. Both areas are considered free from FMD and fruit flies. Breeding stock is traded between these two regions. Commercial meat shipments are also allowed; however, passengers cannot bring meat over the borders. The vast majority of the contraband agricultural and food products confiscated are fish products and certain fresh plant/fruit products are also prohibited into the area.

A standard certificate for export/import must be presented by shippers at the border crossing. SENASA must be notified so staff can be present when the shipment arrives at the border, but staff from the Border Patrol can also inspect shipments. The border posts are staffed 24 hours a day, seven days a week by Border Patrol officials, who check seals and documents but do not open the seals to inspect cargo. The seals are inspected to ensure that they have not been broken and that they match the entries on the export/import documents.

Customs turns over all contraband products seized to Border Patrol or SENASA officials. A record of all seized products is made and products are then put in a barrel and sprayed with methylene blue or povidone to render them inedible. They are then burned in large holes and covered with soil once the holes are filled.

Patagonia Region: Internal borders [10]

Land control posts between the Patagonia Region and the northern part of Argentina run along the Barrancas River. They are located near bridges at Barrancas, Desfidero, Mora and El Porton. There are 10 control posts around the city of Neuquén in the Confluent Department between Patagonia North B and North A. The rest of the land control posts between North A and B run along the Negro River. They are located near bridges at Paso Cordova, Valle Azul, Pomona, and San Antonio Oeste. The site visit review team visited the control post at San Antonio Oeste.

San Antonio Oeste is a small post near the sea port of the same name. It is only an animal and animal product post. The staffing in this post has increased from six employees in 2003 to ten in 2009, and the post operates 24 hours a day. All vehicular traffic going south into Patagonia North B and all cargo vehicles going north into Patagonia North A are checked for proper paperwork. FMD-susceptible species are not allowed to pass this post and proceed south into Patagonia North B. Around 500 vehicles pass through this point daily. Inspectors have stopped wool being shipped without the correct documentation. There is a documented case in which a sealed truck could not be adequately inspected, so the staff re-sealed it and notified SENASA at the destination point so that officials could inspect the truck during unloading.

Before 2003, due to an increased rate of smuggling of bone-in meat to Neuquén, SENASA decided to vaccinate animals in the surrounding area to guard against potential introduction of FMD. A circular area around the city of Neuquén with ten control posts was established and included as part of Patagonia North A (Department of Confluencia). That area is the only region in the Province of Neuquen that is a part of Patagonia North A. This zoning was done in consultation with OIE. More than 18,000 vehicles cross the bridge daily between the cities of Neuquén and Cipolleti.

The area between the control posts separating Patagonia North A from the rest of the Patagonia Region is very inhospitable in the western region with very few animal movements from North to South. It is mainly an oil-producing area with no electricity or water. FUNBAPA has mobile units to patrol the area and check vehicles. Vehicles passing through this area will eventually have to pass through a town, and police will stop anyone attempting to bypass a control post.

Land control points between Patagonia North A and the northern part of Argentina run along the Colorado River. They are located near bridges at 25 de Mayo, Dique Catnel, Medanitos, Casa de Piedra, La Japonesa, Pichimahuida, Río Colorado, Adela, Pedro Luro, and Km 714.

All control posts along the border are for animal and animal product inspection; only some of them include plant and fruit inspection. The 2003 and 2009 site visit review teams visited the control posts at Km 714 and Pedro Luro.

The control post at Km 714 is located north of the barrier between Patagonia North A and the northern part of Argentina. It is located north of the Colorado River at the point just before the main road splits in two. Most of the traffic heads west toward Neuquén, while a small amount goes south to Pedro Luro. Seventy percent of the traffic going into Patagonia goes through this control point, and it is strategically situated for fruit fly control (outside of the production area). There are at least two signs on each side of the highway warning travelers to stop for agricultural inspection as they approach the control post. All vehicles heading south into Patagonia are inspected, and all trucks and cars are sprayed and disinfected for fruit flies; however, not all vehicles are sprayed for FMD virus disinfection. Only in an emergency situation, such as an active outbreak of FMD, are trucks and cars disinfected for FMD. The site review team witnessed a truck going through the disinfection process which consisted of sprayers in the road that spray the vehicles from the sides and from below.

The post has an adequate infrastructure (employees, space, electricity, equipment). There were three eight hour shifts with a total of 52 people staffing the post as of 2009. Agricultural inspectors number 10-11 during the day and eight at night, when there is less traffic. Officials can dispatch police for violations of trucks and autos. In some instances, confiscated animal or fruit products (originating in areas that vaccinate against FMD or areas considered at risk for fruit flies) from this control post can be donated to underserved populations north of the post; however, only the large confiscated shipments can be donated. Substances seized from personal vehicles are destroyed in front of their previous owners so that the public knows the products are not just being stolen. Data is entered into a computer about what animals, animal products, and fruits are transported and for what purpose, and all confiscated materials are recorded on paper records. Since 2004, the post has used sniffer dogs to help with vehicle and cargo inspection. During the 2009 site visit, team members observed a beagle detect meat products in a passenger's luggage. The product was confiscated, treated, and disposed of properly, and all necessary forms documenting the violation were completed. An average of around eight kg of plant/fruit and animal products are confiscated daily.

The Pedro Luro Control Post is a smaller post (the office is in a small trailer) through which a small minority of the main traffic through Km 714 passes. Generally, more traffic heads out of the area than goes in on that road. This post distributes about 30,000 leaflets per year to let people know what they can and cannot bring into the region. Generally, people do know what is prohibited and are cooperative. The post is staffed by five people and there is also a police car at all times outside of the office with at least two policemen. The same standard procedures are followed in this post as in Km 714 and other posts visited. The staff appeared to be adequately trained and knowledgeable of their duties and responsibilities.

The control post inspectors confiscate about ten kg of meat products per day. Meat in-bone is returned to the place of origin, unless it had been hidden, in which case it is destroyed. Examples of other interdictions include sausage, ovine meat, bees, dirty empty trucks, trucks without proper paperwork, and dirty trucks carrying passengers. Most of the confiscated items, such as prohibited foodstuffs and animal products, are burned immediately after seizure and buried in a hole in the ground on the side of the road by the post.

Training of personnel

SENASA personnel conduct training of security and other forces working on border security. A manual of procedures applies at a national level for all types of border crossings [4]. The manual includes:

- The legal framework;
- The national and international zoosanitary status;
- A glossary of terms;
- The list of officials that are authorized to sign the international certificates and a list of authorized border control posts throughout the country;
- An epidemiological characterization of the border posts (in the process of implementation); and
- Import and export procedures.

In addition to the procedures manual, SENASA has a product manual that lists products allowed to enter the country (Resolutions 295/99 and 299/99 list approved plant/fruit and animal products). The policies and guidelines in these documents are applicable at a national level and define a standardized approach for border personnel.

FUNBAPA employees receive a one-day instruction course prior to employment and then are given materials to study at home. At the end of ten days they are required to take written and oral examinations on the materials. If the scores are satisfactory, they are subjected to an interview before the hiring decision is made. They are also trained in various technical duties, including recognition of FMD clinical signs and laws and regulations. The probationary period is six months. Employees receive mandatory training once a year in a refresher course that covers any new rules or regulations. All posts are audited monthly by FUNBAPA and every four months by SENASA.

Conclusions

APHIS considers SENASA officials in Argentina, including the ones in the Patagonia Region, to have adequate controls at ports of entry for legal commercial and noncommercial importation of FMD-susceptible species and livestock products. SENASA also has the legal framework, proper coverage of borders, and adequate staffing to monitor the influx of animals and products via traffic from adjacent areas of higher risk and to deal with the entry of illegal animal or animal products into the region. The border control posts (land and air) visited during the site visits demonstrated adequate staffing levels, knowledge of requirements and procedures, and professionalism and efficiency. Staff were well trained and updated on a regular basis and employed the use of appropriate technology when available.

8. Livestock demographics and marketing practices in the region

Livestock production systems in the Patagonia Region are mainly extensive on large farms where large numbers of sheep are kept. These sheep farms traditionally send lambs and culled ewes directly to slaughter with little movement of animals between holdings. Cattle farming is

limited to small cattle breeding areas with low stocking rates. The climate and the environment of Patagonia are major factors that make the sheep industry the prevailing livestock activity. This area contains almost 60 percent of the entire sheep population of Argentina. There were over seven million sheep in 2003 (8.4 million in 2008) and more than 72 percent of Argentina's best wool is produced in this region.

Prevailing breeds in the region are Merino and Corriedale. Average livestock density is 14 sheep per km^2 with Santa Cruz province having the lowest density at 9.5 sheep per km^2. Total sheep exports from the Patagonia Region surpassed 90 percent of the total of sheep exports from all of Argentina. Currently, Argentina is exporting 10,000 tons/year of sheep meat to the EU. Argentina estimates that it will export 6,000 tons/year of sheep meat to the United States, with a maximum of 9,000 tons/year and a minimum of 4,000 tons/year. Sheep production is highest in the province of Chubut, followed by Santa Cruz and then Tierra del Fuego [1, 2, 34].

Bovine production is secondary, and beef produced in the Patagonia Region is consumed locally. Matured and deboned beef must be imported to meet the consumption demands of the population in Patagonia South. Pigs are also raised only for local consumption. Fresh pork meat (chilled and frozen) and pork sausages are not allowed into the Patagonia Region from other parts of Argentina. Livestock statistics for 2009 are listed in Tables 4 and 5 below. During the 2013 visit, SENASA reported that there were not significant differences between the 2009 and 2013 livestock statistics.

Table 4. Livestock Producers, Establishments, and Bovine and Sheep Populations in the Patagonia Region in 2009 [35]

Province	Total Establishments	Total Producers	Establishments with Bovines	Bovine Population	Establishments with Sheep	Sheep Population
Chubut	4,593	5,178	2.214	252,582	3,605	4,786,274
Santa Cruz	773	807	230	58,968	595	3,324,012
Tierra del Fuego	81	90	72	32,770	52	572,464
TOTAL	5,447	6,075	2,516	344,320	4,252	8,628,750

Table 5. Pig and Goat Livestock and Establishments in the Patagonia Region in 2009 [35]

Province	Establishments with Pigs	Pig Population	Establishments with Goats	Goat Population
Chubut	256	8,890	953	144,681
Santa Cruz	47	3,101	10	1,296
Tierra del Fuego	8	630	0	0
TOTAL	311	12,621	963	145,977

Premises identification

SENASA requires that all premises involved in animal production register with SENASA and obtain a RENSPA (Registro Nacional Sanitario de Productores Agropecuarios [National Sanitary Registry of Agricultural Producers]) number. This is an alphanumeric identifier that encodes information about individual premises and identifies the province, the municipality, and various aspects characterizing a particular premise such as ownership, rental status, or shared occupancy [1, 11]. A diagram of the RENSPA number is represented in figure 6.

Figure 6. Explanation of RENSPA Number

XX	XXX	X	XXXXX	XX
Province	District	Internal Control No.	Unique Farm No. (unique in province)	Possession Type Owner (00) Renter (01) Etc.

The name of a responsible veterinarian must be included on the application for a RENSPA number and is entered into the database. The veterinarian is held accountable for failing to report problems that he or she might observe on the premises. Veterinarians named on registration documents are required by law to report problems on the premises, such as unusual numbers of sick and dead livestock. If the veterinarian or owner of the animals fails to report suspicion of disease, indemnity will not be paid. This can be a significant loss, since the indemnity paid is typically the market value of the animal. In addition, a fine is levied on the veterinarian, the owner, or both, depending on who fails to notify SENASA.

The RENSPA database is maintained by field officials and includes census information on all species on the premises, permit information showing animal movements, as well as other pertinent data. The database also records the FMD test status of the premises, as defined by the national surveillance program. Monthly statistical reports are generated from this database.

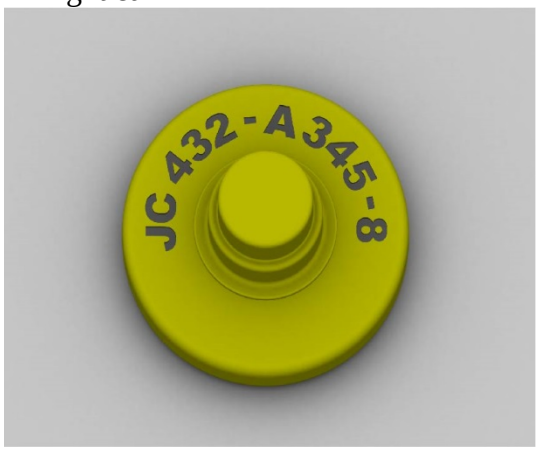
In addition to the RENSPA number, livestock owners are assigned a unique identifying code called a CUIG number (unique holding identification code), consisting of a series of four digits. The CUIG number is shorter than the RENSPA number and is used as a more convenient form of premises identification. The CUIG must be included on eartags of cattle (CUIG on the front). The RENSAPA and CUIG codes are linked to the integrated management system for animal health (*Sistema Integrado de Gestión en Sanidad Animal* – SIGSA), which ensures prompt access to all information needed in case of any animal health event, such as the number and individual identification of animals (for cattle) present in a particular farm at a certain time, all animal movements in and out and detailed geo-referenced data that allow for a quick identification of other farm or geographical areas at risk of any possible transmission of a reportable disease. All cattle and sheep movements are individually authorized and registered by the SIGSA through the issuing of the electronic animal movement permit (*Documento de tránsito electrónico* – DT-e), which must accompany all cattle and sheep that are moved in Argentina. The owner could request the DT-e either electronically or from the local office.

In 2007, Argentina instituted a compulsory cattle identification program, requiring that all calves born after September 2007 carry official tags (Resolution 754/2006). Resolution 563/2012 requires that bovines from the older age groups be individually identified. At the time of the 2013 site visit, SENASA reported that the entire Argentine herd was individually identified. Individual identification of bovines is unique and permanent. The number of tags needed is requested by the animal owner and is crosschecked at the local office to the inventory in the SGS (animal health information system software). The owner is responsible for applying the tags and then notifying the local office as to which tags have been used. The color of tags issued to cattle holders is determined by the FMD status of the region in which the cattle reside. Green tags are used in regions that are FMD-free without vaccination, yellow for regions that are FMD-free with vaccination, red in buffer areas, and blue tags are used for tag replacement purposes only. Figure 7 shows the IDs used for bovine

Figure 7. Individual Bovine ID system in the FMD Free with Vaccination Region

Left ear

Right ear



For sheep, individual identification is required in the event the farm is approved for export to the EU; otherwise premises identification is required, either by eartag, which includes the CUIG number of the farm, or ear notch. The eartag color and shape may be selected by the farmer (the color is not specific to the FMD status of the region as in cattle). Ear notches are controlled by and registered with SENASA to ensure that they are unique.

Movement controls within Argentina

A DT-e is required when animals move to slaughter, to market, or from farm to farm in Patagonia, cross provincial lines, or if they are exported. These permits are required in order to establish that the farm of origin is registered so that tracing can be conducted quickly. The identification numbers of both the premises of origin and the premises of destination must be recorded on the DT-e. Permit applications are checked against farm inventory in the SGS database. If a registered farm attempts to ship more animals than are recorded in the inventory, the discrepancy is noted and the permit application is denied. The number and species are then recorded on the permit, the information is entered into the database, and the inventory is updated.

Movement of FMD-susceptible animals is limited in the Patagonia Region. The local SENASA office issues a DT-e to keep track of all animal movements off each farm. Another movement permit, a provincial transit certificate (Guia), is issued by the Provincial Authority to validate ownership and identification of the animals. When animals are shipped from farm-to-farm, the DT-e must be returned within five days to the local office of destination, which will inform the local office of origin of the shipment arrival (http://www.senasa.gov.ar/Archivos/File/File1528-Anexo%20356-08.pdf). SENASA Resolution 38/2010 describes penalties for not complying with the animal movement requirements. If animals are going to slaughter for domestic consumption, the veterinary inspection is limited to the antemortem inspection at the slaughter facility. If the carcasses are going to be exported to the EU, the local SENASA veterinarian goes to the farm and seals the transportation vehicle, which is later opened by the veterinarian responsible for the antemortem inspection at the slaughter facility [10].

Movements of cattle are carried out under the conditions established by SENASA Resolutions No. 178/01 and related Resolutions 356/2008, 810/2009, and 238/2013. These resolutions require that the animals be accompanied by a DT-e and the pertinent livestock Guia, have individual animal IDs, and be transported in a vehicle approved by SENASA with a certificate accrediting washing and disinfection of the vehicle before loading and seals on each of the vehicle doors. It establishes joint liability among the official staff that issues the health certificate, the owners or persons responsible for the animals, the shippers, and the slaughter plants [1, 2,19].

All vehicles carrying commercial shipments must also be registered with and approved by SENASA and issued a number. SENASA Resolution No. 809/81 (updated by Resolution 238/2013) establishes the mandatory washing and disinfection of all livestock vehicles that transport livestock within the country. Typically, the number issued by SENASA is painted on the trucks and the driver must show proof of the authenticity and validity of that number. Trucks must be cleaned and disinfected before every transportation and must show a proof of truck disinfection in the form of a bill issued by a SENASA-approved facility. There is only one bill per movement. No dirty animal trucks are allowed on the road or they will be cited. Disinfection is carried out in all freight transports, including farm machinery, and is performed at random in automobiles at all entrance points into the country and into the free areas where vaccination is not practiced. These points are approved by SENASA and are located at certain risk borders [1, 2].

Transport washers must be approved by SENASA. They are required to use products specific for veterinary use and approved by SENASA. The washing and disinfection tasks are performed by official staff or staff hired by SENASA using motor-propulsion machinery or sprinkler equipment and products approved for vehicular disinfection [2].

There is no charge for work done at the control posts (except for the spraying done at points of first entry into Patagonia North A). There are automatic sprayers at all commercial entry points and handheld sprayers at others. Currently, there is a charge for the DTA (one Argentine peso, which is equivalent to $0.5 U.S. dollars). The Province charges for the Guia, which includes a fee that is then used for agricultural projects in the Province (e.g., herd improvement) and funding for the Guia issuing offices. There is also a fee per kilo of wool shipped that is collected by the Province and used the same way. It is only the fruit and vegetable industry that funds FUNBAPA via fees collected for spraying at the border and for cargo per ton shipped. The animal industry funds go to the Province, except for the vaccination programs where the farmers must pay for the FMD vaccine and the brucellosis vaccine [10].

Movement controls within the Patagonia Region

Movements of livestock within the Patagonia Region are limited. There are no livestock concentration markets in this region. Annual exhibitions/fairs for selling breeding rams occur once a year in Santa Cruz (Río Gallegos) and Chubut (Comodoro Rivadavia, Trelew, and Esquel). Each auction sells about 400 rams. Also, large farms carry out their annual breeder auctions on their own premises so breeding livestock transport is limited mainly from farm to farm.

Due to the type of production and marketing systems in Patagonia, there are no livestock concentration markets for fattening and slaughter. Trade is carried out directly from the farm to the slaughterhouse with direct selling of cull animals and lambs to slaughter plants. Lambs are usually destined for export.

Slaughter Facilities in the Patagonia Region

There are 19 slaughter plants approved by SENASA in the Patagonia Region that comply with the established regulations. All plants approved by SENASA are federally inspected. Three plants are approved for export of sheep meat to the EU; two are located in the city of Río Gallegos in the Province of Santa Cruz and one is in the city of Puerto Madryn in the Province of Chubut. No slaughter facilities are currently approved for export to the United States.

The procedures to approve plants for export are regulated by SAGPyA Resolution 310/04, which updates the requirements of Decree 4238/68 and other previously abolished standards. The facility must first be registered on a list of establishments authorized to export. The Bureau of Supervision of Products of Animal Origin then has to conduct an assessment of the compliance of building, operative, and documentary requirements, in accordance with a Procedures Initiative. Also, it must verify that the requirements of the country of destination and those of the National Bureau of Agricultural and Livestock Trade Control, an agency of the Secretariat of Agriculture, Livestock, Fisheries, and Food, have been met.

The following parameters are taken into account for the assessment of compliance:

- Capacity of pens at the export area;
- Daily slaughter numbers intended for export;
- Slaughter capacity (animals/hour);
- Capacity of the maturations chambers, if pertinent; and
- Capacity of carcasses that can be introduced into chambers intended for "maturation," complying with the following items in accordance with Decree 4238/68:
    - Prohibition of commingling of carcasses coming from areas of different sanitary conditions.
    - Presence of viable technical methods to register environmental temperature in the maturation chambers.

The slaughter establishments must be approved for the activity appropriate to the requested destination and a predetermined volume of production. The establishment has to have documented procedures to identify and trace the products to be exported and provide the Service of Veterinary Inspection an updated list of livestock suppliers. They must not have any infringements of the Residues and Food Hygiene Plan and must correct any problems that were observed by auditors of foreign sanitary authorities. Documentary proof of compliance with all the requirements of the country of destination must be provided.

According to the regulations, by the authority of Decree 4238/68, the following controls must be carried out at all SENASA-approved slaughter facilities:

- Pens: Animals are kept within pens and cannot leave the slaughtering plant once they enter the premises.
- Effluent treatment: All effluents from the coldstore (pens, slaughter yard, and water used in all the processes) are treated by separating out solids, fats, liquids and chlorinates before releasing them to the general sewage system.
- Sanitary complex: Effluents from the sanitary complex are individually treated by disinfection before dumping them with the rest of the common, treated effluents.
- Fallen and dead animals: Fallen animals are slaughtered at the emergency yard and their meat and products not used for export. Dead animals, including their skin, are treated at the necropsy digester after diagnosis.
- Raw slaughter wastes: Wastes are sent to processing plants with thermal treatments for nonedible uses in closed vehicles approved for the purpose. They may be processed at the same plant in melters or digesters with thermal treatment to make nonedible byproducts.
- Slaughter pathology wastes: Wastes are processed in digesters with pressurized steam or in melters to obtain byproducts.

A slaughter facility visited in Río Gallegos buys animals (sheep) from regional farms and markets the meat. It is approved for export to the EU, Israel, and Islamic countries and has about 70 employees.

A SENASA official conducts antemortem inspection, and any sick animals are placed in an isolation pen. Animals from the same ranch are all placed in the same pen. The number of

animals and other information are recorded on a card which is kept in the office. A postmortem examination of any animals that die is performed in a nearby necropsy room.

After animals are killed, an inspector examines the carcass and organs. There are SENASA inspectors plus four plant staff that examine the organs. Condemned whole carcasses go through a different line and are put into the digester. There are no rendering plants in Patagonia South. Carcasses are stamped with the flock number and animal number. The barcode label includes weight, animal number, and flock number. Carcasses for market are stored at about -22°C.

The 2009 site visit team observed activities at a sheep slaughter facility in Puerto Madryn which has been exporting to MERCOSUR (Southern Common Market) member nations and other countries, and since 2004 to the EU.

Conclusions

Large extensive sheep operations and export-approved slaughter facilities would likely be the source of sheep meat and products exported to the United States from the Patagonia Region of Argentina. The livestock industry in Patagonia appears to be well organized, committed to the production of quality products, and aware of necessary biosecurity precautions. There appears to be high awareness and compliance with these measures. Processing facilities are under adequate official control and inspection. APHIS did not identify significant risk pathways as a likely source for introducing FMD into the United States.

The SGS system is able to consistently and reliably capture farm inventory, animal movement information, sanitary information, and identification numbers, as well as to control movements as necessary. Observations indicated that the structure, effectiveness, and organization of SENASA were adequate to perform official animal health functions. In addition, APHIS observed that the identification system in place is able to track cattle movements and keep a reliable farm inventory. The National Identification System is comprehensive and able to comply with U.S. certification requirements for exporting products from the Patagonia Region to the United States.

9. The type and extent of disease surveillance in the region

Documenting a surveillance system sufficient to ensure early detection of FMD is essential for the assessment of risk. An effective surveillance system combines both active surveillance (including ongoing laboratory-based testing) and passive surveillance (reporting and/or testing of animals with clinical signs of disease). This section explains the characteristics of the FMD surveillance program in place in Argentina.[2]

[2] The Epidemiology and Risk Analysis Unit of SENASA's National Animal Health Directorate is responsible for designing the sampling and evaluating the results. It collaborates with and seeks technical assistance from the Epidemiology Advisory Commission, whose members are experts from SENASA, the National Farm Technology Institute, the Animal Virology Centre of the National Council for Technical and Scientific Research, and schools of veterinary sciences. Samples are collected by local SENASA veterinarians and specimens are processed by the Animal Department of the Official Laboratory and Technical Control Directorate of SENASA (Ref: Annex IV_Muestreo 2004 end.pdf).

Objective of surveillance

The primary objective of Argentina's epidemiological surveillance activities since the July 2000 epidemic has been to search for and eradicate FMD. This is done in accordance with the country's FMD National Eradication Plan, of which serological sampling has been an integral part [24]. In addition, SENASA's goal in conducting repeated countrywide serological samplings has also been to monitor the disease during the 2000/2001 outbreaks, and to measure the progress of its FMD-Eradication Plan [22, 36]. In particular, serological sampling in Argentina is conducted for the following reasons:

- To detect viral activity (or infection), and
- To estimate population immunity given by vaccination against FMD where vaccination was practiced.

FMD surveillance activities in Argentina may be broadly characterized as passive and active surveillance. These two methods work in a complementary fashion resulting in efficient and effective surveillance. Passive surveillance gathers qualitative information about the disease and active surveillance gathers quantitative data.

Passive surveillance

Passive surveillance is accomplished by a wide variety of activities in Argentina. The most salient feature of passive surveillance is the education and involvement of the entire community in watching for any suspicion of FMD. Observations and qualitative information gathered under the passive surveillance effort are an integral part of the overall surveillance efforts in Argentina. Information from passive surveillance activities is utilized effectively in the national serological sampling design to help achieve better stratification and to concentrate sampling effort where needed the most (i.e., targeted sampling). Passive surveillance and follow-up efforts are further described under Factor 11 (Policies and infrastructure for animal disease control in the region) below.

Active surveillance

Active surveillance in Argentina primarily constitutes sampling of animals for serological testing. This sampling is conducted under the national plan (see Factor 11—Policies and infrastructure for animal disease control in the region). The design consists of a two-stage sampling strategy, at the herd level and the individual animal level, within each region (regions are based on the number and type of herds and animals and the disease history of each zones).

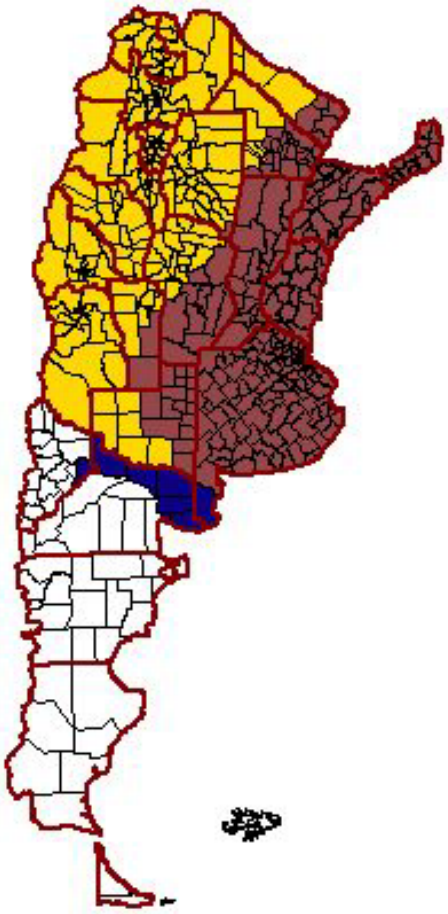
As mentioned earlier, northern Argentina vaccinates cattle for FMD and, in addition to the surveillance sampling described above, SENASA also conducts annual nation-wide serological samplings to estimate the immunity offered by the FMD vaccine. These samplings, together with other surveillance activities, serve to assess the epidemiological status of FMD in the country and collect specific indicators on the evolution of the disease.

Argentina has been conducting serological surveillance on a yearly basis since 2001 with a frequency of at least once a year. Additionally, other surveillance studies are conducted frequently for various purposes. Examples of such studies include assessing immunity levels in the young vaccinated cattle population, or in sheep and goats in areas that do not vaccinate for FMD, or for animal movements out of the Cordon Fronterizo bordering Bolivia, Paraguay and Brazil. During the 2012 FMD outbreak in Paraguay, Argentina also conducted intensive surveillance in the six border provinces. These studies are detailed below.

Description of the sampling design

The random selection of animals for serological testing is conducted according to a standard stratified two-stage probabilistic design. Under this design, the country — which has a surface area of 2,780,199 km^2 and 270,000 establishments, with a population of 52.5 million bovines and 13.8 million sheep — is first divided into zones and subzones (i.e., strata) according to several factors such as livestock production systems and animal movement patterns, geographical and climatic conditions, and epidemiological characteristics with respect to the history of disease in the region and to the vaccination program (see Figure 8 below). From each zone, herds (establishments) are randomly selected at the first stage of sampling, and animals within herds are then randomly selected at the second stage of sampling. The design is flexible enough to permit changes and adjustments to target high-risk areas based on epidemiological and other relevant considerations at the time of sampling and the surveillance goals. APHIS considers Argentina's sampling design to be appropriate, efficient, and scientifically sound.

Figure 8: Epidemiological Zoning of Argentina for the Purpose of Serological Sampling



Determining sample size[3]

The number of herds to be selected in each region (stratum) at the first stage of sampling is determined according to the following standard statistical formula [37]:

$$(1.1) \qquad n_h = \left[1-\left(1-\gamma_h\right)^{1/D_h}\right]\times\left(N_h-\frac{D_h-1}{2}\right)$$

where

n_h	Number of herds to be selected for sampling
γ_h	Level of confidence for the detection of at least one positive herd
D_h	Total number of infected herds in the population
N_h	Total number of herds in the population.

Similarly, the number of animals to be selected from each of the selected herds is determined according to the following standard statistical formula [37]:

$$(1.2) \qquad n_{w-h} = \left[1-\left(1-\gamma_{w-h}\right)^{1/D_{w-h}}\right]\times\left(N_{w-h}-\frac{D_{w-h}-1}{2}\right)$$

where

n_{w-h}	Number of animals to be selected from each of the n_h selected herds
g_{w-h}	Level of confidence for the detection of at least one positive animal within the selected herd
D_{w-h}	Number of infected animals within the selected herd (i.e., within-herd prevalence)
N_{w-h}	Average number of animals within a herd (i.e., average herd size).

Changes in serological sampling from year to year

The objectives, approaches, and intensity of serological sampling in Argentina might change slightly from year to year. In prior years, the main objective of surveillance was to estimate the prevalence of the FMD virus in different regions of the country,[4] and to estimate the level of immunity in the national bovine population of herds with the application of the systematic vaccination for each region.[5] Since the last outbreak occurred in 2006, the surveillance objectives have been modified to serve the purpose of early detection of FMDV if it were to be present in the country, and to continue to evaluate population immunity in areas that vaccinate.

[3] Sample size refers to the number of herds n_h and the number of animals within herds n_{w-h} to be selected for serological sampling in each region in a given sampling year. These are determined according to formulae (1.1) and (1.2), respectively.

[4] Viral activities were measured in susceptible animals that were recently and/or previously infected with the FMD virus, as well as in vaccinated animals. Different species were sampled, including sheep, which were not vaccinated; and bovine, stratified in animals from 1 to 2 years old and animals older than 2 years.

[5] The samples from the premises that were completely negative to the detection of viral activity were used in order to carry out a subsampling to determine seroprotection levels in the population.

The sampling approach under the surveillance objectives remained the same through 2010, with changes in surveillance objectives and sampling design implemented in 2011. The changes in surveillance from 2011 onward are described later in this section. The random selection of animals is always conducted in two stages in accordance with the national sampling design described above. The country is divided into different regions (strata) from which herds are selected at the first sampling stage, then individual animals from within the selected herds are selected for sampling. Both targeted and random samplings may be conducted.

For early detection of FMDV, a herd prevalence of five percent and a statistical confidence of 95 percent were typically assumed each year through 2010. To determine the population immunity level, a prevalence (*P*) of protected bovines of 75 percent was assumed, with an acceptable error of six percent and a statistical confidence level of 95 percent. These were the typical assumptions each year in each region. Similarly, the number of animals to be selected from within a selected herd was determined for each region using formula (2) above. For the purpose of determining the within-herd sample size, the typical assumptions were two percent within-herd prevalence and a 95 percent statistical confidence.

Each year, samples from the premises that were completely negative to the detection of viral activity were used to estimate the sero-protection levels in the population. The statistical design typically required that at least 80 establishments be sampled in each region and approximately 1200 samples be taken. This was done each year (approximately) by analyzing 15 bovine sera from each of the 80 establishments (960 from bovines aged one to two years and 240 of bovines older than two years). All of the sampled farms had complied with both vaccination campaigns corresponding to the current year, established by the National Plan, with at least 30 days from the last vaccination.

The list of herds, as well as all livestock census data in Argentina, are compiled and updated by RENSPA. Table 6 shows some of the demographic information and livestock figures used to construct sampling.

Table 6: Livestock figures used to construct sampling lists

Province	Flocks	Total Bovine	Total Sheep	Total Swine	Total Goats
BUENOS AIRES	61,742	21,050,731	1,194,435	532,465	9,620
CORDOBA	29,444	6,508,375	98,619	444,343	45,089
ENTRE RIOS	39,572	4,697,308	35,8300	42,155	3,277
LA PAMPA	9,351	3,342,981	12,8724	95,093	25,377
SANTA FE	30,252	6,968,040	55,738	695,451	47,635
CATAMARCA	3,690	154,575	11,388	3,159	54,695
JUJUY	4,032	88,918	473,463	6,518	106,126
LA RIOJA	3,092	278,874	8,209	26,658	142,781
SALTA	3,037	447,933	46,725	34,830	70,899
SANTIAGO DEL ESTERO	9,394	1,179,385	99,813	134,939	278,428
TUCUMAN	6,013	125,361	7,009	14,102	7,609
CORRIENTES	10,047	4,480,962	1,540,590	18,956	5,314
CHACO	10,911	1,640,889	284,351	59,811	129,262
FORMOSA	8,945	1,565,381	60,619	83,805	155,562
MISIONES	26,252	315,442	6,792	68,619	2,646
MENDOZA	894	137,378	8,680	4,529	192,020
SAN JUAN	733	30,727	0	2,811	30,639
SAN LUIS	5,747	1,523,289	43,225	21,327	38,940
NEUQUEN	3,757	133,758	194,007	6,039	568,500
RIO NEGRO	5,306	697,501	1,728,045	7,668	176,353
CHUBUT	4,095	188,347	4,633,518	10,818	140,364
SANTA CRUZ	1,567	46,798	2,333,526	1,481	1,250
TIERRA DEL FUEGO	87	30,815	520,403	432	0
Total	**276,306**	**55,556,155**	**10,982,250**	**2,314,096**	**2,231,136**

Serology results

Compliance with sampling

In some regions, the total number of samples could not be collected for the following reasons:

- Problems submitting the samples (e.g., spills, broken tests tubes, storage problems, etc.), and
- Samples not fit for testing (e.g., hemolysis).

Table 7 demonstrates compliance with sampling by region.

Table 7: Compliance with Sampling for Viral Activity During 2004 and 2005

Region	Farm Prevalence %	Holdings required to be sampled	Holdings sampled	Percent sampled	Species
Central – Mesopotamia	1	372 (313)	381	102.4	Bovine
Fattening	1	335(313)	326	97.3	Bovine
Border	1	459 (313)	456	99.3	Bovine
NOA – Cuyo	1	459 (300)	455	99.1	Bovine
Patagonia North A	1	330 (313)	329	99.7	Bovine
Patagonia South and North B	1	459(313)	459	100	Bovine/sheep/goat
Total		**2414(1,865)**	**2406**	**99.6**	

Table 8 shows the results of the tests to detect antibodies against nonstructural proteins in bovine category one (six to 12 months of age) and category two (12 to 24 months of age) per region during 2004.

Table 8: Results of tests to detect antibodies against nonstructural proteins in bovines

Region	Holdings tested	Positive holdings sampled		Category 1			Category 2		
				N	Positive		N	Positive	
		N	%		N	%		N	%
Central – Mesopotamia	305	10	2.6	2272	2	0.08	1510	11	0.7
Fattening	324	5	1.5	1942	2	0.1	1283	3	0.2
Border	455	8	1.7	2717	15	0.5	1818	3	0.16
NOA – Cuyo	453	5	1.1	2674	2	0.047	1782	3	0.17
North A Patagonia	329	9	2.7	1973	3	0.1	1297	8	0.6
Total	1941	37	1.9	11578	24	0.2	7690	23	0.3

All holdings with animals that tested positive in the first sampling were sampled a second time. Positive holdings were immediately reported to the Epidemiology Division and follow-up was based on OIE standards. From each holding with a positive reactor, 60 cattle and 60 sheep or goats were identified by eartags, tested, and retested 21 days later. In addition, other holdings within the same area were included in the serological testing. During 2006, there were three positive bovines aged six to 12 months (two from Central Mesopotamia/Cuyo/NOA and one from the fattening area) and seven positive bovines aged 12 to 24 months (three from Central Mesopotamia/NOA/Cuyo, three from the fattening area, and one from the border area). Follow-up of the positive cases showed no evidence of clinical disease. In addition, epidemiological surveys failed to demonstrate any risk situation that could be associated with FMD. Further, sampling of contacts show that from the three cattle that remained reactive, only one maintained the same results after the initial sampling. No evidence of viral circulation was found after follow-up of premises with reactive animals.

Table 9 summarizes the sampling for 2007 to 2008 by region.

Table 9: Sampling to determine viral activity by region, 2007 and 2008

Zone	Year	Establishments Sampled	Bovines Sampled	Ovines Sampled	Total Animals Sampled
Central-Mesopotamia	2007	312 bovine 222 ovine	8,182	2,183	10,365
	2008	300 bovine 238 ovine	8,028	2,307	10,335
Fattening	2007	281 bovine 148 ovine	5,123	1,218	6,341
	2008	338 bovine 144 ovine	8,883	1,398	10,281
Border	2007	290 bovine 23 ovine	7,809	283	8,092
	2008	289 bovine 62 ovine	8,530	590	9,120
Frontera	2007	290 bovine 23 ovine	7,811	283	8,094
	2008	289 bovine 62 ovine	4,573	590	5,163
Patagonia Norte A	2007	301 bovine 129 ovine	5,471	1,094	6,565
	2008	340 bovine 154 ovine	8,688	1,536	10,224

Through 2008, the sample design was determined at the regional level. Beginning in 2009, the design is determined at the central SENASA level taking into account regional differences, which ensures a more consistent sampling approach.

In addition to the serological testing, SENASA conducts official inspection of cattle in farms, livestock market, and slaughterhouses. The total number of individual bovine and ovine inspections reported in 2009 was 31,333,478 [29].

Population immunity

To evaluate the population immunity, the titer obtained using ELISA LP (ELISA monoclonal-based liquid phase) from each serum sample was classified into low, medium, and high based on the percentage protection expectancy (PPE) for each of the serotypes under study. The ranges of each category are described in table 10.

Table 10: Interpretation of the LP ELISA according to percentage protection expectancy

O1 Campos (titre)	A2001 (titre)	PPE	Result
<1.77	<2.1	<75%	Low
1.77-1.91	2.1-2.3	75%-85%	Medium
>1.91	>2.3	>85%	High

Animals with PPE over 75 percent are considered to have adequate protection against FMD.

Results of the 2005 studies showed a PPE with medium-high immunity level for each category, zone, and type of virus [36].

Changes in Surveillance Sampling Design, 2011 [25]:

In 2011, serological sampling was conducted to demonstrate the absence of disease in the Northern region that vaccinates against FMD and the Patagonia region that does not vaccinate. The surveillance objectives in the Northern region were to evaluate for presence of antibodies against non-structural proteins (NSP) in cattle and against structural proteins (SP) in other FMD-susceptible species, but also to assess the population immunity in the vaccinated region by determining presence of antibodies against SP for the types of viruses present in the administered vaccines in cattle that had tested negative to NSP. Four zones were established for sampling: Zone 1 with the highest bovine population density; Zone 2 which has predominantly extensive production systems; Zone 3 which corresponds to Patagonia North A; and Zone 4 comprised the areas without vaccination.

The sampling strategy was designed based on detection of FMD if present at prevalence of 1% among herds and a10% prevalence among individuals within the selected herd, with a 95% confidence level. Based on the sampling design, a minimum of 313 farms were randomly selected in each zone. In Zones 1 to 3, 28 animals were sampled from each farm, 17 of which were from six to 12 months and 11 were 12-24 months. In addition, samples were collected from ten sheep and goats between six to 24 months for each farm that also raised these species. In Zone 4, a total of 28 cattle, sheep or goats were sampled from each of 313 farms.

For Zones 1 to 3, a total of 25,421 cattle (15,360 from six to 12 months old and 10,061 from 12-24 months) were sampled from 997 farms, while a total of 5,758 sheep and goats were sampled

from 564 farms. No reactors were found among all sheep and goat sampled. Table 11 below shows the results for cattle and sheep/goats, respectively.

Table 11. ELISA 3ABC and EITB Results from Cattle in the Areas that Vaccinate Against FMD

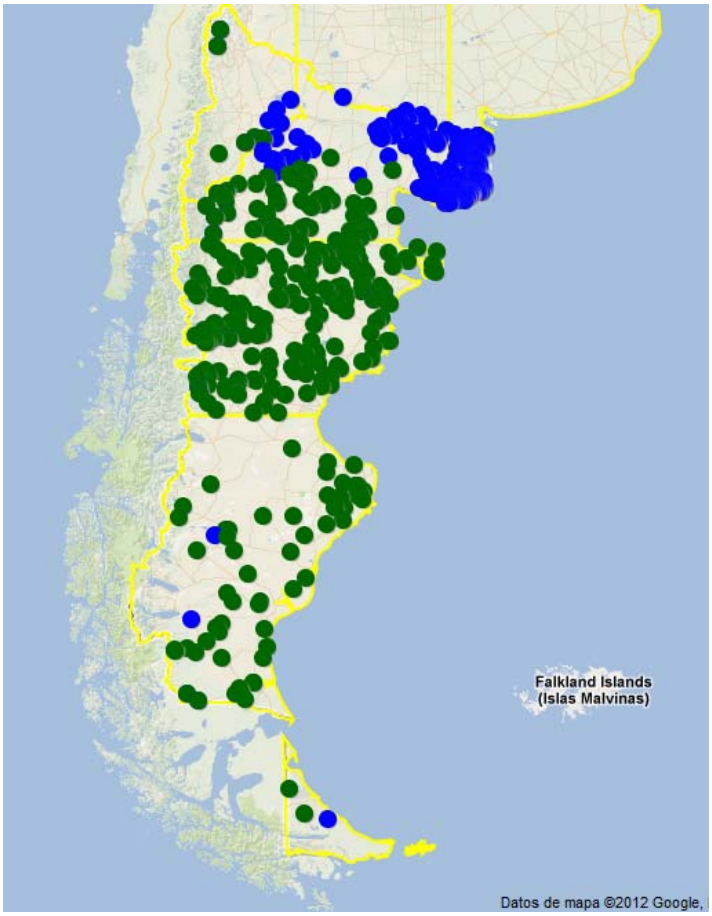
	Cattle 6-12 months			Cattle 12-24 months		
		Reactors			Reactors	
Zone	Number of Samples	No.	%	Number of Samples	No.	%
1	5794	0	0	3743	0	0
2	4771	1	0.02	3294	4	0.12
3	4795	0	0	3024	1	0.03
Total	**15360**	**1**	**0.01**	**10061**	**5**	**0.05**

Follow-up activities for all reactors included visits to each of the six premises to collect epidemiological information including animal movements in and out of the farm. Complementary serological sampling was conducted on the same animals initially sampled, their cohorts, and any unvaccinated sheep or goats if present on the farm or in a neighboring ranch. A total of 474 additional samples were collected in the follow-up studies which identified one more reactor to the ELISA EITB test. Esophageal-pharyngeal fluid (LEP) samples were taken from all reactors for Complement Fixation testing (CFT 50 percent) in each of two passages in BHK cell culture. Probang sampling was repeated after 21 days. All LEP samples from reactors were negative.

Due to the predominance of sheep production operations in Zone 4 (areas that do not vaccinate against FMD), the majority of samples were collected from sheep and goats in this area. A total of 350 facilities were sampled, 326 of which were primarily sheep/goat operations.

Figure 9 shows the geographical distribution of bovine and ovine/caprine farms sampled in Zone 4.

Figure 9. Bovine (blue) and Ovine/Caprine (green) Premises Sampled



No reactors were found in a total of 9,259 samples tested.

Other Directed Surveillance Efforts, 2011-2013

In addition to their routine active surveillance, Argentina has conducted additional serosurveillance studies to assess viral activity or to estimate herd immunity in different subpopulations.

2012 Studies [26]: Subsequent to the FMD outbreak in Paraguay, an enhanced surveillance effort was focused on the Northern provinces with international borders: Salta, Formosa, Corrientes, Misiones, Chaco, and Jujuy. A two-stage stratified random sampling design was based on a one percent prevalence among herds and a ten percent prevalence within individual animals in a herd, with a 94 percent confidence level. A total of 345 premises were selected and 28 cattle were sampled in each premises. Up to ten sheep and goats were also sampled if present on these premises. Cattle between six to 12 and 12-24 months of age were sampled, while sheep and goats under 24 months were sampled. ELISA 3ABC/EITB was used to detect non-structural proteins in cattle, and the liquid-phase ELISA was used to detect antibodies against structural proteins in sheep and goats.

A total of 8,336 cattle were sampled. Three reactors (0.06 percent) were identified out of the 4,800 which were in the six to 12 month age grouping; no reactors were found in the 12-24 month age group. A total of 1,698 sheep and goats from 183 premises were also sampled with no reactors identified. Although the overall percent of reactors (0.03 percent) from all cattle sampled was in accordance with the specificity of the diagnostic test used, epidemiological follow-up of all reactors and cohorts was conducted, which included serological and LEP (repeated after 21 days) sampling of all reactors and serological testing of all cohorts. All follow-up tests were negative for FMDV.

In a separate enhanced surveillance effort focused on the international border in 2011, 100 animal movements (transport trucks typically carrying between 40-50 cattle) were sampled to detect viral activity and determine the immunity levels for cattle leaving the Cordon Fronterizo. Animals moved out of this area are considered high risk and these movements are regulated under SENASA Resolution No. 44/11 as described in earlier sections. The objective was to identify animals with inadequate protection with 95 percent confidence, so level of protection of animals within a single movement grouping was set at 70 percent. Sample size for this objective was set at 15 animals per transport unit or movement. A second sampling stage was conducted, assuming a 50 percent protection level. The focus of sampling was young cattle between six to 12 months of age destined for slaughter.

A total of 104 transport units of cattle were tested with 1,560 individual animals sampled. Test results for FMDV strain immunity showed that 89 percent of the animals tested showed protective levels against serotype O (the predominant strain in the Paraguay FMD outbreak), while 74 percent and 83 percent were protected against serotype A and C respectively. Five (4.8 percent) out of 104 transport units had insufficient levels of protection. All sera were tested to detect circulating virus, with all negative results on ELISA 3ABC/EITB.

Additional immunity studies were also conducted by SENASA in 2012 in the same six provinces. A total of 272 farms were randomly selected and a total of 3,521 serum samples from young cattle were tested using liquid-phase ELISA for detection of antibodies against structural proteins. An Expected Percent of Protection (EPP) of 75 percent was used as a standard for each serotype. Cattle in the six to 12 month age category would have likely received only one dose of vaccine, while those in the 12-24 month age range would have received more than one dose, resulting in higher antibody titers. Results show satisfactory immunity levels conferred by vaccination particularly in the older age grouping.

2013 Serological Survey – Patagonia North A [27]:

This survey was designed to supplement the information needed to apply for recognition of Patagonia North A as an FMD free zone without vaccination following the *OIE Terrestrial Code* guidelines. Thus the study was designed to demonstrate the absence of FMDV in the provinces of Rio Negro, Buenos Aires and Neuquen. Indicators of infection were evaluated by testing for presence of antibodies against non-structural proteins in cattle and against structural proteins (A24/Cruzeiro and O1/Campos) in pigs. The last vaccination campaign in this area was held in late 2012 with a final date for complete cessation of vaccination set on March 4, 2013. Subsequently, the surveillance strategy for this area, for which annual surveillance has occurred since 2001, was revised to a risk-based sampling approach.

The last vaccination campaign in this area was held in late 2012 with a final date for complete cessation of vaccination set on March 4, 2013. Subsequently, the surveillance strategy for this area, for which annual surveillance has occurred since 2001, was revised to a risk-based sampling approach. Factors considered included proximity to waterways, recent herd introductions, and proximity to slaughterhouses and landfills. This surveillance effort, designed to detect FMDV if present in the Patagonia North A area, focused on young cattle aged six to 12 months. Fifteen animals in that age category were sampled in each facility. If the farm did not have fifteen cattle between six to 12 months of age, cattle up to 24 months were sampled. A total of 247 cattle establishments and of 3,674 animals were sampled, the majority (3,228) of which were in the six to 12 month age category.

Two complementary studies were conducted involving swine and wild boars. In the serological study conducted in swine, a total of 462 samples were collected from 76 establishments in the Patagonia North A area. The wildlife surveillance consisted of a total of 21 samples. All porcine samples were tested using the LF ELISA test.

All cattle samples were analyzed using the ELISA 3ABC and EITB tests, while all porcine samples were tested using LF ELISA. No reactors were identified in any of the samples collected.

2013 Ongoing Surveillance Efforts [28]:
Following an audit by the European Commission's Food and Veterinary Office (FVO), and in collaboration with external animal health experts, Argentina revised its surveillance sampling design, focusing on the effectiveness of various vaccination campaign plans as implemented by the local offices. The surveillance objectives remain basically unchanged: to estimate herd immunity of the vaccinated cattle population and to demonstrate the absence of FMDV circulation. The sampling frame included all regions that conduct vaccination campaigns twice annually. Three-stage random sampling consisted of:

- identifying and selecting the different vaccination campaign plans at the local level;
- selecting establishments within each of the local units of consideration; and
- selecting animals to be sampled within each selected establishment.

Thirty-three establishments were randomly selected for each type of vaccination plan under evaluation. A minimum of 13 samples are to be taken in each establishment, or ten cattle between six to 12 months of age and three cattle between 12-24 months of age. A total number of 429 samples are expected to be collected for each vaccination plan. A total of 85 vaccination plans are under evaluation in this study. Table 12 details the number of vaccination plans, farms, and samples to be collected in each province under this sampling design.

Table 12: Sampling Design for 2013 Surveillance Study to Evaluate Implementation of the National Vaccination Plan at the Local Level.[1]

Coordinación Regional Tematica de Sanidad Animal	cantidad		
	Planes	Establecimientos	muestras
Buenos Aires Norte	15	495	6.435
Buenos Aires Sur	9	297	3.861
Chaco -Formosa	11	363	4.719
Cordoba	14	462	6.006
Corrientes-Misiones	8	264	3.432
Entre Rios	4	132	1.716
La Pampa-San Luis	11	363	4.719
Metropolitana	1	33	429
Noa Sur	5	165	2.145
Santa Fe	7	231	3.003
TOTAL	85	2.805	36.465

[1]The first column represents the coordinating region under which the different vaccination plans are implemented. The second column lists the number of operational vaccination plans in that area. The third and fourth columns list the number of farms to be sampled and the number of samples to be collected from individual animals.

At the time of the November 2013 site visit, over 50 percent of samples had already been collected with only two reactors identified. On completion of the study, SENASA expects to be able to compare effectiveness of operational implementation of the National Vaccination plan at the local level.

Conclusions

APHIS believes that the design under which serological sampling is conducted in Argentina is both valid and efficient and the sampling coverage is adequate. APHIS also considers that the serological sampling conducted in Argentina is adequate to detect disease and identify and measure viral activity (if any) in the area. Furthermore, APHIS considers the levels of immunity adequate to stop viral circulation if the virus were to be introduced in the susceptible population.

10. Diagnostic laboratory capacity

SENASA has one FMD diagnostic laboratory in Buenos Aires with a biosafety level NBS4 Ag (equivalent to biosafety level 4 [BSL 4]). The laboratory is authorized to handle the FMD virus and other microorganisms requiring a BSL-4 facilities or lower status. SENASA Resolution No. 219/95 allows accreditation of private laboratories by SENASA to produce FMD vaccines [1, 2]. There are also ten regional laboratories within the structure of SENASA; however, those laboratories do not handle FMD virus; any suspicion of a vesicular disease is handled at the central laboratory. In addition, there are four experimental fields where SENASA conducts biological testing of veterinary products; one of those fields conducts testing of FMD vaccines for potency, safety, and purity.

The FMD diagnostic laboratory is part of the OIE/FMD Reference laboratories Network. The FMD Reference Laboratory Network is a vital contributor to the global FMD control and provides expertise for developing FMD laboratory capacity and capability, exchange of materials and technologies, harmonizing approaches to FMD diagnosis, and supporting complementary research. Laboratories within the network regularly receive samples for FMD diagnosis from many parts of the world. This analysis assists the monitoring of the 'real-time' emergence and spread of FMD virus globally.

The staff at the central laboratory is trained in manipulating FMD virus and diagnosing the disease. Training includes specific laboratory techniques, biosecurity standards, and quality and laboratory good practice standards.

The Virology Advisory Committee also provides support to SENASA with the best technical expertise and human resources in the country. It was established in 1992, and its members include professionals from the INTA and the Animal Virology Center (CEVAN) of the National Council for Technical and Scientific Research (CONICET).

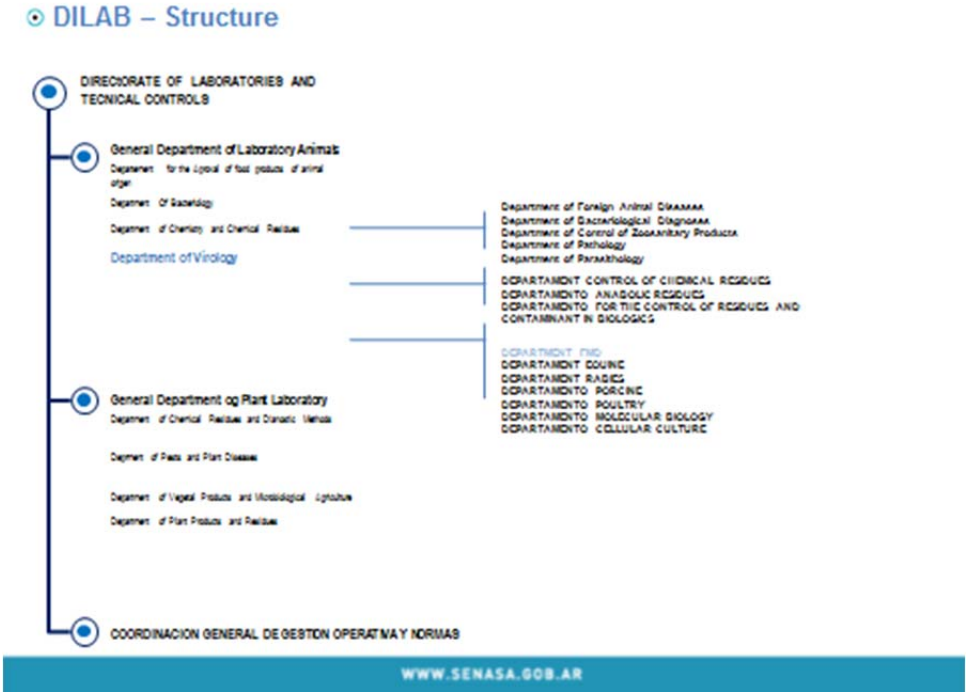
The APHIS team visited with the Director of the DILACOT, Director of the General Department of Animal Laboratory, and the head of FMD section, at SENASA Central Laboratory in Buenos Aires in 2003 and 2013. Below are some observations from the visit [10, 20, 21]

I. Laboratory structure and organization

The DILACOT (figure 10) comprises the General Department of Animal Laboratory and the General Department of Plant Laboratory and Laboratory Networks. The General Department of Animal Laboratory includes the Department of Bacteriology, Department of FMD Virology, Chemistry and Chemical Resources, and Department of Food Products and Related Products. The Department of FMD Virology consists of Diagnostic Virology, Diagnostic Serology, Seroepidemiology, and Vaccine Control and Experimental Farm. The advisory board for Virology includes SENASA, INTA, and CEVAN laboratories. The FMD Laboratory is staffed with 16 professionals (12 veterinarians, 11 doctorates or maters in sciences, one biologist, one chemist, one geneticist, and one engineer), 13 technicians, five administrative, and three cleaning personnel. A list of training activities for DILAB staff has been provided during the site visits, including the latest activities in 2013 [20].

The laboratory uses a laboratory information management system (LIMS) for recoding samples coming in and for laboratory testing results that go out to the epidemiologists. The site review team was able to observe how the data was entered into the computer as well as the follow-up of the samples within the lab and the reporting of the testing. The staff was very capable in managing the system.

Figure 10. Functional Organizational Chart of SENASA Laboratory



II. National reference laboratory functions

The main functions of the national reference laboratory are to establish protocols and validate reference assays for disease control as dictated by SENASA, perform quality control testing on FMD vaccines produced by the manufacturers, serve as a reference laboratory in confirming positive cases, apply biosafety standards as set by SENASA, and set forth the sampling strategy for disease control and surveillance. The laboratory has been accredited by the Argentine Accreditation Organization (Organismo Argentino de Acreditación – OAA) under international standard ISO 17025 in 2006.

In addition, DILAB inspects and certifies the biosafety of the FMD vaccine manufacturers in Argentina. DILAB personnel perform on-site inspections of biologics manufacturing annually. They grant the licenses for the manufacturing of biological products. DILAB tests each serial of FMD vaccine for safety, potency and specificity. SENASA issues the Argentinian import and export permits for FMD strains and antigens.

III. Diagnostic samples

Epithelial tissue samples are preserved and transported in Vallee medium composed of phosphate glycerin (pH 7.2) with phenol red. Diagnostic samples (excluding samples for FMD virus isolation) are checked in at the front desk and logged into the database. Each submission is barcoded and each specimen is given a serial number within the submission. Sample history is kept confidential from the technical staff as part of the laboratory quality control standards. Submission for biocontainment is labeled on the package and opened in the BSL-3 lab.

Epithelial tissues for FMD virus isolation are homogenized and frozen immediately upon arrival. Homogenates are thawed out and screened for FMD virus by the antigen ELISA. If ELISA results are negative, the homogenate is inoculated on to baby hamster kidney (BHK) cells for 48 hours and then tested by ELISA for the presence of FMD virus. If the ELISA results are negative on the first passage, a second passage is carried on for another 48 hours and tested for FMD by ELISA. If the ELISA results are negative on the second passage the sample is considered negative. In 2011 and 2012, the laboratory received nine and five investigations, respectively, for suspect vesicular disease. The primary target of these investigations is FMD.

For detection of viral activity in vaccinated cattle, random serum samples (with no animal IDs) from vaccinated cattle are screened for antibodies to nonstructural proteins by the 3ABC ELISA. Positive samples are confirmed by EITB tests. A second set of samples is collected from the farm if EITB is confirmed positive on the first set of samples. If animals remain positive for antibodies to nonstructural proteins, Probang samples are collected from the suspected herd. These samples are not necessarily from the same animals tested positive by serology. Probang samples are tested for the presence of FMD virus by carrying out virus isolation on BHK cell lines.

Since 2006, the SENASA laboratory has the capability to run PCR for FMD. Consequently, samples submitted for PCR testing are processed in the BSL-3 facility where samples containing live FMD virus can be processed. Table 13 summarizes the FMD tests conducted during 2008, and Table 14 summarizes the FMD samples analyzed in 2012.

Table 13. Number of Diagnostic Tests for FMD and VS Serology 2008 [35]

Test	First Semester	Second Semester
VIAA	910	252
3ABC ELISA	30,265	15,214
EITB	1,180	830
Structural ELISA	28,280	5,191
Typing ELISA	50	41
Total	60,685	21,528

Table 14. Number of Diagnostic Tests for Vesicular Disease Suspect Cases, 2012 [19]

ELISA 3ABC	EITB	VIAA	Structural ELISA	Typification	
				Vesicular suspects	Antigen detection (vaccinated)
33,560	1,259	2,957	15,574	1	41

IV. Diagnostic tests capability

The following technology is available for FMD diagnosis and ruling out other vesicular diseases:

1. FMD
   a. Serology: 3ABC ELISA, EITB, VIAA and monoclonal-based liquid phase ELISA are used for serotyping.
   b. Virus detection: Antigen ELISA is used, with reagents produced by the PANAFTOSA laboratory. Virus isolation tests are conducted in BHK cells. The complement fixation test is used for antigen detection. Reagents for this test are produced in-house. PCR is also available

2. Vesicular stomatitis
   a. Serology: Reagents for the IgG ELISA are purchased from the PANAFTOSA laboratory. Virus neutralization test is also available.
   b. Agent detection: Ag ELISA and PCR are used in the central laboratory.

Conclusions

Argentina has the laboratory capacity to accurately diagnose FMD. In addition, quality control activities within the laboratories are sufficient, laboratory equipment is routinely monitored and calibrated, sufficient staff is available, an effective and efficient recordkeeping system for storage and retrieval of data is in place, and samples are turned around quickly.

11. Policies and infrastructure for animal disease control in the region

Elements of the FMD disease control program are provided in the *Foot and Mouth Disease: Manual of Procedures for Focus Attention* (the Manual) [2].

Law No. 24.305 requires immediate and mandatory reporting of FMD in Argentina. SENASA has legal authority to apply severe penalties to any individual or company that fails to report an FMD case. The Animal Health Law Enforcement Act (3959/1903) requires all veterinarians in private practice that work in rural areas to report epizootic diseases. This law, with its amendments, specifies the penalties that a person could incur in different situations as a consequence of not notifying animal health authorities of a disease outbreak so that compliance of the regulations in force can be achieved with the purpose of preventing, detecting or applying the measures laid out in the FMD National Eradication Plan. Private diagnostic laboratories must also immediately report epizootic diseases. They, too, are subject to severe penalties for failure to comply with statutory requirements [1, 2].

Identification of outbreaks or suspicious signs of FMD is mainly carried out through passive surveillance in the Patagonia Region. Observations are made by the producers, animal caretakers, transporters and other people who see the animals every day and are well aware of FMD or other vesicular disease symptoms, reporting requirements and available resources to avoid the disease. In spite of the large size of the farms in Patagonia, animals are periodically inspected by the staff in charge of them. Also, the INTA has a network of experimental and extension facilities in rural areas that work with the farmers and receive updated information on the health conditions of the herds.

Routine examinations of livestock occur during wool industry-related activities and official surveillance programs. Animals are also inspected at fairs and before and after slaughter. Many private veterinarians sit on the boards of technical subcommittees of the regional and local Animal Health Committees, so they are highly motivated and support the national eradication programs.

In the event of an outbreak of exotic or endemic diseases that present as a health hazard to the national livestock herd, and if SENASA decides to follow a stamping-out policy, SENASA's actions and level of involvement are defined in Resolutions 1410/2000 and 488/2002. The actions are listed in Resolution 779/1999 through which the National Animal Health Emergency System (SINAESA) was created as authorized by Law 24.305, Act 3959/1903 and Decree 1585/1996 and 643/1996. By Decree 394/2001 that updated Decree 1585/1996, the president of SENASA has authority to take prompt actions to respond to emergency situations involving animal health. SENASA has special policies, logistics and a budget for zoosanitary and phytosanitary emergency situations.

The SINAESA defines the responsibilities and functions to control FMD in emergency situations. It operates at three levels: central, regional, and local. At the central level, there is a Central Animal Health Emergency Committee that is responsible for describing the emergency scenario; defining the control measures, financing mechanisms and responsibilities; and assigning the human and other resources required for the eradication operations.

In 2010, the registration and notification system for reportable diseases in animals was updated and enhanced under Resolution 540/10, creating a single uniform system for all reportable diseases. This system includes a standardized protocol and establishes forms of communication within and between institutions to ensure the rapid transmission of consistent, reliable collection of epidemiological information and follow-up on suspect cases. Within 12 hours of receiving notification of a suspect case, a veterinarian from the local SENASA office must visit the involved facility, collect the necessary epidemiological information, and fill out a reportable disease form determining the disposition of the suspect case. Necropsy and laboratory samples, where applicable, are linked to the original report by a single case number. A final report summarizes the particular case/incident, and all incidents are summarized in an annual report.

At the regional level, response actions are carried out by SENASA's regional resources. The Regional Animal Health Emergency Team is the functional unit of the system. It is coordinated by the Epidemiology Office of DNSA at SENASA headquarters. The team includes SENASA professionals, technicians, and administrative staff specialized in responding to emergency situations. The members of the team are specifically selected for their technical and psychophysical profile because they must be continuously available and able to respond immediately in cases of emergency. An alternate is available for each person in case a member is unable to respond.

At the local level, the staff of the local SENASA Office in the affected area collaborates with the field technicians to provide support. The responsibilities of the local office include the following:

- Provide a primary response to suspect cases (collection and remittance of samples, description of the operation, and implementation of preliminary measures);
- Notify the Regional Supervisor;
- Submit a status report to the Local Animal Health Emergency Committee;
- Carry out the actions defined by the chief of operations;
- Supply updated maps of the local area, including cadastre drawings;
- Keep updated records on the characteristics of the production system in the area, including a geographic description;
- Keep updated information on local suppliers and service suppliers, such as mobile telephone companies, equipment suppliers, transportation and rental companies of said equipment, trucks, etc;
- Keep updated information on the livestock population, inventory of other products, shippers of animal products and byproducts, cattle dealers, other professionals related to the farming sector (veterinarians, agronomists, cattle buyers, dairy farm inspectors, etc.);
- Keep updated records of the local authorities, such as municipal officials, law enforcement authorities, fire brigade, veterinarians in private practice, and others; and
- Oversee the surveillance and repopulation of farming operations.

The main control measure in the case of a confirmed FMD outbreak in the FMD-free area without vaccination is the stamping-out policy of all the affected animals and contacts. Other measures such as vaccination will depend on each situation (e.g., a primary outbreak or not, the number and location of the affected premises, the number and species of involved animals). Due to the regulations in force and the established Epidemiological Surveillance System, the time to

detect a case of FMD in susceptible species in Patagonia should be no more than 48 hours. At that time, OIE is notified within 24 hours of the outbreak or suspicion of FMD. Argentina also notifies the EU, due to trade commitments, and bordering countries, if the outbreak occurs in a border area.

At the international level, Argentina gives timely required notification of the diseases according to the time and conditions agreed upon with the world health entities. The Bureau of Epidemiology of SENASA develops weekly and monthly reports of animal health news. These reports are written using the information collected through the different levels of epidemiological surveillance and are submitted through the Coordination of International and Institutional Affairs of SENASA to international entities such as the OIE, the European Community, and the OPS/WHO Continental System for Vesicular Disease Surveillance. Likewise, a system of reciprocal systematic information was established through bilateral agreements with bordering countries. This system would allow immediate notification of any reportable disease detected in the country that could represent a sanitary potential risk for a neighboring country. One such bilateral agreement is the Cuenca del Plata Agreement among Argentina, Brazil, Uruguay, Paraguay, Bolivia, and Chile.

There is a training and promotion program for the staff of SENASA including the performance of drills. The training is carried out by the Bureau of Epidemiology. In addition, the Field General Coordination carries out permanent meetings on updating of information, methodology and standards that the local veterinarians should know. Training records are maintained by the Bureau of Human Resources and Training in which official agents get credits for the various classes they attend. The credits are added up in a score which is used towards promotions in the organization. The Bureau coordinates the training activities of each of the National Bureaus through training consultants. In the case of the National Bureau of Animal Health, by virtue of the complexity of personnel, two professionals work as consultants who will lead the 22 training delegates of the provinces who shall coordinate, audit and guide the process of teaching the official veterinarians. This program is under implementation. The training legal framework includes SAGPyA Resolutions 51/2003 and 02/2002 and SENASA Resolution 166/2003.

Reporting of FMD suspect cases is infrequent in the Patagonia Region, with few animals presenting with clinical conditions compatible with vesicular diseases. In order to determine the ability of veterinary officials at local offices to respond to a suspicious case of disease, the site visit team asked to view records of reports of a suspected notifiable disease (in this case, mange) during the 2009 site visit. The information shared revealed that a visit to the affected farm was made within 24 hours of the report, and all animals on the farm were inspected, with samples collected and submitted to the lab on the same day. A quarantine was immediately applied upon suspicion and remained in place throughout the duration of the investigation. At the initial visit, neighboring farms were contacted to alert the owners of the disease suspicion and were told to make their animals available for inspection. At our request, the local office simulated a request for movement from the affected farm. Upon accessing the farm records a red warning screen appeared containing the disease and quarantine status of the farm, plus information on the course of the investigation. The issuance of movement permits for animals from the affected farm were prohibited without approval from the director of the office.

All local offices maintain copies of a SENASA issued manual on procedures related to FMD outbreaks (Manual de Procedimientos para la Atencion de un Foco). Additionally, SENASA developed a containment plan (plan de contencion) in 2007, a copy of which is maintained at each local office. Veterinarians in local offices were well versed in the procedures contained in both documents.

Conclusions

Argentina has the infrastructure and legal authority to declare an emergency and take appropriate action in case of an FMD outbreak. The country has a disease control program that is in written form in the *Foot and Mouth Disease: Manual of Procedures for Outbreaks*. The manual sets forth operating standards and is legally authorized by several SENASA Resolutions and Regulations. A plan developed by SENASA in 2007 (*Plan de Contencion*) also addresses procedures for rapid containment of disease in case of an outbreak. There are also systems for notification and training that ensure emergency preparedness and response with a legal framework to authorize needed actions. Local veterinary officials are well-trained in procedures for controlling and containing FMD outbreaks. The APHIS site visit team assessed the region's emergency response capabilities by evaluating the procedures implemented in response to notifiable disease outbreaks. For example, the 2009 team reviewed documentation confirming that local veterinary officials had responded in a timely and effective manner to reports of suspect mange in local farms.

Release assessment: Summary of risk factors and mitigations considered

APHIS identified risk factors that might be associated with the importation of FMD-susceptible animals and their products into the United States from the Patagonia Region. APHIS discusses these risk factors in the context of the potential for counterbalancing circumstances or the application of appropriate risk mitigations to reduce the risk of introducing and establishing FMD in the United States.

Likelihood of FMD introduction into the Patagonia Region

Risk factors

FMD has not been diagnosed in South America for almost two years (the last outbreak was reported in Paraguay in 2012). In addition, all sides of the Patagonia region are bordered by either the ocean or areas that are free of FMD with or without vaccination according to OIE standards. The last outbreak in Chile was in 1987. The last outbreak in Northern Argentina was in 2006.

Consequently, there is a very low risk of reintroduction of FMDV from adjacent affected areas into the export region. Therefore, there is a very low risk that FMD-susceptible species or products from such species exported to the United States could originate from or be commingled with animals or animal products from affected neighboring areas.

Discussion: Argentine authorities do not allow live susceptible animals to enter the Patagonia Region except from regions recognized as FMD free without vaccination by SENASA and the OIE.

Matured, deboned fresh beef is imported into the Patagonia Region from areas in northern Argentina for local consumption only, since beef is not produced in sufficient quantities for local demand. This meat has a very low risk of introducing the FMD virus into the export region since it must go through a maturation and deboning process consistent with the EU and current U.S. requirements, and the associated drop in pH inactivates the FMD virus. Border control posts visited during the site visits appeared capable of monitoring this movement and preventing illegal entry of animals and animal products into the Patagonia Region. Additionally, swill which may contain meat scraps must be properly treated before being fed to pigs, and sheep do not come into contact with the meat since they go directly from the range to the slaughter facilities.

Conclusion: Based on the production systems in the Patagonia Region, lamb meat is the major product that could potentially be exported to the United States. Under the U.S regulations, any sheep or sheep products exported to the United States will originate only from the Patagonia Region and are highly unlikely to be commingled with infected FMD-susceptible species or products originating from areas considered by APHIS to have a different FMD status.

Mitigations: In order for live animals, meat or other FMD-susceptible commodities to be exported from the Patagonia Region to the United States, certification by a full-time salaried veterinary officer of the Government of Argentina will be required to certify that the commodity did not originate from outside the Patagonia Region and was not commingled with commodities that originated from outside the Region.

Likelihood of detection of FMD if re-introduced into the Patagonia Region

Risk factors

Sheep in the Patagonia Region of Argentina are primarily grass-fed on extensive establishments, and, depending upon the pasture rotation scheme in use, may not be subject to routine observation. Because some of the farms are extremely large, close observation of individual animals may not occur for significant periods of time, with the potential that clinical signs could be missed. However, producers, animal caretakers, transporters and other industry employees are well aware of the clinical signs of FMD or other vesicular diseases, reporting requirements, and available resources to avoid the disease.

Conclusion: Husbandry and surveillance practices in the Patagonia Region serve to mitigate the lack of close animal supervision on extensive farms. The risk of missing FMD clinical signs in export herds is minimal.

Release assessment: Summary

Based on evaluation of the 11 factors, including observations from its several site visits, APHIS concludes that Argentina possesses the legal framework, animal health infrastructure, disease

detection capabilities, reporting systems, and emergency response capacity that are necessary for maintaining the Patagonia Region as free of FMD. We further conclude that the region is free of FMD and that the likelihood of release of FMD virus from the region into the United States via exports of susceptible species or their products is very low.

Exposure assessment

As determined in the release assessment section, the likelihood of release of FMD from the Patagonia Region is very low. Nonetheless, in order to take a conservative approach to this analysis, we discuss the pathways through which the virus could be transmitted to susceptible livestock in the unlikely event that it was imported into the United States.

Exposure assessment describes the biological pathway(s) necessary for exposure of animals and humans in an importing country to the hazards released from a given risk source and estimates the probability of the exposure(s) occurring, either qualitatively or quantitatively [15]. The following sections describe the likelihood of exposure to the FMD virus through the importation of contaminated sheep meat, infected live animals, and infected embryos or semen.

Exposure through the importation of FMD-infected sheep meat

Lamb meat is the major product that will potentially be exported from the Patagonia Region to the United States. APHIS considers that the most likely pathway of exposure of domestic livestock to FMD virus in imported sheep meat is through feeding of contaminated food waste to swine [25], based on APHIS' prior studies analyzing the likelihood of exposure of FMD-susceptible species to FMD-infected beef. APHIS considers that exposure through the importation of FMD-infected sheep meat would take a similar pathway as that posed by imported beef. In 1995, VS conducted a pathway analysis to estimate the likelihood of exposing swine to infected waste [39]. The analysis included two pathways for exposure of swine to contaminated waste: exposure associated with illegal household imports and exposure associated with legal imports. With 95 percent confidence, VS estimated that 0.023 percent or less of plate and manufacturing waste would be inadequately processed prior to feeding to swine [39]. Based on this fraction, less than one part in 4,300 of imported beef that are fed to swine as plate or manufacturing waste is likely to be inadequately cooked.

VS also conducted a survey in 2001 of the U.S. swine waste-feeding sector to update a similar study done in 1994 [40]. Based on this survey, VS estimated that the proportion of plate and manufacturing waste fed to swine diminished by about 50 percent between 1994 and 2001 due to a decrease in the number of waste-feeding operations. The study also found that:

- The number of waste-feeding premises has decreased significantly since 1994;
- Several States have prohibited feeding food wastes to swine;
- The continental United States saw a 40.5 percent decrease in the number of waste-feeding premises, Hawaii a 37.5 percent decrease, and Puerto Rico a 52.3 percent decrease; and
- Institutions and restaurants provide nearly 90 percent of all plate waste fed to swine.

APHIS considers that prohibiting the feeding of unprocessed plate waste to swine contributed to the reduction of waste feeding to swine. In that regard, waste-feeder operations must be licensed

and inspected regularly by USDA inspectors (9 CFR 166) [41]. The licensing process requires that producers adequately cook the waste fed to swine according to methods designed to reduce the probability of survival of foreign animal disease agents in the waste.

Based on the 1995 estimate that a very small proportion of food waste is inadequately processed prior to feeding to swine, and the substantial reduction in waste-feeding operations in recent years, APHIS considers the likelihood of exposure of susceptible swine to FMDV through inadequately processed food waste to be low. Based on the results of the release assessment, APHIS further concludes that the likelihood of exposure of susceptible swine through the feeding of contaminated food waste originating in the Patagonia Region is very low.

Exposure to FMD virus through importation of live susceptible species

The likelihood of exposure of susceptible species to infected live animals was evaluated by briefly reviewing virus persistence and shedding in live ruminants and swine, as well as standard import requirements for these species.

Considering the animal disease control program in the Patagonia Region, the chance of importing FMD-infected animals into the United States is very low, since any introduction of FMD into the Patagonia Region is likely to be detected. In the unlikely event that undetected infected animals were imported, they are required to undergo quarantine, which will mitigate that risk pathway. Only animals that have not been vaccinated for FMD are eligible for import, and infected unvaccinated animals will develop clinical signs of the disease during their quarantine of 30 days.

Current U.S. import regulations require certification that ruminants and swine have been kept in a region entirely free of FMD for 60 days prior to export (9 CFR 93.405 and 93.505) and also require a minimum quarantine of 30 days for most imported ruminants (9 CFR 93.411) and 15 days for all imported swine (9 CFR 93.510) from the date of arrival at the port of entry. These requirements serve to partially mitigate the risk of exposure by increasing the probability of disease detection once the animal is quarantined in the United States.

Based on the release assessment, APHIS concluded that the risk of importing FMD-infected animals from the Patagonia Region is very low. This, coupled with the additional safeguards provided by our import regulations, leads APHIS to conclude that the likelihood of exposure of susceptible species in the United States via the importation of live animals from the Patagonia Region is also very low.

Exposure to FMD virus through the importation of genetic material

Genetic materials have been implicated in the introduction of foreign animal diseases into susceptible populations, as well as the spread of established disease epidemics over considerable distances. Embryos present a negligible risk of infecting an exposed recipient with FMDV, as the zona pellucida is an important barrier against pathogens, and only zona-pellucida-intact bovine embryos are permissible in international trade [42]. Furthermore, embryo washing could significantly reduce the risk of FMD if the virus was present. FMD virus may be present in

semen up to four days before clinical signs become apparent. However, if the donor animal develops clinical signs, it becomes unlikely that embryos or semen would be collected from an infected herd or from a diseased donor.

Based on the above, APHIS considers the risk of transmission of FMD via embryos to be low. Regarding semen, due to the extended period of survival of FMD virus in frozen semen, APHIS considers there is a likelihood of exposure of susceptible animals to this virus, if unmitigated, if the semen is collected from an infected animal. Based on the conclusion of the release assessment that diseased animals are not likely to exist in the Patagonia Region or, if they do, are not likely to go undetected, however, APHIS considers it highly unlikely that U.S. animals would be exposed to infected semen from the Patagonia Region.

Exposure assessment: Summary

Based on the pathway analyses, APHIS concluded that the likelihood of exposure of susceptible swine to FMD virus through inadequately processed food waste to be very low. This conclusion is supported by evidence that only a very small proportion of food waste is inadequately processed prior to feeding to swine and the substantial reduction in waste-feeding operations in recent years. Furthermore, based on the conclusion of the release assessment that diseased animals are not likely to exist in the Patagonia Region or, if they do, to go undetected, APHIS considers the probability of exposure of susceptible swine to FMD virus through inadequately cooked infected meat from the Patagonia Region to be very low.

In addition, APHIS considers the likelihood of exposure of susceptible U.S. livestock to FMD virus via infected live ruminants or swine from the Patagonia Region to be very low. Under APHIS regulations, once a country is listed as FMD-free following USDA's evaluation, certain requirements must be met to import ruminants into the United States. These requirements include the following:

- The ruminants must be accompanied by a health certificate issued by a full-time salaried veterinary officer of the national government of the region of origin (9 CFR 93.405.a);
- The ruminants must have been kept in the FMD-free region during the last 60 days immediately preceding the date of shipment to the United States (9 CFR 93.405.a.1)
- The ruminants are not in quarantine in the region of origin (9 CFR 93.405.a.2); and
- All ruminant imported into the United States (except from Canada, Mexico, Central America, and West Indies) must be quarantined for not less than 30 days starting from the date of arrival at the port of entry (9 CFR 93.411.a).

These requirements serve to partially mitigate the risk of exposure by increasing the probability of disease detection prior to export and during quarantine in the United States.

Based on the conclusion of the release assessment that FMD-infected animals are not likely to exist in Patagonia South or, if they do, to go undetected, APHIS considers exposure of a susceptible U.S. animal population to imported infected semen or embryos from the Patagonia Region to be highly unlikely.

With regard to importation of animal products from regions that have less restrictive trade practices than the United States, as Argentina does, the requirements in 9 CFR 94.11 mitigate the risks associated with imports from such regions by, inter alia, (1) restricting the sourcing of meat of ruminants and swine to the FMD-free region, (2) prohibiting commingling of live animals, meat, or meat products for export with such commodities from regions not considered free of FMD, and (3) requiring exporting slaughter establishments to be approved by the U.S. Department of Agriculture's Food Safety and Inspection Service. In addition, an official veterinarian of the exporting country must certify that these conditions have been met.

Consequence assessment

A consequence assessment describes the biologic and economic consequences of FMD introduction into the United States. This consequence assessment addresses both direct and indirect consequences as recommended by the OIE [18].

The magnitude of the biologic and economic consequences following an introduction of FMD would depend on a number of factors, including the location of the introduction, the FMDV serotype introduced, the rate of spread of FMD virus and whether other environmental conditions at the introduction site that might facilitate this spread, ability to detect the disease rapidly, livestock demographics and movement patterns, and ease of employing eradication procedures [43]. In addition, depending on the extent of export of livestock and their products, trade restrictions imposed by trading partners often result in severe economic consequences.

Direct consequences

Direct consequences include effects of the disease on animal health and the subsequent production losses, the total costs of control and eradication, the effect on the environment, and public health consequences.

Effects on animal health and production

FMD causes significant distress and suffering to animals regardless of the size and sophistication of their livestock unit. High mortality rates in young animals can occur, particularly among pigs and sheep [44]. In pigs, Dunn and Donaldson [45] estimated a general mortality rate of 40 percent for two outbreaks in Taiwan in 1997. Geering [46] cites mortality rates of 40, 45, and 94 percent of lambs in several outbreaks. Mortality in older animals occurs less frequently but may be significant with certain virus strains.

FMD causes significant losses in the production capacity of affected animals. Productivity losses of ten to 20 percent are reported in FMD-infected livestock [43] if the disease is allowed to run its course. For example, the drop in milk yield of dairy cattle averages approximately 25 percent per year [47]. In addition, FMD can cause reduction in the growth rate of animals raised for meat. According to Doel [48], estimates vary considerably but one study has indicated that cattle would require approximately 10 to 20 percent longer to reach maturity. The comparatively greater severity of FMD in pigs would imply at least similar losses to those described for cattle [48].

Control and eradication costs

The overall cost of control and eradication depends on the mitigation or policy option chosen to control and eradicate the disease. Potential costs include disease control measures such as imposing quarantines and movement controls, direct costs related to stamping out of affected and other herds, carcass disposal, indemnity payments, vaccination costs, surveillance, and laboratory testing.

For FMD-free countries like the United States that have a substantial export market for livestock and livestock products, the preferred option for control and eradication has traditionally been to stamp-out infected herds without the use of vaccine. In fact, the U.S. policy for FMD emergencies is to follow strict quarantine measures and stamping-out of infected and contact herds with ongoing assessment for the need for and implementation of strategic vaccination.

Published studies indicate that where FMD eradication without vaccination is feasible, it is the least-cost policy option, even allowing for the costs of prevention and emergency preparedness and the risk of outbreaks. However, if the extent of the outbreak were large or if the disease were spreading at a fast rate, vaccination might be beneficial in protecting high-producing livestock 49]. A recent study using a stochastic simulation model showed that ring vaccination decreased the duration of outbreaks. Depending on the magnitude of the outbreak and the number of herds involved, the time and cost needed to dispose of vaccinated animals could be substantial [50].

Available data do not allow quantification of the number of herds/farms that would be infected if FMD were introduced. Nevertheless, the cost of control, eradication and compensation is likely to be significant. Bates et al [51] used results from a FMD simulation model to estimate the direct costs associated with indemnity, slaughter, cleaning and disinfecting livestock premises for various vaccination and eradication strategies to control transmission of FMD virus in a cattle population of 2,238 herds and five sale yards located in three counties of California. The study found that mean herd indemnity payments were $2.6 million and $110,359 for dairy and nondairy herds, respectively. Cleaning and disinfection costs ranged from $18,062 to $60,205 per herd. The mean vaccination cost was $2,960 per herd and the total eradication cost ranged from $61 million to $551 million depending on eradication strategy.

At the national level, McCauley et al. [43] conducted a comprehensive study to assess the potential economic impact of FMD in the whole of the United States. The study estimated the direct costs (control and eradication program costs) and increased costs borne by consumers of FMD introduction over a 15-year period (1976-1990). The study examined several control and eradication options. Relevant to this assessment are strategies employed to eradicate the disease by stamping out or area vaccination. In the extreme event of endemic FMD in the United States, the impact of compulsory or voluntary control programs was also considered. A summary of the findings are shown in table 14. The results were updated using the difference in the Implicit Price Deflator (DPI) in 2011 [52].

Table 15. Economic Impacts of FMD

McCauley Estimates	Consumer Impacts		Program Costs		Totals	
	----------millions of dollars ----------					
	1976 $	*2011 $*	*1976 $*	*2011 $*	*1976 $*	*2011 $*
Endemic FMD w/ voluntary control	$11,600	$37,215	Na	Na	$11,600	$37,215
Eradication by strict slaughter & quarantine	$10,600	$34,007	$539	$1,729	$11,139	$ 35,736
Eradication by area vaccination	$11,600	$37,215	$690	$2,214	$12,290	$ 39,429
Compulsory vaccination program w/ endemic FMD	$8,900	$28,553	$4,200	$13,474	$13,100	$ 42,027

1., Source: 1976: 34.8 IPD, 2011: 111.668 (3.2 = ratio IPD start 1976) 1/IPD = Gross Domestic Product Implicit Price Deflator - U.S. Department of Commerce: Bureau of Economic Analysis http://research.stlouisfed.org/fred2/data/GDPDEF.txt
Source: Adapted, McDowell 2011, personal communication.

In a 2008 study modeling the economic impact and disease-spread effects from a hypothetical outbreak of FMD arising from feeding garbage in small farrow-to-finish operations, the total trade losses plus other disease-related costs to capital and management, totaled between $2,773 million and $4,062 million compared with the 2001-2004 disease-free baseline [47].

Effect on the environment

Environmental effects have been considered under all applicable environmental review laws in force in the United States. These are considered in a separate, but related, environmental assessment (APHIS proposed rule). The environmental assessment complies with the National Environmental Policy Act (NEPA) and implementing regulations [53].

Effect on public health

Although public health consequences are not issues under APHIS' regulatory authority, we address the issue in this assessment. FMD may rarely affect humans. The number of cases reported is so small when compared with the number of persons exposed that FMD is generally not considered a threat to humans. FMD virus has been isolated and typed in only 40 patients during the last century. Symptoms in humans are mostly mild and mainly include fever and blisters on the hands, feet, mouth, and tongue. Patients usually recover within a week after the last blister formation [54].

Perhaps more importantly, a FMD outbreak of the magnitude observed in the United Kingdom can result in severe psychosocial effects on farmers and farming communities. Farmers and their families can suffer from grief over losing animals, in some cases blood lines kept over many generations, as well as loss of control over their lives due to movement restrictions, disruptions in community life, and short- and long-term stress over their financial future. Researchers from Lancaster University in the United Kingdom conducted a new study into the social consequences of FMD in the Cumbria community; it revealed high rates of depression, alcohol consumption, and mortality among farmers during the crisis (Lancaster University, unpublished report) [55].

Indirect consequences

In addition to the direct costs of FMD introduction, impacts on international trade and related domestic consequences need to be considered. Export losses due to restrictions imposed by trade partners on FMD-susceptible animals and products can run into billions of U.S. dollars. The value of U.S. exports of beef products alone, which would be immediately lost, was over US$3 billion in 2001. The impact of an outbreak of FMD on the rural and regional economic viability, including businesses reliant on livestock revenue, could also be substantial.

In 2002, Paarlberg et al. [56] conducted a study to estimate the potential revenue impact of an FMD outbreak in the United States similar to the one that occurred in the United Kingdom. The study suggested that greatest impact on farm income would be due to loss of export markets and the decrease in demand by consumers. For example, losses of gross revenue for the animal sector were as follows: cattle (17 percent), beef (20 percent), milk (16 percent), swine (34 percent), pork (24 percent), sheep and lambs (14 percent), and sheep and lamb meat (10 percent). Thompson et al [57] estimated the loss of about 20 percent of the estimated total income from farming in 2001 because of the FMD outbreak in the United Kingdom.

Japan, Korea, and Mexico constitute the three major U.S. export markets for ruminant products. The value of lost exports to these three ruminant markets would total $3 billion annually if trade restrictions were enforced against the United States: Japan ($1.2 billion), Mexico ($1.12 billion), and South Korea ($712 million). Indirect economic losses to U.S. firms that support ruminant exports to these three markets would equal an additional $2.5 billion annually. The magnitude of these values reflects both animal and product exports [58].

More than 33 thousand full-time U.S. jobs, accounting for almost $1 billion in wages annually, could be jeopardized by loss of these three markets. In the longer term, if trade restrictions persisted and alternative export markets did not develop, the U.S. ruminant production sector could contract, allowing other supplying countries to establish trade relationships in the absence of U.S. supply [58].

Other losses due to restrictions on live swine, pork, and pork products are likely to be significant as well. The U.S. exports of pork and pork products are estimated at $1.3 billion dollars in 2003 [59]. Since the U.S. exports only small amounts of lamb and mutton, economic losses associated with these commodities are not likely to be significant compared to cattle and swine.

Risk Estimation

Risk estimation consists of integrating the results from the release assessment, exposure assessment, and consequence assessment to produce overall measures of risk associated with the hazards identified at the outset. Thus, risk estimation takes into account the whole risk pathway from hazard identified to the unwanted event [15].

APHIS concludes from the assessment that the surveillance, prevention, and control measures implemented by Argentina are sufficient to minimize the likelihood of introducing FMD into the United States via imports of FMD-susceptible species or products from such species from the Patagonia Region. APHIS further concludes that the likelihood of an outbreak occurring via exposure of the domestic livestock population to animal products imported from the Patagonia Region is very low.

The consequences of a FMD outbreak in the United States would be extremely high. The major economic consequence of importing FMD would be export trade losses. The sum of the consumer impacts, direct costs and trade losses over a 15-year period would be between $37 billion and $44 billion (in 2001 dollars) depending on the magnitude of the outbreak and eradication strategy. Although such consequences are significant, it is important to note that the results of both the release and exposure assessment indicate that the likelihood of introduction and establishment of FMD is very low.

In summary, although the consequences of a FMD outbreak in the United States would be very high, APHIS considers the risk of FMD-infected animals or products entering the U.S. from the export region and exposing the U.S. livestock to susceptible animals to be very low, based on the findings of the release and exposure assessments.

References

1. Secretariat of Agriculture, Livestock, Fisheries and Food - National Animal Health and Agrifood Quality Service (SENASA). *Information provided by SENASA to attain recognition of Argentina's Patagonia as a region, as defined in section 92.2, Title 9, of the Code of Federal Regulations for foot and mouth disease (FMD).* July 2003.
2. Secretariat of Agriculture, Livestock, Fisheries and Food - National Animal Health and Agrifood Quality Service (SENASA). *Further information requested by USDA-APHIS of the information provided by SENASA to attain recognition of Argentina's Patagonia as a region, as defined in section 92.2, title 9, of the Code of Federal Regulations for foot and mouth disease (FMD).* November 2004.
3. Secretariat of Agriculture, Livestock, Fisheries and Food - National Animal Health and Agrifood Quality Service (SENASA). *Clarification to the information requested for recognition of Newcastle disease Status.* June 2003.
4. Secretariat of Agriculture, Livestock, Fisheries and Food - National Animal Health and Agrifood Quality Service (SENASA), *Information provided by SENASA to attain recognition of Argentina as a region, as defined in section 92.2, title 9, of the Code of Federal Regulations for foot and mouth disease (FMD).* November 2002.
5. Secretariat of Agriculture, Livestock, Fisheries and Food - National Animal Health and Agrifood Quality Service (SENASA). *Laws and regulations covering FMD eradication (In Spanish).* 2000.
6. Secretariat of Agriculture, Livestock, Fisheries and Food - National Animal Health and Agrifood Quality Service (SENASA). *Further information requested by USDA-APHIS during December 2003 visit to support Patagonian region status for foot and mouth disease (FMD).* November 2004.
7. Secretariat of Agriculture, Livestock, Fisheries and Food - National Animal Health and Agrifood Quality Service (SENASA). *Border control system presentation.* 2003.
8. Secretariat of Agriculture, Livestock, Fisheries and Food - National Animal Health and Agrifood Quality Service (SENASA). *Additional information with regards to Patagonia region requested by APHIS after the visit of December 1-5, 2003.* December 1-5, 2003.
9. USDA/APHIS/VS. Administrative document, *Schedule and participants of site visit.* December 2003.
10. Secretariat of Agriculture, Livestock, Fisheries and Food - National Animal Health and Agrifood Quality Service (SENASA) *Personal Communication: discussions held with SENASA officials and observations made during the site visit.* December 2003.
11. Secretariat of Agriculture, Livestock, Fisheries and Food - National Animal Health and Agrifood Quality Service (SENASA) *Personal Communication: discussions held with SENASA officials and observations made during the site visit.* June 2003.
12. Secretariat of Agriculture, Livestock, Fisheries and Food - National Animal Health and Agrifood Quality Service (SENASA) Personal Communication: discussions held with SENASA officials and observations made during the site visit. May, 2005.
13. Secretariat of Agriculture, Livestock, Fisheries and Food - National Animal Health and Agrifood Quality Service (SENASA) Personal Communication: discussions held with SENASA officials and observations made during the site visit. September, 2006.
14. Secretariat of Agriculture, Livestock, Fisheries and Food - National Animal Health and Agrifood Quality Service (SENASA) PowerPoint Presentation (Institucional SENASA

nov.pdf) and Personal Communication: discussions held with SENASA officials and observations made during the site visit. November 2013.
15. World Organization for Animal Health, Office International des Epizooties (OIE). International Animal Health Code: mammals, birds and bees. 2013.
16. Code of Federal Regulations, 9 CFR 94. Rinderpest, foot-and-mouth disease, fowl pest (fowl plague), exotic newcastle disease, african swine fever, classical swine fever, and bovine spongiform encephalopathy; prohibited and restricted importations. 2004.
17. Code of Federal Regulations, 9 CFR 92.2. Application for recognition of the animal health status of a region. 2004.
18. Foreign Agricultural Service, Gain Report, Foreign Agricultural Service, USDA. #AR 1049. August 3, 2001.
19. Secretariat of Agriculture, Livestock, Fisheries and Food - National Animal Health and Agrifood Quality Service (SENASA). Additional information requested by USDA-APHIS. November 2013.
20. Secretariat of Agriculture, Livestock, Fisheries and Food - National Animal Health and Agrifood Quality Service (SENASA). Direccion General de Laboratorios y Control Tecnico. Control of Vaccinations – APHIS 2013 (Powerpoint Presentation). November 2013.
21. Secretariat of Agriculture, Livestock, Fisheries and Food - National Animal Health and Agrifood Quality Service (SENASA). Direccion General de Laboratorios y Control Tecnico. Institutional Structure of DILAB – APHIS 2013 (Powerpoint Presentation). November 2013.
22. Secretariat of Agriculture, Livestock, Fisheries, and Food; National Animal Health and Agrifood Quality Service - SENASA. Sero Epidemiological Surveillance Serological Sampling 2004 2005.
23. Secretariat of Agriculture, Livestock, Fisheries, and Food; National Animal Health and Agrifood Quality Service - SENASA - Clarification to the information Requested for Recognition as Region, Newcastle Disease, June 2003, Part 4, Annex V
24. Secretariat of Agriculture, Livestock, Fisheries, and Food; National Animal Health and Agrifood Quality Service - SENASA. FMD Eradication Manual. 2001.
25. Secretariat of Agriculture, Livestock, Fisheries and Food - National Animal Health and Agrifood Quality Service (SENASA). Additional information requested by USDA-APHIS. Annex VI – Epidemiological Surveillance for FMD, Serological Survey 2011. November 2013.
26. Secretariat of Agriculture, Livestock, Fisheries and Food - National Animal Health and Agrifood Quality Service (SENASA). Additional information requested by USDA-APHIS. Annex III – Epidemiological Surveillance for FMD, Serological Surveys 2012. November 2013.
27. Secretariat of Agriculture, Livestock, Fisheries and Food - National Animal Health and Agrifood Quality Service (SENASA). Additional information requested by USDA-APHIS. Annex VIII – Epidemiological Surveillance for FMD, Patagonia North A Serological Surveys 2013. November 2013.
28. Secretariat of Agriculture, Livestock, Fisheries and Food - National Animal Health and Agrifood Quality Service (SENASA). Additional information requested by USDA-APHIS. Annex VIII – Epidemiological Surveillance for FMD, Serological Survey 2013. November 2013.

29. Secretariat of Agriculture, Livestock, Fisheries and Food - National Animal Health and Agrifood Quality Service (SENASA). FMD Situation in Patagonia, Argentina (SENASA) power point presentation). 2009.
30. Code of Federal Regulations, 9 CFR 94.1. Regions where rinderpest or foot-and-mouth disease exists; importations prohibited. 2013.
31. Secretariat of Agriculture, Livestock, Fisheries and Food - National Animal Health and Agrifood Quality Service (SENASA). Report on Conformance with Article 2.2.10.4. of the OIE Animal Health Code for the territory of Patagonia. 2007.
32. Secretariat of Agriculture, Livestock, Fisheries and Food - National Animal Health and Agrifood Quality Service (SENASA). Resolution 148/08. 2008.
33. World Organization for Animal Health. Recognition of FMD Status of Member, OIE Web site, http://www.oie.int/en/animal-health-in-the-world/official-disease-status/fmd/list-of-fmd-free-members/#c156.
34. Secretariat of Agriculture, Livestock, Fisheries and Food - National Animal Health and Agrifood Quality Service (SENASA). Personal Communication: discussions held with SENASA officials by e-mail. August 2005.
35. Secretariat of Agriculture, Livestock, Fisheries and Food - National Animal Health and Agrifood Quality Service (SENASA). Additional Information received. March 2009.
36. Secretariat of Agriculture, Livestock, Fisheries and Food - National Animal Health and Agrifood Quality Service (SENASA). Seroepidemiological Surveillance 2005-2006. 2006.
37. Cannon, R.M. Demonstrating disease freedom - Combining confidence levels. Preventive Veterinary Medicine 2002. 52: p. 227-249.
38. USDA/APHIS/VS/CEAH. Pathway assessment of foot-and-mouth disease (FMD) risk to the United States: an evaluation in response to international FMD outbreaks in 2001. 2001.
39. USDA/APHIS/VS/CEAH. Risk Assessment of the Practice of Feeding Recycled Commodities to Domesticated Swine in the U.S. 1995.
40. USDA/APHIS/VS/CEAH, 2001 waste-feeder survey, Unpublished data. . 2002.
41. Code of Federal Regulations, C., Parts 1 to 199, Animals and animal products. 2004. 2004.
42. Sutmoller, P. and Wrathal, A. A quantitative assessment of the risk of transmission of foot-and-mouth disease, bluetongue and vesicular stomatitis by embryo transfer in cattle. Prev Vet Med, 1997. 32: p. 111-132.
43. McCauley, E.H. Potential economic impact of foot-and-mouth disease in the United States. 1979. St. Paul, Minnesota: Government Printing Office, 1979.
44. Alexandersen, S., et al. The pathogenesis and diagnosis of foot-and-mouth disease. J Comp Patho, 2003a. 129(1): p. 1-36.
45. Dunn, C.S. and Donaldson A.I. Natural adaption to pigs of a Taiwanese isolate of foot and mouth disease virus. Vet Rec, 1997. 141: p. 174-75.
46. Geering, W.A.,Foot and mouth disease in sheep. Aust Vet J, 1967. 43: p. 485-89.
47. Paarlberg PL, Seitzinger AH, Lee JG, Mathews KH. Economic Impacts of Foreign Animal Diseases. USDA Economic Research Service Report No. 57. May 2008. 71 pages.
48. Doel, T.R., Optimisation of the immune response to foot-and-mouth disease vaccines. Vaccine, 1999. 17(13-14): p. 1767-71.

49. James, A.D. and Rushton, J. The economics of foot and mouth disease. Rev Sci Tech, 2002. 21(3): p. 637-44.
50. Schoenbaum, M.A., and Terry Disney, W. Modeling alternative mitigation strategies for a hypothetical outbreak of foot-and-mouth disease in the United States. Prev Vet Med, 2003. 58(1-2): p. 25-52.
51. Bates, T.W., Carpenter TE, and Thurmond MC. Benefit-cost analysis of vaccination and preemptive slaughter as a means of eradicating foot-and-mouth disease. Am J Vet Res, 2003. 64(7): p. 805-12.
52. McDowell, R. Economic impacts of FMD adjusted from 1976 dollars to March 2001 dollars by Consumer Price Index. 2002.
53. National Environmental Policy Act (NEPA) of 1969, as amended (40 U.S.C. 4321 et seq.) AND regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500-1508) AND USDA regulations implementing NEPA (7 CFR part 1b) and APHIS' NEPA Implementing Procedures (7 CFR part 372). 1969.
54. World Health Organization, Foot and mouth disease: consequences for public health. http://www.who.int/emc/diseases/zoo/FMD.html.
55. Anonymous. Unpublished report. Lancaster University, United Kingdom. 2004.
56. Paarlberg, P.L., J.G. Lee, and A.H. Seitzinger. Potential revenue impact of an outbreak of foot-and-mouth disease in the United States. J Am Vet Med Assoc, 2002. 220(7): p. 988-92.
57. Thompson, D., et al. Economic costs of the foot and mouth disease outbreak in the United Kingdom in 2001. Rev Sci Tech,, 2002. 21(3): p. 675-87.
58. Economic impact of alternative management strategies for regulating Canadian ruminant/product imports. Centers for Epidemiology and Animal Health. 2003.
59. Foreign Agricultural Service, FAS. U.S. beef, pork and poultry trade charts. http://www.fas.usda.gov/dlp/tradecharts/. 2003.

Appendix I

Hazard identification—Foot and Mouth Disease

OIE lists several animal diseases that are considered primary hazards associated with trade of animals and animal products. APHIS regulations mitigate the risk of introduction of these foreign animal diseases in to the United States. As such, APHIS conducts an import risk analysis addressing hazards of primary concern prior to initiating or resuming trade of animal commodities. APHIS considers FMD virus to be a potential hazard associated with trade of live ruminants and swine, as well as certain products and by-products derived from these species. FMD virus was eradicated from the United States in 1929.

Causative agent

FMD is a highly communicable disease caused by an *Aphthovirus* of the family *Picornaviridae*. FMD has seven immunologically distinct serotypes—O, A, C, SAT1, SAT2, SAT3, and Asia 1—which do not confer cross immunity [1]. FMD virus serotype O (PanAsia strain) is the most prevalent and widely distributed, causing outbreaks in many parts of Africa, Asia, South America, and Europe since 1998 [2-4].

Host range

The range of domestic hosts includes all cloven-hoofed animals such as cattle, swine, sheep, goats, water buffalo, and yaks [2-5]. All cloven-hoofed wild animals are also susceptible, including buffalo, deer, impala, and gazelles; hedgehogs, armadillos, nutrias, elephants, rats, and mice are also susceptible. Camels may be affected by some FMD strains whereas llamas, alpacas, and vicuñas have low susceptibility [5].

Incubation period

The incubation period of the FMD virus is two to 14 days in cattle, depending on the viral strain and dose and the level of susceptibility of the animal [6]. The incubation period in pigs also varies with the strain, dose, and route of infection [7]. Serotype O—highly virulent in pigs—can produce clinical signs within 18 to 24 hours, while pigs with low-level exposures may take up to 11 days to develop clinical signs.

Morbidity and mortality

Clinical signs in cattle during acute infection include fever, profuse salivation, and mucopurulent nasal discharge [6]. The disease is characterized by development of vesicles on the tongue, hard palate, dental pad, lips, muzzle, gum, coronary band, and interdigital spaces. Vesicles may develop on the teats. Affected animals lose condition rapidly, and there is a dramatic loss of milk production. The animal usually recovers by 14 days post infection provided no secondary infections occur [8]. Morbidity in unvaccinated herds can be high, but mortality usually does not exceed 5 percent. If an outbreak occurs during the calving season, calf mortality can be considerable [9]. Young calves may even die before the development of clinical signs usually because the virus attacks the heart muscles [6].

The most consistent clinical signs in pigs are lesions around the coronary bands and lameness; fever may be inconsistent [7, 10]. Pigs may develop vesicles on the tongue and snout, but these may be less conspicuous than lesions seen in ruminants. The severity of clinical disease depends

on the age of the infected pig. Adult swine may recover or become chronically lame while younger pigs, especially those less than 8 weeks of age, may die from acute myocarditis without developing other clinical signs.

FMD infection in sheep and goats is often subclinical or produces only mild clinical signs that may go unrecognized [11]. Reduced milk production may be seen in milking animals and death of young stock may occur without clinical signs.

Sources of virus and transmission

Sources of FMD virus include (1) incubating and clinically affected animals; (2) breath, saliva, feces, and urine; (3) milk and semen (up to 4 days before clinical signs); and (4) meat and by-products in which pH has remained above 6.0 [11, 12]. Transmission occurs by direct or indirect contact or by aerosol. Fomites such as feed, drinking water, equipment, animal products, as well as human clothing, transportation vehicles, rodents, stray dogs, wild animals, and birds can transmit FMD over long distances. The five main elements that influence the extent of FMD spread are:

(1) The quantity of virus released;
(2) The means by which the virus enters the environment;
(3) The ability of the agent to survive outside the animal body;
(4) The quantities of virus required to initiate infection at primary infection sites; and
(5) The period of time the virus remains undetected [13, 14].

The respiratory tract is the usual route of infection, particularly in environments that are heavily contaminated with FMD virus. Infection can also occur through abrasions of the skin or mucous membranes. Pigs may become infected through ingestion of FMD virus-contaminated products [7, 11].

In cattle and sheep, the earliest sites of virus infection and possibly replication appear to be in the mucosa and the lymphoid tissues of the pharynx [8, 15-17]. Following initial replication in the pharynx, the virus enters the bloodstream. Viremia in cattle lasts for three to five days, during which the virus spreads throughout the body and establishes sites of secondary infection, localizing in various organs, tissues, body fluids, bone marrow, and lymph nodes.

Viral replication in cattle may reach peak levels as early as two to three days after exposure [15, 16]. Recent data indicate that the most viral amplification occurs in the epithelia of the skin and mouth, including the tongue [18, 19]. Although some viral replication also occurs in the epithelia of the pharynx, the amount of virus produced there is apparently much less than the amount produced in the skin and mouth during the acute phase of the disease. By comparison, the amount of virus (if any) produced in other organs like salivary glands, kidneys, liver, and lymph nodes is negligible.

Immunity to FMD is primarily mediated by circulating antibodies [17]. The host reaction, including antibody production, occurs from three to four days after exposure. In infected pigs, the virus is cleared in less than three to four weeks. In contrast, around 50 percent or more of cattle will develop a low-level persistent infection, localized to the pharynx [10, 20, 21].

Inactivation and survival

FMD virus is a relatively resilient virus. It can survive up to 15 weeks in feed, four weeks on cattle hair, and up to 103 days in wastewater. The survival of the virus in animal tissues is closely associated with the acidity of that tissue [22, 23]. For example, in muscular tissues the acidity of rigor mortis, which occurs naturally, inactivates the virus. The production of lactic acid in these tissues during maturation is considered the primary factor for inactivation. An acid environment where the pH is less than 6.0 will destroy the virus quickly. Several studies showed that in tissues where no acidification occurs (e.g., lymph nodes, bone marrow, fat, and blood), the virus may survive for extended times in cured, uncured, and frozen meat [16, 22-25]. Heating at 50° C [26] and up to 155° F [27] will inactivate the virus.

Vaccination

Inactivated virus vaccines of varying composition are available commercially [12]. Many FMD vaccines are multivalent to provide protection against the different serotypes likely to be encountered in a given field situation. The finished vaccine must be shown to be free from residual live virus. Live attenuated vaccines are not suitable due to danger of reversion to virulence.

Inactivated FMD vaccines may be classified as either standard potency (commercial vaccines) or higher potency (emergency vaccines) [12]. Standard potency vaccines are formulated with sufficient antigen to have a minimum potency level of 3 PD_{50} and provide six months of immunity after two initial vaccinations given one month apart. Higher potency vaccines are formulated with sufficient antigen to have a minimum potency level of 6 PD_{50} to provide for more rapid onset and a wider spectrum of immunity against relevant field viruses.

Laboratory diagnostics

Field diagnosis of FMD relies heavily on recognition of clinical signs, which are similar to those seen in other vesicular diseases such as vesicular stomatitis, mucosal disease of cattle, bluetongue, and rinderpest. Virus isolation or demonstration of FMD viral antigen or nucleic acid in samples of tissue or fluid is therefore necessary for confirmatory diagnosis.

Enzyme-linked immunosorbent assays (ELISA) can be used to detect FMD viral antigens and for serotyping [12, 14]. Lateral flow devices can also be used to detect FMD viral antigens. The ELISA has replaced complement fixation in most laboratories as it is more specific and sensitive; in addition, it is not affected by pro- or anti-complement factors. If the sample is inadequate or the diagnosis remains uncertain, sample materials can be tested by reverse transcription polymerase chain reaction and/or virus isolation.

Demonstration of specific antibodies to structural proteins in non-vaccinated animals is indicative of prior infection with FMD virus [12, 14]. Virus neutralization tests (VNTs) and ELISAs for antibodies to structural proteins are used as serotype-specific serological tests. Tests for antibodies to some nonstructural proteins (NSPs) of FMD virus are useful in providing evidence of previous or current viral replication in the host, irrespective of vaccination status. Unlike structural proteins, NSPs are highly conserved and therefore are not serotype specific, so detection of antibodies to NSPs is not serotype restricted.

References

1. Kitching, R., et al, *Development of foot-and-mouth disease virus strain characterization - a review.* Trop An Health Prod, 1989. **21**: p. 153-166.
2. Knowles, N.J., et al., *Pandemic strain of foot-and-mouth disease virus serotype O.* Emerging Infectious Diseases, 2005. **21**(12): p. 1887-1893.
3. Knowles, N.J. and A.R. Samuel, *Molecular epidemiology of foot-and-mouth disease virus.* Virus Research, 2003. **91**: p. 65-80.
4. Sakamoto, K. and K. Yoshida, *Recent outbreaks of foot and mouth disease in countries of East Asia.* Rev Sci Tech, 2002. **21**(3): p. 459-463.
5. Torres, A., *Foot and mouth disease*, in *Foreign Animal Diseases, 7th edition*, C. Brown and A. Torres, Editors. 2008, Committee on Foreign and Emerging Diseases of the United States Animal Health Association. Boca Publications Group, Inc: Boca Raton, Florida. p. 261-276.
6. Kitching, R.P., *Clinical variation in foot and mouth disease; cattle.* Rev Sci Tech, 2002. **21**(3): p. 499-504.
7. Kitching, R.P. and S. Alexandersen, *Clinical variation in foot and mouth disease; pigs.* Rev Sci Tech, 2002. **21**(3): p. 513-518.
8. Woodbury, E.L., *A review of the possible mechanisms for the persistence of foot-and-mouth disease virus.* Epidemiol Infect, 1995. **114**(1): p. 1-13.
9. Seifert, H., *Foot-and-mouth disease*, in *Tropical Animal Health*1996, Kluwer Academic Publishers: London, Massachusetts. p. 418-431.
10. Kitching, R.P., *Identification of foot and mouth disease virus carrier and subclinically infected animals and differentiation from vaccinated animals.* Rev Sci Tech, 2002. **21**(3): p. 531-538.
11. Alexandersen, S., et al., *The pathogenesis and diagnosis of foot-and-mouth disease.* J Comp Pathol, 2003. **129**: p. 1-36.
12. World Organization for Animal Health (OIE), *Chapter 2.1.5 Foot and mouth disease*, in *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* 2011: Available from :http://www.oie.int/international-standard-setting/terrestrial-manual/access-online/.
13. Mann, J. and R.F. Sellers, *Foot and mouth disease*, in *Virus Infections of Vertebrates*, Z. Dinter and B. Morein, Editors. 1990, Elsevier. p. 903-912.
14. Thomson, G., *Foot-and-mouth disease*, in *Infectious Diseases of Livestock*, Coetzer, Thomson, and Tustin, Editors. 1994, Oxford University Press: Cape Town, South Africa. p. 825-852.
15. Sellers, R.F., *Quantitative aspects of the spread of foot-and-mouth disease.* Vet Bull, 1971. **41**(6): p. 431-439.
16. Cottral, G.E., *Persistence of foot-and-mouth disease virus in animals, their products and the environment.* Bull Off Int Epizoot, 1969. **70**(3): p. 549-568.
17. Alexandersen, S., Z. Zhang, and A.I. Donaldson, *Aspects of the persistence of foot-and-mouth disease virus in animals; the carrier problem.* Microbes Infect, 2002. **4**(10): p. 1099-1110.
18. Alexandersen, S., M.B. Oleksiewicz, and A.I. Donaldson, *The early pathogenesis of foot-and-mouth disease in pigs infected by contact; a quantitative time-course study using TaqMan RT-PCR.* J Gen Virol, 2001. **82**(4): p. 747-755.

19. Oleksiewicz, M.B., A.I. Donaldson, and S. Alexandersen, *Development of a novel real-time RT-PCR assay for quantitation of foot-and-mouth disease virus in diverse porcine tissues.* J Virol Methods, 2001. **92**(1): p. 23-35.
20. Salt, J.S., *The carrier state in foot and mouth disease; an immunological review.* Br Vet, 1993. **149**(3): p. 207-223.
21. Zhang, Z. and R.P. Kitching, *The localization of persistent foot and mouth disease virus in the epithelial cells of the soft palate and pharynx.* J Comp Pathol, 2001. **124**: p. 89-94.
22. Cottral, G.E., B.F. Cox, and D.E. Baldwin, *The survival of foot-and-mouth disease virus in cured and uncured meat.* Am J Vet Res, 1960. **21**: p. 288-97.
23. Henderson, W.M. and J.B. Broodsby, *The survival of foot and mouth disease virus in meat and offal.* J Hyg (Lond), 1948. **46**(4): p. 394-402.
24. Cox, B.F., G.E. Cottral, and D.E. Baldwin, *Further studies on the survival of foot and mouth disease virus in meat.* Am J Vet Res, 1961. **22**: p. 224-226.
25. Lasta, R., et al, *Combined treatment of heat, irradiation, and pH effects on the infectivity of foot-and-mouth disease virus in bovine tissues.* J Food Sci, 1992. **57**(1): p. 36-39.
26. Green, W. and J.L. Grannis, *Economic impact of alternative management strategies for regulating Canadian ruminant/product imports.* 2003: p. Unpublished report, Center for Epidemiology and Animal Health.
27. Heidelbaugh, N. and J. Graves, *Effects of some techniques applicable in food processing on the infectivity of foot and mouth disease virus.* Food Tech, 1968. **22**: p. 120.

Appendix II

11 factors described under 9CFR 94.2 before 2012	**8 factors described under 9CFR 94.2 after 2012**
Scope of the evaluation	*Scope of the evaluation*
The extent of an active disease control program, if any, if the agent is known to exist in the region.	Veterinary control and oversight
The authority, organization, and infrastructure of the veterinary services organization in the region.	
Disease status—i.e., is the restricted disease agent known to exist in the region? If "yes," at what prevalence? If "no," when was the most recent diagnosis?	Disease history and vaccination practices
The vaccination status of the region. When was the last vaccination? What is the extent of vaccination if it is currently used, and what vaccine is being used?	
The degree to which the region is separated from adjacent regions of higher risk through physical or other barriers.	Epidemiological separation from potential sources of infection
The extent to which movement of animals and animal products is controlled from regions of higher risk, and the level of biosecurity regarding such movements.	
The status of adjacent regions with respect to the agent.	
Livestock demographics and marketing practices in the region.	Livestock demographics and traceability
The type and extent of disease surveillance in the region—e.g., is it passive and/or active; what is the quantity and quality of sampling and testing?	Surveillance practices
Diagnostic laboratory capabilities.	Diagnostic laboratory capabilities
Policies and infrastructure for animal disease control in the region—i.e., emergency response capacity.	Emergency preparedness and response